PROTOCOL TITLE:

Improving Healthcare Outcomes in **A**merican Indian and Hispanic Transplant Recipients Using **C**ulturally-**T**ailored Novel Technology (**IMPACT**)

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REGULATORY FRAMEWORK:

Please indicate all that apply:

☐	DOD (Department of Defense)
☐	DOE (Department of Energy)
☐	DOJ (Department of Justice)
☐	ED (Department of Education)
☐	EPA (Environmental Protection Agency)
☐	FDA (Food and Drug Administration)
☒	HHS (Department of Health and Human Services)
☐	VA
☐	Other:

FUNDING:

Dialysis Clinic, Inc.

CLINICAL TRIALS

Is this a clinical trial per the NIH definition of a Clinical Trial? ☒ Yes ☐ No

NIH Definition of a Clinical Trial:

A research study in which one or more human subjects are prospectively assigned to one or more interventions. An "intervention" is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Use the following four questions to determine the difference between a clinical study and a clinical trial:

1) Does the study involve human participants? ☒ Yes ☐ No
2) Are the participants prospectively assigned to an intervention? ☒ Yes ☐ No
3) Is the study designed to evaluate the effect of the intervention on the participants? ☒ Yes ☐ No
4) Is the effect being evaluated a health-related biomedical or behavioral outcome? ☒ Yes ☐ No

Note that if the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial, even if…

- You are studying healthy participants
- Your study does not have a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study is utilizing a behavioral intervention

If yes to all 4 questions, please confirm that the research team is familiar with and agrees to comply with the investigator requirement to register the study on the ClinicalTrials.gov database. Additionally, the approved consent document(s) must be uploaded to the ClinicalTrials.gov database ☒ Yes ☐ No

For any assistance with registration of your trial or the requirements, please contact HSC-CTSCResearchConcierge@salud.unm.edu

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1. Objectives

Aim 1: Examine IMPACT's acceptability and feasibility in AI and HL KT recipients.
1a. We will assess acceptability by patient ratings of satisfaction with the culturally-tailored diet and exercise intervention, as well as the Twistle patient engagement platform.
1b. We will assess feasibility by determining recruitment and retention rates and assessing participant adherence to the IMPACT intervention.
1c. We will determine the ideal personnel hours and number of staff required for the physical therapist/exercise physiologist and registered dietitian nutritionist roles.

Aim 2: Test the efficacy of IMPACT on proximal outcomes (e.g., weight, lipid profile, HbA1c, sleep quality, QOL) and distal outcomes (e.g., occupational functioning) in kidney transplant recipients.
2a. We will assess participants' adherence to the exercise and diet intervention aspects of IMPACT.
2b. We will begin to examine the relationship between adherence to IMPACT and patient outcomes.

2. Background

Kidney transplantation (KT) is the treatment of choice for patients with end-stage kidney disease (ESKD). Although KT reduces cardiovascular events, cardiac death rates in KT recipients remain up to 10 times greater than in the general population.[1,2] Similarly, KT recipients with diabetes-associated ESKD have higher mortality rates compared to recipients with ESKD due to other causes.[3,4] New-onset diabetes after transplantation is also a major contributor to the burden of cardiovascular disease.[5,6] Further, although aggressive treatment with post-transplant immunosuppressive agents[7,8] has decreased rejection, use of these agents is associated with a host of other complications, such as hyperlipidemia, hypertension, post-transplant diabetes, and glomerulopathy.[9-22] Currently, the most common approach to treating these cardiometabolic complications is medication. However, medications are limited in their effectiveness,[2,23,24] and patients may face contraindications and unwanted side-effects, given their complex post-transplant immunosuppression regimen.[9-22] Given the tremendous resources that go into evaluating and transplanting ESKD patients, it is important to explore effective, yet less costly, approaches to reducing cardiovascular and diabetes-related risk post-transplant.[2]

Weight gain in the first year after KT, and especially an increase in fat mass, is a very common contributor to elevated cardiometabolic risk. In addition, low levels of physical activity and reduced physical functioning are common after KT, associated with a reduced quality of life (QOL)[25] and poor sleep quality.[26] Lifestyle modification (dietary changes and exercise) has been the mainstay for initial management of diabetes and cardiovascular disease for decades in the general population. Because of the presence of both traditional and transplantation-specific risk factors for cardiovascular events and diabetes after transplantation,[27-29] it is important to validate the feasibility and efficacy of an early post-transplant lifestyle modification specifically for the KT population.[30] Although an approach specifically tailored to KT recipients may be an optimal solution,[31,32] Takahashi's[33] seminal review of physical activity in the KT population noted that previous programs had limited testing (e.g., small sample sizes; brief follow-

up),[17,33-35] and have not resulted in specific lifestyle management guidelines for KT recipients.[36] Similarly, a recent Cochrane review of dietary interventions for adults with CKD[37] highlighted the limitations of current evidence of dietary interventions on CKD patients. Further, a meta-analysis of multi-behavior lifestyle interventions in chronic disease and community populations[38] found that most intervention studies are targeted at White (WH) or African American (AA) patients, with lowest representation of American Indian (AI) or Hispanic/Latina(o) (HL) populations; overall, only 10% of interventions were culturally appropriate to the target population.

In **Imp**roving Healthcare Outcomes in **A**merican Indian and Hispanic Transplant Recipients Using **C**ulturally-**T**ailored Novel Technology (**IMPACT**), we will pilot the feasibility and acceptability of a culturally-tailored, multi-behavior lifestyle intervention using a novel technology for 14-20 AI, HL, and White KT recipients. Because of KT recipients' varied stability immediately post-transplant, and the need to individually monitor their post-transplant immunosuppression regimen,[1,23,24,33] a critical component of IMPACT will be an individually-tailored exercise and diet plan with a physical therapist/exercise physiologist and a registered dietitian nutritionist, who will work closely with the post-transplant team to carefully monitor patient stability. IMPACT will combine a personalized assessment of the patient's food preferences and access to exercise resources within their environment (based on a standard list of factors developed by our nutrition and rehabilitation experts) along with clinical specifications from the transplant team. Our study is innovative because it addresses previous limitations,[33,37] while adapting the intervention to meet the needs of the culturally-diverse ESKD population. The final innovation of the IMPACT Pilot is our use of the Twistle Patient Engagement Platform[39] to follow-up with participants between their scheduled appointments, ensure adherence to the intervention, collect all questionnaire data, and enhance participant retention.

