I. Objectives

The purpose of this study is to determine the best way to help people that have had a kidney transplant perform daily physical activity. Currently, we do not know the best way to help people who have had a kidney transplant to remember to perform regular physical activity. This study will help us explore how to promote routine daily physical activity.

(a) Determine if perceptions (usability, sustainability, and acceptability) of activity tracker use differs for older adult KTRs participating in a SystemCHANGETM intervention compared to a control group at 1, 2, 3, 6, &12 months.
(b) Determine the degree to which a SystemCHANGE™ + activity tracker intervention improves physical activity, health outcomes, and quality of life for older adult KTRs from baseline to 3, 6, & 12 months, compared to a control group using only activity trackers.

II. Background and Rationale

The combination of the SystemCHANGE TM and activity tracker intervention holds promise for increasing and sustaining activity among older kidney transplant recipients. This study will incorporate with an accessible popular device with a simple intervention in a population of kidney transplant recipients who are at particularly high risk of cardiovascular disease and death. The findings from this study would have a significant impact on the lives of these individuals and costs associated with their ongoing care.

We will conduct a randomized study with intervention and control arms. Sixty kidney transplant recipients age 65 and older will be recruited and randomized into two groups. Participants in the intervention group will receive the combination of the SystemCHANGE TM and activity tracker intervention while participants in the control group will use activity trackers only. Intervention and control groups will receive the same instruction on use of the activity tracker, and have the same number of study contacts. Study procedures include group sessions with 10-12 participants for 6 months and a 6-month maintenance phase without contact from study personnel until month 12. Outcome analyses will be conducted at baseline, 1, 2, 3, 6, and 12 months. Outcome measures include perception of activity tracker use, physical activity, functional ability, health outcomes, and quality of life.

It is possible that those enrolled in this study may experience improved functional ability and quality of life. Moreover, the general population of kidney transplant recipients is likely to benefit from the knowledge to be gained about the effectiveness of interventions to increase physical activity and sustain it over time. Potential risks include psychological and social risks associated with the study intervention. It is possible that

participants could experience distress or discomfort as a result of discussing issues relating to changing their routines during the intervention.

Rationale: While previous SystemCHANGE™ studies have made use of electronic devices to monitor outcomes, none have employed a widely available, popular consumer-based technology which could facilitate more widespread and rapid adoption of a critically important self-management practice. The rationale for using Fitbit activity trackers is that they are affordable, unobtrusive devices which have become popular with consumers and can assist individuals to become aware of their daily physical activity.

III. Procedures

The procedures should include the following:

A. Research Design

We will conduct a single-center randomized pilot study with intervention and control arms and outcome analyses conducted at baseline, 1, 2, 3, 6, and 12 months.

B. Sample

***Setting*.** The study will be conducted with The Ohio State University Medical Wexner Center Kidney Transplant Program. This Midwest transplant program performs 300 kidney transplants annually (see Appendix A.1 for Letter of Support). Situated in Columbus, Ohio, the transplant program functions as a regional referral center, serving a highly racially diverse population from both urban and rural communities.
***Sample*.** Our study sample will be recruited from patients receiving care at The Ohio State University Medical Wexner Center Kidney Transplant Program. Our goal is to recruit 60 KTRs in a manner that will yield a sample reflective of the racially diverse population served by the Transplant Institute and is consistent with recommendations for the conduct of pilot studies that evaluate effects of an intervention.

Recruitment .A list of all kidney transplant recipients with scheduled clinic appointments will be generated weekly and reviewed by the health care providers who will be seeing the patients and research staff to identify patients who meet inclusion criteria. The health care providers seeing the patients will inform possible participants about the study during their clinic appointment; if participants express interest, the health care providers will then inform the investigator. The investigator will coordinate the best time during the clinic visit to approach the potential study participant to explain the study, answer questions, and solicit consent to participate in the study. In addition, at support group gatherings, transplant staff hosting the event will introduce the PI who will tell the audience about the study, welcome their questions, and provide information about study enrollment if requested. Following the meeting, those who expressed interest in the study will the investigator will schedule a time to meet with them to explain the study, answer questions, and solicit consent to participate in the study.

