PROTOCOL

Together Eating and Activity Matter Plus: Feasibility of Conducting an Online Family Dyadic/Couple Skills Training for Black Adults Enrolled in a Behavioral Weight Loss Intervention

NCT number NCT05981508
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Together Eating and Activity Matter Plus: Feasibility of conducting an online family dyadic/couple skills training for Black adults enrolled in a behavioral weight loss intervention

Protocol Number*: 1.1

National Clinical Trial (NCT) Identified Number:

Principal Investigator*: Candice L. Alick, PhD

Sponsor: University of North Carolina at Chapel Hill

"Sponsor" indicates an institution, foundation, or individual who takes responsibility for and initiates a clinical investigation; often times this is the university with which the Principal Investigator is affiliated.

Grant Title: <Grant Title>

Grant Number*: <Grant Number>

Funded by: National Institute for Diabetes, Digestive and Kidney Disorders

Version Number: v.1.1

23 February 2023

All versions should have a version number and a date. Use an international date format (e.g.,YYYY-MM-DD [2017-12-21] or write out the month (e.g., 21 December 2017).

For the initial submission of a protocol to the IRB, indicate "Not applicable; this is the first version of the protocol." in the table below. For any subsequent amendment being submitted to the IRB, add details of the specific changes that are being implemented in the amendment. Please note that Section 10.4 is a high-level summary of <u>all</u> formal protocol versions/amendments.

CONFIDENTIALITY STATEMENT

This document is confidential communication. Acceptance of this document constitutes agreement by the recipient that no unpublished information contained herein will be published or disclosed without prior approval of the Principal Investigator or other participating study leadership and as consistent with the NIH terms of award.

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STATEMENT OF COMPLIANCE

[The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.]

INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the *Statement of Compliance* above.

Principal Investigator or Clinical Site Investigator:

Signed: Candice L Alick Date: 02/23/23

Name*: Candice L. Alick, PhD

Title*: Postdoctoral Fellow

Investigator Contact Information

Affiliation*: Center for Health Promotion and Disease Prevention (a CDC funded Prevention Research Center) at the University of North Carolina at Chapel Hill.
Address: 1700 Martin Luther King, Jr BLVD Chapel Hill, NC 27599
Telephone: (919) 966-6080
Email: alick@email.unc.edu

[For multi-site studies, the protocol should be signed by the clinical site investigator who is responsible for the day to day study implementation at his/her specific clinical site.]

Signed: Date:

Name:

Title:

Affiliation:

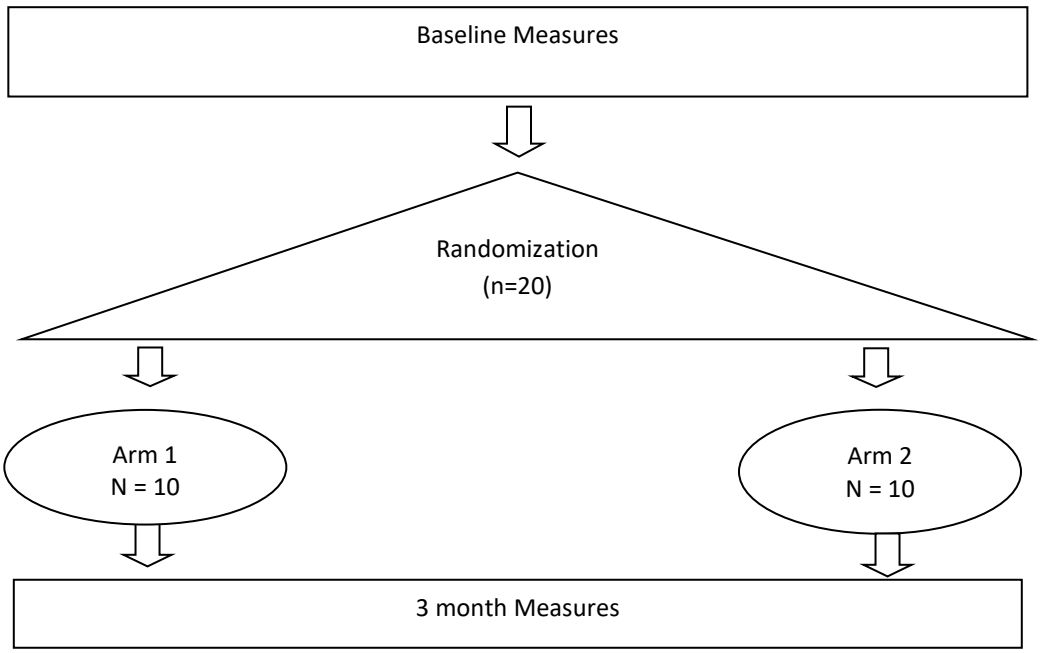
1 PROTOCOL SUMMARY

No text is to be entered in this section; rather it should be included under the relevant subheadings below. It may be useful to complete this section after the relevant sections in the protocol have been completed.

1.1 SYNOPSIS

Title:	Feasibility of conducting an online family dyadic/couple skills training for Black adults enrolled in a behavioral weight loss intervention
Grant Number:	
Study Description:	TEAM Plus is an in-person 3-month family enhanced BWL intervention designed for Black adults consisting of a family dyadic skills training and core behavioral weight loss sessions testing the feasibility and acceptability of an interactive counselor-led online training, the family dyadic skills training will be delivered online using a web-conferencing platform (e.g., Zoom).
Objectives*:	**Primary Aim:** To test the feasibility of implementing and acceptability of an online family dyadic/couple skills **Secondary Aim:** To explore the experience of administering a family dyadic/couple skills training online from a counselor perspective (i.e., facilitators, barriers, acceptability).
Endpoints*:	Described previously
Study Population:	Participants must be 1)≥18 years of age, 2) self-identify as Black/African American, 3) reside in the Raleigh/Durham/Chapel Hill area. (n=19)
Phase* or Stage:	Pilot
Description of Sites/Facilities Enrolling Participants:	Participants will be recruited from community organizations, local universities, through social media and word of mouth.
Description of Study Intervention/Experimental Manipulation:	The study intervention is a 3-month behavioral weight loss intervention adapted from the Diabetes Prevention Program (DPP). Core group sessions, and individual or small group family skills trainings are included. Family skills trainings are delivered in person or virtually.
Study Duration*:	7 months
Participant Duration:	4 months