3. Study Design

Due to heterogeneity among the exercise programs used in previous post-KT studies, it is difficult to make definitive conclusions regarding the benefit of aerobic versus resistance training.[33] **Thus, our project is innovative because it combines instruction that is professionally guided by a therapist, and incorporates a rehabilitation approach to slowly increasing KT recipients' physical activity[40-42] until they can engage in exercise at levels consistent with the KDIGO guideline.** We argue that in the current era of personalized medicine, it would not be appropriate to prescribe one form of exercise across all patients. Rather, a tailored approach to physical rehabilitation with the end goal of a patient's ability to meet the KDIGO guidelines (and within their specific cultural environment) is optimal for patient health and outcomes. Our intervention is innovative because it addresses the limitations identified by Takahashi's[33] review of physical activity and the Cochrane review of dietary guidelines[37] in the KT population, while having the capacity to be culturally adapted to meet the needs of the diverse ESKD population that exists in the US today.

Another innovation of our approach is to work with the existing resources of the core transplant team in any transplant center (namely, the transplant registered dietitian) and empower that team member to develop a culturally-tailored diet approach

that helps patients reduce weight gain, lower their HbA1c levels, and decrease their risk of post-transplant cardiovascular events. This is an innovative health services research approach that will allow our team to determine the cost effectiveness of expanding the role of the registered dietitian on the KT team in a subsequent R01 project. Only one study of a lifestyle modification intervention targeting diet and exercise with KT recipients has been published, but it lacked a randomized controlled trial because it confounded intervention with health condition and studied patients who were at least 6 months post-transplant.[43] In contrast, our intervention will focus on patients when they are still in the hospital immediately post-transplant. Hospitalization has been hypothesized to serve as a "teachable moment" that could more clearly demonstrate to patients the connection between behavior and health and be particularly amenable to making changes in patient health behavior (e.g., in-patients with unhealthy alcohol use, diabetes, pediatrics, cancer).[44-47]

The most critical innovation of the IMPACT pilot is our collaboration with the makers of Twistle (Fig. 1).[39] Twistle is a HIPAA-compliant patient engagement platform designed to perform across all clinical specialties, procedures, and chronic conditions. Twistle is used for patient education, reminders, and secure messaging. Clinicians and patients can automatically send and receive HIPAA-compliant messages including text, emojis, photos, and videos. Twistle has an automation engine that can engage, respond and manage conversations, allowing staff and clinicians to take over conversations that need extra attention. It can also automatically send alerts and follow-up messages based on survey responses and triage appropriately based on pre-defined rules and on-call schedule. Twistle is designed to integrate with electronic health records, registries, databases and predictive analytics tools. It also automatically synchronizes data from smart devices, such as blood pressure cuffs, weight scales, CPAP machines, and activity trackers. Because Twistle is a multimodal platform, it can deliver messages and reminders through smartphone apps (Apple and Android), text message (SMS), computer browsers, EHR portal and regular landlines using interactive voice response (IVR) or recorded voice. So our intervention with Twistle will be used by those with or without a smartphone, and addresses recent

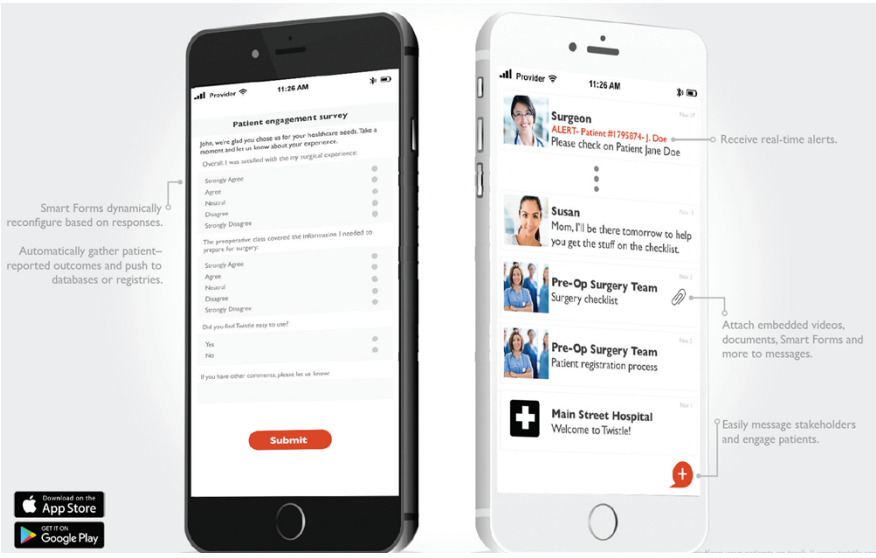


Figure 1. Screen shots of Twistle patient engagement platform

and ongoing concerns regarding broadband internet and provider access in rural communities.[48,49]

For our research purposes, we will use Twistle to create and deploy our participant questionnaires because it is compatible with RedCap. We will also use it to send personalized reminders and check-in with participants based on the culturally-tailored exercise and diet plan developed by our intervention team to assess and maintain adherence to the intervention. Twistle also enables the data to be pushed to a reimbursement database, so that our research team is triggered to provide participant payments. Finally, we will use Twistle to track participant status throughout the research protocol. The application will allow us to confirm message delivery, patient engagement, and monitor triage alerts.

