Multifaceted Intervention To Improve Graft outcome disparities in African American Kidney Transplants: MITIGAAT Study Protocol

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Abstract

Background: Outcome disparities for African American (AA) kidney transplant recipients is a public health issue that has plagued the field of transplant since its inception. Based on national data, AA recipients have nearly twice the risk of graft loss at five years post-transplant, as compared to Caucasians. Evidence demonstrates that medication non-adherence and high tacrolimus variability substantially impact graft outcomes and racial disparities, most notably late (>2-years) after transplant. Non-adherence is a leading cause of graft loss. Prospective multicenter data demonstrates that one-third of all graft loss is directly attributed to non-adherence. We have spent ten years of focused research to develop a comprehensive model explaining the predominant risk factors leading to disparities in AA kidney recipients. However, there are still gaps in patient level data that hinder a deeper understanding of the disparities. Lack of data from the patient often leads to provider biases, which will be addressed with this intervention. Culturally competent pharmacist-led interventions in medication therapy management (MTM) will also address therapeutic inertia. Pharmacist interventions will mitigate medication access barriers as well (cost, insurance denials). Thus, this multidimensional intervention addresses patient, provider, and structural factors that drive racial disparities in AA kidney recipients.

Objective: The goal of this prospective, randomized study is to determine the impact of multimodal health services intervention on health outcomes disparities in African American kidney transplant recipients.

Methods: MITIGAAT is a 24-month, two arm, 1:1 randomized controlled clinical trial involving 190 participants (95 in each arm) measuring the impact on adherence and control of late clinical issues for racial disparities in kidney recipients, through a technology-enabled, telehealth-delivered four-level intervention.

Results: The aims of this study are to improve adherence and control of late clinical issues, which are predominant factors for racial disparities in kidney recipients, through a technology-enabled, telehealth-delivered four-level intervention. The key clinical issues for this study include tacrolimus variability, blood pressure, and glucose control (in those with DM). We will also assess the impact of the intervention on healthcare utilization (hospitalizations and ED visits) and conduct a cost-benefit analysis. Finally, we will assess the impact of the intervention on acute rejection and graft survival rates as compared to a large contemporary national cohort.

Conclusions: With this report, we describe the study design, methods, aims, and outcome measures that will be utilized in the ongoing MITIGAAT clinical trial. Clinical Trial: ClinicalTrials.gov NCT06023615: https://www.clinicaltrials.gov/study/NCT06023615

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Trial Registration: ClinicalTrials.gov NCT06023615: https://www.clinicaltrials.gov/study/NCT06023615

Key Words: Kidney Transplant; Mobile Health; Medication Adherence

Introduction

Racial disparities in kidney transplant is a public health issue that has persisted for more than 50 years. As compared to Caucasians, African American (AA) kidney recipients have nearly twice the risk of graft loss at five years post-transplant. Despite recent data demonstrating modest improvements in this disparity, a kidney transplanted today is still expected to function about half as long in AAs.[1-3] Marginal improvements in AAs are due to improved access to transplant, stemming from organ allocation policy changes, and reductions in early acute rejection through better understanding of immunologic risk and use of potent immunosuppression. [4-6] However, recent studies from our team and others demonstrate that post-transplant outcome disparities in AAs can predominately be explained by issues that arise late (≥2-years) after transplant. [8-10] These issues include late medication non-adherence leading to high tacrolimus variability

and rejection and poor control of diabetes and hypertension. [7-13] In models adjusting for these late issues, the risk of graft loss in AAs was reduced by up to 75%, as compared to non-AAs, and losing statistical significance. [7-11]