Questions will be answered, and if verbal agreement is obtained, inclusion/exclusion criteria will be reviewed and a cognitive screening test using the 6-item Mini-Mental Status (Appendix B.1).39 If eligible for study participation, the potential study participant will be scheduled for the first group meeting at which time informed consent will be obtained.

Inclusion Criteria

a) age 65 or older; (b) functioning kidney transplant (not on dialysis); (c) clearance by healthcare provider for study participation; (d) ability to speak, read, and hear English; (e) possession of a smartphone capable of accessing mobile activity tracker data; (f) no cognitive impairment; (g) ability to secure a device similar to a watch to the wrist; (h) no use of assistive devices for walking (cane or walker); (i) greater than 3 months post-transplant to ensure recovery; and (j) not hospitalized

Exclusion Criteria

a) disability of arms or legs (activity trackers require movement of the arms and legs); (b) participation in a weight loss program; (c) participation in a structured exercise program; (d) currently wearing an activity tracker; or (e) planning to move out of the area within the next 6 months.

Characteristics of the Sample

Estimated Age of Kidney Transplant Recipients Based on 2015 Health Resources and Services Administration, U.S. Department of Health & Human Services Data: United States, and, The Ohio State University Transplant Program (1988-2016)[14]

Age	**United States**		**OSU**	
18-34 years	72,768	19%	898	18%
35-49 years	124,303	32%	1,696	33.1%
50-64 years	140,669	37%	1,961	38.2%
65+years	48,005	12%	514	10%
All ages	385,745	100%	5,127	100%

Estimated Race of Kidney Transplant Recipients 65 and Older Based on 2015 Health Resources and Services Administration, U.S. Department of Health & Human Services Data: The Ohio State University Transplant Program (1988-2016)[14]

Race	**United States (N = 48,005)**		**OSU (N = 514)**	
White	30,898	64%	409	80%

Black	8,923	19%	96	19%
Hispanic	4,928	10%	2	0.4%
Asian	2,542	5%	4	0.7%
American Indian/Alaska Native	376	.8%	0	0%
Pacific Islander	144	.3%	0	0%
Other Race	194	.4%	3	0.6 %

Purposive Enrollment Schema

Number (n = 60)	**Black (n = 12)**	**White (n =48)**
Male Intervention	4	16
Female Intervention	3	9
Male Control	3	15
Female Control	2	8
Total	12	48

C. Measurement / Instrumentation

Identify the variables of interest and study endpoints (where applicable). Justify measurement techniques selected. Provide validity and reliability data for selected measures.

Study Measures: In addition to demographic and inclusion/exclusion screening (including cognitive screening), the following measures will be collected: perception of activity trackers use (Appendix C.1), Six-Minute Walk Test, blood pressure, heart rate, body mass index, waist circumference**,** and Short Form Health Survey (SF-12) (Appendix C.2). An iPad will be used to administer all questions that will enable direct data entry into REDCap. RAs will provide assistance as needed by reading questions to participants and assisting with indicating responses on the iPad. Outcome data from both study groups will be collected at the appropriate

Measurement Timeline

	Data Collection Timeline												
	Months												
Data Collection	Baseline	1	2	3	4	5	6	7	8	9	10	11	12
Basic Demographic	X												
Cognitive Screening	X												
Perception of Activity Tracker		X	X	X			X						X
SF-12	X			X			X						X
Number of Steps	X			X			X						X
Six-Minute Walk Test	X			X			X						X
Blood Pressure	X			X			X						X
Heart Rate	X			X			X						X
BMI	X			X			X						X
Waist Circumference	X			X			X						X

sessions as shown in the Table 6.

Demographic or Sample Measures: Demographic information will be obtained during the screening phone call and will include: gender, race, marital status, income, education, transplant date, prescribed medications, type of diet, smoking status, and co-morbidities.