We will randomly assign participants to either the IMPACT intervention of usual care (UC) prior to their first intervention point. Dr. Zhu (lead statistician) will develop a random allocation scheme by considering stratification to form blocks with respect to important determinants such as ethnicity, gender, etc. Within each stratum or block, we will accomplish random allocation to IMPACT vs UC with systematic sampling (e.g. alternating the assignment of IMPACT and UC with a random start). This scheme will result in a nearly equal number of patients in IMPACT and UC within a block. We will reduce potential bias using stratified randomization by preventing potentially inferring treatment allocation a priori. It also reduces bias by balanced assignment so that potential determinants of outcomes are comparable across intervention groups. We can also use systematic sampling to reduce sampling variation in comparison with simple random sampling. Because of the close interaction between the clinical team and the research interventionists, we will not be able to blind the clinical team to group assignment.[50,51] After Dr. Zhu creates the allocation scheme, he will give it to the research coordinator, who will put the allocation assignments into separate sealed envelopes. The research coordinator will place the master list in a locked file cabinet drawer in the office of the PI's Office Administrator. Only the sequence numbers (A1 – block A patient #1, A2, A3, etc.) will appear on the sealed envelopes and the corresponding group assignment will be placed inside the envelope. The research coordinator will open the sealed envelope sequentially and inform the consented participant of his or her assigned group. After random assignment, the research coordinator will direct participants in the IMPACT intervention to the study interventionists (the physical therapist and dietitian).

4. Inclusion and Exclusion Criteria

We plan to recruit participants shortly before or after undergoing KT at the UNM HSC Transplant Center. The Transplant Center provides transplant services to all New Mexico residents as well as the surrounding Pueblos and the Navajo Nation. Reflecting the demographics of the state, only 3% of patients are AA at UNM. Male and female KT recipients aged 18 and older will be eligible for enrollment.

Transplant Patients

Inclusion criteria:

1. Received kidney transplant at the University of New Mexico
2. Greater than 18 years of age

3. American Indian (AI) or other race, White (WH) or Hispanic/Latina(o) (HL)
4. Mentally competent

Exclusion criteria:

1. Children under the age of 18
2. Incarcerated patients
3. Pregnant women

Team Members

Inclusion criteria:

1. Transplant clinic staff
2. Key administrators involved in the transplant process

5. Number of Subjects

To estimate the number of patients we can expect to recruit for the study, we used data from the last five years of KT recipients at UNM HSC. The center transplants an average of 33 patients per year. For the study, we plan a 12-month recruitment period. Of all eligible patients who receive a KT, we expect that 80% will agree to participate in our study (n=26), based on previous intervention research with KT patients,[13,16,17,34,41,52-54] and our own work.[55-57] Thus, for this pilot trial, we aim to recruit and retain 14-20 KT recipients. Virtually all of UNM ESKD patients are (a) HL (44%) or AI (33%), (b) income <$25K, (c) on public insurance, (d) high school or lower education; and/or, (e) low occupational status. Thus, our patient sample will include members of different vulnerable populations that have been underrepresented in past research, and hence prepare us to conduct a formal study in a diverse population.

Team members will include up to fifteen people from the following groups: transplant clinic staff and key administrators.

6. Study Timelines

Participant expected duration in the study will be one year, if they complete all study visits. Patient recruitment and enrollment will be completed in 12 months of the study (Month 4, Year 1 through Month 3, Year 2). Participant follow-up, data analysis, and manuscripts are schedule to be completed in Year 2 of the study.

Project Period: 03/01/2020 – 02/28/2022		
Year: Month: **Activity**	**01** 1-3 4-6 7-9 10-12	**02** 1-3 4-6 7-9 10-12
Project Startup (e.g., hiring and training staff; database creation)	----	
Participant Recruitment	----------	-----

Participant Follow-up		----------
Team Member Surveys		----------
Data Quality Evaluation and Observation Logging	----------	----------
Data Analysis		----------
Present Initial Findings at Conferences		----
Report and Manuscript Preparation		----

7. Study Endpoints

The primary endpoints for the pilot trial are intervention **acceptability** and **feasibility**. To assess **intervention acceptability** we will measure patients' satisfaction with the interventions with a revised version of the Client Satisfaction Questionnaire;[58-60] where higher satisfaction will indicate greater intervention acceptability, and the System Usability Scale (SUS),[61] where higher scores indicate ease of usability. We will assess questionnaire acceptability using open-ended patient questions. In addition to quantifying **feasibility** using **recruitment and retention rates**, to provide concrete estimates of the expected rates of missing data and participant attrition, we will keep a detailed log of relevant factors that could create barriers to subsequent study completion. We will measure time spent sedentary (sitting/lying), standing, and stepping (and the intensity) during awake hours with the activPAL3 accelerometers, and compare these values between the IMPACT and UC groups. Time required for study participation will be measured using survey completion times as well as intervention session time estimates.

In addition to the primary endpoints noted above, we will assess the feasibility and acceptability of collecting a number of patient outcomes that will be the key target outcomes in a large scale R01. A systematic review of 35 randomized controlled trials of exercise training in solid organ transplant recipients, including 9 kidney, 21 heart, 3 lung, and 2 liver transplant studies, found that there were a total of 62 patient outcome measures, including peak VO2, SF-36 score, and muscle strength.[52] Of these, our team determined that the most relevant outcomes to assess in our pilot include: (a) variables that we will gather from participants' medical records (i.e., % weight change, lipid profile, and HbA1c); (b) patient reported outcomes, including the PROMIS Sleep Related Impairment[62] and Sleep Disturbance[63] Measures and PROMIS Global Health[64]; and, (c) occupational functioning, using the occupation subscale of the CHART-SF.[65] The CHART-SF is the most widely used participation measure in rehabilitation research,[66] and has been used in various ethnic groups.[67]

8. Research Setting

We plan to recruit participants shortly before or after undergoing KT at the UNM HSC Transplant Center. The Transplant Center provides transplant services to all New Mexico residents as well as the surrounding Pueblos and the Navajo Nation. Reflecting

the demographics of the state, only 3% of patients are AA at UNM. Thus, their number will be too small to examine as a separate racial group. Male and female KT recipients aged 18 and older will be eligible for enrollment.

