Study Title: A Telehealth Lifestyle Intervention for Adolescent Girls with Prediabetes: A Pilot Study

ClinicalTrials.gov ID: NCT05396443

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WEILL CORNELL MEDICAL COLLEGE
Informed Consent and HIPAA Authorization for Research

Project Title: A telehealth lifestyle intervention for Black adolescent girls at risk f type 2 diabetes: a pilot study

Research Project/ Protocol #: 21-04023546

Principal Investigator: Tashara M. Leak, PhD, RD

Subject MRN:

Please note, are you currently or have been (within the last 6 months) a participant in any other research study at Weill Cornell Medicine, Brooklyn Methodist Hospital, NewYork-Presbyterian Hospital or elsewhere? If so, please inform the research team.

INSTITUTION: Weill Cornell Medical College/College University

KEY INFORMATION ABOUT THIS RESEARCH STUDY	
We are asking you to choose whether to volunteer for a research study about a telehealth lifestyle intervention program to prevent type 2 diabetes in Black adolescent girls. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.	
Purpose: **What is the study about and how long will it last?**	By doing this study, we hope to learn whether a virtual program that focuses on wellness, cooking, and dancing can help prevent type 2 diabetes in adolescent girls and their primary female caregiver. The activities of the program are similar to activities that would be recommended to maintain general health. Your participation in this research will last about 18 weeks.
Benefits: **Key reasons you might choose to volunteer**	We hope to learn ways we can support Black adolescent girls improve their health and overall wellbeing. The study will not include a direct benefit to you. However, some participants appreciate knowing they have contributed to research that may benefit others in the future. For a complete description of benefits, refer to the Consent Document below.
Risks: **Key reasons you might choose NOT to volunteer**	In the beginning and end of the program, you will be asked to do a blood draw. This may result in some discomfort. You also may experience some discomfort during the program. But we will try to minimize any discomfort you may feel. For a complete description of risks, refer to the Consent Document below. Taking part in the study is entirely voluntary. You may choose not to take part in this study.
Voluntary Participation: **Do you have to take part in the study?**	If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care you would normally have if you choose not to volunteer.

What if you have questions, suggestions, or concerns?	The person in charge of the study is Tashara M. Leak, [PI]. If you have questions, suggestions, or concerns regarding this study or you want to leave the study her contact information is: 607-255-7664or email at leakresearchgroup@cornell.edu If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Weill Cornell Medicine Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 646-962-8200 or send an e-mail to irb@med.cornell.edu
This overview does not include all the information you need to know before deciding whether to take part in the study. Much additional detail is given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.	

INTRODUCTION

Dr. Tashara M. Leak, PhD, RD, Associate Professor at Cornell University and Weill Cornell Medical College is conducting a study titled "A telehealth lifestyle intervention for Black adolescent girls who are at risk for type 2 diabetes: a pilot study." In this study, we're interested in learning about how participating in a 12-wk telehealth lifestyle program with nutrition lessons, cooking experience, and dance classes may affect the diet and health of Black adolescent girls who are at risk for type 2 diabetes and their primary female caregiver.

We are inviting you to participate because of your status as a patient in the Pediatric Endocrinology Clinic or Adolescent Clinic at Weill Cornell Medicine (WCM), or Brooklyn Methodist Hospital (BMH). We are working with these hospitals to invite any adolescent who is 12-18 years old, self-identify as Black or African American, and has a Body Mass Index ≥ 95th percentile.

It is important that you read and understand several general principles that apply to all who take part in our studies:

(a) Taking part in the study is entirely voluntary.

(b) If you choose not to participate in the study or if your decision changes, your regular care will not be affected. In addition, you will not lose any of the benefits to which you are entitled.

(c) Personal benefit to you may or may not result from taking part in the study, but knowledge gained from your participation may benefit others.

You can read more about the study below. Participation in this study is completely voluntarily; meaning that the decision to participate or not to participate is yours. Please take your time to make your decision. If you decide to participate, please sign and date at the end of this form. If you choose not to participate in the study or if your decision changes, your regular care will not be affected. In addition, you will not lose any of the benefits that belong to you.

Also, your relations with WCMC, BMH, NewYork-Presbyterian Hospitals, your physicians, or other personnel will not be affected.

If there is any new information that might affect your decision to participate or remain in the study, this information will be given to you while you are a participant in this study. If you have any questions about this information, you can discuss them with members of the research team.