1.2 SCHEMA


Baseline Measures
Randomization
(n=20)
Arm 1
N = 10
Arm 2
N = 10
3 month Measures

1.3 SCHEDULE OF ACTIVITIES

	Pre-screening (Pre-consent)	Consent/ Baseline (Pre-Visit 1)	Visit 1 Day 1 ±7	Visit 2 Day 7 ±7	Visit 3 Day 14 ±7	Visit 4 Day 21 ±7	Visit 5 Day 35 ±7	Visit 6 Day 49 ±7	Visit 7 Day 79 ±7	Post Assessment Day 91 ±7
Review Eligibility	X									
Informed Consent		X								
Demographics		X								
Clinical history		X								
Height		X								X
Outcome Evaluation										
Weight		X	X	X	X	X	X	X	X	X
Surveys		X								X
Randomization		X								
Control & Experimental Interventions		X	X	X	X	X	X	X	X	
Adverse Events Reporting		X				X	X	X	X	X

2 INTRODUCTION

2.1 STUDY RATIONALE

See section 2.2

2.2 BACKGROUND

Nearly half (49.9%) of Black adults in the United States live with obesity. Black adults are underrepresented in standard behavioral weight loss interventions (BWLI) and experience sub-optimal weight loss outcomes when included in such programs. Cultural adaptations to BWLI that recognize the family behavioral context and address the cultural value of family among Black populations are needed to improve weight loss outcomes. Prior research, including our randomized controlled pilot, Together, Eating and Activity, Matter (TEAM), have incorporated family skills training to enhance family involvement, targeting cohesion and communication, in addition to core weight loss curriculum. However, family inclusion in weight loss interventions can result in additional barriers to retention and adherence.

Technology has become an attractive delivery format to increase reach to at-risk populations, as a well-designed online program can address issues of timely access and geographical location (or distance from program sites), which are linked to low retention of Black participants. However, technology uptake among Blacks populations still lags due to mistrust, skepticism, concerns about confidentiality, privacy, and remote interaction with staff. Increases in acceptance and utilization of telemedicine and mobile-health were reported during the COVID-19 pandemic. Considering the time and location burden already associated with behavioral weight loss sessions, it is important to identify strategies to increase access that are both feasible and acceptable in the target population. Currently the feasibility and acceptability of an online family dyadic skills training is unknown among Black adults.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

The possible risks and discomforts from being in this study are few and are listed below.

- We do not think there is risk from the dietary advice given as part of the study
- Those who increase their level of physical activity may experience minor muscle pain, but this type of activity rarely causes serious health problems such as chest pain or asthma.
- In all studies, there is a very slight chance of loss of privacy (that is, others may see your study information). As stated below, we will do all we can to make sure this does not happen.

2.3.2 KNOWN POTENTIAL BENEFITS

Research is designed to benefit society by gaining new knowledge. A benefit from being in this study is improvement in lifestyle and losing weight. However, some not benefit from being in this study

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

The potential risks are small, as noted above. We outline our approach to minimizing risk above. We believe there is much to be gained from this study, especially in the context of minimal risk.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS	PUTATIVE MECHANISMS OF ACTION
Primary			
Primary Aim: To test the feasibility of implementing and acceptability of an online family dyadic/couple skills	Feasibility will be measured by the number of participants who consent, and the percent of dyads that attend both sessions. Acceptability will be measured by a satisfaction survey complete by both dyad members	Primary Outcome	
Secondary			
Secondary Aim: To explore the experience of administering a family dyadic/couple skills training online from a counselor perspective (i.e., facilitators, barriers, acceptability).			

4 STUDY DESIGN

4.1 OVERALL DESIGN

Randomized controlled pilot enrolling 20 participants in a weight loss program and followed for 3 months. Participants will be randomized 1:1

- Arm 1: Family Skills Training In-person;
- Arm 2: Family Skills Training On-line

Randomized assignment will be completed by a random number generator in Excel.

From the perspective of NIH, this is a single site study as the intervention is given by one investigational team.

The acronym for the study is TEAM Plus (Together Eating & Activity, Matter). The names of the study arms are given above.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

Describe the rationale for the type and selection of control or comparison condition(s) and study design. Discuss known or potential problems associated with the control group chosen in light of the specific disease, health behavior, and intervention(s) being studied.

<Insert text>

4.3 JUSTIFICATION FOR INTERVENTION

Technology offers a promising way to reach at-risk groups, like Black communities, by reducing barriers such as distance and scheduling that often lead to low participation in weight loss programs. However, Black populations have been slower to adopt technology due to concerns about trust, privacy, and remote communication. During the COVID-19 pandemic, more people began using telemedicine and mobile health tools, showing potential for wider acceptance. Given the time and travel demands of traditional weight loss programs, it is important to find tech-based solutions that are both practical and trusted by the target population.

4.4 END-OF-STUDY DEFINITION

The end of study is defined as completing the 3 month follow-up visit.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

Participants must

1) be ≥18 years of age,

2) self-identify as Black/African American,
3) reside in the Raleigh/Durham/Chapel Hill area,
4) a family member willing to participate in program sessions together, and
5) have internet access.

5.2 EXCLUSION CRITERIA

An individual who does not meet all of the above criteria on section 5.1 will be excluded from participation in this study.

A participant cannot be taking any weight loss medication.

5.3 LIFESTYLE CONSIDERATIONS

During this study, participants are asked to:

- Follow the lifestyle recommendations for both dietary change and to be modestly physically active.
- If they are unable to make the recommended changes, they will continue in the study. Specifically, participants will not be excluded if they fail to achieve lifestyle goals.

5.4 SCREEN FAILURES

Screen failures are defined as participants who consent to participate in this study but are not subsequently assigned to the study intervention or entered in the study. Individuals who do not meet the criteria for participation in this trial (screen failure) because of meeting one or more exclusion criteria that are likely to change over time may be rescreened. Examples include weight loss of more than 10% of their baseline weight prior to the visit 1 or moving away from the Raleigh/Durham/Chapel Hill area.