For the past decade, our research team has focused on improving post-transplant outcomes and reducing disparities in AA kidney recipients by developing and using mobile health (mHealth) and telehealth interventions. [14-20] Our mHealth app and intervention are founded on self-determination theory (SDT) and designed to improve patient autonomy, competence and relatedness. [21-23] This is coupled with the use of pharmacist-led motivational interviewing (MI) delivered during televisits, designed to improve care and identify and address barriers preventing optimal adherence and comorbidity management, including medication costs. [24-27] Our mHealth, telehealth intervention improves access to care through remote patient monitoring (RPM) and MTM; addressing structural barriers, racial bias, and therapeutic inertia that induce disparities. [28-30] Through robust preliminary research, we developed, refined, and tested the functionality, acceptance, and durability of our intervention. [14-17] We completed a 60 patient (65% AA) pilot study (NIDDK K23DK099440) demonstrating significant improvements in the control of diabetes and hypertension through our mHealth intervention; improvements in hypertension control were more substantial in AAs. [16] In 2020, we completed a 12-month randomized controlled trial (AHRQ R18HS023754) in 136 patients (64% AA) that used our mHealth, RPM, pharmacist-led telehealth intervention to improve medication adherence and reduce hospital readmissions and costs by over 40%.[14,20] These two clinical trials demonstrated our intervention is highly accepted in AAs; 55% of our kidney transplant population is AA, while 65% of study participants were AA. Dropout rates were 3%.[16,20] An economic analysis demonstrated the intervention provided a net cost savings of $368,839 through reduced hospitalizations and had a return of investment of $4.30 for every dollar spent. [31]

Objectives: The next clear step in our research trajectory is to conduct a long-term, large-scale study and assess whether this four-component health services intervention can improve health outcome

disparities in AA kidney transplant recipients. Thus, we propose a randomized control trial (RCT) to use this system to deliberately address post-transplant disparities in AAs entitled the “Multifaceted Intervention to Improve Graft outcome disparities in African American Kidney Transplants (MITIGAAT)” study. The overarching hypothesis for MITIGAAT is that late non-adherence and suboptimal control of diabetes and hypertension are more common in AA kidney transplant recipients and are major contributors to health disparities. A multimodal intervention that addresses these issues will significantly reduce health care disparities among AA kidney transplant recipients.

Methods

Study Design: This is a single-center, 24-month, two-arm, semi-blind, 1:1 randomized controlled clinical trial involving 190 participants (95 in each arm), with roughly 55% (100 participants) being AA. We will also conduct a retrospective longitudinal cohort study, comparing a large contemporary national cohort of adult Veteran kidney recipients transplanted between 2015 and 2021 to our RCT intervention arm. This study meets all guidelines set by clinicaltrials.gov and has been approved by the local Institutional Review Board.

Aims: The primary aim of this study is to determine the impact of multilevel health services intervention on achieving improved adherence to tacrolimus. Additionally, we will determine the impact of multilevel health services intervention on blood pressure (BP) and glucose control (in those with diabetes). We will conduct a cost- benefit analysis, assessing the estimated costs of hospitalizations and emergency department (ED) visits compared with the cost to deliver interventions. Finally, we will track the incidence of acute rejection, graft loss, and death in the intervention patients and compare our data with a large national cohort of veteran kidney transplant patients and assess for racial disparities for these health outcomes.

Recruitment, Screening and Enrollment Procedures: Adult (≥18 year at the time of transplant) kidney transplant ≥2 years post-transplant that meet eligibility will be approached by researchers for consideration for participation. After discussing the details of the study, providing time, and gaining informed consent, patients will be randomized in a 1:1 fashion (blocks of 10) to either the enhanced control group (usual care + attention control) or the intervention group (usual care + four-level intervention (Table 1). For the Aim 4 cohort study, we will include all adult solitary kidney recipients transplanted between 2015 and 2021 with ≥2 yrs of follow-up to match the RCT.

Eligibility:

Inclusion: Participants must be adults (≥18 years of age at the time of enrollment) kidney transplant recipients that are ≥ 2 years post kidney transplant.

Exclusion: We will exclude patients who are multi-organ transplant recipients or those patients who received a transplant of an organ that is not a kidney (liver, lung, heart, intestine, pancreas, bone marrow). Any patients who are not capable of measuring their own BP and glucose (if applicable), using mobile health applications after adequate training, or speaking, reading, and hearing English will be excluded.

Sample Size and Considerations:

For the RCT (Aims 1 through 3), we will recruit and enroll 190 participants (95 in each arm), with roughly 55% (100 participants) being African American. For the Aim 4 cohort, we will include all adult solitary kidney recipients within the Veterans Health Administration system transplanted between 2015 and 2021 with ≥2 yrs of follow-up to match the RCT. We expect to have between 8,000 and 10,000 patients in this retrospective cohort.

