Official Title:

Changes in Weight and Physical Function for Older African American Women in a National, Nonprofit, Community-Based, Peer-Led, Weight Loss Program

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DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
ADULT
Changes in Weight and Physical Function for Older African American Women in a National, Nonprofit, Community-Based, Peer-Led, Weight Loss Program
Healthy Me: A Program for Older Women

Principal Investigator: Nia S. Mitchell, MD, MPH
Other Investigators: Connie Bales, PhD; Anna Hung, PharmD, PhD, MS; Kathryn Starr, PhD

CONCISE SUMMARY

We are doing this research study to learn more about the effects of a community-based weight loss program called TOPS (Take Off Pounds Sensibly) on weight, heart health, physical function, quality of life, and healthcare utilization in African American women who are at least 55 years old and have excess weight. We are asking women who live in and around Durham, North Carolina to take part in this study. We are asking you to join this research study because you may have a medical need to lose weight.

If you join this study, you will be asked to attend an introduction session and weekly or monthly sessions for weigh-ins, and to be given study information. You will have checkups by the study team at the beginning and again at 3 and 6 months. During these checkups, the team will measure your weight and draw blood from you. You will also be asked to perform some physical function tests, for example, walking or getting up from a chair. You will also be asked questions about your diet and healthcare visits. Your participation in the study will last for approximately 7 months.

We do not expect you to have any major physical risks from taking part in the study except for those with diabetes who are taking either insulin or medications known as sulfonylureas. Those participants may experience episodes of low blood sugar with weight loss if their insulin or medication is not adjusted based on your weight loss. Low blood sugar can cause sweatiness, weakness, and heart palpitations. Very low levels, can cause confusion, seizures, and death. We will minimize this risk by asking your primary care provider, to agree to manage your insulin or medication needs while you take part in this study.

Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask them to explain anything that you do not clearly understand. We encourage you to speak with family and friends before you decide to take part in this research study.

The details of the study risks, inconveniences, discomforts, and other important information about the study are listed below.

A grant from the National Institute on Aging (NIA) of the National Institutes of Health (NIH), is funding this study. Part of Dr. Nia S. Mitchell's and her research team's salaries will be paid by this grant.

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WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Nia S. Mitchell will be in contact with your regular health care provider while you are in the study and afterwards if necessary.

WHY IS THIS STUDY BEING DONE?
We are doing this research study to learn about the effects of a community-based weight loss intervention called the Take Off Pounds Sensibly Program ("TOPS") on weight, heart health, physical function, quality of life, and healthcare utilization in African American women who are at least 55 years old with excess weight. TOPS is a national, nonprofit weight loss program that offers information about diet and physical activity, and is based on participation in peer-led group meetings.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
About 120 people will take part in this study.

WHAT IS INVOLVED IN THE STUDY?
If it is safe for you to participate and you agree to join this study, we will ask you to sign and date this form. Being in this study is voluntary, so you can refuse to participate with no penalty.

As a participant in this study you will be asked to attend an introduction session, and weekly or monthly 1-hour sessions with a dietitian for weigh-ins and be given study information. You will also have checkups by the study team at the beginning and again at 3 and 6 months from the start of the study. During each of the checkups, the study team will take body measurements, draw a blood sample, and ask you to perform some physical function tasks such as walking and getting up from a chair. You will also be asked to complete questionnaires about your diet and healthcare visits. These tasks could take up to 3 hours to complete. Your participation in the study will last for approximately 7 months.

In two to three weeks after you join the study, you will be assigned to one of two study plans: the TOPS Now Plan or the TOPS Later Plan. You have a 50/50 chance of being placed in either plan. Both plans are <u>equally important</u> to the study. The details about each of the plans are explained below:

<u>TOPS Now PLAN</u>:

- If you are in the TOPS Now PLAN you will: Attend an introduction session for weigh-ins and receive study information
- Be enrolled in the TOPS (Take Off Pounds Sensibly) Program immediately
- Attend weekly group meetings for about an hour at a central location in Durham, North Carolina for up to 7 months.

