

BMJ Open Randomised controlled trial of a video intervention and behaviour contract to improve medication adherence after renal transplantation: the VECTOR study protocol

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ABSTRACT

Introduction Non-adherence after kidney transplantation contributes to increased rejections, hospitalisations and healthcare expenditures. Although effective adherence interventions are sorely needed, increasing education and support to transplant recipients demands greater use of care providers' time and resources in a healthcare system that is stretched. The objective of this clinical trial is to determine the effectiveness of an electronically delivered video series and adherence behaviour contract on improving medication adherence to immunosuppressant medications.

Methods and analysis A multicentre, parallel arm, randomised controlled trial will be conducted with four sites across North America (Saskatoon, Calgary, Halifax, Chicago). Adult patients will be randomised (1:1) to either the intervention (ie, home-based video education +behaviour contract plus usual care) or usual care alone. De novo transplant recipients will be enrolled prior to their hospital discharge and will be provided with electronic access to the video intervention (immediately) and adherence contract (1 month post-transplant). Follow-up electronic surveys will be provided at 3 and 12 months postenrolment. The primary outcome will be adherence at 12 months post-transplant, as measured by self-report Basel Assessment of Adherence to Immunosuppressive medications and immunosuppressant levels. Secondary outcomes include the difference in knowledge score between the intervention and control in groups (measured by the Kidney Transplant Understanding Tool); differences in self-efficacy (Generalised Self-efficacy Scale), Beliefs of Medicine Questionnaire (BMQ), quality of life (Short Form-12), patient satisfaction and cost utilisation. The study aims to recruit at least 200 participants across participating sites.

Ethics and dissemination Ethical approval was obtained from the University of Saskatchewan Behavioural Ethics Committee (Beh 18–63), and all patients provide informed consent prior to participating. This educational intervention aims to improve information retention and self-efficacy, leading to improved medication adherence after kidney transplantation, at low cost, with little impact to existing healthcare personnel. If proven beneficial, delivery can be easily implemented into standard of care.

Strengths and limitations of this study

- This multicentre study employs a randomised, controlled design.
- The intervention, which does not require substantial resources to deliver, incorporates an educational component (which was developed with patients) and a behavioural strategy to support autonomy, an important aspect of medication adherence.
- The main limitation is the lack of power to evaluate clinical outcomes such as graft function or mortality; however, the primary endpoint is adherence to medications, which has been directly linked to major clinical events.
- Subjects in the experimental group cannot be blinded due to the nature of the educational interventions, and may be prone to a Hawthorne effect.

Trial registration number NCT03540121; Pre-results.

INTRODUCTION

Kidney transplantation is the gold-standard treatment for patients with end-stage renal disease, and the benefits are immense compared with dialysis. Transplantation is associated with a better quality of life and patients live two to three times longer.^{1–3} However, following the transplant, patients must commit to indefinite therapy with immunosuppressive medications. Failure to adhere to these medications can result serious consequences, such as graft rejection, graft loss and significant costs to the healthcare system.⁴ Approximately one out of five transplant recipients fail to take their regimen as prescribed.⁵ Consequently, up to one-third of all solid organ rejections may be precipitated by non-adherence.⁶ Considering that more than 30 000 kidney transplants are

performed yearly in the USA alone,⁷ medication non-adherence is a problem that must be taken seriously.

Immunosuppressive therapy is initiated at the time of transplant surgery, leaving little time for patients to prepare for the reality of multiple medication use following hospital discharge. The early postoperative period is often associated with anxiety and confusion, and may not be the most effective time for patients to receive information.^{8–11} However, due to logistical factors, medication and lifestyle teaching is often performed by the healthcare team prior to the patient's discharge. Even though patients are educated during the transplant process, poor knowledge about medications remains a major problem following transplant surgery^{11–13} for reasons largely unknown. Furthermore, patient self-efficacy for taking medications and medication adherence wanes over time.¹⁴

Effective educational opportunities can help patients prepare for the complexities of transplantation and may positively influence outcomes. The evidence, however, is strongest in the pretransplant period, where a number of well-designed trials have recently been undertaken. Literature has illustrated the benefits of using educational strategies to improve knowledge and willingness to discuss living organ donation, as well as predicting success at identifying donors.^{15–18} Video and printed education has also been effective at increasing willingness to serve as an organ donor in ethnic populations where donation rates are typically low.¹⁹ Nevertheless, well-designed interventional studies examining educational outcomes after transplant are rare. Randomised controlled trials (RCTs) investigating adherence as an outcome have historically been even more uncommon.

