Title: Quality Improvement Intervention to Enhance Access to Kidney Transplantation and Living Kidney Donation (EnAKT LKD) Table of Updates to the EnAKT LKD Protocol

Trial Registration: NCT03329521

Date: May 4th, 2021

The published trial protocol "*Quality Improvement Intervention to Enhance Access to Kidney Transplantation and Living Kidney Donation (EnAKT LKD) in Patients with Chronic Kidney Disease: Clinical Research Protocol of a Cluster-Randomized Clinical Trial*" can be found online at https://journals.sagepub.com/doi/full/10.1177/2054358121997266.

Table of Protocol Updates

**** All protocol updates below were made without reviewing any between-group trial outcome data (viewing and analysis will only occur after the trial period is over) and were done after the start of the EnAKT LKD Trial period (November 1, 2017).**

Revision	Date of Revision	Details of Revision	Rationale
Official Title	August 10, 2020	**Changed from**: A Protocol to Evaluate the Effectiveness of a Multi-component Initiative to Enhance Access to Kidney Transplantation and Living Donation: the Enhance Access to Kidney Transplantation and Living Kidney Donation Trial **Changed to:** Quality Improvement Intervention to Enhance Access to Kidney Transplantation and Living Kidney Donation (EnAKT LKD) in Patients with Chronic Kidney Disease: A Pragmatic, Registry-based, Cluster-Randomized Clinical Trial	We changed the title to provide more details on the trial design. The change was also made to align the title with the published trial protocol.
Study Description (B*rief Summary*)	August 10, 2020	**Changed from**: Compared to dialysis, kidney transplantation is associated with improved survival, better quality of life and substantial cost savings to healthcare systems. Despite these advantages, many individuals with kidney failure never receive a kidney transplant. A multi-component quality improvement initiative was developed to enhance access to kidney transplantation and living kidney donation in Ontario's chronic kidney disease (CKD) programs. These CKD programs provide care to individuals with reduced kidney function. The initiative includes four main components: Data (e.g., data collection and reports to CKD programs about their transplant related performance); 2. Education (e.g., education toolkits for CKD program staff, kidney patients and families, including living kidney donor candidates); 3. Transplant Ambassadors (e.g., kidney transplant recipients and living kidney donors who discuss transplantation and living donation to patients and their families) and 4. Administration (e.g., provincial administrative support and resources provided to CKD programs to support local work). This trial will provide high-quality evidence about the effectiveness of a multi-component quality improvement initiative aimed to enhance access to kidney transplantation and living kidney donation.	The four main trial components and their delivery have not changed; we have simply refined how we describe these components. Please refer to our published trial protocol for further details on each of the intervention components.

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		Changed to: Compared to dialysis, kidney transplantation is associated with improved survival, better quality of life and substantial cost savings to healthcare systems. Despite these advantages, many individuals with kidney failure will never receive a kidney transplant. A multi-component quality improvement intervention (vs. usual care) provided in chronic kidney disease (CKD) programs located in Ontario, Canada was developed to determine if it can enable more patients with no recorded contraindications to kidney transplant to complete more steps towards receiving a kidney transplant. These CKD programs provide care to individuals with CKD (including patients approaching the need for dialysis and patients receiving dialysis). The intervention has four main components: (1) local quality improvement teams and administrative support; (2) tailored education and resources for staff, patients, and living kidney donor candidates; (3) support from kidney transplant recipients and living kidney donors (i.e. Transplant Ambassador Program); and (4) program-level performance reports and oversight by program leaders. The Enhance Access to Kidney Transplantation and Living Kidney Donation (EnAKT LKD) trial will provide high-quality evidence on whether a multi-component quality improvement intervention helps patients complete more steps towards receiving a kidney transplant.	
Study Description (*Detailed Description*)	August 10, 2020	**Added:** *Detailed Description:* 1. Statement of the health problem or issue: Compared with dialysis, a kidney transplant offers patients a better quality of life and many gain 10 or more years of life expectancy. A transplant also costs the healthcare system less—over a five-year period. Living donor transplants offer further advantages, including superior graft and patient survival compared with deceased donor transplants. Unfortunately, many patients with kidney failure who would benefit from a transplant will never receive one. There is a chronic shortage of organs	We have provided more details on the trial for people to view on ClinicalTrials.gov as per our published trial protocol.

