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I. Objectives

The purpose of the study is to test the feasibility mHealth dietary app + health coaching for improving primary outcomes (recruitment, retention, and adherence) and secondary outcomes (perceived stress [Perceived Stress Scale], exercise self-efficacy[Exercise Self-efficacy Scale], vegetable intake [Fruit, Vegetables, and Fiber Screen] fat intake [Lose-it Premium database], carbohydrate intake [Lose-it Premium database], weight, blood pressure [Wi-Fi weight scale using the Lose-it Premium database], heart rate [Wi-Fi blood pressure cuff using the Lose-it Premium database], and the minutes of physical activity per day [Lose-it Premium database])

Background and Rationale Weight gain and obesity are common after kidney transplant, often leading to the development of cardiovascular disease, post-transplant diabetes, and death.[1] The increase in weight gain during the first year after transplant is associated with the use of immunosuppressive medications, and changes in lifestyle, such as dietary intake and insufficient physical activity. Moreover, weight gain is affected by factors such as, age, sex, race, and stress.[2] Evidence indicates that kidney transplant recipients who gain less weight after transplant are physically active, consume fewer carbohydrates, consume more vegetables, and experienced less stress.[3] Further, limiting dietary fat and increasing post-kidney energy expenditures aid in preventing early insulin resistance and cardiovascular disease.[4] [5]

However, few studies have tested dietary and physical activity interventions using real-time mobile health applications (mHealth) to enhance lifestyle self-management of care with kidney transplant receipents.[6]

Our proposed study seeks to shift the paradigm for promoting diet intake and physical activity using education and self-report to provide a powerful combination of mHealth dietary app and health coaching (set goals, provide ongoing feedback, and self-monitor behaviors). To our knowledge, this is the first time a mHealth dietary app and health coaching intervention has been used in kidney transplant recipients to link real-time data for monitoring dietary intake and physical activity.

The long-term goal of this work is to enhance well-being in kidney recipients via lifestyle self-management of care for dietary intake and physical activity to ultimately prevent chronic diseases. The proposed study is important because early weight gain after kidney transplant is associated with adverse effects on the transplanted kidney function resulting in increased health care cost and poor quality of life.[7] Interventions are needed to monitor kidney transplant recipients diet and physical activity in real-time to prevent health decline.

The goal of the proposed feasibility study is to recruit a sample (N = 20) of post-kidney transplant recipients (age 18 and above) who will receive the mHealth dietary app + health coaching intervention for 12 weeks. We will assess changes over time for the primary outcome and secondary outcomes from baseline to 4, 8, and 12 weeks. We plan to submit our findings for publication to the Journal of Progress of Transplantation (Impact factor 0.958) or Trends in Transplantation (Impact factor 0.1.69). We *hypothesize* that the mHealth dietary app + health coaching intervention will improve adherence for recording diet and physical activity, decrease perceived stress, increase exercise self-efficacy, increase vegetable intake, decrease fat intake, decrease carbohydrate intake, improve weight control, improve blood pressure control, improve heart rate and an increase the number of minutes of physical activity per day. We will

also examine biological differences among the secondary outcomes of perceived stress, exercise self-efficacy, vegetable intake, fat intake, carbohydrate intake, weight, blood pressure, heart rate and minutes of physical activity per day, as previous studies have reported differences in outcomes based on age, sex, and race.[8,9] The rationale for our hypothesis is that progression of cardiovascular disease and chronic disease may be slowed with daily tracking of dietary and physical activity.

II. Procedures

The procedures should include the following:

A. Research Design

A feasibility study will be utilized to establish the recruitment, retention, and adherence with post-kidney transplant recipients using a consumer-based mHealth dietary app + health coaching.

B. Sample

Inclusion Criteria

(a) age 18 or older men and women, (b) functioning KTR (not on dialysis), (c) ability to speak, read, and hear English, (d) possession of a smartphone capable of accessing and downloading a mHealth dietary app (e) Wi-Fi or Internet access, (f) greater than 3 months post-transplant (due to medication adjustments and decreased functional levels), (g) not hospitalized, and (h) capable of self-consent per capacity screening.[32]

Exclusion Criteria

(a) Participation in a weight loss program, (b) participation in a structured exercise program, and (c) diagnosis of dementia.