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

Recruitment: We will recruit from this sample of over 50,000 residents in the Raleigh/Durham/Chapel Hill, NC area who meet our race and BMI inclusion criteria through multiple recruitment channels: 1) advertisement on social media, 2) community partnerships, 3) university listservs, 4) medical practices, and 5) word of mouth. We also have community partnerships with local Black churches, local chapters of Historically Black Fraternities and Sororities (i.e. National Panhellenic Council), and Durham County Department of Public Health – our partnerships with these entities should help us achieve our recruitment goals.

At least 20 individuals will be enrolled in the pilot study.

Retention: At enrollment, we will ask for home and cell numbers, if it is OK to send text messages. We will also ask participants to provide contact information for an alternate contact (friend or family member) in case we are unable to reach them directly.

Incentive: Study visits were compensated with $40 per visit and Skills training sessions $20 per visit. This amount was to compensate for time and travel to study site. We do not think this compensation is coercive and think the rate is in line with what the IRB typically endorses.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION

Core Weight Loss Sessions: All Family dyads will be asked to attend 7 in person behavioral weight loss group sessions over 3 months covering content on dietary change, physical activity and behavioral modification to lose weight. Participants will have lessons, set goals, and receive individual feedback on their progress. The theoretical underpinning of this component is the social cognitive theory.

Family dyadic skills training: Concurrently, the brief family dyadic skills training will include two 30 minutes sessions delivered by a counselor using a secure Zoom platform. The training provides skills that should optimize implementation of the recommendations, strategies, and tips provided in the behavioral weight loss core curriculum that has been adapted for family inclusion. To assess for differences between in-person and online skills training, families will be randomized to**: online and in-person delivery modes**. Session one will address strategies to improve cohesion, an important aspect of healthy family functioning. Research has shown greater cohesion has been associated with greater weight loss among Black adults. Session two will address communication and conflict; these are important in handling stressful events and have been identified as essential skills to target for family inclusion in behavioral weight loss interventions. The content for the sessions will be informed by the couples skills training from TEAM. The theoretical underpinning for this component is Interdependence and Communal Coping, Social Interdependence Theory, and Olson's Circumplex of Family Model of Family Functioning.

6.1.2 ADMINISTRATION AND/OR DOSING

- The intervention will be given by trained research staff.
- For participants recruited from the Raleigh/Durham/Chapel Hill area, the intervention will be delivered in person and/or online:
    - In person, face-to-face group sessions visits, will be given at the UNC Center for Health Promotion and Disease Prevention, located at 1700 Martin Luther King, Jr BLVD, Chapel Hill, NC 27599.

    - The other session may be given in person or by online e.g., Zoom.
- We will encourage participants to take part in all sessions. However, a participant will not be dropped from the study based on session participation
- If a participant takes part in 70% or more of anticipated visits, we will consider this a "full-dose."
- The intervention format for this study is group or dyad.

6.2 FIDELITY

6.2.1 INTERVENTIONIST TRAINING AND TRACKING

- Process data:
    - number of sessions attended (including dates of visits),
    - Visit weights (if available)
    - A proportion (20%) of skills training will be audio-recorded to ensure that the counselor is correctly conducting the training as per the protocol

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

Randomization

Participants will be randomized 1:1, to either:

- Group 1: TEAM (in-person family skills training);
- Group 2: TEAM Plus (on-line family skills training).

Randomized assignment will be done by using the randomization number generator in excel.

Blinding Plan

As an open-label study, participants, providers, and many study staff will know to which group individual participants have been randomized.

6.4 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

All session visits will be recorded. A session checklist will be completed by counselor at the end of every session.

The extent to which participants perform weight management behavioral skills and cognitive strategies will be assessed from questionnaire data addressing self-monitoring of weighing, dietary behaviors, and goal-setting.

6.5 CONCOMITANT THERAPY

For this protocol, participants may not use weight loss drugs. Medication usage will be assessed at each study visit and documented in the relevant Case Report Form (CRF).]

6.5.1 RESCUE THERAPY

No rescue therapy outside of the study protocol is planned if participants do not lose weight.

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

The study intervention will not be discontinued unless the participant withdraws or is withdrawn as outlined in the above section.

If a participant withdraws or is withdrawn, no attempts will be made to collect follow-up measures.

If a participant requests to withdraw from the intervention but is willing to continue the measurement component of the study, he/she will be invited to continue with follow-up measures.

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request.

Participants will be withdrawn according to protocol for the following reasons:

- Other medical diagnosis typically associated with significant weight loss (5% or more of body weight). In addition to malignancy, examples include nonmalignant gastrointestinal disease, endocrinopathies, infectious disease, rheumatologic diseases, etc. As Dr. Berkowitz (study Co-I, general internist) will be blinded to participants' study group assignment, he will adjudicate in these situations, seeking consultation from medical colleagues as appropriate.
- New diagnosis of medical condition such that participation in a behavioral weight loss intervention is no longer appropriate.
- Permanent change in living situation (e.g. from home to nursing home) such that the participant has limited food options.

Pregnancy: Study participants who become pregnant may continue to participate in the study with the understanding that weight loss goals will be suspended during pregnancy through 3 months postpartum. If a pregnant participant wishes to continue with counseling session during pregnancy, the focus on counseling will be on dietary quality. The participant may resume full participation 3 months postpartum. Any data collected while the participant is pregnant will be censured and follow-up data will not be collected until the participant is 6 months postpartum.

A participant will be considered lost to follow-up if we are unable to contact him/her according to this algorithm.

- Attempts at telephone contact:
    - We will call up to 5 times over a 2 week period. We will attempt 2 calls during regular work hours (8:30 to 5:30 on weekdays) and 3 after hours, including Mon-Thurs evening between 5:31 and 9:00 pm and on Saturday calling between 8:30 and 5:30 pm.
    - We will leave up to 2 phone messages.
    - If no contact is made over this initial 2 week period as outlined above, we will undertake more limited contact attempts for an additional 2 weeks including up to 2 phone calls per week, 1 during business and the other during evening hours or on the weekend.
- Email: If a participant gives us permission to contact by email, we will send up to 4 weekly emails.
- Text: If a participant gives us permission to contact by text, we will send up to 4 weekly texts.
- Alternative contact: During enrollment, we will collect information on an alternative contact that we are given permission to contact. We will attempt to contact this individual up to 3 times a week for 4 weeks.