Successful adherence interventions have generally employed a multidimensional strategy including education and counselling on medication taking, discussion of adherence barriers and goal setting.²⁰ Adherence interventions often include strategies to promote self-efficacy and have linked to improved confidence, empowerment,⁸ medication adherence and quality of life.^{21–22} Chisholm-Burns and colleagues explored the impact of using education from a clinical pharmacist in combination with a behavioural contract (patient agreement to work on adherence), compared with usual care.²³ Significantly higher adherence rates were noted in the intervention group, along with decreased hospitalisations at 12 months. However, the intervention involved individualised collaboration between patients and a study pharmacist, necessitating additional resources and time. Hence, replication into other settings may be challenging.

'Solid Organ Transplantation: An Educational Mini-Series for Patients' is a patient-centred video series that describes the kidney transplant process. It was developed with patients, for patients and input from additional patient stakeholders was provided throughout the development process. Best practice for designing education for patients pursuing transplant was used²⁴ and a multidisciplinary team including experts in medication

adherence, video education, motivational psychology, cultural education and healthcare providers were involved in this process. A manuscript detailing the video development process has been published elsewhere.²⁵ The videos consist of animated segments which accommodate patients with low health literacy. Narratives by actual patients and healthcare providers help personalise the information, and provide real world advice, aligning the content with principles of the adult learning theory, which states that adults should be involved in the planning and evaluation of the learning, and are most interested in topics that have personal relevance and are problem centred.^{26–27} Video-based education has been shown to be at least as effective as traditional methods of education,^{28–29} and allows the opportunity for information to be consistently delivered, and replayed as often as needed.^{30–32}

We hypothesise that patient-centred video education combined with an adherence contract, will enhance information retention about medications, and self-efficacy, leading to improved medication adherence to immunosuppressive medications after kidney transplantation. The intervention will be provided electronically to supplement routine interactions with the transplant program, without additional heavy burden on health providers who are already have a high workload. Furthermore, patients will have the opportunity to watch and replay information as desired in the comfort of their home.

METHODS AND ANALYSIS

The Video Education and Behaviour Contract to Optimize Adherence in Renal Transplants (VECTOR) study is a multicentre, parallel design RCT that will be conducted to test the effectiveness of the video intervention plus adherence contract on improving kidney transplant candidate's medication adherence to immunosuppressive medications, compared with usual care. Four transplant sites across North America will be participating in this study: the Saskatchewan Transplant Program (located in Saskatoon, SK), Southern Alberta Transplant Program (Calgary, AB), Multi-organ Transplant Program of Atlantic Canada (Halifax, NS), University of Illinois Health Sciences System (Chicago, IL). A study lead at each site will take responsibility for local research ethics submission, recruitment, enrolment and follow-up activities.

Patient recruitment, eligibility and enrolment

Patients who have received a de novo kidney transplant at one of the study sites during the enrolment period will be invited to participate in the study. Eligible patients will be 18 years or older, and can speak, understand and read English (or have a support person that helps them). Participants will be excluded if they have previously received a kidney transplant, or have a visual along with a hearing impairment that would absolutely prohibit viewing the educational materials. Many transplant recipients

experience language barriers or other impairments that can impede the delivery of education. These individuals usually rely on a designated support person to assist with the transplant process and their postoperative care. In order to represent the population cohort and 'real life' as accurately as possible, we will accept participation from individuals who need assistance with completing the tasks, provided that a designated support person is able to assist them, and an adequate accommodation can be made. (For instance, in the case of a language barrier, participation may be feasible with the assistance of a family member. Or, in the case of a hearing impairment, closed captioning can be turned on for participants randomised to the intervention group.) Finally, patients who have previously participated in another study entitled: 'Improving health outcomes of kidney recipients: A Randomized controlled trial of a pre-transplant education intervention', which is taking place at two of the study sites (SK, AB) will also be excluded, since this study uses a version of the video intervention in a pretransplant cohort. The importance of keeping all study materials confidential is stressed to patients participating in both studies, to minimise the possibility of contamination.