9. Resources Available

The PI and the research team bring extensive expertise to this project, and are well-known for their interdisciplinary work in KT. Dr. Myaskovsky has a national reputation in KT disparities by examining issues related to organ donation and transplantation.[68-73] Dr. Unruh has national recognition in clinical trials and patient-reported outcomes in chronic kidney disease[74-88] and KT.[71,85,89-101] Drs. Unruh and Myaskovsky have a long history of collaboration on longitudinal studies that encompass a broad range of cultural issues related to kidney donation and transplantation.[102,103] Dr. Singh is the Medical Director of Transplant Services at the (UNMHSC). She collaborates with Drs. Unruh on issues related to the medical care of CKD and ESKD patients.[106,108-110] Dr. Zhu has done extensive work in developing data analytic methods and collaborating and supporting health and clinical research in a broad spectrum of fields.[111-114] From 2005-2011, Dr. Zhu served on the Advisory Committee on Organ Transplantation (ACOT) to advise the Secretary of the Department of Health and Human Services on national policies concerning all aspects of solid organ transplantation. He is also collaborating with Drs. Myaskovsky and Unruh, on adherence and healthcare disparities in kidney transplantation.[105,106] Dr. Jimenez is an Associate Professor in the Department of Internal Medicine at UNM HSC, and the Director of the Nutrition Research Network (NRN) for the Academy of Nutrition and Dietetics. She has served as a Co-I or PI on studies focused on developing and testing interventions to better prevent and treat obesity and diabetes in high risk and underserved populations in New Mexico, and studies focused on testing the impact of nutrition care from a registered dietitian nutritionist on medical outcomes in different patient populations, including kidney disease.[115-118] Dr. Jimenez works closely with Dr. Steiber, the Chief Science Officer the Academy of Nutrition and Dietetics, and an Adjunct Professor in the Department of Nutrition, School of Medicine at Case Western Reserve University. Dr. Steiber has conducted a number of studies focused on nutrition assessment for malnutrition in patients with CKD, and will contribute her expertise in validation and feasibility studies focused on nutrition and assessment[117,119-121] as a consultant for our IMPACT pilot trial. Finally, our team's licensed physical therapist will be an expert in evaluating, developing and implementing individualized, evidence-based physical therapy services to increase patients' functional abilities.

Our team conducted a qualitative assessment with HL and AI patients, KT clinical providers, a registered dietitian and physical therapist to ensure that the IMPACT intervention is culturally and contextually appropriate. This work will form the basis of our pilot intervention. We also worked with KT clinical team to develop the timing and deployment of the intervention. We developed a detailed protocol to ensure that the intervention is standardized across all research participants, while still responding to individual needs.

We also worked closely with the Twistle team[39] to personalize the research intervention, participant questionnaires and prompts, and participant tracking tools. We will use the

personalized platform to deploy the IMPACT pilot study and we will revise it for the large-scale R01 trial, per findings from this pilot study.

10. Prior Approvals

UNM HSC IRB Approval will be obtained before beginning any study activities. Departmental Approval has been obtained and uploaded into Click IRB.

11. Multi-Site Research

NA

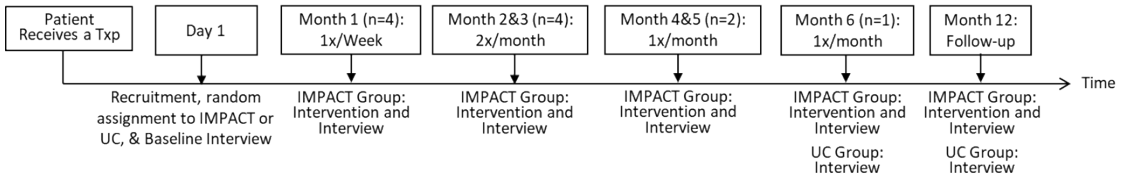
12. Study Procedures

Intervention

Intervention timing: We will minimize participant burden by applying the interventions during patients' standard post-transplant clinic visits. We display how the intervention time points correspond to the standard clinic schedule in Figure 2. The transplant team schedules patients for appointments at the post-transplant clinic 1x/week for the first month, then every two weeks for the next two months, then once a month at 4-6 months post-KT. Surgical clearance usually occurs 6-8 weeks post-KT, at which point the exercise intervention can begin. We will take advantage of these frequent in-person visits to deploy our exercise and diet intervention. Prior to the start of the exercise intervention, we will include a "baseline" test. We will measure time spent sedentary (sitting/lying), standing, and stepping (and the intensity) during awake hours with the activPAL3 accelerometers. At the baseline visit for both groups, we will assess self-reported exercise and physical functioning prior to transplant. Those in usual care will not undergo any diet or exercise intervention, but will wear an activity monitor. They will only undergo the baseline interview, and a follow-up at 6 and 12-months post-transplant. We will repeat the objective assessment of sedentary and physical activities at the 6 and 12-month follow-ups for all participants.

Participants in either arm may have delayed activPal monitor assessments at any of the four timepoints, based on current health status and at the discretion of the PI.

Figure 2. IMPACT and UC Participant Pathway



Exercise intervention: Patient-reported levels of physical activity and objective measures of physical fitness indicate lower levels of exercise in ESKD patients awaiting KT. After KT, physical activity increases, but it remains lower than in the general population.[122-125] Based on the most recent meta-analyses/reviews of physical activity post-transplant,[33,126,127] our approach combines instructions that are professionally-assessed with the culturally-tailored assessment of exercise needs (Appendix A), guided by a therapist, and incorporate a rehabilitation approach to slowly increasing KT recipients' physical activity[40-42] with appropriate build-up to more intense physical activity until they can engage in KDOQI guideline-based exercise.[128] After the initial

rehabilitation intervention, the latter set of KDOQI guideline-based target activities will include movements that can be performed in the home without supervision or the use of equipment such as abdominal curls, pushups, running in place, vertical jumps, stretching exercises, movement to music, study-provided therapy bands, and some basic yoga exercises. Each at-home session will last about 30-minutes, with the goal of engaging participants in continuous movement.