No replacement is planned for those who withdraw from the intervention for the study.

7.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if we are unable to contact him/her according to this algorithm.

- Telephone contact:
    - We will call up to 5 times over a 2 week period. We will attempt 2 calls during regular work hours (8:30 to 5:30 on weekdays) and 3 after hours, including Mon-Thurs evening between 5:31 and 9:00 pm and on Saturday calling between 8:30 and 5:30 pm.
    - We will leave up to 2 phone messages.
    - If no contact is made over this initial 2 week period as outlined above, we will undertake more limited contact attempts for an additional 2 weeks including up to 2 phone calls per week, 1 during business and the other during evening hours or on the weekend.
- Email: If a participant gives us permission to contact by email, we will send up to 4 weekly emails.
- Text: If a participant gives us permission to contact by text, we will send up to 4 weekly texts.
- Alternative contact: During enrollment, we will collect information on an alternative contact that we are given permission to contact. We will attempt to contact this individual up to 3 times a week for 4 weeks.

If we are unable to contact a participant as outlined above, a letter will be sent to the current mailing address and inviting the participant to contact us if he/she still wishes to participate in this study.

Should the participant continue to be unreachable and does not respond to the mailed letter within 4 weeks, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

Study data will be collected at baseline, and 3 months. Process data will be collected as part of the intervention via the web-based platform by counselors immediately after sessions.

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS	Collection Time (min)	Data Collection times (month)			
Primary				0	1	2	3
Primary Aim: To test the feasibility of implementing and acceptability of an online family dyadic/couple skills	Feasibility will be measured by the number of participants who consent, and the percent of dyads that attend both sessions. Acceptability will be measured by a satisfaction survey complete by both dyad members	Primary Outcome	*1* *15*	*X*		*X*	*X* *X*
Secondary							
Secondary Aim: To explore the experience of administering a family dyadic/couple skills training online from a counselor perspective (i.e., facilitators, barriers, acceptability).			*45*				*X*

- ***Physical examination-based assessments*** *(e.g., weight)*
- At study outset, weights (seven 50 pound weights) assessed and adjusted for accuracy on 12/3/19 by North Carolina Department of Agriculture and Consumer Services Standards Laboratory.

- Weights to be re-assessed and adjusted for accuracy annually.
- Scales tested for accuracy the first week of each month during their use in this study.

Seca 874 dr Scale Tolerance Testing
(updated 1/28/20)

The scale's 6 AA batteries should be replaced at least once a year.

It is **imperative** that tolerance weights be handled carefully (no slamming around or banging against one another) to maintain their accuracy.

Before starting the test set the **ON-OFF** switch to **ON.** Press the **start** key with no load on the scale. If necessary switch the weight display from **kg** to **lbs** by pressing the **2 in 1** key for approximately 3 seconds.

1) Place a 50 lb wt in the center of the scale and record weight. (~50 lbs) Remove the 50 lb wt. Press **start** key.

2) Carefully stack two 50 lb wts on top of one another in the center of the scale. The first weight must be gently vibrated until the second is in place to prevent the scale from prematurely locking in and giving an erroneous reading. Record the weight reading (~ 100 lbs). Press the **2 in 1** key.

3) Place a third 50 lb wt on the scale and record weight. (~50 lbs The sum of this weight and the weight observed in step 2, ~ 100 lbs, is the observed reading for the expected weight of 150 lbs) **Remove the top 50 lb wt. only**.

4) Place two 50 lb wts on top of the two remaining weights vibrating the stack as before. Record the weight reading (~ 100 lbs The sum of this weight and the weight observed in step 2, ~ 100 lbs, is the observed reading for the expected weight of 200 lbs). Remove all four weights. Press **start** key.

5) Carefully, but quickly, stack five 50 lb wts on top of one another in the center of the scale, gently but firmly vibrating the stack until the fifth weight is added. Record the weight reading (~ 250 lbs). Press the **2 in 1** key.

6) Place a sixth 50 lb wt on the scale and record weight. (~50 lbs The sum of this weight and the weight observed in step 6, ~ 250 lbs, is the observed reading for the expected weight of 300 lbs) **Remove the top 50 lb wt. only**.

7) Place two 50 lb wts on top of the five remaining weights vibrating the stack as before. Record the weight reading (~ 100 lbs The sum of this weight and the weight observed in step 6, ~ 250 lbs, is the observed reading for the expected weight of 350 lbs). Remove all weights.

8) Set **ON-OFF** switch to **OFF.**

During the testing if any observed reading falls outside the tolerance range repeat the testing steps to verify the reading. No need to continue testing the scale if a weight is out of range and verified. Scales failing the tolerance testing should no longer be used.

lbs	0.40% Tolerance Limit	Range
50	0.2	49.8 - 50.2
100	0.4	99.6 - 100.4
150	0.6	149.4 – 150.6
200	0.8	199.2 – 200.8
250	1	249.0 – 251.0
300	1.2	298.8 – 301.2
350	1.4	348.6 – 351.4

Scale S/N _____

Date _____

Expected Weight (lbs.)	Observed Weight (lbs.)	Difference (lbs.)	0.40% Tolerance Limit (lbs.)
50	_____	_____	0.2
100	_____	_____	0.4
(50)	_____		
150	_____	_____	0.6
(100)	_____		
200	_____	_____	0.8
250	_____	_____	1
(50)	_____		
300	_____	_____	1.2
(100)	_____		
350	_____	_____	1.4

WEIGHT MEASUREMENT PROTOCOL
(last updated 10/28/19)

Prior to the appointment the participant is instructed to wear light clothing and informed that the weight measurements will be made with shoes removed.