During the transplant hospitalisation (as the patient is getting ready for discharge), a healthcare provider will explain the purpose of the study and assist patients in enrolling by setting up a study account using a study iPad. Depending on the site's workflow, the 'enroller' may be a healthcare provider (eg, nurse, pharmacist, nurse or physician), or study coordinator. A standardised script will be used to ensure consistency between all enrollers and sites. The study lead at each site will follow a strict protocol for maintaining patient data to prevent any breach of privacy/confidentiality.

Randomisation and blinding

Following consent, patients will be randomised (1:1) to either the intervention (ie, home-based video education plus a behaviour contract plus usual care) or usual care alone, using pregenerated survey participation links. Randomisation will be performed in permuted blocks of either six or eight, stratified according to site a custom Python (V.2.7.11) script. A third-party research organisation, the Social Science Research Laboratory (SSRL) at the University of Saskatchewan, will perform the randomisation centrally and provide sequentially numbered survey participant links to the study sites, that will conceal the treatment.

The study team will remain blind to participant allocation. Participant blinding is not possible in behavioural studies, however, every attempt will be made to treat the two groups consistently to minimise bias. Participants in both groups will be informed that they will be randomised to one of two groups, and that the intervention group will receive 'extra education and materials about taking medication'. They will not be explicitly told what the intervention entails. Further, patients in the control group will receive communications of similar content and frequency

to the intervention group to help maintain consistency. Patients in the trial will be reminded not to discuss the nature of the intervention with friends or the program staff, or other patients. They will also be provided with a personalised, password-protected unique login credentials to access the video content and prevent uncontrolled sharing of the video links.

Baseline questionnaire

Participants that provide consent will be asked to complete a baseline questionnaire on the study iPad. The questionnaire assesses demographic and clinical information such as age, sex, race/ethnicity, levels of education, whether or not a patient is on dialysis and what type (ie, haemodialysis or peritoneal), marital status, resident location, travel time to transplant centre, self-reported adherence and health literacy. Similar to previous research in transplantation, health literacy will be assessed with two items scored on Likert-type scales: 'How often do you have someone (like a family member, friend, hospital/clinic worker or caregiver) help you read hospital materials?', and 'How confident are you filling out forms by yourself?'.^{33,34} Baseline transplant knowledge will be measured by the Kidney Transplant Understanding Tool (K-TUT), while self-efficacy, beliefs of medicine and quality of life will be measured by the Generalised Self-efficacy Scale (GSE), Beliefs About Medicines Questionnaire (BMQ) and Short Form-12 (SF-12) scales, respectively.³⁵⁻³⁸

Intervention: standard of care + video education + behaviour contract

Participants randomised to the intervention group will receive standard education along with the home-based video education plus an adherence contract. Following the baseline assessment, access to videos will be provided. A personalised, password-protected link is provided to the participant, and the videos are accessible using this link from any electronic device. Participants may view them on a device in the hospital and/or they can watch and replay them at home. Patients who wish to view the videos in the hospital setting are provided with headphones to protect the participant's privacy and study contamination. The link is active throughout the duration of the study so that the videos can be accessed as often as desired. The videos are part of a series entitled 'Solid Organ Transplantation: An Educational Mini-Series for Patients', which consists of six videos outlining all stages of the transplant process. In the present study we will be using a modified version of the series consisting of three of the videos; Video 1: Introduction, Video 2: Medications, Video 3: Your New Life. The first video sets the stage for the intervention and introduces the viewer to the series. An animated overview of the immune system is presented and some commonly used transplant terms are discussed. The second video provides an overview of commonly used transplant immunosuppressants. It discusses common side effects and provides information on how to cope with lifelong medication taking. Testimonials from actual patients and