How will subjects be selected?

The participants will be recruited or contacted from a list of kidney recipients that have already requested they be contacted for future studies from our previous study **(IRB Protocol Number: 2017B0084**). This list consists of approximately 60 people. This study will also be advertised at the Ohio State University Medical Center Kidney Transplant monthly support group. Fliers with study information will be made available at the support group. The support group leader will also inform the group participants about the study.

After participants meet the initial screening requirements in the recruitment process, we will determine capacity to obtain verbal consent using the Evaluation to Sign Consent Form (ESC). The ESC consists of five questions ("What are risks associated with the study?" "What are two potential risks for participating in the study?" "What is expected from you in this study?" "What if you do not want to continue the study?" "What if you experience discomfort?") and takes less than 10 minutes to complete. The ESC allows the participant to reflect upon their understanding of the research protocol by answering the five questions. Participants must answer all five questions correctly to be included in the study. Anybody who is able to answer all five questions correctly will then be read verbal consent script by the study team.

C. Measurement / Instrumentation

Participant **Demographic Information** (10 minutes) will be obtained using a seven-item questionnaire demographics form and **Comorbidity Data** will be gathered using the Charlson Comorbidity Index[33] to describe the patient population. **Aim 1: Recruitment** (percent approached),

will be recorded in REDCap by the RA. **Retention** (percent dropped) will be recorded in REDCap by the RA. **Adherence** (percent to adhere to logging daily dietary intake and physical activity) will be recorded continuously each day by the "Lose-It" app. **Aim 2: Perceived Stress** (10 minutes) will be evaluated by using the Perceived Stress Scale (PSS).[35] The PSS is a 10-item questionnaire using a Likert Scale to rate feelings of stress from 0 "never" to 4 "very often." The PSS has demonstrated excellent test-retest reliability (intraclass correlation coefficient = 0.954) and internal consistency (Cronbach's alpha = 0.810) with adults who have chronic disease.[36] **Exercise Self-Efficacy** (10 minutes) will be evaluated by using the Self-Efficacy for Exercise (SEE) Scale. The SEE is a 9-item questionnaire using a Likert Scale to rate feelings of stress from 0 "not confident" to 10 "very confident." The SEE has demonstrated excellent internal consistency ($\alpha = 0.92$) for adults living with chronic disease.[37] **Vegetable intake** will be measured using the Block Fruit-Vegetable-Fiber Screener. The Block Fruit-Vegetable-Fiber Screener (5 minutes) has demonstrated high reliability (Spearman *r*-value of 0.71).[38] This brief screening tool includes seven questions about fruit and vegetable intake and three questions about foods high in fiber, magnesium, and potassium. **Fat Intake and Carbohydrate Intake** (5 minutes) will be recorded each day by the participant using the "Lose-It" app. **Weight** will be measured each day by the participant using a wireless Wi Fi weight scale. The data from the wireless weight scale will sync the data from the participant's mobile phone to the premium password-protect "Lose-It" database each day. **Blood Pressure and Heart Rate** will be recorded each day by the participant using a wireless Wi Fi blood pressure cuff. The data from the wireless cuff will sync from the participant's mobile phone to the premium password-protect "Lose-It" database each day. **Minutes of Physical Activity per Day** will be recorded each day by the participant using the "Lose-It" app. **Clinical Frailty Scale** (5 minutes) will be used to measure the frailty level of each participant. The screening tool has demonstrated high reliability in adults. This brief screening tool consist of nine questions about a person's level of frailty.