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		from deceased donors, and in Canada, the rate of living donor kidney transplantation has stagnated. In addition to the shortage of transplantable kidneys, several other barriers impede patient access to transplantation. 2. Objective of your project: To determine if a quality improvement intervention provided in chronic kidney disease (CKD) programs (vs. usual care) enables more patients with no recorded contraindications to kidney transplant to complete more steps towards receiving a kidney transplant. 3. How will you undertake your work? We will conduct a pragmatic two-arm, parallel-group, open-label, registry-based, cluster-randomized clinical trial—the Enhance Access to Kidney Transplantation and Living Kidney Donation (EnAKT LKD) trial. Our study will include the 26 chronic kidney disease (CKD) programs in Ontario, Canada which are expected to care for over 10,000 adult patients with CKD (including patients approaching the need for dialysis and patients receiving dialysis) with no recorded contraindications to a kidney transplant during the trial. Patients in 13 of the 26 CKD programs will receive a quality improvement intervention or usual care. The intervention has four main components: (1) local quality improvement teams and administrative support; (2) tailored education and resources for staff, patients, and living kidney donor candidates; (3) support from kidney transplant recipients and living kidney donors; and (4) program-level performance reports and oversight by program leaders. Patients in the other 13 programs will receive usual care and will continue to support	

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		access to kidney transplantation and living kidney donation as usual. 4. <u>What is unique/innovative about your project?</u> An investigator usually needs to study a large number of patients in a clinical trial to reliably understand the effects of a treatment. Normally, a study with 10,000 patients would cost more than $10 million dollars to conduct; however, this study will provide a reliable answer to the question being asked and can be done at a fraction of the cost. This is because we will use data already collected by the healthcare system. The investigator will be able to analyze these healthcare data at the end of the study. This means that the study will cost less than a traditional clinical trial. This pragmatic trial includes all CKD programs in the province of Ontario. By including patients from a variety of backgrounds, the results of the trial should be broadly generalizable. 5. <u>What is the impact of the proposed research?</u> The EnAKT LKD trial will provide high-quality evidence on whether a multi-component quality improvement intervention helps patients complete more steps towards receiving a kidney transplant. This is important as compared to dialysis, kidney transplant offers patients a better quality of life and many gain 10 or more years of life expectancy. A transplant also costs the healthcare system less. If our intervention is successful, more transplants may ultimately be performed and result in improved survival and a better quality of life for patients with CKD. Kidney transplantation achieves the *triple aim in healthcare*: better outcomes, better experience of care, and lower costs.	

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Objective	August 10, 2020	**Changed from**: To determine if a multi-component kidney transplant quality improvement program increases the kidney transplant referral rate in Ontario renal programs. Specifically, we will be comparing renal program level kidney transplant referral rates between the multi-component quality improvement group and the standard-of-care group. **Changed to**: To determine if a quality improvement intervention provided in chronic kidney disease (CKD) programs (vs. usual care) enables more patients with no recorded contraindications to kidney transplant to complete more steps towards receiving a kidney transplant.	We have refined our objective to incorporate our refined primary outcome (*see Primary Outcome Measures below*). The intent of this work was always to assess access to kidney transplant and with the availability of new datasets we can now do this in a refined way. Our outcome now captures the complete patient journey in access to kidney transplant. We changed the term "renal program" to "chronic kidney disease program" or "CKD program" to align with the terminology used in our published trial protocol. This also aligns with the nomenclature used by the Ontario Renal Network (part of Ontario Health) when it refers to the programs. To keep consistent with our published trial protocol we have changed the term "standard of care" to "usual care".
Study Status	February 24, 2020	**STUDY STATUS REVISION 1:** **Changed from**: *Estimated Primary Completion Da*te: November 2019 *Estimated Study Completion Date*: November 2019 **Changed to***: Estimated Primary Completion Date*: March 31, 2021 *Estimated Study Completion Date*: March 31, 2021	**STUDY STATUS REVISION 1:** We increased the length of the trial to improve statistical power (*please see power section*). This will allow a better understanding of whether the multi-component quality improvement intervention had an impact on increasing access to kidney transplantation in Ontario.
	December 4, 2020	**STUDY STATUS REVISION 2:** **Changed from**: *Estimated Primary Completion Date*: March 31, 2021 *Estimated Study Completion Date*: March 31, 2021 **Changed to**: *Estimated Primary Completion Date*: December 31, 2021 *Estimated Study Completion Date*: December 31, 2021	**STUDY STATUS REVISION 2:** On March 16, 2020 nearly all kidney transplants and evaluations for deceased and living donor transplants were suspended in Ontario due to the COVID-19 pandemic. Similarly, most components of the multi-component quality improvement intervention were halted. The four components of the intervention started ramping up again in September 2020 and