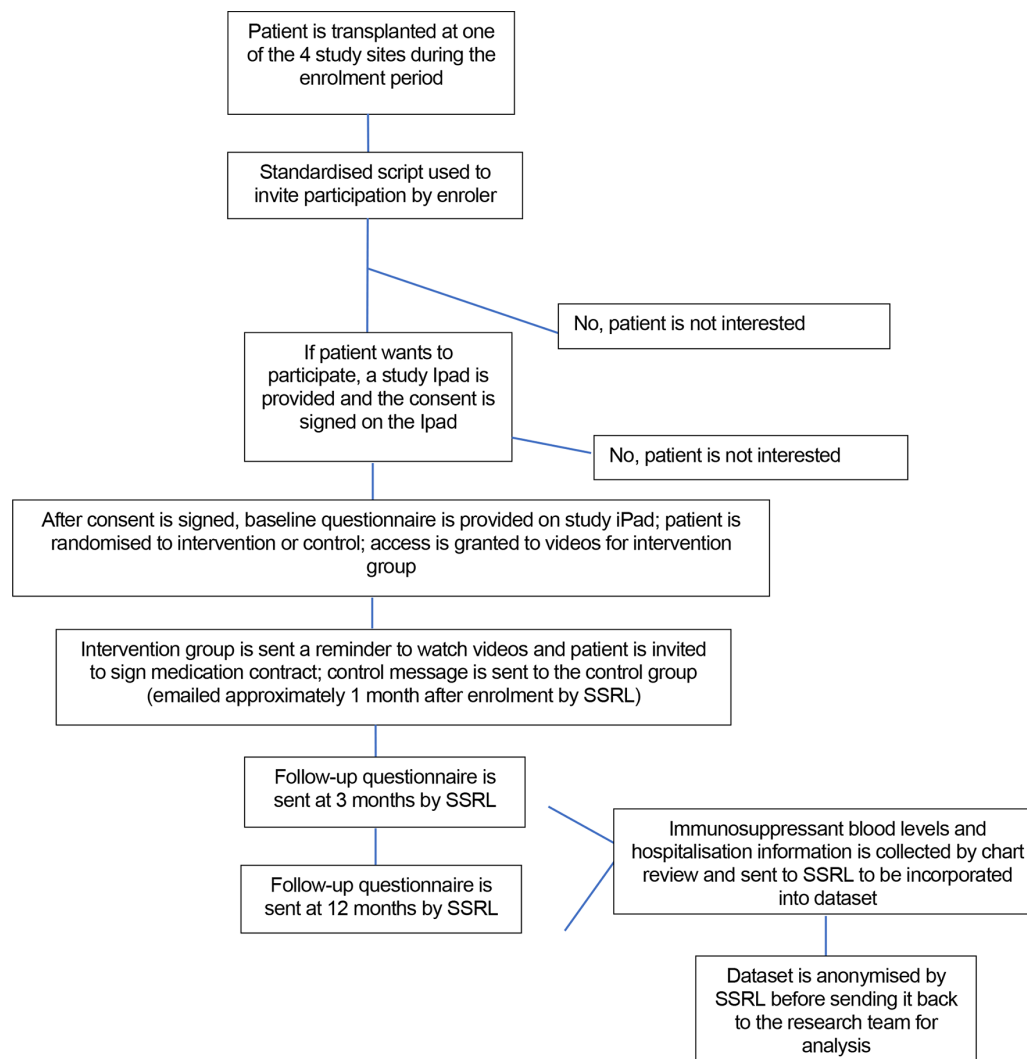


Figure 1 Depicts a flow chart describing the study process. SSRL, Social Sciences Research Laboratory.

a donor family supplement the information and provide patient perspectives on medication adherence. The final video addresses common questions that patients have about life after transplant, which were curated from actual patients. Some of the topics pertain directly to post-transplant health (such as infection prevention, cancer screening and risk minimisation, post-transplant monitoring and medication-related questions), while others are more general in nature (such as exercise, returning to work, how to honour your donor). Three of the videos from the original series will not be shown because they pertain to issues pretransplant. The SSRL will be monitoring video viewing statistics throughout the course of the study. Patients in the intervention group who have not accessed the videos prior to the 1-month behavioural contract will receive reminders to do so.