This study is powered to detect clinically meaningful and statistically significant improvements in

medication adherence, systolic blood pressure (SBP) control, DM control, and graft survival while also demonstrating significant reductions in AA disparities for these endpoints. Over the 2-year study, a 5% trajectory difference between arms for tacrolimus variability is considered clinically meaningful and is feasibly achievable given our pilot data (time*treatment). Tacrolimus concentration coefficient of variation (Tac CV) has an expected standard deviation of 8.5 with an approximate Gaussian distribution (see histogram below); thus, meeting normality assumptions. A sample size of 87 per group (n total=174) achieves >0.999 power, assuming both arms start with a tac CV of 35% and changing over the 2-year study to 32% in the control arm and to 27% in the treatment arm. The study is also powered (0.800) to specifically test for reductions in racial disparities between the intervention and control arms, using a 3-way interaction term in the model (time*treatment*race. We have 0.998 power to detect a difference in SBP changes between arms, assuming a mean SBP of 135 mmHg in both arms at baseline and a 5-mmHg reduction in the treatment arm, using 25 repeated measures. SBP has an expected standard deviation of 9.0 with a Gaussian distribution. We have 0.800 power to test for reductions in racial disparities between the arms for SBP, using the time*treatment*race 3-way interaction term. We have 0.998 power to detect a difference between arms for glucose changes, assuming a mean baseline glucose of 160 mg/dL in both arms, 50% of patients having DM (N=82) at time of randomization and a trajectory difference in glucose of 24 mg/dL between arms. We have 0.803 power to test for significant reductions in racial disparities between the two arms for glucose control, modeled using the time*treatment*race interaction term. Mean glucose has an expected standard deviation of 10.8 and distribution approximates Gaussian. To account for dropouts and censoring events, we will increase each arm sample size to 95, totaling 190 participants.

Intervention:

Patients randomized to the intervention arm will be provided the same usual care as the control

group. In addition, these participants will receive comprehensive supplemental remote monitoring and follow-up by utilizing our smartphone-enabled mHealth app and dashboard, integrated with home-based monitoring of BPs and glucoses, and pharmacist-led scheduled televisits. Subjects in this group will be provided with a smartphone and data plan if they are not current owners of a device that is compatible with the mHealth app (iOS or Android). All will also be provided with a Bluetooth-enabled, automated, cuff-style bicep home BP monitor. Those with diabetes will be provided a Bluetooth enabled glucometer with testing supplies. On the mobile device, our mHealth app will be installed which displays the patient's med list and alerts them when it is time to take each medication, requiring them to respond via push button when they have taken the specified medications, providing a time stamp of intake as part of a multi-method adherence tracking system. [14] The intervention will include pharmacist-led telemonitoring of patient adherence to medications, appointments, BP measures, glucose readings in DMs, and electronic health records (EHR) information (tacrolimus variability, appointments and insurance status) and 21 scheduled telehealth visits with patients that cover specific topics.

Telehealth visits activities and schedule: We have a detailed plan we developed from previous work we will use for televisits in this study. [14,20] The pharmacists will first introduce themselves and provide a synopsis regarding the call rationale. Following this, they will conduct medication reconciliation, discuss lifestyle, diet, and review home measures to determine causes of suboptimal adherence and BP/DM control, if applicable. Motivational interviewing (MI) will be used to develop and implement a patient-centered plan to address identified issues leading to sub-optimal control of BP, DM, and/or medication non-adherence. The MI six step process is as follows: 1) establish rapport; 2) assess knowledge, health literacy, motivation, and confidence; 3) define barriers, concerns, and positive self-motivational statements about their behaviors; 4) summarize 'pros' and 'cons' of proposed interventions to address behaviors; 5) provide options to help with adherence; and 6) give a summary of the session, having the patient repeat back key details. During calls, the

pharmacist will implement agreed upon changes to medications and monitoring plan. This process was purposely developed so that it can be entirely conducted during televisits. [24-27] Each televisit will have a predominant theme, such as BP management, DM management, adherence, lifestyle, etc. During these 21 visits (Table 1), we will consistently use MI to better understand patient's ambivalence towards specific issues and their intrinsic motivations and values to resolve these self-contradictory factors. Culturally competent MI will be used to work collaboratively towards goals and as a means towards improved overall well-being and health. MI is well-known to our investigator team, as we have used these in our formative research and demonstrated successful outcomes. [14,16,20] The already developed and tested mHealth and remote monitoring dashboard are supplemental technology-enabled tools that will help reinforce the telehealth sessions and provide the patient and team objective comprehensive data to gauge successes and continued barriers. All encounters will be documented in the EHR. [14,20]

