THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

A peer and family-based approach to obesity in racial ethnic minorities 2017-0827

Subtitle: Parent/caregiver

Study Chair: Lorna H. McNeill

_____ _____
Participant's Name Medical Record Number or Study ID

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by the MD Anderson Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

The goal of this research study is to test the effectiveness of parent and family-oriented support interventions that are designed to help with weight loss among racial ethnic minority families.

This is an investigational study.

Taking part in this study may help teach you ways to improve your level of physical activity and dietary habits. Racial ethnic minority families who are interested in improving levels of physical activity and healthy eating may benefit from what is learned in the future. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including potential expenses and time commitment. If you take part in this study, you may experience some of the potential risks listed below in the Possible Risks section of this consent.

Your participation in this study will be over after you complete the study visit at Month 3, but may last up to a total of 5 months for those who participate in the follow-up individual interviews.

There will be no cost to you for taking part in this study.

You may choose not to take part in this study.

1. STUDY DETAILS

Up to 600 families (1,200 participants total, 600 parents/caregivers and 600 children) will be enrolled in this study.

Screening/Baseline Visit

If you are found to be eligible and agree to take part in this study, the following procedures will be performed at this visit:

- Before your in-person visit,
  - You will complete computer-based questionnaires about your mood, diet, stress levels, how your family functions, your ability to solve problems, your level of physical activity and overall health behaviors. You will also be asked about the types of buildings in your neighborhood (gas stations, apartments and homes, grocery stores, gyms, churches, and so on) and how easy it is for you to get to these buildings. The questionnaires will be sent to you via email or text message and should take 60 minutes to complete.
- During your in-person visit:
  - Your height, weight, % body fat, visceral fat and muscle mass will be measured using a body composition scale.
  - Your waist to hip ratio will be measured using a measuring tape.
  - Your blood pressure will be measured using a blood pressure monitor.
  - Your carotenoids levels will be measured by inserting your index finger on top of a lens in a small machine device called spectrometer “Veggie meter”
  - You will be given a small device called an accelerometer that will measure the amount of physical activity you do over the next 7 days. The accelerometer should be worn on your hip. You will be given a prepaid envelope to return the accelerometer to study staff after you wear it for 7 days. The study staff may ask you to re-wear your accelerometer if you did not wear it during the 7-day period.

Study Groups

At the visit described above, your study site (church, school, or neighborhood center) will have been randomly assigned (as in the roll of a dice) to 1 of 3 study groups. This is done because no one knows if one study group is better, the same, or worse than the other groups. Your study site will have an equal chance of being in any of the 3 groups.

- If your study site is in **Group 1**, you will receive parent/caregiver-focused intervention.
- If your study site is in **Group 2**, you will receive family-focused intervention.
- If your study site is in **Group 3**, you will not receive a focused intervention. Instead, you will receive a handbook that will include important health education information on how to prevent different types of cancers, but you will not receive additional support.

Groups 1 and 2

If your study site is assigned to Groups 1 or 2, you will receive health coaching sessions by trained counselors, participant navigation and support delivered by lay health workers, and a peer support group. The difference is that in Group 1, the sessions will be for parents/caregivers only. In Group 2, sessions will be for the parent/caregiver and the whole family (this may include any family member the parent/caregiver chooses).

You will receive 1 phone call each month over the course of 3 months by trained counselors. Your first session will be through Zoom video conferencing which is vetted through MD Anderson to ensure confidentially to the best of our ability. The rest of the sessions will be done either by telephone or video conferencing. Each session should last about 50-60 minutes. The counselor will help you develop goals for you and/or your family. These goals may include decreasing the amount of time you and/or your family spend in front of TV and computer screens or increasing the amount of fruits and vegetables you eat. Each call will be recorded. If you are in Group 2, only you will receive the phone calls. Your family members will not receive the phone calls.

In addition to the above phone calls, trained lay health workers will meet with you every month for 3 months using Zoom video conferencing. These health workers will try to help you make your home a healthier environment. For example, they may help you place TVs in a different place in your home or they may help you with grocery shopping. The lay health workers will also show you neighborhood parks nearby that may help you stay physically active. If you are in Group 2, the community health workers will be working with both you and your family (if possible).