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			transplant activity started increasing in June 2020 but did not return to full capacity for several months. Extending the length of time of the multi-component quality improvement intervention in the first arm will allow adequate time for CKD programs to be exposed to the intervention when it is functioning at its full potential.
Study Follow-up Period	February 24, 2020 December 4, 2020	**STUDY FOLLOW-UP PERIOD REVISION 1:** **Changed from**: 2 years **Changed to:** 3.4 years **STUDY FOLLOW-UP PERIOD REVISION 2:** **Changed from**: 3.4 years **Changed to:** 4.1 years	*Please see study status section above for rationale.*
Arm	August 10, 2020	**Changed from:** *Arm title (experimental arm)*: Multicomponent Initiative *Arm description*: A number of quality improvement initiatives will be provided at the CKD programs. **Changed to:** *Arm title (experimental arm)*: Multi-component quality improvement intervention *Arm description:* A multi-component quality improvement intervention will be provided at chronic kidney disease (CKD) programs. **Change from:** *Arm title (no intervention)*: Routine Care **Changed to:** *Arm title (no intervention)*: Usual Care	No changes to the intervention were made. The change was made to make the terminology consistent with the published trial protocol. No changes in the delivery of care were made to the no intervention group. We changed the terminology to “usual care” to reflect the terminology used in our published trial protocol.
Intervention	August 10, 2020	**Changed from**: *Intervention name*: Multi-component Initiative	The four main trial components and their delivery have not changed; we have simply

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		Changed to: *Intervention name*: Multi-component quality improvement intervention **Changed from:** *Intervention description*: The initiative is grounded in a quality improvement framework and has four main components for the chronic kidney disease (CKD) programs, including: 1. Data (e.g., data collection and reports to CKD programs about their performance using best practices in audit and feedback); 2. Education (e.g., education toolkits for CKD program staff, renal patients and families, including living donor candidates); 3. Transplant Ambassadors (e.g., kidney transplant recipients and living kidney donors who discuss transplantation and living donation to patients and their families) and 4. Administration (e.g., provincial administrative support and resources provided to CKD programs to support local work). **Changed to:** *Intervention description*: The multi-component quality improvement intervention has four main components for the chronic kidney disease programs: (1) local quality improvement teams and administrative support; (2) tailored education and resources for staff, patients, and living kidney donor candidates; (3) support from kidney transplant recipients and living kidney donors; and (4) program-level performance reports and oversight by program leaders.	refined how we describe these components. Please refer to our published trial protocol for further details on each of the intervention components.
Primary Outcome Measures	November 19, 2019	**Changed from**: *Primary Outcome*: Composite outcome of living kidney donor candidate referral and transplant recipient referral event rate. *Description:* The primary outcome has not been finalized. It will be finalized well before the trial ends and before the analysis of results. The outcome will be published in the peer-reviewed protocol. *Time Frame*: Two years **Changed to**: *Primary Outcome:* Number of key steps completed towards receiving a kidney transplant.	The primary outcome was refined based on our analysis of historic records. The intent of this work is to test an intervention to improve access to kidney transplant and with the availability of new datasets this can now be done in a refined way. The four steps that comprise the primary outcome are key steps to receiving a kidney transplant. This outcome now captures the complete patient journey in access to transplant.

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		Description: The average number of key steps completed towards receiving a kidney transplant per 100 person-years during the trial period and analyzed at the cluster-level (chronic kidney disease program). Each step will only be counted once per patient (the first time it occurs), and each patient can contribute a maximum of four steps to their group total. The four steps include: Step I: patient referred to a transplant centre for evaluation, Step II: at least one living kidney donor candidate contacts a transplant centre for an intended recipient and completes a health history questionnaire to begin their evaluation, Step III: patient added to the deceased donor transplant wait list, and Step IV: patient receives a kidney transplant from a living or deceased donor. Patients who complete steps before the trial starts can contribute new steps during the trial period. *Time Frame*: 4.1 years	
Secondary Outcome Measures	June 24, 2020	**Changed from**: 1. Kidney transplantation rate (living and deceased donor kidney transplants examined separately and together) *Description*: The secondary outcome has not been finalized. It will be finalized well before the trial ends and before the analysis of results. The outcome will be published in the peer-reviewed protocol. *Time Frame*: Two years 2. Rate of pre-emptive kidney transplantation *Description:* The secondary outcome has not been finalized. It will be finalized well before the trial ends and before the analysis of results. The outcome will be published in the peer-reviewed protocol. *Time Frame*: Two years	The average wait time for a deceased donor kidney transplant is five years in Ontario, therefore, we hypothesize that the intervention is likely to have only a small impact on the rate of deceased donor kidney transplants. For this reason, five secondary outcomes have been pre-specified to examine the impact of the intervention on the rate of living kidney donor activity.