Smartphone mHealth application: Through an iterative, patient-centered process, we developed, tested, and validated a mHealth app that will be used within this study. [14-18] This app was used for a recently completed RCT demonstrating efficacy in reducing medication errors and improving adherence (NCT03247322). [20] The app performed well and feedback from enrollees is that it was well-received and is useful to help with medication adherence and comorbidity self-monitoring and regulation. [20] A brief description of the app and function is as follows: After a patient logs into the app using a HIPAA-compliant PIN, they are taken to their home screen. From here, they can record and/or review medications, BPs, glucoses, and medication side effects. They can also directly call the transplant center, study coordinator or pharmacy for refills, and send real-time email alerts to the clinician if they need to document a medication change, a visit to the ED, or admission to the hospital. When the patient taps the medications button, they can review their complete medication list, which is automatically updated from the EHR. Patients can review their medication regimen

scheduled times and select which medications they are taking to document adherence. If the patient wants to document medication side effects, they tap the “Side Effects?” button, which brings them to the survey to document incidence and severity of side effects. To review and automatically upload (using Bluetooth) BPs and blood glucoses, the patient taps the appropriate button, which brings them to the BP or glucose page. The data from Bluetooth connected home monitoring is automatically synced to the mHealth app, encrypted, and transmitted to the web-based portal. The mHealth app also provides several important and timely push notifications to patients, including when it is time to take their medications, check their BP/glucose and take a survey. The push notifications have a snooze function as well (every 30 min, up to 3 snoozes). The app provides daily individualized motivational text messages to patients, based on SDT and a comprehensive survey the patient completes at initiation. [18] These messages are automated based on how well the patient is adhering to the medication regimen and monitoring. We will enhance the app by making it compatible on Android (currently only on iOS), improve the medication data from the EHR to make it real-time (currently on an overnight delay), and add surveys.

Remote monitoring dashboard: We will also utilize a web-based dashboard portal that was developed as part of the aforementioned RCT. [20] The system curates data from the EHR and app and presents it in summary form on a single screen, where the clinician user can efficiently review patients (each row is a single patient), sort relevant measures (each column) and identify and triage at-risk patients. Each patient row is color-coded based on risk factors. Blue demonstrates a patient with all measures within goal, yellow demonstrates a patient with one measure out of range, while red indicates two or more measures outside targets. The thresholds for out-of-range values were set based on validated levels from previous research. [8-11] From this portal, the clinician can also edit patient contact information, change the passwords or login credentials for the app, update the medication regimen timing, update timing of notifications to check home measurements and directly text patients.

Several different reporting capabilities are available through the system; reports display trends in BPs, glucoses, and medication adherence. These data can be downloaded as raw values into a spreadsheet and shared with patients or outside providers.

Enhanced usual care control arm: The standard care that is provided to all transplant kidney recipients will continue to be provided to both arms in this study. The structure and processes involved within this care model are well-established, as evident by our institutions ranking amongst the top-performing U.S. transplant centers for length of stay, readmissions, and outcomes. Our kidney program was bestowed the American Society of Health-System Pharmacists Foundation Award for Excellence in Medication-Use Safety for demonstrating improvements in outcomes through a pharmacist-led, comprehensive multi-disciplinary quality improvement initiative. As part of this initiative, specific protocols, which delineate immunosuppressant regimens, laboratory evaluations and timing, follow-up clinic schedules and the treatment of comorbidities (hypertension, diabetes, hyperlipidemia) will continue to be utilized. During the long-term ambulatory care phase, patients are followed with serial labs and clinic visits as follows. From months 6 to 12 post-transplant, patients have labs every month with clinic visits every three months. From year 1 to 3 post-transplant, patients are seen every six months with labs every two to three months. After year 3, patients are seen annually with labs every three months. For the enhanced usual care arm, to ensure we have home BP and glucose measure results to compare between arms, patients will be given access to the app to use in a passive mode, meaning data will be collected, but no interventions will be delivered. Within this usual care arm, no alerts or alarms will be set within the app. If a patient does not have a compatible smartphone and/or data plan, one will be provided. All will be provided a Bluetooth-enabled BP device and glucometer (for DMs) and supplies. To minimize attention control bias, we will provide enhanced attention control as follows: Subjects in the control group will receive text messages every seven days on general health-related topics. These messages include healthy lifestyle tips related to physical activity, dietary intake, non-exposure to first- or second-hand