Materials
- Seca model 874 dr electronic personal scale

Preparation
- Place the scale on a hard level surface.
- Turn the scale ON with the ON-OFF switch. Press the start key with no load on the scale. The scale is automatically set to zero and ready for use.
- Once the digital display reads zero **verify that "lbs" unit is showing**. If "kg" appears in the display press the 2 in 1 key for approximately 3 seconds. "lbs" should then show in the display.

Procedure
Participant
- With shoes removed, scale displaying zero; step onto the middle of the scale.
- Stand on both feet, knees extended (straight) with arms by sides.

Research Staff
- Once the reading in the digital display is stable, record the first weight on the Weight Measurement Form in lbs, **recording the tenths of lb** (i.e. 81.4 lbs).
- Have the participant step off the scale.
- Have the participant step back onto the scale once zero is displayed. **Note:** You may need to restart the scale by pressing the start key to obtain the zero and lbs display before instructing the participant to step back onto the scale.
- Once the reading in the digital display is stable, record the second weight on the form.
- Record the difference between the first and second readings.
- If the **difference is greater than 1 lb repeat** and record a third weight.
- When finished weighing participants turn the scale OFF with ON-OFF switch.

Note
- A stabilized reading in the scale display is needed for recording. The participant needs to stand very still while breathing naturally. If moving too much the weight will not stabilize in the display.

Scale Accuracy Testing
- To insure accuracy the scales have been tested using certified tolerance weights. (Performed by research center staff each month).
- Staff should weigh themselves whenever the scale is set up for participant measurement

Scale Care
- Treat the scale as a laptop. Do not bump against other objects or expose to extreme temperatures.
- Store in the horizontal position without stacking anything on top.

- Do not allow anyone to weigh without your supervision and instructions.
- When not using, turn the ON-OFF switch to OFF to conserve the battery.
  -
  - ***Performance-based assessments*** *(e.g., physical function – gait, balance; sensory testing – pain perception, proprioception; neuropsychological/cognitive assessments – dementia assessment, executive function, memory performance tests)*
  - ***Administration of questionnaires, interviews,*** *or other instruments for patient (or other, e.g., family, caregiver-) reported outcomes, such as a daily diary*

Collecting questionnaire data

- See Section 5.5, Strategies for Recruitment and Retention, which outlines how eligibility and baseline questionnaires will be administered.
- In brief, at the outset of the study, participants will complete questionnaires on-line using the qualtric interface.
- The data collection windows are 2 weeks before baseline, and 3 month follow-up.

8.2 SAFETY ASSESSMENTS

As noted, this study is considered minimal risk. The following safety procedures are included as part of this protocol.

- As part of the physical activity intervention, an information sheet on safety while being active will be provided.
- A participant will be withdrawn from the study if they lose more than 15 lbs over the course of the month due to non-intervention protocol reasons. Participant will be instructed to contact their PCP to determine if additional evaluation is warranted for underlying medical disease that may be contributing to weight loss.

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.3.1 DEFINITION OF ADVERSE EVENTS

This protocol uses the definition of adverse event from 21 CFR 312.32 (a): any untoward medical occurrence associated with the use of an intervention in humans, ***whether or not considered intervention-related***.

8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS

For this study a serious adverse event includes, as outlined at: *https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html*:

1. results in death;

2. is life-threatening (places the subject at immediate risk of death from the event as it occurred);

3. results in inpatient hospitalization or prolongation of existing hospitalization;

4. results in a persistent or significant disability/incapacity;

5. results in a congenital anomaly/birth defect; or

6. based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse)

8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

8.3.3.1 SEVERITY OF EVENT

For adverse events (AEs) not included in the protocol defined grading system, the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious".

8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed by an appropriately-trained clinician based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below.

- **Definitely Related** – There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event, including an abnormal laboratory test result, occurs in a plausible time relationship to study procedures administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the study procedures should be clinically plausible. The event must be pharmacologically or phenomenologically definitive.
- **Probably Related** – There is evidence to suggest a causal relationship, and the influence of other factors is unlikely. The clinical event, including an abnormal laboratory test result, occurs within a

reasonable time after administration of the study procedures, is unlikely to be attributed to concurrent disease or other drugs or chemicals, and follows a clinically reasonable response on withdrawal.

- **Potentially Related** – There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after administration of study procedures). However, other factors may have contributed to the event (e.g., the participant's clinical condition, other concomitant events). Although an AE may rate only as "possibly related" soon after discovery, it can be flagged as requiring more information and later be upgraded to "probably related" or "definitely related", as appropriate.
- **Unlikely to be related** – A clinical event, including an abnormal laboratory test result, whose temporal relationship to study procedures administration makes a causal relationship improbable (e.g., the event did not occur within a reasonable time after administration of the study procedures) and in which other drugs or chemicals or underlying disease provides plausible explanations (e.g., the participant's clinical condition, other concomitant treatments).
- **Not Related** – The AE is completely independent of study procedures administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by the clinician.

8.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

Solicited potential adverse events will occur at each visit and follow-up measurement visit. They include the following and we will ask if evaluation for these events included emergency room visit or overnight hospital stay.

- Acute myocardial infarction
- Angina pectoris
- Stroke
  - Thrombotic
  - Hemorrhagic
- TIA
- Heart failure
- Coronary bypass surgery
- Cancer
  - Type of cancer
- Broken bone
  - Type of fracture
- Light headedness or dizziness
- Pneumonia
- Other infection
  - UTI
  - Other
- Hypoglycemia
  - Other

Unsolicited adverse events (AE) or serious adverse events (SAE) may come to the attention of study staff during counseling visits, phone calls, or via other channels of communications. They will be categorized as above and entered into the appropriate follow-up questionnaire at the time of occurrence.

Information to be collected about AEs and SAEs includes event description, time of onset, study clinician's assessment of severity, relationship to study procedures (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study will be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical or psychiatric condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition deteriorates at any time during the study, it will be recorded as an AE.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. Documentation of onset and duration of each episode will be maintained for AEs characterized as intermittent.

Study staff will record events with start dates occurring any time after informed consent is obtained until the last day of study participation.

8.3.5 ADVERSE EVENT REPORTING

Adverse events will be reported as follows:

SAEs that include the following and are 1) definitely, 2) probably, or 3) potentially related to the study will be reported to the chair of the DSMC and IRB within 1 working day:

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred)

Reports of adverse events to the UNC IRB will follow their policy as outlined below:

1. Do not wait to submit a reportable event to the IRB until you have all the information about the event. Report the event promptly and follow-up with additional information as it becomes available.
2. A UPIRSO (Unanticipated Problem Involving Risks to Subjects or Others) that is also a Serious Adverse Event must be reported ASAP, but no later than one (1) week from the time you become aware of the event.
3. All other UPIRSOs must be reported ASAP, but no later than two (2) weeks from the time you become aware of the event.

8.3.6 SERIOUS ADVERSE EVENT REPORTING

See above.

8.3.7 REPORTING EVENTS TO PARTICIPANTS

Participants will be aware of events we consider AEs and SAEs as they will be reported to us by participants. Given the low risk nature of this study, we do not anticipate reporting summary information on adverse events to participants.

8.3.8 EVENTS OF SPECIAL INTEREST

N/A

8.3.9 REPORTING OF PREGNANCY

Study participants who become pregnant may not continue to participate in the study due to the study duration (3 months) and the anticipated duration of a full term pregnancy

8.4 UNANTICIPATED PROBLEMS

8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS

This protocol uses the definition of Unanticipated Problems as defined by the Office for Human Research Protections (OHRP). OHRP considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized

8.4.2 UNANTICIPATED PROBLEMS REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number
- A detailed description of the event, incident, experience, or outcome
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP

- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB but no later than one week of when the investigator becoming aware of the event.
- Any other UP will be reported to the IRB but not later than within 2 weeks of the investigator becoming aware of the problem

8.4.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

N/A

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

Outcome measures: Feasibility will be measured by the number of participants who consent, and the percent of dyads that attend both sessions. Acceptability will be measured by a satisfaction survey complete by both dyad members. Fidelity of skills training by study counselor will be determined from recorded sessions.

9.2 SAMPLE SIZE DETERMINATION

The study is pilot in nature. A sample of 20 is considered sufficient.

9.3 POPULATIONS FOR ANALYSES

N/A

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

This is covered in Section 9.4.2.

9.4.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

This is covered in Section 9.4.2.

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

This is covered in Section 9.4.2.

9.4.4 SAFETY ANALYSES

Prior to analysis, any data-captured adverse events will be coded by the principal investigators. Each type of event (by seriousness, severity, relationship to study) will be descriptively summarized in frequency tables by group (including only a single occurrence of any distinct type of event for any participant). Number of CVD events, ER visits, and hospitalizations will also be descriptively summarized by group. No inferential statistics (p-values or confidence intervals) are planned for comparing safety data between groups.

9.4.5 BASELINE DESCRIPTIVE STATISTICS

We will summarize baseline data (i.e., pre-randomization data). Measures of central tendency and dispersion for continuous and certain discrete variables will include means, standard deviations, medians, minima, and maxima. Categorical data will be summarized with frequencies and percentages. Some continuous variables may also be grouped into categorical levels and evaluated in frequency tables. No inferential statistics (i.e., p-values and/or confidence intervals) for comparing data between groups will be presented.

9.4.6 PLANNED INTERIM ANALYSES

N/A

9.4.7 SUB-GROUP ANALYSES

N/A

9.4.8 TABULATION OF INDIVIDUAL PARTICIPANT DATA

N/A

9.4.9 EXPLORATORY ANALYSES

N/A

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: _8/17/2023_____
IRB Study # 23-1598

Title of Study: Feasibility of conducting an online family dyadic/couple skills training for Black adults enrolled in a behavioral weight loss intervention - Together, Eating and Activity, Matter+ (TEAM+)
Principal Investigator: Candice L. Alick
Principal Investigator Department: Center for Health Promotion and Disease Prevention
Principal Investigator Phone number: (919) 966-6080
Principal Investigator Email Address: alick@email.unc.edu
Faculty Advisor: Carmen Samuel-Hodge
Faculty Advisor Contact Information: (919) 966-0360

This is a research study to find out if components of a family-based weight loss program can be delivered online for Black adults. When you enroll in this study with a family member, you will attend family skills training on-line or in-person together. All participants (including family members) will receive in-person group sessions about weight loss as well. The two family skills training sessions will last approximately 30 minutes. The seven weight loss group sessions will last 60 minutes each. We will take measurements (e.g., weight, etc), and surveys at the beginning and end of the program. Half of the family pairs will be asked to complete interviews asking questions about their experiences in the program. There are minimal risks to this study that are described in this document. If you are interested in learning more about this study, please continue reading below.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.
Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to test the feasibility and acceptability of an interactive counselor -led online family skills training as part of a behavioral weight loss program for Black Adults.

You are being asked to be in the study because you:
- self-identify as a Black or African American,
- are between 18-75 years old
- have a family member willing to attend study session with you
- have Internet access
- reside in the Raleigh/Durham/Chapel Hill area,

Are there any reasons you should not be in this study?

You should not be in this study if you do not self-identify as Black or African-American, not interested in losing weight, do not have a family member willing to attend study sessions,

How many people will take part in this study?

Approximately 40 people (20 family dyads) at University of North Carolina at Chapel Hill will take part in this study.

How long will your part in this study last?

Your expected participation will last approximately 4 months. The seven group sessions will last approximately 60 minutes. The 2 family skills training sessions will last approximately 30 minutes. If invented to participate for an interview, the interview will last approximately 60 minutes.

What will happen if you take part in the study?

You will be invited to participate in a in-person 3 month behavioral weight loss program. The first 4 sessions will be weekly, two sessions will be biweekly and the last session will be in the last month. You will attend these group sessions with a family member of your choice. You will also be randomly assigned to attend two family skills training session either 1) in-person or 2) online by change, like flipping a coin.. Surveys and body measurements will be administered at the beginning of the program and the end of the program. Those participants invited to participate in the interview may chose not to answer a question for any reason.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. We think you may benefit from being in this study by improving your lifestyle and losing weight. However, you may not benefit from being in this study.

What are the possible risks or discomforts involved from being in this study?