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		3. Rate of kidney transplant waitlisting *Description:* The secondary outcome has not been finalized. It will be finalized well before the trial ends and before the analysis of results. The outcome will be published in the peer-reviewed protocol. *Time Frame*: Two years 4. Average Healthcare Costs *Description:* The secondary outcome has not been finalized. It will be finalized well before the trial ends and before the analysis of results. The outcome will be published in the peer-reviewed protocol. *Time Frame:* Two years **Changed to**: We have pre-specified five secondary outcomes to examine the impact of our intervention on living kidney donor activity. *1.* A living donor candidate contacts a transplant centre for a patient and completes a health history questionnaire to begin their evaluation or a patient receives a living donor transplant. *Description:* Given that the average wait time for a deceased donor kidney transplant is five years on average in Ontario, our intervention is likely to have only a small impact on the rate of deceased donor kidney transplants. For this reason, we have pre-specified five secondary outcomes to examine the impact of our intervention on the rate of living kidney donor transplant activity. *Time Frame*: 4.1 Years *2.* A living kidney donor candidate contacts a transplant centre for a patient and completes a health history questionnaire to begin their evaluation. *Description:* Secondary outcome selected to examine the rate of living kidney donor transplant activity.	

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		Time Frame: 4.1 Years *3.* A transplant centre receives a patient's complete referral package from a chronic kidney disease program and a living kidney donor candidate contacts a transplant centre for a patient and completes a health history questionnaire to begin their evaluation. *Description:* Secondary outcome selected to examine the rate of living kidney donor transplant activity. *Time Frame*: 4.1 Years *4.* A patient receives a living donor kidney transplant. *Description*: Secondary outcome selected to examine the rate of living kidney donor transplant activity. *Time Frame*: 4.1 Years *5.* Pre-emptive living donor kidney transplants *Description*: Secondary outcome selected to examine the rate of living kidney donor transplant activity. This outcome is restricted to patients who were not receiving dialysis when they entered the trial and not on dialysis at the time of transplant. *Time Frame*: 4.1 Years	
Other pre-specified outcomes	August 7, 2020	**Added:** We will consider several other outcomes in an exploratory analysis. Other outcome measures, include: 1. Rate of deceased donor kidney transplant *Description:* Rate of deceased donor kidney transplant censoring at death and receipt of a living donor kidney transplant. *Time Frame*: 4.1 Years 2. Average number of months from the date of dialysis initiation (i.e. trial entry) to the date of referral.	All other outcomes provide additional important information about access to kidney transplant. Further details on these measures can be found in our published trial protocol.

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		Description: This outcome is assessed in patients receiving maintenance dialysis who were referred to a transplant centre. *Time Frame*: 4.1 Years 3. Rate of living kidney donor transplants *Description:* This outcome is assessed in patients waitlisted for a deceased donor kidney transplant and censored at death and receipt of a deceased donor kidney transplant. Time Frame: 4.1 Years 4. Proportion of pre-emptive transplants *Description*: This outcome is assessed in recipients of a living kidney donor transplant and restricted to patients who were not receiving dialysis when they entered the trial and not on dialysis at the time of transplant. *Time Frame*: 4.1 Years 5. Average number of months from the date of referral to a transplant centre to the date the first living donor candidate contacts the transplant centre for the intended recipient *Description*: This outcome is assessed in recipients of a living kidney donor transplant. *Time Frame*: 4.1 Years 6. Average number of months from the date of referral to a transplant centre to date of the transplant surgery *Description:* This outcome is assessed in recipients of a living or deceased donor kidney transplant. *Time Frame*: 4.1 Years	
Balancing Measures	August 7, 2020	**Added:** Balancing Measures	We added balancing measures to track whether our multi-component quality improvement