D. Detailed study procedures

The "Lose-It" app will be set up with Gmail accounts with unique unidentifiable codes developed by the research team. Participants will be instructed how to download the "Lose-It" app virtually using Zoom. In addition, participants will be taught how to sync to their smartphone and retrieve data from their app. The participants will be trained to enter their dietary intake and physical activity daily for 12-weeks. Participants will monitor their vegetable intake, fat intake, carbohydrate intake, weight, blood pressure, heart rate and the minutes of physical activity per day using the "Lose-It" app. Wi-Fi connected weight scales and blood pressure cuff will be supplied for weight and blood pressure monitoring. Participants will be taught how to sync the data from the scales and blood pressure cuff to the "Lose-It" app using the Premium database which will Sync all of the data into password protected database for the research team to access. Participants will perform a return demonstration to confirm that they can record their dietary intake daily, physical activity, weight, and blood pressure using the "Lose-It" app. We also review with the participant the "My Plate" method for proper nutrition and the steps to distance conversion chart. Each participant will be given a copy of both via email.

Session	mHealth App + Health Coaching Intervention Setting: Online video- conference call (Zoom)
Baseline Session (Session 1) **Time for session: 90 minutes**	The research assistant (RA) will demonstrate proper "Lose-It" app use, set up the smartphone application, and how to enter their dietary intake, physical activity, weight, blood pressure, heart rate and the minutes of physical activity per day using the "Lose-It" app. The RA will demonstrate how to sync the data from the Wi Fi weight scales and blood pressure cuff to the "Lose-It" app. Participants will perform a return demonstration to confirm that they can access the "Lose-It" app, sync the data from the Wi Fi scales and blood pressure cuff.

Week 1-12 (Sessions 2-13) **Time for session: 30 minutes**	**Phase 1:** The participant will place the goals (dietary and physical activity) into their "Lose-It" app via smartphone for goal attainment. **Phase 2:** The participant and the RA will review the electronic report generated from the "Lose-It" app for monitoring or assessing progress for dietary intake and physical activity each week from baseline to week 12. **Phase 3:** The RA will review with the participant each week for 12 weeks how many days they implemented and achieved the solution for their daily goals. **Phase 4:** Time will be allowed for any questions.

Risk and Benefits

The risks for harm to you for participating in this study are minimal. You may feel uncomfortable about having the research team knowing about your dietary intake or physical activity level. It is not unusual for people with a transplant to occasionally have difficulty with being physical active and controlling their weight. We are trying to help people with these common problems.

If you agree to take part in this study, there may or may not be direct medical benefits to you.
We hope the information learned from this study will in the future benefit other patients with a kidney transplant who are having difficulty becoming physically active and assessing their dietary intake.

E. Internal Validity

In the previous K award[22] study, we found that the primary reason for participants not enrolling (65%) into the study was due to the distance of traveling to the research site. Thus, there is a need to deliver the intervention activities in home settings via Zoom. The delivery of our study research activities is timely due to the Coronavirus (COVID-19) and the fact that our population is immunocompromised. Due to the recent pandemic outbreak of the coronavirus (COVID-19) and since our population is immunocompromised. We will promote sustainability for participating in the study by sending weekly text messages to the participants to thank them for their participation in the study. The conduct of this feasibility study will help identify other limitations to consider for future studies in a larger multisite clinical trial. We will collect data regarding the time spent on delivering the intervention so that we can conduct a cost-effective analysis at a later date.

F. Data Analysis

Descriptive statistics will be used to summarize sample characteristics. **Aim 1)** percent approached, percent dropped, and percent to adhere to logging daily dietary and physical activity will be analyzed using means and standard deviations of these variables and analyzed as differences between the baseline and 3-month measurements using the Wilcoxon Signed-Ranked test. **Aim 2)** Perceived Stress Scale, Exercise Self-efficacy Scale, Fruit, Vegetables, and Fiber Screener, fat intake, carbohydrate intake, weight, blood pressure, heart rate, and the minutes of physical activity per day will be analyzed using the differences among baseline, 4,8, and 12 weeks using repeated measures analysis of variance using the Friedman's Test. Frailty levels will be collected at baseline and 12 weeks and will be analyzed using means and standard deviations of this variables. **Missing Data**: We will carefully record and code various reasons for missing data (e.g., participants forget to record data into the "Lose-It" app) and examine the pattern of missing data.

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