Informed Consent

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+)

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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+)
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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