Participants will be asked to wear the activPAL3, an electronic activity monitor, for the objective assessment of sedentary activity and physical activity. The small, thin device (like a patch) will be worn on their mid-thigh (day and overnight) for 4-7 days after transplant stabilization, at the end of near the end of rehabilitation, at 6 months, and at 12 months. This is not a tracking device. The activity monitor will record general movement (sitting, standing, and stepping) and will enable us to get a better idea of the participant's daily activity and inactivity levels (versus self-report alone). We will also provide participants instructions for applying and removing the monitor. The activPAL3 monitor will be mailed to the study team after each use. After data collection, participants will be given the following instructions:

Once you have completed using the ActivPAL monitor, please remember to return it to our office using the pre-paid mailer we provided. You can drop off the mailer at any post office location. Please contact the study coordinator at (505) 795-1780 if you have any questions.

Participants will be given safety instructions (see Exercise Instructions) related to at-home exercise, in writing and orally, to help support their physical activity after transplant. The instructions will also be delivered through Twistle for intervention participants.

The study team will follow COVID safe practices as outlined in the related attachment. Additionally, if participants are transitioned to remote clinic visits per the transplant team and therefore not coming in-person to the hospital for their routine appointments in order to minimize COVID exposure, activPal monitors may be mailed. (see attached sample letter)

Dietary intervention: As in most other KT centers, post-transplant usual care in our transplant center includes one post-transplant visit with the registered dietitian. Patients only see a dietitian again if they return to clinic specifically with a nutritional issue. In contrast, KT recipients in our IMPACT trial will see the dietitian interventionist at every post-transplant appointment through six months post-transplant, with follow-up at 12 months post-txp (Figure 2). Based on dietary and nutritional guidelines from KDOQI and other national and international sources,[128,129] we plan to have the first nutrition visit (including the culturally-tailored assessment of dietary needs and access, Appendix B) occur immediately after transplant because patients are dealing with a lot of information and instructions post-transplant and may otherwise lose sight of their dietary needs. Thus, recruiting patients and starting the intervention early post-transplant will ensure that they

perceive the importance of diet and exercise with the same seriousness as immunosuppression and other aspects of their post-transplant regimen. The continued support they receive from a registered dietitian at the additional follow-up visits will support dietary patterns that meet their individualized nutritional needs post-transplant while also helping to establish behaviors that reduce the risk of excess weight gain and elevated cardiometabolic risk.

Usual care groups: All participants will continue to receive care according to national standards. As required, all patients will have laboratory evaluations 2-3x/per week during the first month post-txp with a clinic visit 1-2x/week. Between months 1 and 3, labs will be drawn weekly or bi-weekly (depending on the stability of the patient), with a clinic visit every 2 weeks. In months 3-6, patients have labs drawn every 2 weeks, or once a month (depending on the stability of the patient), with a monthly clinic visit. Finally, in months 6-12, patients get labs every 1-2 months, and have a monthly clinic visit. However, none of these lab draws will be used for the research study.

Questionnaires: Questionnaires will be delivered via Twistle or REDcap. See Appendix F for Twistle Script listing all comments being used throughout the study that will be delivered according to the relevant questionnaire and the timeline in Fig. 2. Brief surveys will be conducted over the phone.

In-Depth Interviews with Participants. We will conduct interviews with participants in the IMPACT condition, either in-person, over the phone or via HIPAA compliant Zoom, and focus on participants' experience with the intervention and recommendations for improvement (Appendix D). Interviews will be recorded and transcribed for analysis.

Periodic Survey. Periodically, the Project Coordinator will contact clinical, and administrative teams asking to what extent, if any, barriers and/or facilitators to the intervention they have observed or experienced and suggestions for change if indicated. We will ask the transplant team to elicit feedback on the intervention process and provide any feedback to the Project Coordinator. We will elicit impressions of the IMPACT intervention and solicit suggestions regarding optimizing the future large-scale study (Appendix D). The Project Coordinator also will document all observations and experiences in a log (Appendix E), noting the date and source of the observation. We will review the log during research team standing meetings, and identify need for process changes. We will then communicate the problems identified and planned changes to the research, clinical and administrative teams. We will capture this data in REDCap, either over the phone or via direct link, whichever is more convenient for the team member. Interviews conducted over the phone will be recorded and transcribed.

Types of data

In addition to the in-depth interviews and brief/periodic surveys, we will collect data using questionnaires and from medical records. We selected the measures (see Appendix C for all measures) for data collection because they (a) are widely used in organ donation

and/or transplantation studies, other medical populations, or both; (b) have known psychometric properties, including (for scaled measures) Cronbach's α's of ~.80-.92 (see references cited with each instrument for psychometric data); and/or (c) used in our previous research.

Outcomes

1. Questionnaires
    a. PROMIS Global Health Measures
    b. PROMIS Sleep Related Impairment and Sleep Disturbance Measures
    c. Satisfaction with Intervention
    d. Usability Scale for Twistle Platform
    e. Occupational functioning

2. Medical records
    a. % weight change
    b. Lipid profile
    c. HbA1c

Predictors and Covariates

1. Questionnaires
    a. Demographics
    b. Sense of Mastery
    c. Social Support
    d. Kinesiophobia
    e. Diet and exercise adherence

2. Medical records
    a. Immunosuppression protocol
    b. BMI
    c. Other transplant relevant medical history

13.Data Analysis

Intervention Evaluation

We will evaluate the process of implementing the IMPACT intervention using a mixed-methods approach consistent with a Type I Hybrid Intervention/Implementation design.[130] Using the Consolidated Framework for Implementation Research (CFIR)[131] as a theoretical framework, we will assess barriers and facilitators to implementation to provide real-time feedback for the pilot and to inform the future large-scale project. This evaluation will be comprised of a periodic survey of research, clinical, and administrative staff regarding barriers and facilitators of implementation and in-depth interviews with participants regarding experiences with the interventions.