Approximately 1 month after the patient has been enrolled into the study and been provided with access to the videos, participants will receive an email link inviting them to reflect on their goals about transplantation and pledging to taking their immunosuppressant medications as directed. The adherence contract used in this study was

inspired by previous research performed by Chisholm-Burn and colleagues.^{23 39} The participant is asked to consider the health goal of remaining adherent to his or her immunosuppressive therapy regimen, and reflect on motivation, and consequences of failing to perform the behaviour, and then set an action plan for taking medications as directed. Example goals are provided to the participant, along with free-formed text boxes so that the participant can type in their own personal responses. Although the goal setting aspect of the intervention is somewhat visionary in nature (ex: ‘My health goal is to be adherent to my immunosuppressant therapy regimen to remain healthy for my family’), the participant is asked to provide a specific plan to achieve the goal, and to consider problems that may interfere with reaching the goal, along with potential solutions. The contract will be non-enforceable (no penalties or rewards are provided for contract adherence), but it will provide patients with the opportunity to formally commit to a goal of taking the medications as prescribed. A signature box has been programmed into the software, so that participants can provide a personal handwritten signature. The behaviour

Table 1 Summary of interventions, assessments and data collected at specified time points

	De Novo Transplant Admission	1 month after transplant	3 months after transplant	12 months after transplant
Demographic and medical characteristics	√ ₁			
Prior education regarding transplant and health literacy	√ ₁			
Knowledge assessment	√ ₁		√ ₁	√ ₁
Behaviour contract (intervention) or control email message		√ ₁		
Video viewing habits		√ ₃	√ ₃	√ ₃
Satisfaction with education			√ ₁	√ ₁
Self-efficacy			√ ₁	√ ₁
Beliefs of medicine			√ ₁	√ ₁
Quality of life			√ ₁	√ ₁
Adherence to transplant medications			√ ₁	√ _{1,2}
Adherence to appointments				√ ₂
Days in hospital				√ ₂

√₁ =self-report questionnaire sent by SSRL; √₂ =data collected and submitted by study site; √₃ =data populated by study software.

intervention uses self-reflection and the contract is completed autonomously, without health care provider witness or interference. The participant is encouraged to contact their transplant team if they require any support with taking their medications. However, since the intent is to test an intervention that can be delivered without substantial resources, and minimise bias that goal coaching may introduce in this multicentre trial, the contract is not formally reviewed with the transplant centre. The goal setting activity is revisited with participants during the 3 months and 12 months postenrolment surveys.

Based on Saskatchewan data,⁴⁰ over 90% of transplant candidates have access to the internet and will be able to obtain the intervention and outcome assessments in the form of surveys over a computer from home. Videos will be distributed electronically to all intervention participants by the SSRL using a password protected link. The SSRL has extensive experience in overseeing experimental research activities and will manage the study for the duration of the follow-up period, allowing a standardised process that will be used across all four sites. They will disseminate videos, administer surveys and collect data and deidentify the final dataset prior to analysis by the research team. Participants that do not have access to the internet at home will be able to view the videos electronically, access the questionnaires and sign the contract when they present to the transplant clinic for their routine post-transplant appointments, using their phone and the hospital's Wi-Fi, or the study iPad. The SSRL will streamline this process by providing a site-specific list of patients requiring face to face follow-up during appointments. Study site leads will ensure that participants are

followed up at key check points (1 month, 3 months and 12 months postenrolment).