smoke, and limited alcohol intake.

Safety Monitoring:

The data safety monitoring plan (DSMP) will include the use of a safety officer and the MUSC IRB to monitor the study-related safety, clinical outcomes, and potential adverse events. Additionally, the DSMP will utilize the study statistician to review the data generated by the MITIGAAT study and ensure data integrity and assess potential for futility. Summaries of adverse event reports and safety concerns raised by the safety officer will be made to the NIH in yearly progress reports unless the nature of a particular event is such that it bears reporting to the NIH immediately. The designated safety officer for the MITIGAAT study is a well-experienced transplant physician who is not directly involved in the intervention component of the study. The designated statistician responsible for data oversight and creating the reports needed for the DSMP meetings is an experienced biostatistician with knowledge in monitoring clinical research data integrity. Both the safety officer and the biostatistician will coordinate data review and analysis and communicate with the study PI and the co-investigators. The functions of the designated safety officer are to: 1) provide scientific oversight; 2) review all serious adverse effects or complications related to the study; 3) monitor accrual; 4) review summary reports relating to compliance with protocol requirements; and 5) provide advice on resource allocation.

Statistical Analysis Plan: We will use intent-to-treat principles; all randomized patients will be included in the analysis according to their allocated arm, even if they dropout, are lost to follow-up or have a censoring event.

To assess for balance between arms, we will compare a comprehensive set of baseline recipient and donor variables, and transplant characteristics, using standard univariate tests (chi square, Fisher’s exact test, t-test, Mann-Whitney U tests), as appropriate, based on data distributions and test

assumptions. For the recipient, baseline variables will include age, sex, End Stage Renal Disease cause, dialysis type and vintage, comorbidities (diabetes, hypertension, Coronary Artery Disease, Congestive Heart Failure, etc), infection serologies (cytomegalovirus[CMV], Epstein-Barr virus[EBV], Herpes simplex virus[HSV], Hepatitis C virus [HCV], Hepatitis B virus[HBV]), waitlist time, insurance status, education level, disability, geographic location and social determinants of health measures, as specified by the NIH PhenX SDOH toolkit. For the donor, measures include age, sex, past medical history, infection serologies (CMV, EBV, HSV, HCV, HBV), and kidney donor risk index. For the transplant characteristics, variables include time from transplant to enrollment, immunosuppression, Human Leukocyte Antigens, Panel-Reactive Antibodies, cold ischemic time, warm time, and Delayed Graft Functioning. We will use modern statistical approaches to determine the potential confounders, effect modifiers and mediators in addition to the initial screen of identifying variables that differ between arms as potential confounders in multivariable modeling, as described in the following sections below. [34]

Results:

The aims of this study are to improve adherence and control of late clinical issues which are predominant factors for racial disparities in kidney recipients, through a technology-enabled, telehealth-delivered four-level intervention. The key clinical issues for this study include tac variability, BP, and glucose control (in those with DM). We will also assess the impact on the intervention on healthcare utilization (hospitalizations and ED visits) and conduct a cost-benefit analysis. Finally, we will assess the impact of the intervention on acute rejection and graft survival rates vs a large contemporary national cohort. The study design and intervention were developed using our formative research, providing insights into interventions that change behaviors, improve access, and address provider bias and structural racism, while being highly acceptable to patients. [8-21]