Outcome Measures: (Aim 1) Perception of activity tracker use (Appendix C.1) (15 minutes) will be assessed using 9 open-ended questions to determine participants' perceptions (usability, sustainability, and acceptability) of using mobile activity trackers. (Aim 2a) Number of steps will be recorded continuously each day by a mobile wristband activity tracker called "Fitbit Charger HR" that will sync data from the participant's cellular phone into the Fitabase each day. Fitabase step-data will be downloaded directly into REDCap. The Fitbit Charger HR uses a 3-axis accelerometer to record activity. The device turns movement (acceleration) of a body into digital measurements (step-data) when attached to the non-dominant wrist. In addition, the Fitbit Charger HR provides information about the frequency, duration, intensity, and patterns of movement to determine the number of steps taken each day. In a study comparing the validity of two activity tracker accelerometers, the Fitbit Charger HR and the Physical Activity Monitor (PAM), the Fitbit Charger HR performed more accurately (r =.77) than the PAM (r = .41) for measuring energy expenditure.[44] In another study[45] with 30 adults, no difference was found between the Fitbit Charger HR for steps counted and actual steps observed (*ICC* >.95).

(Aim 2b) Functional Ability will be assessed with The Six-Minute Walk Test (6MWT)[46] (10 minutes) which measures the distance walked on a hard flat surface in 6 minutes. A section of 30 meters will be marked off using two orange cones and participants will be asked to walk at a comfortable pace for a 6-minute period between the cones while being timed. Test-retest reliability has been documented as high as .90 at baseline, .88 at 18 weeks, and .91 at 43 weeks[47] for older patients with heart failure.[47] Participants may have different levels of current activity. In order to control for this, step-data will be adjusted for baseline.

(Aim 2c) Health Outcomes (10 minutes). Resting blood pressure will be measured on each participant in a seated position using a Withings blood pressure cuff by the RA who will be a registered nurse. The RAs will be blinded to the study groups. The RAs will also obtain a radial pulse (heart rate) over a 60-second count while the participant remains seated. Weight for determining Body Mass Index (BMI) will be measured without shoes and in light clothing and be calculated to the nearest 0.1 pound using a digital scale that will be calibrated prior to testing.[48] Height will be measured without shoes using a self-retracting tape measure and rounded to the nearest 0.1 cm. Body mass index (BMI; kg/m^2) will be calculated as [mass (lb)/ height (in)^2 x 703]. Waist circumference (WC) will be obtained by measuring the individual's circumference halfway between the illac crest and the lower anterior ribs with the person standing upright during expiration.[49]

(Aim 2d) Quality of Life. The Short Form Health Survey (SF-12) (5 minutes) (Appendix C.2) contains 12 questions that explore a person's physical (functional) and mental (well-being) health over the previous 4 weeks.[50] The SF-12 includes 8

domains—Physical Functioning, Role-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional, and Mental Health[50]—and uses a Likert-like scale from 1 to 3 for the physical function items which focus on bodily pain, social function, vitality, mental, and general health perceptions. A dichotomous yes/no scale is used for emotional and physical role function items.[51] Physical and mental component scores, ranging from 0 (lowest level of health) to 100 (highest level of health), are derived from the individual items and will be used as study outcomes. The questionnaire has been found to have high internal consistency (Cronbach's alpha coefficients of .72 to .89) and adequate test-retest reliability (r = .73-.86).[51,52]

D. Detailed study procedures

All study data will be entered directly into electronic research forms using Research Electronic Data Capture system (REDCap, surveys, and other instruments by study participants and research staff that will automatically upload into REDCap. Similarly, mobile activity tracker data (steps) aggregated by the secure Fitabase will also upload into REDCap. The REDCap Admin will provide technical support for project duration.