You will meet with a support group at your study site 1 time each month for up to 3 months using Zoom video conferencing. If you are in Group 2, you may bring your family members with you to this support group. The support group will be led by the lay health workers. During these sessions, you may ask questions, discuss barriers or problems you and/or your family faces, and discuss any successes you have had. The health worker will also repeat the information you learned during your phone calls or activity sessions (such as how to read food labels, how to start a walking program, and so on).

Group 3

If your study site is assigned to Group 3, you will be given a handbook that will include cancer prevention health education information, instead of attending support groups or receiving phone calls and home visits.

<u>Study Visits</u> ***(All Groups)***

At Month 3:

- Before your in-person visit,
    - You will complete the web-based questionnaires about your diet and physical activity. It should take about 60 minutes to complete these questionnaires.
- During your in-person visit,

- Your height, weight, % body fat, visceral fat and muscle mass will be measured.
- Your waist to hip ratio will be measured
- Your blood pressure will be measured.
- Your carotenoids levels will be measured.
- You will be given an accelerometer to wear for 7 days. You will be given a prepaid envelope to return the accelerometer to study staff after wearing it for 7 days. The study staff may ask you to re-wear your accelerometer if you did not wear it during the 7-day period.

Some participants will be randomly selected and asked to have a follow-up interview about 2 months after the Month 3 visit. In this interview, you will be asked about how you feel in general (for example, regarding church, school, or neighborhood center participation in the study) and what you thought about the study. This interview may last up to 90 minutes. The interview will be audio recorded and then transcribed (written down) without your name or any other identifying information. The digital audio files will be destroyed right after they are transcribed.

Other Information

Everything the health worker sees will be confidential. However, if child abuse is witnessed, it will be reported.

You will be asked to give the names and contact information for family members and/or friends for the study staff to contact in the event there is trouble reaching you.

If the accelerometer is lost or stolen, you will not be responsible for the replacement cost, but you should tell the study staff right away.

Your data and identifying information (such as first and last name, phone number, mailing address, and email address) may be shared with future researchers. Before your data can be used for future research, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson. The IRB is a committee of doctors, researchers, and community members. The IRB is responsible for protecting study participants and making sure all research is safe and ethical.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with the study staff. The known side effects are listed in this form, but they will vary from person to person.

Questionnaires/interviews may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

About 1 month after you complete the questionnaire each time, the research staff will review and score your responses. If your scores suggest signs of depression, you will be given a list of resources for mental health screening.

If you give your family and/or friends' contact information to the study staff to contact in the event there is trouble reaching you, they may learn that you are taking part in a weight-management program. This may be upsetting.

You may have discomfort while completing **waist and hips measurements**. You may refuse to complete any of these procedures that may make you feel uncomfortable.

Mild to moderate **physical activity** may cause sore or pulled muscles, heart problems, physical discomfort, and/or accidental injuries such as falling. You may also experience some physical discomfort such as increased heart rate, chest pain, shortness of breath, headache, nausea, and/or fatigue.

Although every effort will be made to keep study data safe, there is a chance that your **personal health information** may be lost or stolen. All study data will be stored in password-protected computers and/or locked file cabinets.

Certificate of Confidentiality
This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. The researchers with this CoC may not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information protected by this CoC cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below).

The CoC cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation. You should understand that a CoC does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The CoC will not be used to prevent disclosure for any purpose you have consented to.

This study may involve unpredictable risks to the participants.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Unless otherwise stated in this consent form, all of the costs linked with this study, which are not covered by other payers (health maintenance organization [HMO], health insurance company, etc.), will be your responsibility.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive a $75 gift card after completing each study visit (Baseline and Month 6) for a total up to $150 for your time and effort.

Additional Information

4. You may ask the study chair (Dr. Lorna H. McNeill, at 713-563-1103) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson.

   If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can continue to collect data from your routine medical care. If you agree, this data will be handled the same as research data.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and/or shared with other researchers and/or institutions for use in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If you do not want your data to be used for future research, tell the study doctor. However, the data already collected will be kept and may be used.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson may be collecting and using your PHI. For legal, ethical, research, and safety-related reasons, the research team may share your PHI with:
   - The Office for Human Research Protections (OHRP)
   - The IRB and officials of MD Anderson
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible according to state and federal law. However, in some situations, health authorities could be required to reveal the names of participants.

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer of MD Anderson at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT