COVER PAGE

Official Title:
Building on the Dietary Guidelines: 3 Dietary Pattern (DG3D) Study – Testing a Teaching Kitchens and Food is Medicine Approach for Type 2 Diabetes Prevention

Brief Title:
Optimizing Lifestyles Through Increased Vegetable-rich Eating Pilot Study

Acronym:
OLIVE Pilot

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Informed Consent

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UNIVERSITY OF SOUTH CAROLINA

CONSENT TO BE A RESEARCH SUBJECT

Title: *Building on the Dietary Guidelines: 3 Dietary Pattern (DG3D) study – Testing a Teaching Kitchens and Food is Medicine Approach for Type 2 Diabetes Prevention.*

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 a Professor in the Department of Health Promotion, Education, and Behavior at the University of South Carolina.

The purpose of this study is to examine how receiving ingredients for a Mediterranean diet (with or without nutrition classes) impacts healthy eating. This study is being conducted virtually via Zoom and will involve approximately 40 volunteers.

Participants in this study must be 18-65 years old, have access to a digital body weight scale, and must be overweight or obese (Body Mass Index between 25-49.9 kg/m^2). Potential benefits include weight loss and/or a decrease in T2DM risk factors. The risks related to participation are minor and include discomfort related to changes in diet.

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

1. Attend an online orientation to learn about the study and electronically sign this consent form. This orientation will last approximately two hours.
2. Complete online questionnaires, including a dietary recall and physical activity survey, and submit a self-reported body weight with a picture of your scale's body weight reading. This will occur in the two weeks between your orientation session and the beginning of the study.

Note: Once you complete all online questionnaires and report your body weight, you will then be randomized to one of two groups: 1) Receive weekly grocery deliveries and recipes for a Mediterranean diet, or 2) Receive weekly grocery deliveries and virtually attend nutrition and cooking classes for four weeks. It is important to note that group assignments will be randomized, meaning you will not be able to choose your group assignment.

3. Receive a weekly Instacart grocery delivery containing up to $25 worth of food items related to the provided Mediterranean recipes for four weeks.
4. Participants randomized to the grocery deliveries and virtual classes group, attend a 75-minute class, once a week for four weeks online via Zoom. Class will

be offered in the evening.

During these classes, you will learn how to prepare and follow a Mediterranean diet. Classes involve cooking demonstrations, virtually touring a grocery store, and learning how to eat healthier in social situations, as well as in restaurants. While you will not be removed from the study as a result of missing classes, make-up sessions will not be offered. Participants are highly encouraged to plan to be present for each of the four classes.

After 4 weeks:

5. Complete online questionnaires, including a dietary recall and physical activity survey, and submit a self-reported body weight with a picture of your scale's body weight reading.

Timeline for Assessments

	Orientation	**Assessment 1 (Baseline)**	**Assessment 2 (4 weeks)**
Sign consent	X		
Provide demographics	X		
Body weight (self-report – online form and photo of digital scale reading)		X	X
Online questionnaires and diet recall		X	X

DURATION:
As described above, the study involves participating various activities over a period of 6 weeks.

Each online class will last approximately 75-minutes and the self-reported weight assessment at the start of the study and at 4 weeks will last approximately 5-minutes. The online questionnaire will take approximately 20 minutes to complete (and you will complete one at baseline and 4 weeks) and each dietary recall will take approximately 15 minutes to complete (you will complete 1 at baseline and at 4 weeks).

RISKS/DISCOMFORTS:
We do not anticipate that there will be any risk associated with participating in this study.

BENEFITS:
You may experience improved health including weight loss, improvements in your blood pressure and cholesterol levels, 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 the 4-week assessment, you will receive a comparison report of your weight and diet changes (pulled from your dietary recalls).

COSTS:
There will be no direct cost to you for participating in this study.

PAYMENT TO PARTICIPANTS:
You may receive $10 (electronic gift card) for completing your baseline and 4-week assessments (self-reported weight assessment, dietary recall, and physical activity survey) and participating in a post-study focus group.

CONFIDENTIALITY OF RECORDS:
Any information that is obtained in connection with this study will remain confidential and will be disclosed only with your written permission. You will be given a unique identifier number to protect your identify throughout the study and your name will not be included on these records. 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 attend the weekly classes.
- You do not complete the questionnaires.
- You are unwilling to accept your group assignment or are unwilling or unable to change your diet.
- 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.

Questions about your rights as a research subject are to be directed to, Lisa Johnson, Director, Office of Research Compliance, University of South Carolina, 1600 Hampton Street, Suite 805, 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