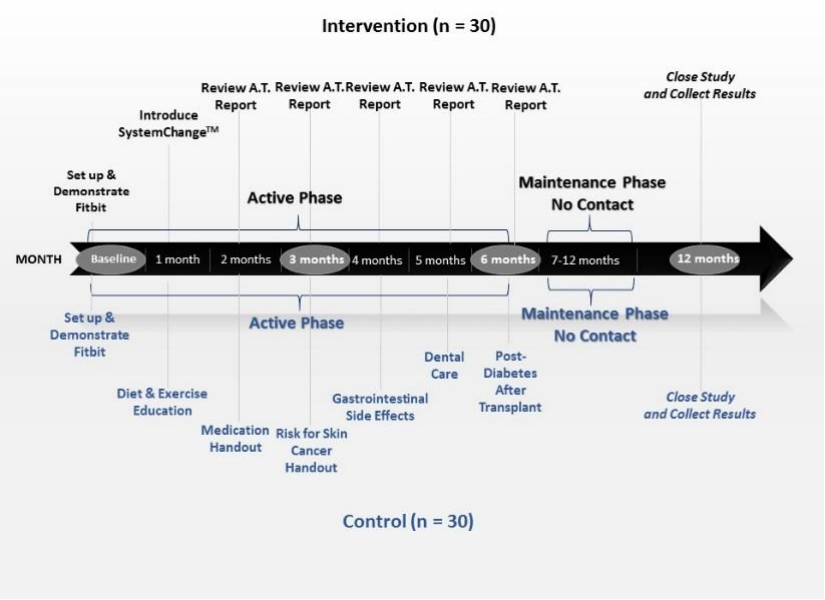
Overview of Intervention and Control Groups

Intervention and control groups will be enrolled in the study in the same manner, receive the same instruction on use of the Fitbit Charge HR, and have the same number of study contacts. Study procedures include group sessions at the OSU Transplant Clinic with 10-12 participants for 6 months and a 6-month maintenance phase without contact from study personnel until month 12. One research assistant will be assigned to the intervention group and one to the control group.

Intervention Group Active Phase, Group Session 1 (1 hour, 20 minutes) Dr. O'Brien and a research assistant (RA) will demonstrate proper Fitbit Charger HR activity tracker use, set up the smartphone application, and assist entry of daily step goals into the smartphone application. Fitbits will be set up with Gmail accounts with unique unidentifiable codes. Participants will be taught how to sync to their smartphone and retrieve data from their Fitbit. Participants will perform a return demonstration to confirm they can apply the activity tracker to their wrist, access their Fitbit account, and charge the activity tracker. One week following this session, participants will be called to troubleshoot problems and be encourage to increase their step goal 5% each month (total phone time 15 minutes).

Figure 3. Intervention/Control Group Timeline

Intervention Active Phase, Group Session 2 (1 hour) This session will begin with brief introductions of research staff and study participants followed by a session overview. The first topic to be reviewed will be Fitbit activity tracker reports (Appendix B.2). Participants will be oriented to the report, including the steps being monitored, the range of dates for the report, and general information (number of monitored days, number of daily steps taken, and number of activity minutes per day). Consistent with SystemCHANGE™, phrases such as "opportunities for improvement" and "possibilities for doing better" will be employed when discussing the report with participants. Questions will be solicited and answered before proceeding to delivery of the SystemCHANGE™ component of the intervention.



A PowerPoint presentation will briefly introduce SystemCHANGE™ component of the intervention followed by participants being divided into small groups of 5 each. In these small groups and with the aid of a workbook (see Appendix B.3), RAs and the PI will guide participants through the 4 steps of SystemCHANGE™.

During Step 1, participants will be asked to identify important people that influence their physical activity. This information will be noted on the Important People Form. In Step 2, participants will be helped to identify activities or habits that routinely occur daily, weekly, or monthly, focusing on the impact of these routines on physical activity. This process starts by asking participants to describe activities that routinely occur on a daily, weekly, and monthly basis along with the time most likely for their occurrences. Participants will also include things that influence their participation in physical activity (e.g., availability of facilities as a walking path getting home from work late, or sleeping late on a weekend). Social activities and any rituals associated with physical activity such as gardening, housecleaning, shopping, and hobbies will also be noted. This information is documented on the Life Routines Form. During Step 3, RAs will place the collaboratively identified routines (daily, weekly, monthly) identified in Step 2 into the Cycles Figure, a graphic format that helps participants understand how routines are related to each other and can work for, or against, changing physical activity behavior. The daily, weekly, and monthly cycles will be discussed to help understanding of how a routine involving family demands, for example, may influence participation in physical activity. The discussion during Step 3 informs Step 4 at which time RAs and participants, together, consider possible approaches (solutions) to achievement of their daily steps goal. These possible solutions are documented on the Possible Solutions Form and rated on the Possible Solutions Scale for the perceived level of a systems-oriented versus personal effort/motivation required for implementation. If greater personal effort/motivation is required than systems orientation, participants will be guided in identifying another solution. Participants will be encouraged to discuss ideas with the person identified as most involved in their physical activity. As implementation of the solution is discussed, goals for increasing steps will be mutually agreed upon (generally, a 5% increase) and use of their activity tracker reports for monitoring progress

toward improvement will be discussed and demonstrated. In this session and throughout the Active Phase of the intervention, participants will be encouraged to look beyond personal motivation and explore their life routines and the people who shape those routines.