Study Endpoints

- Tacrolimus variability (Primary Outcome, Aim 1): Defined as the intrapatient tacrolimus concentration coefficient of variation (CV): standard deviation divided by the mean for each patient. All outpatient true trough tacrolimus levels drawn will be used to calculate the tacrolimus CV. We will assess every three months, which aligns with the minimum lab draw schedule for kidney transplant recipients at out center. This is the sole primary outcome and will be analyzed using repeated measures methodology, estimating efficacy effect size using the time*treatment interaction term and disparity using the time*treatment*race interaction term.
- Time in therapeutic range (TITR, Secondary Outcome, Aim 1): Defined as the proportion of time the tac levels for a given patient are within desired therapeutic range, typically 6-10 ng/mL. Goal ranges may vary by patient but is well-documented in the medical record. TITR will be calculated using a modified version of the linear extrapolation Rosendaal method, as proposed by Reiffel et al. All outpatient trough tacrolimus levels will be used to calculate the TITR. We will aggregate these and assess every 3 months, analyzed using repeated measures.
- Medication adherence survey (Secondary Outcome, Aim 1): Defined based on a self-reported questionnaire administered to patients in both arms through the app every 3 months (9 total, including baseline). The IMAB-Q 10 will be used; a validated, easy to administer, 10 question instrument. A score of <20 (range 10 to 50) indicates medication adherence.
- BP assessments (Secondary Outcome, Aim 2): Defined as the mean of all SBPs checked by patients at home and the transplant center (ambulatory measures). Patients with a mean of SBP ≤140 mmHg will be considered controlled. All patients will utilize the same home-based device for these measures and taught proper technique.
- Glucose assessments (Secondary Outcome, Aim 2): This will only be assessed in those with a diagnosis of diabetes, estimated to be more than 50% of the study population. Glucose control will

be defined as the mean measure of all glucoses (random or fasting). Only those with diabetes will be included in this outcome. Those with DM and a mean random glucose ≤160 mg/dL will be considered to controlled. All patients will utilize the same meter and strips for these measures.

- Healthcare utilization (Secondary Outcome, Aim 3): Defined as any hospitalization or ED visit that occurs during the study period. Assessments will be analyzing using count data modeled using Poisson or negative binomial link. Total length of stay will also be assessed.
- Hospitalizations (Secondary Outcome, Aim 3): Defined as any admission to a hospital with at least one overnight stay. Hospitalizations that occur outside the study institution will be gathered at the end of the study by querying the South Carolina Revenue and Fiscal Affairs Office , which tracks all hospitalizations for South Carolinians, regardless of payer.
- ED visits (Secondary Outcome, Aim 3): Defined as any visit to the ED with a documented encounter during the study period. ED visits that occur outside the study institution will be gathered at the end of the study by querying the South Carolina Revenue and Fiscal Affairs, which tracks all ED visits.
- Acute rejection (Aim 4): Defined as a renal allograft biopsy showing at least grade 1A rejection by Banff criteria. [32-33] Per usual care practices, all patients are required to have biopsy confirmation of rejection episodes within 24 hours of onset of treatment for acute rejection. It is standard care that all kidney allograft biopsies performed for transplant recipients occur at the transplant center (study institution). Biopsies will be read by a blinded local pathologist, as usual care. This will be assessed using time to event analyses.
- Graft failure and death (Aim 4): Graft failure will be defined as return to chronic dialysis, nephrectomy, re-transplant, or death. The timing and cause of each graft loss will be recorded for comparative analysis. Patient death will also be captured, with timing and cause. These will be analyzed using time to event methodology. For primary and secondary outcomes, graft loss and death will be considered censoring events; data accrued until these events will be used in analyses.

Discussion:

We propose an RCT to use this system to deliberately address post-transplant disparities in AAs entitled the “Multifaceted Intervention to Improve Graft outcome disparities in African American Kidney Transplants (MITIGAAT)” study. The overarching hypothesis for MITIGAAT is that late non-adherence and suboptimal control of diabetes and hypertension are more common in AA kidney recipients and are major contributors to health disparities. A multimodal intervention that addresses these issues should significantly reduce health care disparities among AA kidney transplant recipients.

Conflict of Interest: DJT has received research grants from Veloxis Pharmaceuticals, Inc, Merck, Sharp and Dohme, Takeda Pharmaceuticals U.S.A., Inc., and CareDx inc.