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		• Proportion of patient referrals to a transplant centre where the referral was declined. • Proportion of patient referrals to a transplant centre where the referral information was incomplete (e.g. missing diagnostics and/or other required patient information). • Proportion of patient referrals to a transplant centre where the referral was deferred. • Proportion of patient referrals to a transplant centre where the referral was accepted. • Proportion of patients referred to a transplant centre who were not waitlisted or transplanted within 1-year of referral. • Average time from patient referral to transplant centre to consulting with a transplant nephrologist (restricted to patients who had a referral that was accepted). • Average time from referral to transplant centre to being waitlisted (restricted to patients who were waitlisted). • Average time from consulting with a transplant nephrologist to being waitlisted (restricted to patients who were waitlisted). • Average time from referral to living kidney donor transplantation. • The proportion of living donor candidates who complete all the following: a nephrology consultation, a surgeon consultation, and a computed tomography angiogram. • Average time from completing the health history questionnaire to the computed tomography angiogram. • Average time from completing the health history questionnaire to donor nephrectomy.	intervention, which was designed to improve access to transplant, did not inadvertently introduce problems in other aspects of care. Further details on balancing measures are described in our published trial protocol.

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		• Average time from nephrologist consultation to donor nephrectomy.	
Statistical Significance	December 5, 2019	**Added**: To avoid type I errors due to multiple comparisons, we will use the fixed-sequence procedure, a stepwise multiple-testing procedure where two-sided hypothesis tests for superiority will be performed at the 0.05 significance level in a pre-specified order. We will test the primary outcome first. This will be followed by the five secondary outcomes. Once a hypothesis test is not significant, no further testing will be done. Rather, the analyses of any subsequent secondary outcomes, as well as additional outcomes and other analyses will be reported as point estimates with 95% confidence intervals (without p values); we will indicate that interval widths are not adjusted for multiple testing and therefore inferences drawn may not be reproducible.	During the course of our trial newly recommended guidance was published to avoid Type 1 errors due to multiple comparisons.[1,2,3] To avoid type I errors due to multiple comparisons we will use the fixed-sequence procedure, a stepwise multiple-testing procedure. 1. Harrington D, D'Agostino RB, Gatsonis C, et al. New Guidelines for Statistical Reporting in the Journal. N Engl J Med. 2019;381(3):285-286. doi:10.1056/NEJMe1906559 2. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER). Multiple Endpoints in Clinical Trials: Guidance for Industry. Silver Spring, MD; 2017. 3. Massachusetts Medical Society. Submitting to NEJM - Statistical Reporting Guidelines. https://www.nejm.org/author-center/new-manuscripts. Accessed December 4, 2019.
Statistical Power	August 10, 2020	**Added:** Statistical power calculations for the primary outcome (the number of steps completed towards receiving a kidney transplant) were informed by an analysis of historical administrative healthcare data in Ontario (from November 1, 2016 to October 31, 2017). We estimate a 3.5 year trial should have at least 80% power to detect a rate ratio of 1.5 (this corresponds to patients in the intervention group	At the beginning of the trial the only way we could get power estimates was through conducting a literature review. However, a much more refined way to calculate power is to use historic transplant data that became available to us. Specifically, we could analyze historic data and get event rates which in turn

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		completing an average of 12 more steps per 100 person-years than patients in the control group [35 steps vs. 23 steps, respectively]; 2-sided α=0.05).	informed our power calculations. See our published trial protocol for further details on our statistical power calculations.
Cohort Selection	August 10, 2020	**Added:** The primary analysis will be focused on individuals in multi-care kidney clinics (provide care to patients with kidney disease approaching the need for dialysis) or in dialysis programs with no recorded contraindications to kidney transplant in ICES administrative healthcare databases (i.e. patients that are eligible for transplant). Examples of recorded contraindications to transplant include dementia, use of home oxygen, living in a long-term care home, and any comorbidities likely to preclude transplantation. We will also restrict our primary analysis to individuals aged 18 to 80 as few people over age 80 are healthy enough to receive a transplant. Additional details can be found in our published trial protocol. We will also exclude patients from our analysis with invalid or missing data on date of birth or sex, and patients who are not permanent residents of Ontario (<1% will be excluded for a reason of invalid or missing data).	Although the analysis will be restricted to individuals approaching the need for dialysis or patients on dialysis with no recorded contraindications to transplant, the delivery of the intervention is at the CKD program level and all CKD programs in Ontario are included. The analysis will also be done at the program level. At the time of the final analysis, pre-specified selection criteria will be applied to restrict the statistical analysis to the patients of interest for trial inclusion.
Eligibility (*as described on ClinicalTrials.gov*)	August 10, 2020	**Changed from**: *Eligibility Criteria*: This is a pragmatic cluster randomized controlled trial with eligibility criteria detailed below. **Inclusion Criteria:** •All 26 chronic kidney disease (CKD) programs in Ontario. These programs provide care for all chronic dialysis patients in the province. Each CKD program also provides a multi-care kidney clinic for patients with advanced CKD who are progressing to end-stage renal disease. **Changed to**: *Eligibility Criteria*: This is a pragmatic, two-arm, parallel-group, open-label, registry-based cluster randomized clinical trial with eligibility criteria detailed below. **Inclusion Criteria:**	No changes were made to the eligibility criteria. We have just provided more detail on the trial design. In the inclusion criteria we also refined the wording to indicate that CKD programs provide a multi-care kidney clinic for patients with advanced CKD who are approaching the need for dialysis (previously we said progressing to end-stage renal disease). The wording now aligns with our published trial protocol.