Intervention Active Phase, Group Sessions 3-7 (1 hour/session) Participants' progress will be reviewed using the Plan-Do-Study-Act Model[33] that employs small participant-designed experiments. Prior to each session, the participants' activity tracker reports will be given to them (Appendix B.2) and reviewed during the group session. Participants will be asked to "Tell me what you are learning about physical activity, and do you think changes that you have made to your routines are changing the level and consistency of your physical activity? Do you need to make other changes to your physical activity routines?" If the participant and RA agree that changes are warranted, participants will be encouraged to identify and try another solution. At the last monthly meeting, participants will be asked to describe their improvements and be encouraged to continue using the activity tracker for the next 6 months during the maintenance phase (see Figure 3).

Intervention Maintenance (6 months) At the final monthly session, participants will be instructed to continue with intervention and reminded that the research team will not be in contact for 6 months, after which time there will be a final group session.

Control Group

Control Active Phase, Group Session 1

Session 1 for the control group will be identical to the Intervention with the only exception being that participants in the control group will NOT be asked to increase their step goal 5% each month based on the step-data we receive from baseline to week 1.

Control Active Phase Group Session 2-7, (1 hour/ session) Session 2 will be used to troubleshoot and discuss any problems with the Fitbit activity trackers. In subsequent sessions, educational information about healthy living as a transplant recipient will be presented, including topics such as diet, taking medication, risk for skin cancer, gastrointestinal side effects, dental care, and new onset post-transplant diabetes. The meeting time will be equivalent to those of the intervention group

Control Maintenance Phase, (6 months) Identical to the intervention group; at the final month 7, group session participants will be reminded to continue to use the Fitbit activity tracker and that the research team will not be in contact with them for 6 months, after which time there will be a final group session.

Study Measures: In addition to demographic and inclusion/exclusion screening (including cognitive screening), the following measures will be collected: perception of activity trackers use (Six-Minute Walk Test, blood pressure, heart rate, body mass index, waist circumference**,** and Short Form Health Survey (SF-12) An iPad will be used to administer all questions that will enable direct data entry into REDCap. RAs will provide

Table 6. Measurement Timeline

	Data Collection Timeline												
	Months												
Data Collection	Baseline	1	2	3	4	5	6	7	8	9	10	11	12
Basic Demographic	X												
Cognitive Screening	X												
Perception of Activity Tracker		X	X	X			X						X
SF-12	X			X			X						X
Number of Steps	X			X			X						X
Six-Minute Walk Test	X			X			X						X
Blood Pressure	X			X			X						X
Heart Rate	X			X			X						X
BMI	X			X			X						X
Waist Circumference	X			X			X						X

assistance as needed by reading questions to participants and assisting with indicating responses on the iPad. Outcome data from both study groups will be collected at the appropriate sessions as shown in the Table 6.

1. See document for details describing what will happen at each intervention group meeting.
2. See document for details describing what will happen at each control group meeting

Retention: Text messages will be sent to participants during months when they are not attending a face-to-face session to provide encouragement and reinforcement for their participation in the study. In addition, phone calls will be made during each month to each participant to provide updates on their progress in the study as well as encouragement and support. Participants who complete the study will be allowed to keep their activity tracker.

E. Internal Validity

Treatment fidelity[43] for both study groups will be assured first, though the use of a scripted manual for each group session will be used during RA training sessions which will include role-playing with simulated participants until competency in delivery of group sessions is demonstrated. A log of the time taken for each group session will be kept to ensure equivalent treatment dose across all sessions. Debriefing will be conducted following each session to identify any areas for improvement. A protocol checklist will be used to ensure that content is completely and consistently covered and all outcome measures are collected at baseline, 1,2, 3, 6, and 12 months.