The possible risks and discomforts from being in this study are few and are listed below.

- We do not think there is risk to you from the dietary advice given as part of the study
- Those who increase their level of physical activity may experience minor muscle pain, but this type of activity rarely causes serious health problems such as chest pain or asthma.
- In all studies, there is a very slight chance of loss of privacy (that is, others may see your study information). As stated below, we will do all we can to make sure this does not happen.

Also, there may be other risks we did not list here. You should report to the research team any problems that may be due to this study.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?

Study surveys will be stored with your study ID number and your first and last initial, but NOT with your name (we call this de-identified data). No one other than study staff will be able to connect your name and study ID as we will follow standard procedures to protect the privacy of research data.

We may use your de-identified data, as described above, in future research without additional consent. However, in some cases, the Institutional Review Board (called IRB and described below) may require that you be re-contacted and asked for your consent to use your data in a specific research study. You have the right, at that future time, not to participate in any research study for which your consent is sought.
Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

To protect other participants, we ask you as a participant, not to reveal anything you learn from interviews, group discussions or other activities.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Audio and/or Video Recordings

Family skills training sessions and in-depth interviews will be video and/or audio recorded. These recordings will be converted to written text (transcribed). The written text will be used to assess if the program components were delivered as intended and also determine the acceptability and feasibility of these program components. Recordings will be destroyed after all information is transcribed. Recording and transcriptions will be kept on an encrypted university server accessible only by study staff. Audio/video recordings may be requested to be turned off at any point during the study.

Check the line that best matches your choice:

_____ OK to record me during the study

_____ Not OK to record me during the study

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do. By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do. By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal

Will you receive anything for being in this study?

You will be receiving approximately $320 per family dyad ($40 per session. There are 7 group sessions and 2 family skills training sessions.) for taking part in this study. Those selected for interview, have the opportunity to receive an additional $40. Any payment provided for participation in this study may be subject to applicable tax withholding obligations.

In order to process payments, the University may share certain identifiable information about you, such as name and contact information, with third parties that the University retains to

process payments on its behalf. If you do not want to agree with sharing your information with these third parties, then you will be unable to receive payment/compensation for participating in the study.

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.
Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____
Signature of Research Participant

_____
Date

_____
Printed Name of Research Participant

_____
Signature of Research Team Member Obtaining Consent

_____
Date

_____
Printed Name of Research Team Member Obtaining Consent

_____
Signature of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form)

_____
Date

_____
Printed Name of Witness

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

Contacting participants who expressed interest to assess eligibility

- During eligibly calls, data are entered into the eligibility questionnaire.
- If a potential participant is interested and eligible, staff will email the consent forms to this individual and an appointment will be made for the consent phone call in about 1 week.

Consent phone call

- At this phone call, key components of the consent form are reviewed in detail to insure that the potential participant understands what participation entails. It the potential participant agrees to sign consent form via e-consent, instructions are given on how to do so. If the potential participant prefers to sign at the enrollment visit, then verbal consent to complete baseline questionnaires before the enrollment visit will be obtained, as approved by the IRB.
- Instructions for completing baseline forms, on-line , are given and plans to complete these forms are made accordingly. An appointment date is set for the baseline visit.

Enrollment visit and randomization: At the enrollment visit, all questions will be answered about the study and those who did not sign the consent forms on-line will sign the consent form. Upon completion of baseline measures the participant will be ready for randomization. The research assistant will use a secure excel document to ascertain randomization assignment

10.1.2 STUDY DISCONTINUATION AND CLOSURE

Given the low risk nature of the study, we do not anticipate stopping for adverse outcomes.

10.1.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, the safety and oversight monitor(s), and the sponsor(s) and funding agency. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally-identifiable information from the study will be released to any unauthorized third party without prior written approval of the sponsor/funding agency.

All research activities will be conducted in as private a setting as possible.

The study monitor, other authorized representatives of the sponsor or funding agency, representatives of the Institutional Review Board (IRB), regulatory agencies or representatives from companies or organizations supplying the product, may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records.

The study participant's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor/funding agency requirements.

Measures Taken to Ensure Confidentiality of Data Shared per the NIH Data Sharing Policies
It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see *https://grants.nih.gov/policy/sharing.htm*). The PI will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and security for data dissemination and reuse (e.g., all data will be thoroughly de-identified and will not be traceable to a specific study participant). Plans for archiving and long-term preservation of the data will be implemented, as appropriate.

Certificate of Confidentiality
To further protect the privacy of study participants, the Secretary, Health and Human Services (HHS), has issued a Certificate of Confidentiality (CoC) to all researchers engaged in biomedical, behavioral, clinical or other human subjects research funded wholly or in part by the federal government. Recipients of NIH funding for human subjects research are required to protect identifiable research information from forced disclosure per the terms of the NIH Policy (see *https://humansubjects.nih.gov/coc/index*). As set forth in 45 CFR Part 75.303(a) and NIHGPS Chapter 8.3, recipients conducting NIH-supported research covered by this Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award. It is the NIH policy that investigators and others who have access to research records will not disclose identifying information except when the participant consents or in certain instances when federal, state, or local law or regulation requires disclosure. NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

Data will be stored on secured servers administered by UNC-Chapel Hill IT.

10.1.5 KEY ROLES AND STUDY GOVERNANCE

Provide the name and contact information of the Principal Investigator and the Medical Monitor or Independent Safety Monitor. Update table heading to remove non-relevant role.

Principal Investigator	**Medical Monitor or Independent Safety Monitor**

Candice L. Alick, PhD	*Name, degree, title*
University of North Carolina at Chapel Hill	*Institution Name*
1700 M.L.K. Jr Blvd #7426, Chapel Hill, NC 27514	*Address*
(919) 966-6080	*Phone Number*
alick@email.unc.edu	*Email*

10.1.6 SAFETY OVERSIGHT

Safety oversite is provided by study team self-assessments due to the time frame and minimal risk. In cases of safety, all incidents will be reported to the IRB and study sponsor.

10.1.7 CLINICAL MONITORING

N/A

10.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

As outlined below, data will be stored in identified and de-identified data sets. The overall data management plan has been approved by the UNC IRB.