Abbreviations:

AA: African American

BP: blood pressure

CMV: cytomegalovirus

DM: Diabetes Mellitus

DSMP: data safety monitoring plan

EBV: Epstein-Barr virus

ED: emergency department

EHR: electronic health record

HBV: Hepatitis B virus

HCV: Hepatitis C virus

HSV: Herpes simplex virus

mHealth: mobile health

MI: motivational interviewing

MTM: medication therapy management

RPM: remote patient monitoring

RCT: randomized control trial

SBP: systolic blood pressure

SDT: self-determination theory

Tac CV: tacrolimus concentration coefficient of variation

TITR: time in therapeutic range

Supplemental:

Figure 1

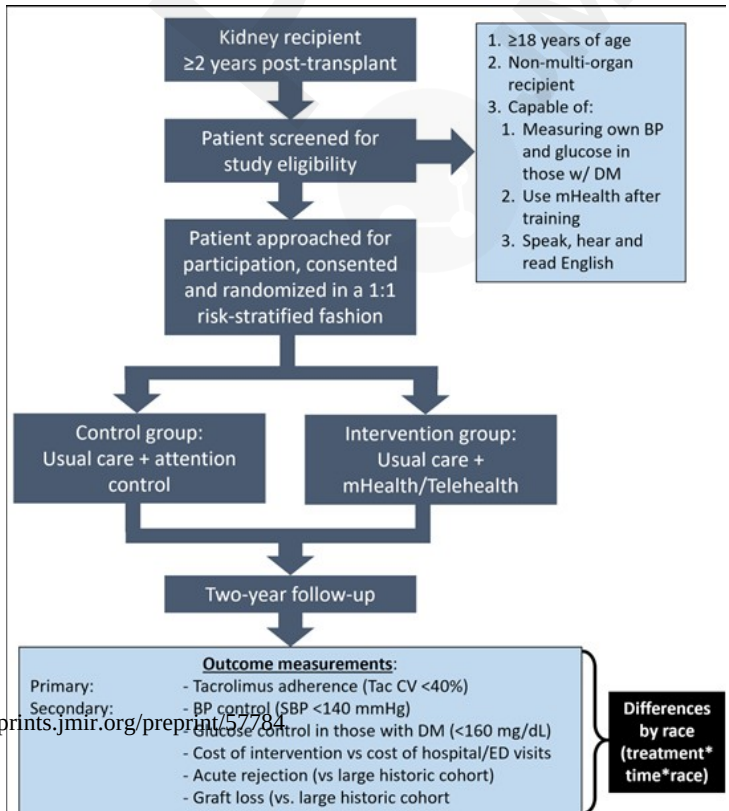

Table 1

Months	Telehealth Visit #	Techniques Used and Topic(s) Covered
1-2	1	Teach patient how to use app and home BP and glucometer
	2	Review technology with patient, troubleshoot any issues, review readings during months 1-2
3-4	3	Using MI, discuss current levels of medication adherence, non-adherence rates and barriers to achieving optimal adherence
	4	Educate on importance of medication adherence & implement strategies to improve adherence
5-6	5	Using MI, discuss current control of HTN & barriers to optimal control
	6	Educate on importance of HTN control & implement strategies to improve self-monitoring & management
7-8	7	Using MI, discuss current control of DM & barriers to optimal control
	8	Educate on importance of DM control & implement strategies to improve self-monitoring & management
9-10	9	Using MI, discuss adherence to immunosuppression & barriers to optimal adherence
	10	Educate on importance of med adherence & implement strategies to optimize adherence
11-12	11	Educate importance of staying active & implement strategies to improve staying active/exercising
	12	Educate importance of smart dietary choices & implement strategies to choose wisely
13-14	13	Review current HTN control & using MI identify barriers to optimal control
	14	Implement additional strategies to improve HTN control
15-16	15	Review current DM control & using MI identify barriers to optimal control
	16	Implement additional strategies to improve DM control
17-18	17	Review current comorbidity burden and control & using MI identify barriers to optimal control
	18	Implement additional strategies to improve comorbidity control
19-20	19	Review medication adherence and implement strategies to improve if not optimal
21-22	20	Discuss any ongoing issues with patient precluding optimal management of comorbidities & adherence
23-24	21	Study close out session. Conduct surveys & implement plan for continued engagement

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