Informed Consent Form

mLIFE (The Mobile Lifestyle Intervention for Food and Exercise Study)

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Brief Title	The Mobile Lifestyle Intervention for Food and Exercise Study
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Study Type	Interventional
Official Title	Increasing Social Support for Weight Loss Through the Use of Social Gaming and Points: The Mobile Intervention for Food and Exercise (mLIFE) Study
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UNIVERSITY OF SOUTH CAROLINA

CONSENT TO BE A RESEARCH SUBJECT

Title: Increasing social support for weight loss: The Mobile Lifestyle Intervention for Food and Exercise (mLife) study

KEY INFORMATION ABOUT THIS RESEARCH STUDY:
You are invited to volunteer for a research study conducted by Principal Investigator, Brie Turner-McGrievy, PhD, MS, RD. I am an Associate Professor in the Department of Health Promotion, Education, and Behavior at the University of South Carolina. The National Institutes of Health is sponsoring this research study.

The purpose of this study is to examine the use of a mobile app on helping people to track their diet, physical activity, and provide social support to one another. We will examine if this app helps people lose weight and reduce risk factors for type 2 diabetes (T2DM). This study is being done at the University of South Carolina's Columbia Campus and will involve approximately 240 volunteers.

Participants in this study must be 18-65 years, have an iPhone or an Android phone with a data plan to participate, and must have overweight or obesity (Body Mass Index between 25–49.9 kg/m^2). Potential benefits include weight loss and/or a decrease in T2DM risk factors.

As part of this study, you will be asked to download an app to your phone. On that app, you will be asked to log the following each day: (1) all the foods and beverages you consume, (2) any physical activity you engage in, and (3) your weight. You will also be asked to interact with other participants by sending them encouraging messages through the app. You can create a username that protects your identity so you can remain anonymous in the study. You will be assigned to two versions of the app. Both are the same, but how the data are presented to you will be different. The app you will download does not access data from your phone, such as passwords, Facebook friends, or location.

PROCEDURES:
If you agree to participate in this study, you will do the following:

1. Attend an online orientation to learn about the study and sign this consent form. This will last approximately 1 hour.
2. Complete online questionnaires, including inventory of current prescribed medications and 24-hour diet recalls, and collect measurements for online self-report (blood pressure, height and weight and waist and hip circumference).
   Notes:
   - You will be mailed a FitBit watch and scale if you don't already own these. You will connect these devices to the study-related app.

- This will occur in the two weeks between your orientation session and the beginning of the study.
- Once you complete all online questionnaires and report your measurements, you will be then randomized to use one of two different versions of the app.

3. Return for an online meeting to download the app and learn how to use it. This will last approximately two hours. You will then start the study using an app and podcasts to help you lose weight.
4. Use your app every day to record all your meals, exercise, and weight. Wear a wrist FitBit monitor to assess your physical activity and sedentary time.

After 6 months (online assessment 2):

1. Complete online questionnaires, including inventory of current prescribed medications, 24-hour diet recalls, and collect measurements for online self-report (blood pressure, weight and waist and hip circumference).
2. Continue to use your app every day to record all your meals, exercise, and weight. Wear a wrist FitBit monitor to assess your physical activity and sedentary time.

After 12 months (online assessment 3):

1. Complete online questionnaires, including inventory of current prescribed medications, 24-hour diet recalls, and collect measurements for online self-report (blood pressure, weight and waist and hip circumference).