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- Be weighed, take part in group discussions, and be given information to help you reach your goals at each weekly meeting
- Receive TOPS materials
- Complete study team checkups at 3 and 6 months
- Complete all study activities in about 7 months from the time you enroll in the study
- Receive a TOPS voucher for an optional free one-year continued membership in a local community TOPS Program

TOPS Later PLAN:

If you are in the TOPS Later PLAN you will:

- Be enrolled in the TOPS (Take Off Pounds Sensibly) Program in approximately 7 months
- Attend an introduction session and monthly sessions for weigh-ins and receive study information
- Receive health education materials
- Complete study team checkups at 3 and 6 months
- Complete all study activities in about 7 months from the time you enroll in the study
- Receive a TOPS voucher for an optional free one-year new membership in a local community TOPS Program

HOW LONG WILL I BE IN THIS STUDY?
If you agree to take part in this study, your involvement will last for approximately 7 months.

You may choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

After the study finishes, the study team will share the results of the weight loss study with your group. The study team will also provide copies of the scientific publications that are written from the study results.

WHAT ARE THE RISKS OF THE STUDY?
There are minimal risks of harm to you in this study. Weight loss has been shown to be safe in older individuals with excess weight. The TOPS program is being safely used throughout the United States and Canada.

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We will send your primary care doctor a letter to let them know you are in a study. If they do not think it is safe for you to be in the study, they can let us know and we will have to take you out of the study. You and your primary care doctor will get copies of the blood tests we check. If we see anything unusual, we will refer you to your primary care doctor for more testing.

If you have diabetes and are taking either insulin or medications known as sulfonylureas, such as glipizide (Glucotrol), glyburide (DiaBeta or Micronase), or glimepiride (Amaryl) and you lose weight, you may experience episodes of low blood sugar with weight loss if your medication is not adjusted, based on your weight loss. Low blood sugar can cause sweatiness, weakness, and heart palpitations. Very low levels, can cause confusion, seizures, and death. We will minimize this risk by asking your primary care provider to approve your participation in the study and to agree to manage your insulin or sulfonylurea needs.

Possible risks associated with needle sticks for drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible risks, although unlikely.

We may ask you questions that may make you feel uneasy. If you do not want to answer, you can stop at any time.

Your private information could become known. We will do all we can to keep your information private, but this cannot be guaranteed.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be benefits to you. You may lose weight, which can decrease your risk for heart disease and early death. You may make healthy lifestyle changes that may help improve medical issues such as Type II diabetes, hypertension, and obstructive sleep apnea. We also hope that what we learn from this study will benefit women like you in the future.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
Instead of being in this study, you could enroll in a different weight loss program.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal

information may be seen by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

A description of this clinical trial will be available on http://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 the website at any time.

As part of the study, results of your study related laboratory tests and procedures may be reported to the National institute on Aging (NIA) and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the NIA, the Duke University Health System Institutional Review Board, and others as appropriate.

Blood specimens collected for research purposes will be labeled with only a study code number and sent to a LabCorp facility for processing. You will not be identified by name, social security number, address or phone number on the specimen tubes.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

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You should understand that a Confidentiality Certificate does not prevent you or a member of your family 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. This means that you and your family must also actively protect your own privacy.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS (Duke University Health System), we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

We will keep your study records for at least six years after the study is done. After six years, we will destroy the records, or we will remove all information identifying you. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

WHAT ARE THE COSTS TO YOU?
There are no costs to you for participating in this study. The TOPS program membership costs up to $92 per year. The study will cover this payment for you.

WHAT ABOUT COMPENSATION?
You will receive a gift card each time you complete the study assessments (body measurements, blood tests, physical function tests and survey questions) at the start of the study and at the 3 and 6 month visits.

- Study start up visit you will receive a $50 payment card
- At 3 months you will receive a $75 payment card
- At 6 months you will receive a $100 payment card

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If you attend all study visits that will be a total of $225 in payment cards.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide money or free medical care to you if you are injured as part of the study.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to take part. Or, if you chose to take part, you can decide to stop at any time. If you drop out of the study, we will ask you to continue showing up for study visits so that we can record your measurements. You can stop participating at any time without penalty.

If you do decide to withdraw, we ask that you contact Dr. Nia S. Mitchell in writing and let her know that you are withdrawing from the study. Her email address is [redacted]

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. If this occurs, you will be notified and your study doctor will discuss other options with you.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Nia S. Mitchell at [redacted] during regular business hours.

For questions about your rights as a study participant, or to discuss concerns, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____ _____ _____
Signature of Participant Date Time

_____ _____ _____
Signature of Person Obtaining Consent Date Time