Quantitative Analysis Plan

Primary and ancillary analysis: We will describe our patient sample with detailed descriptive statistics with respect to demographics and health-related characteristics. We

will record and summarize missing data points during the study, attrition and its underlying reasons when feasible. Our primary analysis will focus on measures of feasibility and acceptability as outlined in Aim 1: Examine IMPACT's acceptability and feasibility in an ethnically diverse KT recipient population. We will use these analyses to determine endpoints, their variation, plausible intervention effect size, sample size, planned analyses, and accrual expectations. These analyses will guide the design of the subsequent study.[132] We will also use these analyses, as well as those of Aim 2 to determine a clear rationale to support the next steps in the study process, including "go versus no go" decisions.[132]

Outcomes: Whereas our primary objective is to establish the feasibility and acceptability of the study intervention, we will also compare the intervention group to the UC group with respect to the type, frequency, and intensity of exercise, as well as diet structure using common statistical methods, we will also compare activity tracking data from both groups. For example, our analysis will answer the question: what is the plausible range of difference in the proportion of participants engaging in the recommended diet and exercise routine? What is the difference in the amount of activity between the two groups? Given the small sample size of this study, we do not expect such differences will be necessarily statistically significant, but such differences will inform our planned large scale R01. In our future large-scale study, we will hypothesize that IMPACT will result in improved exercise and diet and will lead to improvements in post-transplant health and quality of life. When feasible we will also estimate the range of plausible improvements in post-transplant health and quality of life.

Intervention Evaluation Analysis Plan

Survey Data: We will quantitatively analyze the survey data, categorizing comments as to which of the four major CFIR constructs (Intervention, Outer Setting, Inner Setting, Characteristics of Individuals, Process) they refer to and assessing counts and frequencies of comments found in each construct. Sub-analyses will include assessing responses in relation to respondent's role.

Participant Interviews: The core research team will review all of the interview transcripts to develop an annotated provisional codebook, using qualitative analysis software (Dedoose)[133] to support this analyses. Analysis of subsequent interviews will proceed iteratively as follows: two primary coders will apply existing codes and will add new codes to the codebook as needed. We will resolve disagreement in coding through consensus, and we will assess inter-rater agreement between coders will be assessed.[134] We will maintain an audit trail to track coding decisions, and we will use memos throughout the analysis to identify key emerging concepts. We will perform thematic analysis as we conduct line coding to identify key concepts, including confirmation of existing knowledge and identification of novel themes.

Surveys with clinical team and administrators: We will create a provisional codebook with the barriers and facilitators we identified in the brief surveys with key stakeholders. We will pay particular attention to themes that deal with overall ease of use of the intervention and overall satisfaction with implementation.

14. Provisions to Monitor the Data to Ensure the Safety of Subjects

A DSMB will be created to oversee this study. DSMB members will be composed of the Principal Investigator and Co-Investigators with expertise in kidney transplantation, clinical trials, disparities, and biostatistics, plus one independent reviewer (IR), who has no financial, scientific, or other conflict of interest with the study. Written documentation for the IR attesting to absence of conflict of interest will be required. The study team will present the IR with the study protocol, informed consents, and reports to assess study safety and progress. In addition, the co-investigators will explain plans for participant recruitment, accrual and retention, participant risk versus benefit, performance of the trial sites, confidentiality of patient data, monitoring of study progress and assessment of other factors that can affect study outcome during the DSMB meeting.

The IR will review all data captured for the study including unanticipated events. This will allow the Principal Investigator and study team to assess whether more frequent monitoring will need to take place and how it will affect others currently enrolled. The IR will have the authority to recommend stopping the study early or modifying the study design for safety concerns. The DSMB will review the progress of the study within 2 weeks after the first patient is randomized into the study and will conduct meetings routinely thereafter until enrollment is closed. The IR will recommend terminating the study if the safety, welfare and health of patients is jeopardized due to conducting the study according to protocol. Unanticipated events will be reported by the study team to the IR and the IRB within 24 hours of becoming aware of the event. The Principal Investigator will assess the adverse event (AE)/serious adverse event (SAE) relationship to the IMPACT intervention.

15. Withdrawal of Subjects

Subjects are free to withdraw from study participation at any time during this clinical study. The Investigator may withdraw a subject if continued participation is not in the interest of the subject's health and welfare, for noncompliance with protocol-specified procedures, or because of a protocol violation. This will be evaluated on a case-by-case basis by the Investigator. All data collected from a withdrawn participant will be destroyed if the participant withdraws from the study at any point.

The primary reason for discontinuation or withdrawal will be documented as one of the following:

- Adverse Event
- Noncompliance
- Protocol violation

16. Data Management/Confidentiality

The PI will oversee all aspects of data management in close collaboration with the lead study statistician, Dr. Zhu. The study team will work with the Twistle, Inc. team to develop an operations manual to standardize all procedures and staff training in areas such as patient recruitment, measurement, assessment, and data entry, management, and security. Following the guidelines outlined in the operations manual the statistical team will create an electronic data entry system using REDCap,

a mature, secure, and HIPAA compliant web application for building online surveys and databases. REDCap is supported at the University of New Mexico, and will be used to capture data from the study and to temporarily store the resulting research data. Data will be exported from REDCap and imported into SAS for data analysis. The statistical team will work closely with the investigative team and other study personnel to ensure that protocols are being followed, data integrity and confidentiality are maintained, and that the degree of missing data is minimized. All study files residing in designated network folders will be backed-up daily and archived weekly. The weekly data will be stored on a separate server that is physically located > 1 mile from the location of the servers housing the primary study data. The weekly archived files are maintained for 1 year until the data are erased. All study subjects will be assigned unique study identifiers that will appear on all data collection instruments, tapes, documents, and files used in the statistical analysis and manuscript preparation. Only authorized team members will have access to personal information needed for tracking and informed consent. Other data quality assurance measures will include detailed documentation of computer operations and data editing procedures and regular meetings with project staff to review any changes in procedure. The data team also has specific data quality measures that will be implemented. These include data verification, built in data validation mechanisms such as logic and out of range data checks, and repeated evaluation of the data collection and entry process.