Timeline for Assessments

Task	*Orientation*	*Assessment 1 (at the start of the study)*	*Assessment 2 (6-months)*	*Assessment 3 (12 months)*
Sign consent	x			
Inventory of medications (online form)		x	x	x
Online questionnaires and diet recalls		x	x	x
Height (self-report- online form)		x		
Blood pressure (self-report)		x	x	x
Waist and hip circumference (self-report)		x	x	x

Task	*Orientation*	*Assessment 1 (at the start of the study)*	*Assessment 2 (6-months)*	*Assessment 3 (12 months)*
Body weight (self-monitor using FitBit Scale)		x	x	x
Physical activity (using your FitBit wrist monitor)		x	x	x

DURATION:
Participation in the study involves two online meetings and three assessment time-points over a period of 12 months. This includes attending an orientation session, attending your session to learn about the app, and completing your online assessments at baseline, 6 months, and 12 months. You'll also be using your app downloaded to your phone, a FitBit watch, and a FitBit scale each day. The orientation and app training visit will last about 1.5 hours each and the assessment visit will be online, you will receive reminder for completion. No in-person activities are required. The online questionnaire will take approximately 30 minutes to complete (and you will complete one at baseline and one at 6 months and one at 12 months) and each dietary recall will take approximately 15 minutes to complete (you will complete three at baseline and three at 6 months and three at 12 months).

RISKS/DISCOMFORTS:
Loss of Confidentiality: There is the risk of a breach of confidentiality, despite the steps that will be taken to protect your identity. Specific safeguards to protect confidentiality are described in a separate section of this document.

This study will encourage you to engage in moderate exercise. If you are not accustomed to exercising, you may experience some muscle soreness.

BENEFITS:
You may experience improved health including weight loss, improvements in your blood pressure, as well as increased knowledge about diet and health. This research may help researchers understand the effects of changing your diet on your body weight and risk factors for T2DM, including high blood pressure.

RETURN OF CLINICALLY RELEVANT RESEARCH RESULTS:

After your 12-month assessment, you will receive a comparison report of your weight, blood pressure, and diet changes (pulled from your dietary recalls) at baseline and 12 months.

COSTS:
There will be no direct cost to you for participating in this study other than ensuring transportation to attend study sessions.

PAYMENT TO PARTICIPANTS:
You will receive up to $100 for participating in this study. You will receive a $50 Amazon gift card for completing all baseline and 6-month assessments (online self-report measurements and questionnaires) and $50 Amazon gift card for completing all 12-month assessments (online self-report measurements and all questionnaires).

USC STUDENT PARTICIPATION:
Participation in this study is voluntary. You are free not to participate, or to stop participating at any time, for any reason without negative consequences. Your participation, non-participation, and/or withdrawal will not affect your grades or your relationship with your professors, college(s), or the University of South Carolina.

CONFIDENTIALITY OF RECORDS:
Any information that is obtained in connection with this study will remain confidential and will be disclosed only with your express written permission, unless required by law. You will be given a unique identifier number to protect your identify throughout the study. Your information will be securely stored in locked files and on password protected computers, using unique identifier number. The results of the study may be published or presented at seminars, but the report will not include your name or your identifier number or other identifying information about you. Although we ask that all participants in the diet and health classes keep private what other class members say, we cannot promise that they will do so.

CLINICAL TRIAL REGISTRY DATABANK:
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

VOLUNTARY PARTICIPATION:
Participation in this research study is voluntary. You are free not to participate, or to stop participating at any time, for any reason without negative consequences. If you do withdraw from this study, the information you have already provided will be kept in a confidential manner. If you wish to withdraw from the study, please call or email the principal investigator listed on this form.

REMOVAL FROM STUDY: The researchers may decide to remove you from the study without your approval or choice for the following reasons:

- You are unable to keep your appointments;
- You do not complete the questionnaires;
- If you become pregnant;
- If the investigator believes that it is not in your best interest to continue in the study.

If this occurs, we will let you know in detail why you are being removed from the study.

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study, or a study related injury, I am to contact Dr. Brie Turner-McGrievy at 803-777-3932 or email brie@sc.edu, or Dr. Carolina Delgado-Diaz at 803-567-5688 or email delgadoc@mailbox.sc.edu.

Questions about your rights as a research subject are to be directed to, Lisa Johnson, Assistant Director, Office of Research Compliance, University of South Carolina, 1600 Hampton Street, Suite 414D, Columbia, SC 29208, phone: (803) 777-6670 or email: LisaJ@mailbox.sc.edu.

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

_____ _____

Signature of Subject / Participant Date