F. Data Analysis

The overall analytic design is a mixed design model where participants are randomly assigned to one of two intervention or comparison arms. The response over time of the participants will likely be correlated, therefore covariance patterns over time to be considered include compound symmetry, autoregressive, exponential (allows for unequally spaced times) and unstructured. The unstructured covariance pattern allows for less variation in the outcome variable (e.g., days engaged in activities) at baseline—a condition which may occur and will be evaluated.

Aim 1: Perception of activity trackers will be determined by participants' responses to open-end surveys. The responses from these surveys will be analyzed using content analysis to explore narrative responses for each open-ended question for commonalities and placed in emerging patterns or themes.

Aim 2: The test of effectiveness for each intervention arm is assessed by evaluating the treatment group by time interaction with two a priori contrasts (one for each arm) comparing the one-year follow-up mean to the baseline mean (essentially a paired t-test in the context of ANOVA). If an intervention is effective, we expect an initial rapid and sustained increase in the

numbers of steps/day; a subsequent return to near baseline levels would indicate that the intervention is not effective. To quantify the effectiveness of each arm and compare the effectiveness of the two arms at one-year follow-up, we will compute 95% confidence intervals of the changes in the primary outcome variable. The same approach will be used to quantify the effectiveness of the intervention and control groups on the secondary outcome variables. For Aim 2, the primary outcome will be the number of steps per day; secondary outcomes include distance traveled in 6 minutes, health outcomes (blood pressure, heart rate, body mass index, waist circumference) and quality of life (SF-12). Baseline characteristics of participants will be ascertained prior to randomization and all outcomes measured at baseline, 3 months (Follow-up 1), 6 months (Follow-up 2) and 12 months (Follow-up 3). A total of 60 participants will be randomized to either the SystemCHANGE™ + activity tracker intervention or activity tracker control group. Thus, the study has a classical repeated-measures design. Power calculations are based on two-sided t-tests with type-I error rates of 0.05. Effect sizes within arm will be small with standardized differences ranging from 0.37 to 0.58; we assumed a correlation between repeated measures of 0.7. While we used changes from baseline to 12 months to calculate power, we will analyze data for this aim by evaluating the average number of steps/day at baseline and at each follow-up. Results will be analyzed based on intention-to-treat. Using means and standard deviations for accelerometer-based numbers of steps per day from Dontje and colleagues,[7] we estimate the activity tracker control group to record 6326 $\pm$ 2906 steps/day at baseline and 7562 $\pm$ 3785 steps/day at 12-months follow-up. In the context of repeated measures ANOVA, using a t-test within arm to detect change from baseline to 12-months, power is 0.575. Because no data exist for determining the effect on steps/day of the SystemCHANGE™ + activity tracker intervention, we assumed that the differences between the means of the two arms at 12 months might conservatively be between 346 and 662 steps/day. Thus, we expect the intervention group to record 6326 $\pm$ 2906 steps/day at baseline and between 7908 $\pm$ 3785 and 8224 $\pm$ 3785 steps/day at 12-months follow-up. Using a within arm t-test, power is 0.798 to 0.918. Change from baseline in each arm will quantify the effectiveness of each in improving the primary outcome. Although this study is not powered to detect differences between the arms at 12 months, we will be able to compare the relative effectiveness of each arm at one-year follow-up and will compute 95% confidence intervals of the changes in outcome variables. We expect that each of these confidence intervals will include the mean of the comparison intervention. If differences between interventions are detected, we expect that the difference will be attributable to (1) fewer numbers of steps/day at baseline compared to the Dontje study[7] and/or (2) a larger effect on the number of steps/day of the SystemCHANGE™ + activity tracker intervention at 12 months. Data loss due to participant failure to complete all measures is a serious concern in every clinical investigation. Any missing data will be identified at the time of collection and rectified by asking participants to provide the necessary information. However, because subjects have the right to refuse to answer questions (informed consent), we will code null values differently from 'refuse to answer' and 'not applicable'. We will also explore demographics of participants for the effects of influencing outcomes. Missing step-data will occur when participants forget to wear or charge devices overnight; we will identify these missing data prior to the group visit so participants can give information on the reasons for missingness.

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