Participant name and other identifying information will be linked to a unique study ID once consented. This study ID will not display any information that can identify the participant. All of the data collected from the participant, including recorded and transcribed interviews, will be coded using participant study ID and the link will be kept in a locked cabinet, and/or password protected computer files. The master list linking participant identifying information to participant study data will be kept in a separate, secure location at UNM. Only the UNM study team will have access to the master list. We will keep the link between participant identifying information and study data until the end of the research study. This link will only be available to UNM, and will not be accessed by researchers at other institutions.

17. Data and Specimen Banking

NA

18. Risks to Subjects

This trial is voluntary and those undergoing KT who do not wish to participate will have access to usual care. We will obtain consent via a formal signed consent form. Patients will be provided adequate time to weigh enrolling in the trial.

The assessors and interventionists will be sure to interview patients in a respectful manner, and will have enough knowledge to be able to explain what steps would be taken to ensure patient confidentiality. For some patients, discussing the intervention and their adherence to it, may be upsetting. Any patients requesting additional counseling will be provided with contact information for the transplant team social

worker. Participants will be reminded that they have the option of discontinuing study participation at any time or taking a break if the interview length feels too burdensome. Results from our current work indicate that the interview should be completed in approximately 30 minutes or less.

We expect the risks associated with the diet and exercise intervention to be minimal because the licensed dietitian and physical therapist on the research team will closely monitor the patient participants, to minimize risk. However, if the patient feels there is an exercise they cannot do, we will urge them to discuss their concerns with the physical therapist.

Clinical team and administrators' surveys will remain anonymous. Informed consent will be obtained from all participating staff before the start of the first survey via consent letter. Data from these surveys will also be kept confidential.

The study team will follow COVID safe practices as outlined in the related attachment.

19. Potential Benefits to Subjects

Benefits include: reducing the likelihood of weight gain, diabetes, and cardiovascular events post-transplant. Participation in the study will address the limitations of previous physical activity and dietary interventions in KT recipients: (1) small sample size, (2) short patient follow-up, and (3) limited population diversity. Finally, participants will benefit from knowing that they will be helping future patients and other transplant centers easily package and disseminate the intervention using Twistle, which gives them a way to tailor the intervention to the needs of their specific patient population and maintain regular interaction and follow-up.

20. Recruitment Methods

Flyers will be placed and brochures in the UNM HSC Transplant Center. In addition, potential participants will be approached shortly before or after undergoing KT, as they are in recovery, at the UNM HSC Transplant Center. All participants will continue to receive care according to national standards whether or not they participate in the study. All participants who are randomized to the IMPACT intervention will have in-depth interviews. All IMPACT intervention study staff, transplant clinic staff and key administrators involved in the transplant process will be recruited for post-intervention surveys at the time of study initiation.

21. Provisions to Protect the Privacy Interests of Subjects

Face-to-face visits will take place at the UNM HSC Transplant Center in private clinic rooms.

22. Economic Burden to Subjects

Participants will not be charged for any research related visits. All visits will be scheduled during standard post-transplant clinic visits. Twistle is a free service to participants.

23. Compensation

We will compensate participants $20.00 for each completed visit; three visits for participants randomized to usual care and thirteen visits for participants randomized to IMPACT intervention. IMPACT intervention participants will be given an additional $20 for the in-depth interview at their last follow up visit. The payments will be issued at the completion of each visit in the form of a merchandise card.

24. Compensation for Research-Related Injury

If the subject becomes sick or injured as a direct result from the study, they may receive emergency treatment, however, there is no commitment by the UNM HSC to cover the costs related to research related injuries. The subject and/or their third party payer will be charged in the usual way.

25. Consent Process

We will obtain consent via a formal signed consent form. All potential participants will be given as much time as they need for consent review prior to signing the consent form and will be asked to verbalize the purpose of the study as a check for understanding. The consent form will then be signed and dated by the participant before initiation of any study activity.

Subjects not fluent in English

NA

Cognitively Impaired Adults/Adults Unable to Consent/Use of a Legally Authorized Representative

NA

Subjects who are not yet adults (infants, children, teenagers)

NA

Waiver or Alteration of Consent Process (consent will not be obtained, required element of consent will not be included, or one or more required elements of consent will be altered)

We are requesting a partial waiver of HIPAA Authorization for Screening/Recruitment. Pre-screening will include the following details:

- Received kidney transplant at the University of New Mexico
- Greater than 18 years of age
- Race/ethnicity details

26. Documentation of Consent

A copy of the signed/dated ICF will be given to the subject. A copy of the signed/dated consent will be placed in the subject's research file that will be kept in a locked file cabinet. To document our consenting process we will be following the UNM HSC HRPO procedure titled, "SOP: Written Documentation of Consent (HRP-091)."

27. Study Test Results/Incidental Findings

NA

28. Sharing Study Progress or Results with Subjects

Consented participants will not be provided with a summary of the trial progress while the study remains underway nor will they be provided with study results.

29. Inclusion of Vulnerable Populations

No vulnerable populations will be recruited for this study.

30. Community-Based Participatory Research

NA

31. Research Involving American Indian/Native Populations

The study involvement of American Indian populations is critical to the research study and we will be sensitive to community attitudes by engaging them in interventions that are culturally tailored.