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		•All 26 chronic kidney disease (CKD) programs in Ontario. These programs provide care for all chronic dialysis patients in the province. Each CKD program also provides a multi-care kidney clinic for patients with advanced CKD who are approaching the need for dialysis.	
Analysis of Trial Outcomes	August 10, 2020	**Changed from:** To determine if a statistically significant difference in the referral rate exists between the multi-component kidney transplant quality improvement program and the standard of care group a Poisson regression model will be used which includes potential confounders but not the intervention status. This method has been found in simulation studies to be robust even when there are a small number of clusters and when the distribution of cluster sizes is skewed. Study data at ICES will be used. **Changed to:** Study data will be obtained from Ontario's linked administrative healthcare databases at ICES (ices.on.ca). We will account for the study design and covariate-constrained randomization in our analysis. The primary outcome is at the cluster level (the rate of completing steps towards receiving a kidney transplant [per 100 person-years]) and will be compared between groups using a two-stage approach because we have 26 clusters randomized (13 per arm). In the first stage of the model, residuals are obtained from fitting a regression model to the individual level count data adjusting for pre-specified individual-level confounders while ignoring the intervention and clustering effects. In the second stage, the residuals from the first stage are aggregated at the cluster level and used as the outcome to estimate the effect of the intervention. This model fits cluster-level variables and the treatment effect. **Changed from**: We will censor at death or end of study.	We have refined our analysis based on feedback from our study biostatistician and a review of historic records. The new adopted statistical method was thought to be more appropriate given our updated primary outcome and number of clusters within each arm. The analysis will still be completed at the cluster level and still be done using an intent-to-treat approach. Please refer to our published trial protocol for more details. **Reference** Hayes RJ, Moulton LH. *Cluster Randomised Trials*. 1st ed. New York, NY: Chapman and Hall; 2009. We have refined our censoring events to ensure our denominator is capturing the population of interest.

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		Changed to: We will follow patients in our analysis until the end of study, death, receipt of a kidney transplant, or become ineligible for transplant, whichever comes first. **Added**: A patient's follow-up time will begin on November 1, 2017 or on the earliest date when all eligibility criteria were met up until 3 months before the trial end date (3 months is the expected minimum time to complete early steps towards receiving a kidney transplant). Patients can only enter the analytic cohort once.	We provide detail on the timeframe for entering the analytic cohort for analysis.
Additional exploratory analyses	August 10, 2020	**Added:** We have added pre-specified subgroup analyses. Specifically, in additional exploratory analyses we will consider subgroup analyses to determine if the intervention improved access to kidney transplant in the following subgroups: receiving maintenance dialysis at the time of trial entry (in-centre or home dialysis), sex (male vs. female), race (white vs. other), immigration status, geography (average distance from the patient's place of residence to the transplant centre), income quintile (measured by neighbourhood-level median income), and measures of marginalization (i.e. residential instability, material deprivation, ethnic concentration, and dependency).	We want to explore the effects of the intervention in different subgroups, with a focus on subgroups that have traditionally experienced lower access to transplant.
Sponsors and Collaborators	August 10, 2020	**Changed from:** *Collaborators*: Institute for Clinical Evaluative Sciences Canadian Institutes of Health Research (CIHR) **Changed to:** *Collaborators*: Institute for Clinical Evaluative Sciences Canadian Institutes of Health Research (CIHR) Ontario Renal Network (ORN) (part of Ontario Health) Trillium Gift of Life Network (TGLN) (part of Ontario Health)	We added the Ontario Renal Network as a collaborator. The Ontario Renal Network has always been involved with the organization and the delivery of the intervention. We are now officially listing them to align with our published trial protocol. We also now include TGLN as a collaborator.