Official Title:	**The Use of a Consumer-Based mHealth Dietary App and Health Coaching with Kidney Transplant Recipients Study Information**
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The Use of a Consumer-Based mHealth Dietary App and Health Coaching with Kidney Transplant Recipients Study Information

"Hello, my name is [*Research Assistant*]. I am a Research Assistant at The Ohio State University in the College of Nursing. I am undertaking research called 'The Use of a Consumer-Based mHealth Dietary App and Health Coaching with Kidney Transplant Recipients Study Information'. Dr. Tara O'Brien, Assistant Professor at College of Nursing is the head of this study.

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. You have been contacted because you showed interest and gave permission to be contacted by Dr. Tara O'Brien's research team about future studies being conducted with kidney transplant recipients.

Purpose:

The purpose of the study is to test the feasibility of a data-driven dietary intervention designed for kidney transplant recipients using a mobile Health (mHealth) platform. The intervention called mHealth dietary app + health coaching will allow participants to set goals, receive ongoing feedback, and self-monitor behaviors for dietary intake and physical activity.

Procedures/Tasks:

Screening: First, we will ask you four questions to determine your capacity to obtain verbal consent using a standard method called Evaluation to Sign Consent Form (ESC). At the end of the phone screening, we will let you know whether you qualify to participate in the study. The phone screening will take about 5-10 minutes

Lets start …

1. What are two potential risks for participating in the study
2. What is expected from you in this study?
3. What if you do not want to continue the study?
4. What if you experience discomfort?

[If do not qualify, state] "Thank you for being willing to speak with me today. Unfortunately, we will not be able to include you in this study." Then, politely end the call.

[If qualify, state] "Thank's you qualify for the study. I will now explain details of the study procedures.

During this study following sessions will take place:

First session: You will receive training by a research assistant who will work with you via video conference call using Zoom to set up the "Lose-It" app. Zoom is a video conferencing system that has been used successfully for interviews with clinicians in our organization and by others. You will be taught how to sync your smartphone and retrieve data from the "Lose-It app" app. We will instruct you how to enter your dietary intake and physical activity daily for 12-weeks into the"Lose-It app" app. We will mail you Wi-Fi weight scales and blood pressure cuff prior to this session. We will teach you how to use the Wi-Fi connected weight scales and blood pressure cuff to monitor your weight and blood pressure. You will also be taught how to sync the data from the scales and blood pressure cuff to the "Lose-It" app. This will take about 90 mintues of your time. You will complete 6

short questionnaire called, (1) demographics, (2) Charlson Comorbidy Index, (3)Perceived Stess Scale, (4) Self-Efficacy for Exercise Scale, (5) Fruit/Vetgetable/Fiber Screner, and (6) Clinical Frailty Scale.

Sessions (2-13) After the first session, we will meet with you once a week for 12 weeks. Each session will take about 30 minutes. During these sessions we will complete the following four steps:

Step1: You will place your dietary and physical activity goals into the "Lose-It" app via your smartphone.
Step 2: We will review the electronic report generated from the "Lose-It" app for monitoring your progress for dietary intake and physical activity each week.
Step 3: We will review each week with you how many days you achieved the daily goals.
Step 4: Time will be allowed for any questions.

During session five, you will be asked to complete 3 short questionnaires called (1) Perceived Stess Scale, (2) Self-Efficacy for Exercise Scale, and (3) Fruit/Vetgetable/Fiber Screner.

The last session (13) you will be asked to complete 4 short questionnaires called (1)Perceived Stess Scale, (2) Self-Efficacy for Exercise Scale, (3) Fruit/Vetgetable/Fiber Screner, and (4) Clinical Frailty Scale.

Duration: Anticipated duration of a single subject's participation in the study/project is 12 weeks. Session 1 will take about 90 mins and weekly sessions will take about 30 mins each (that means 12X30=360mins).

Risks 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.

As we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you. While data may be coded, it will exist for an extended period of time, which could be affected if there is a data breach. Your data will be stored on a password protected database.
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.

Confidentiality:
Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices

Will my de-identified information be used or shared for future research?
Yes, it may be used or shared with other researchers without your additional informed consent. For example, we may have to release your information if a law requires us to do so, the Agency that is

funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

Participants will receive and keep the Wi Fi wireless blood pressure cuff and weight scale for completing the study. Please keep in mind that we may need to cllect the equiometn back from you at the end of the study.

Participant Rights:
You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

For questions, concerns, or complaints about the study, or you feel you have been harmed as a result of study participation, you may contact the principal investigator Tara O'Brien at 614-292-8045 or email obrien.782@osu.edu

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

Do you have any questions about this research?

In order to provide your verbal consent, you will tell the research team member your responses to the following questions:

1. "Do you agree to participate in the mHealth app + health coaching study?" YES or NO
2. "Do you agree to be contacted to be in a *follow-up* sessions as part of this study?" YES or NO
3. "When the study is completed, would you like to receive a copy of the study results?" YES or NO
4. "Would you like to be contacted about the chance to be in other research studies?" YES or NO

- **Thank you -**
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