Control: standard of care education

The control group will receive the standard of care education that is routinely provided at each transplant centre. In all centres, this includes verbal and written information provided by the healthcare team. Before discharge all patients receive 1:1 medication education with a healthcare provider (nurse or pharmacist) as per a standard teaching checklist. Anything not covered before discharge will be flagged as an outstanding teaching point to the ambulatory transplant pharmacist. Medication teaching sheets and a personalised medication schedule are also provided. Patients randomised to the control arm will receive the same assessments throughout the study period, without access to the videos. In lieu of the adherence contract, participants in the control group will receive an email message thanking them for participating in the study, and explaining that the next assessments (surveys) will occur at 3 months and 12 months after enrolment.

OUTCOME MEASURES

Primary outcome: medication adherence

The primary outcome will be the difference in the percentage of participants adherent to their immunosuppressive medications between the intervention and control groups at 1-year post-transplant. Adherence to immunosuppressant medications will be measured by using self-report using the Basel Assessment of Adherence to Immunosuppressive medications sent electronically to each participant.⁴¹ An answer of 'yes' to any of

the questions (pertaining to missing doses, drug holidays, timing and dose reduction) will constitute non-adherence as a binary outcome.

Two additional measures will also be assessed, a visual analogue scale (VAS) and immunosuppressant blood levels. The VAS will provide a continuous measure of adherence collected through the electronic survey while outpatient immunosuppressant levels (tacrolimus, cyclosporine or sirolimus) will be collected as per routine practice, and will be standardised to the patient-specific target. Inpatient coefficients of variation will be used as a measure of trough level variability, and percentage of subtherapeutic levels will be determined for each patient. The frequency of immunosuppressant monitoring varies depending on the time post transplant, with more intense monitoring performed early in the transplant period (ex. Two or three times per week for up to three months post-transplant, and around once monthly closer to 1-year post-transplant.). In all centres, immunosuppressant monitoring is performed at least monthly during the first year post-transplant. This information will be calculated and reported to SSRL by site leads. All measures described above have been validated in transplant literature and have been significantly associated with rejection.^{42 43}

Secondary outcomes

Secondary outcomes include the difference in change in knowledge score between the intervention and control groups, and differences between the intervention and control in the following measures: self-efficacy, beliefs about medications, quality of life, satisfaction with education, adherence to appointments and days in hospital. Knowledge of kidney transplant will be measured by the K-TUT, which has been evaluated in both pretransplant and post-transplant cohorts, and has been shown to have good internal consistency, reproducibility, content and construct validity.³⁵ Self-efficacy will be captured using the GSE which assesses beliefs for coping with difficult demands in life.³⁶ It has been used in many disease states, including transplantation.^{44 45} Beliefs about medications will be measured using the BMQ, which measures cognitive perceptions of a patient's own medications and beliefs in general.³⁷ It has been validated in patients with chronic illnesses.⁴⁶ Quality of life will be measured by the SF-12 V.2 (SF-12®),³⁸ a validated short version of the SF-36. The SF-12 has been used in several kidney transplant cohorts.^{47–49} Satisfaction about the educational experience will be captured by five questions whereby participants rate their confidence, understanding and satisfaction with education about transplant medications and lifestyle on a Likert scale of 1–5. The above described measures will be collected by way of a self-reported survey administered 3 months and 12 months post-transplant, either at home electronically or on the clinic iPad. The data will be immediately transmitted to SSRL.

Adherence to appointments or 'no shows' are defined as the percentage of times a patient failed to present to

an appointment, or scheduled test without calling ahead. In addition, postintervention hospitalisation rates will be collected to estimate potential reductions in usage and costs associated with the intervention. Further, costs of the intervention will be compared with gains in utility based on the SF12. Adherence to appointments, staff time in administering the intervention and days in hospital during the study period will be collected retrospectively at the study end and reported to the SSRL by the study site leads.⁵⁰ The site leads will remain blind to participant allocation and the SSRL will incorporate the information into the final dataset and deidentify it before providing it to the research team for analysis.