The table below outlines sources of data, where it will be stored, and aspects of data management related to data quality and security. The rows of the tables are organized by the chronological sequence of anticipated data acquisition.

The primary data collection and management program with be UNC Qualtrics.

Type/Use of Data	Data Source	Data Storage	Ident.	Data Review/Other Comments
Eligibility data	From participants, collected by phone by research staff	Qualtrics	yes	Data review: weekly, as outlined above.
Consent forms	Participants	For consent completed on-line, Qualtrics	yes	Research staff ensure that consent documents are signed after all questions are answered.
Participant study data collected using Qualtrics forms and	Participants	Qualtrics	yes	Surveys and forms will have PT-ID# and first and last initial. Data will be collected via phone for those who do

surveys—electronic questionnaires				not want to complete online. Data review: weekly, as outlined above.
Process data	Participants	UNC Server	yes	Data collected by counselor
Data sets for analysis	Participants	UNC Server	yes and no	Analysis datasets created from excel datasets. Will be stored on Study's Microsoft Team's account.

Protocol Deviations – The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

Should independent monitoring become necessary, the PI will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor/funding agency, and inspection by local and regulatory authorities.

10.1.9 DATA HANDLING AND RECORD KEEPING

10.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

The data issues to be described in this section are covered in Section 10.1.8.

10.1.9.2 STUDY RECORDS RETENTION

Study data will be maintained for at least 10 years after final data collection.

10.1.10 PROTOCOL DEVIATIONS

This study will follow the protocol deviation guidelines from the UNC IRB, as outlined below:

Purpose: To record all protocol deviations that occur at a study site for both observational and interventional clinical research studies.

IMPORTANT: This log is maintained in the Study Binder (Synonyms for this binder include Investigator Binder, Regulatory Binder, Investigator Site File [ISF], and Study File.) and should be made available upon request for review by the IRB and the Sponsor's monitor. Deviations should be reported to the IRB of record as per the IRB Standard Operating Procedures. See OHRE/IRB SOP 1401 for reporting requirements for deviations to the UNC IRB.

Audience/User: Study coordinators, principal investigators (PIs), other site staff, clinical monitor

Best Practice Recommendations:

- Record protocol deviations in the tracking log as they occur, to ensure completeness and accuracy of the data.
- The site PI should sign each form after it has been completed or immediately prior to a monitoring visit. If it has been signed with fewer than five deviations entered into it, the next identified deviation should be reported on a new page to ensure that all deviations have been reviewed by the PI.
- Number each page and identify the final page of the log by indicating FINAL in the page number field.
- Store pages in reverse chronological order, with the newest pages of the log placed at the front of the section.
- Remove this page before using the log.

***DEVIATION CATEGORIES:**

A. Informed Consent
B. Eligibility
C. Protocol implementation
D. Reporting
E. Other, specify in log

**DEVIATION CODES: Numbers listed by the sample protocol deviations

Informed Consent (Category A)

1. Failure to obtain informed consent
2. Consent form used was not current IRB-approved version
3. Consent form does not include updates or information required by IRB
4. Consent form missing

5. Consent form not signed and dated by participant
6. Consent form does not contain all required signatures
7. Other, specify in log

Eligibility (Category B)

8. Participant did not meet eligibility criterion
9. Randomization of an ineligible participant
10. Participant randomized prior to completing Baseline Assessment, etc.
11. Randomization and/or treatment of participant prior to IRB approval of protocol
12. Other, specify in log

Protocol implementation (Category C)

13. Failure to keep IRB approval up to date
14. Participant receives wrong treatment
15. Participant seen outside visit window
16. Use of unallowable concomitant treatments
17. Prescribed dosing outside protocol guidelines
18. Missed assessment
19. Missed visit
20. Other, specify in log

Reporting (Category D)

21. Not submitting reportable information to the IRB within 7 days
22. Failure to respond to the NSI stipulations in the requested timeframe
23. Other, specify in log

Other (Category E)

25. Other, specify in log

IRB Study #		**Site Name/Number:**	
Protocol Title (Abbreviated):		**Protocol ID/Number:**	

Principal Investigator:					Page number [1]:				
Ref No.	Subject ID	Date of Deviation	Date Identified	Deviation Description	Dev. Type [2]	Resulted in AE?	Did Subject Continue in Study?	Meets IRB Reporting Req. (I.e. NSI) (Yes/No)	IRB Reporting Date
1									
2									
3									
4									
5									
6									
7									

10.1.11 DATA SHARING POLICY

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As

such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers 2 years after the completion of the primary endpoint by contacting the principal investigators. Considerations for ensuring confidentiality of these shared data are described in Section 10.1.3.

10.1.12 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial according to the guidelines set forth by the Conflict of Interest Program at UNC.

10.2 ADDITIONAL CONSIDERATIONS

N/A

10.3 ABBREVIATIONS AND SPECIAL TERMS

AE	Adverse Event
ANCOVA	Analysis of Covariance
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
CMP	Clinical Monitoring Plan
COC	Certificate of Confidentiality
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DCC	Data Coordinating Center
DHHS	Department of Health and Human Services
DSMB	Data Safety Monitoring Board
DRE	Disease-Related Event
EC	Ethics Committee
eCRF	Electronic Case Report Forms
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FFR	Federal Financial Report
GCP	Good Clinical Practice
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GWAS	Genome-Wide Association Studies
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICH	International Council on Harmonisation
ICMJE	International Committee of Medical Journal Editors

IDE	Investigational Device Exemption
IND	Investigational New Drug Application
IRB	Institutional Review Board
ISM	Independent Safety Monitor
ITT	Intention-To-Treat
LSMEANS	Least-squares Means
MedDRA	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
NCT	National Clinical Trial
NIH	National Institutes of Health
NIH IC	NIH Institute or Center
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SMC	Safety Monitoring Committee
SOA	Schedule of Activities
SOC	System Organ Class
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States

10.4 PROTOCOL AMENDMENT HISTORY

*The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale. A **Summary of Changes** table for the current amendment is located in the **Protocol Title Page**.*

Version	Date	Description of Change	Brief Rationale

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