32. Transnational Research

NA

33. Drugs or Devices

NA - this research does not evaluate the safety or effectiveness of a medical device

The activPAL3 activity monitoring device (worn on the thigh):

a. This is not a device study, i.e., this study does not evaluate the efficacy or safety of a device. There is no information on the FDA website regarding the activPAL3 monitor (NOTE: these monitors are from a company in Scotland, UK). However, these monitors are similar to the ActiGraph monitors except for the attachment method. The activPAL3 monitors are not investigational devices as they are commercially available (http://www.paltechnologies.com/); the shipment of activPAL3 monitors was cleared by the FDA and delivered to the Study PI. These monitors are the gold standard for objectively measuring sedentary behavior and ambulation in research study participants and have been used in many trials in the U.S. The activPAL3 monitors are more expensive than consumer wearable monitors (e.g., FitBit, Jawbone) and require special software to analyze the data, thus these monitors are used in research rather than being purchased by consumers. In this study, the monitors are used to measure outcomes (frequency, duration, and

intensity of free-living sedentary behavior and light physical activity), and are not used to diagnosis or treat disease, or to support/sustain life.

b. These monitors do not present a potential for serious risk to the health, safety, or welfare of the subject. There is a potential for a small risk of skin irritation due to the adhesive used to attach the activPAL3 to the thigh. We are minimizing this risk by asking the research participants to check the monitors daily and if skin irritation occurs, to remove the monitor and contact study staff.

To our knowledge, the FDA has not evaluated this device; however, it would likely fall under the same category as a similar research grade activity monitor, ActiGraph (not used in this study). We believe, that like the ActiGraph monitors, the activPAL3 monitors used in this study poses non-significant risk per the FDA definition: i) it is not an implanted device, ii) it is not a life sustaining/ supporting device, iii) it is not "for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health", and iv) it does not otherwise present "a potential for serious risk to the health safety, or welfare of a subject".

34.Principal Investigator's Assurance

By submitting this study in the Click IRB system, the principal investigator of this study confirms that:

☒ The information supplied in this form and attachments are complete and correct.

☒ The PI has read the Investigator's Manual and will conduct this research in accordance with these requirements.

☒ Data will be collected, maintained and archived or destroyed per HSC Data Security Best Practices, including:

1. **Best Practice for data collection** is for it to be directly entered onto a data collection form that is in a secured access folder on an HS drive behind a firewall, or in a secure UNM Data Security approved system such as RedCap.
2. **Data collection of <u>de-identified data</u>**, if done in a clinical setting or other setting that does not allow direct entry into a secured system, may be done temporarily using a personal or university owned electronic storage device or hard copy document. **The important security safeguard is that no identifiers be include if the data is entered or stored using an untrusted device or storage.**
3. **Permanent (during data analysis, after study closure**) storage must reside on HSC central IT managed storage. Processing of data (aggregation, etc.) are to be carried out in such a way as to avoid creating/retaining files on untrusted storage devices/computers. Trusted devices are HSC managed and provide one or more of following safeguards: access logs, encryption keys, backups, business continuity and disaster recovery capabilities.

4. **Alternate storage media** must be approve by HSC IT Security as meeting or exceeding HSC central IT provided security safeguards.

35.CHECKLIST SECTION

This section contains checklists to provide information on a variety of topics that require special determinations by the IRB. Please complete all checklists relevant to your research.

36.Partial Waiver of Consent for Screening/Recruitment

Complete this checklist if you are requesting a partial waiver of consent so that you can review private information to identify potential subjects and/or determine eligibility prior to approaching potential subjects for consent or parental permission.

A. Describe the data source that you need to review (e.g., medical records):

N/A

B. Describe the purpose for the review (e.g., screening):

N/A.

C. Describe who will conducting the reviews (e.g., investigators, research staff):

N/A

D. Do all persons who will be conducting the reviews already have permitted access to the data source?

☐ Yes

☐ No. Explain:

i. Verify that each of the following are true or provide an alternate justification for the underlined regulatory criteria:

1. <u>The activity involves no more than minimal risk to the subjects</u> because the records review itself is non-invasive and the results of the records review will not be used for any purposes other than those described above.

☐ True

☐ Other justification:

2. <u>The waiver or alteration will not adversely affect the rights and welfare of the subjects</u> because eligible subjects will be approached for consent to participate in the research and are free to decline. Further, the information accessed during the records review will not be disclosed to anyone without a legitimate purpose (e.g., verification of eligibility).

☐ True

☐ Other justification:

3. The research could not practicably be carried out without the waiver or alteration because there is no other reasonably efficient and effective way to identify who to approach for possible participation in the research.

   ☐ True

   ☐ Other justification:

4. Whenever appropriate, potentially eligible subjects will be presented with information about the research and asked to consider participation. *(Regulatory criteria: Whenever appropriate, the subjects will be provided with additional pertinent information after participation.)*

   ☐ True

   ☐ Other justification:

37. Partial Waiver of HIPAA Authorization for Screening/Recruitment

Complete the following additional questions/attestations if the records you will review to identify potential subjects and/or determine eligibility include Protected Health Information (PHI).

A. Will you be recording any PHI when conducting the records review to identify potential subjects and/or determine eligibility?

   ☒ Yes. Describe: We will be recording the patients name and age.

   ☐ No

B. If you answered "Yes" to question 6 above, please describe when you will destroy identifiers (must be the earliest opportunity consistent with the conduct of the research) or provide justification for why they must be retained:

   Identifiers collected will be destroyed upon completion of the study and IRB closure. Records will not be kept for screen failures.

C. The PHI accessed or recorded for identification/screening purposes will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

   ☒ True

   ☐ False

38. Waiver of Documentation of Consent

A. Are you requesting a waiver of documentation of consent for some or all subjects?

   ☒ All

   ☐ Some. Explain:

B. Provide justification for one of the following:

i. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

ii. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

All transplant team participants will be given a letter explaining this portion of the study. There will be no signatures required. Transplant clinic staff and key administrators involved in the transplant process will participate in these surveys, but responses to the questions will be anonymous. No names will appear or be used on research documents, or be used in presentations or publications. No more than minimal risk will be present.

C. Do you intend to provide subjects with a written statement regarding the research in lieu of a traditional consent form?

☒ Yes. Please attach a copy to your submission in Click.

☐ No

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