In the intervention group, individualised viewing statistics will be available from the SSRL allowing an assessment of video viewing habits. The total duration that participants have watched each video in minutes will be recorded and will be divided by the total length of each video to be used as a surrogate marker for whether the video was watched in its entirety. The percentage of patients viewing at least one module, percentage of patients viewing the mini-series in its entirety will be reported. Three additional questions will be used to collect information on whether participants liked or disliked the intervention, and what aspects they believe should be changed. Figure 1 depicts a flow chart of the study process, table 1 describes a summary of the interventions, assessments and data collected at specific time points during the study process.

Incentives

Study participants will be provided with incentives in the form of gift cards during specific time points in the study to encourage continued participation. A \$20 gift card will be provided after the study participants complete the 3-month post-transplant questionnaire. A \$25 gift card will be issued for participants who reach the study endpoint and complete the final survey. Although no penalties are issued for participants in the intervention group that fail to watch the videos or complete the behavioural contract, their participation is monitored.

Sample size

The primary endpoint is the percentage of patients reporting optimal adherence to their immunosuppressants at one year post-transplant. A sample of 100 patients in each group is sufficient to determine a 15% absolute increase (from 75% to 90%) in percentage of adherent patients at an alpha of 0.05 and a beta of 0.20. This sample will allow for exploration of smaller changes (10%) in secondary analyses of mean adherence measured by the visual analogue scale. Thus, assuming a drop-out rate of up to 25%, we will enrol 268 patients to ensure the primary analysis is adequately powered.

Data analysis

All patients who have completed at least one postbaseline assessment will be included in the primary endpoint

analysis. The percentage of patients in each group reporting optimal adherence will be compared using a χ^2 test. In cases where the final assessment is missing, the last observations are carried forward. In a secondary analysis, the additional adherence measures will be analysed and triangulated with the primary endpoint comparison. Also, the primary endpoint comparison will be repeated including all enrolled patients where those missing a postbaseline assessment will be considered non-adherent. Also, a 'per protocol' analysis will be conducted after excluding intervention patients with no record of downloading any videos after randomisation. Finally, additional subgroup analyses will be performed after stratifying on baseline demographic and socioeconomic variables (age, sex, income, education attained, health literacy).

Secondary endpoints examining knowledge, beliefs about medications, quality of life, self-efficacy, satisfaction and days spent in hospital during the 1-year follow-up will be compared using t-tests for independent samples. In addition, predictors of optimal adherence (ie, the binary primary endpoint) independent of the video intervention will be examined using logistic regression analysis. The following independent variables collected at baseline will be examined in univariate analyses: demographics, health literacy, previous self-reported adherence, transplant knowledge, previous education, beliefs about medications and quality of life. Variables that are significant at $p < 0.20$ will be included in a multivariable model containing intervention group.

ETHICS AND DISSEMINATION

All patients provide informed consent prior to participating. The results of this study will be presented at conference proceedings and published in a peer-reviewed journal. The educational intervention aims to improve information retention and self-efficacy, leading to improved medication adherence after kidney transplantation, at low cost, and with little impact to existing healthcare personnel. If proven beneficial, delivery can be easily implemented into standard of care and readily provided to transplant patients across North America.

Patient and public involvement

The video series used in the study was developed with patients based on educational gaps identified by patients. This process involved a series of consultations with kidney transplant patients and their families to determine optimal content, after which 35 patients volunteered their time to be filmed for the videos.²⁵ Finally an intensive review process was undertaken and the videos were modified accordingly. Two renal transplant recipients (PT and EW), were consultants throughout the development of this clinical trial protocol. They reviewed all procedures and documents and tested the burden of the intervention. When the study has been completed, the results will be disseminated on our study website.

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Contributors NR, PT, JW, CD, RM, DB and AS participated in the design of the study and contributed to the revising the protocol manuscript. JL was responsible for the statistical design of the study. HM is the principal investigator of the study and is responsible for overseeing the project, including trial design and manuscript preparation. All authors approved the final manuscript.

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Competing interests HM, NR, RM and AS developed the video intervention used in this project.

Patient consent for publication Not required.

Ethics approval The protocol has been approved by the University of Saskatchewan Behavioural Ethics Board (Beh 18-63).

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