The research study is being funded by the WCM Clinical and Translational Research Center (CTSC), Cornell Center for Health Equity, Cornell University: Schwartz Funds, and NIH NIMHD. Dr. Tashara M. Leak is the primary investigator.

You will be asked to make a visit to the CTSC adult outpatient clinic (525 East 68th St) F260-263 in the beginning of the program and at the end of the program.

WHY IS THE STUDY BEING DONE?

The purpose of this study is to examine the efficacy of a 12-week lifestyle program on type 2 diabetes (T2D) related risk factors among adolescent girls who are 12-18 years old, self-identify as Black or African American, and who have obesity and their primary female caregiver.

This research study is being done because lifestyle programs in adults have shown some benefits in preventing T2D. Currently, however, there are few programs available for adolescents to prevent T2D. Additionally, these programs are rarely done virtually. Thus, we want to evaluate whether a 12-week telehealth lifestyle program that consists of nutrition lessons, cooking experience, and dance classes can improve T2D related risk factors, such as healthy eating and physical activity, in adolescents who are at risk for diabetes and their primary female caregiver. The knowledge gained from this study can help develop future programs to improve health and prevent diabetes in adolescents.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Participants in the study are referred to as subjects.
About 60 adolescent subjects and 60 caregiver subjects will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

Below are details of each of the study's activities that we will ask you to complete if you take part in the study:

1. Make a visit to the CTSC adult outpatient clinic (525 East 68th St) F260-263. We will order an Uber that can pick you up from your location if preferred. At the clinic, you will:
    a. Complete a blood draw that will measure your blood glucose, lipid profiles, and HbA1c.
    b. Complete an online survey that will ask you about your sociodemographic characteristics (age, sex etc.), cooking equipment at home, cooking skills, Black identity scale, perceived stress and adultification, and physical activity.
    c. Be trained to complete 24-hr diet records (where you will record everything you eat and drink in the past day) and use an accelerometer (which is a device you will clip on your wrist so that it can measure your physical activity).
    d. Get your height, weight, body fat percentage, waist circumference, blood pressure, and dermal carotenoid levels measured. We will measure weight and body fat percentage with a scale and dermal carotenoid levels with a Veggie Meter, which involves you placing your finger on a sensor pad for 10 seconds (this will not hurt or cause any physical discomfort).
    e. Receive free lunch and a gift box
2. During the week after your visit, you will be asked to complete three 24-hr diet records where you will be asked to record everything you ate and drank in the past day.
3. During the week after your visit, you will also be asked to wear an accelerometer for 7 days at all moments, except for bathing. You will be asked to send the accelerometer and your completed diet records in a stamped envelope after one week.
    a. You will then participate in a 12-week lifestyle intervention program. Each week will consist of: A virtual live-streamed Wellness Session: nutrition education lesson, a girl chat/reflection, and a dance class with Cumbe: Center for African and African Diaspora Dance (2 hr total). This session will be video-recorded (with only the instructor visible during the dance class).
    b. A cooking experience where you will prepare a dish from a variety of cultures related to the nutrition education lesson (1 hr); the food ingredients will be delivered to your home.
4. Make another visit to the CTSC adult outpatient clinic to repeat everything in numbers 1-3. Participate in an interview, where you can talk about your experience in the program and how the program has impacted you. This interview will be done in-person, during the second clinic appointment.

See the diagram below for a summary of all activities that you will be asked to complete if you take part in this study.

Time	Activities
0 week	Recruitment, screen potential participants by inclusion and exclusion criteria using chart reviews. Schedule participants for baseline data collection.
3 weeks	**<u>Consent/assent participants. Baseline data collection</u>**. A. Data collection 1) survey on REDCap (sociodemographic characteristics, food cooking/shopper responsibilities, cooking equipment/supplies at home, cooking skills/self-efficacy, Black identity scale, perceived stress and adultification scale. 2) three 24-hr diet records. 3) dermal carotenoid levels using Veggie meter. 4) accelerometer to measure physical activity. 5) physical activity/screen time survey. 6) body composition (height, weight, waist circumference, body fat percentages using scales and stadiometers). 7) blood sample (blood glucose, insulin, lipid profiles, HbA1c will all be assessed). 8) blood pressure.
12 weeks	12 weeks lifestyle intervention program 1) online survey to give feedback for the week's lessons
3 weeks	Endpoint data collection 1) same procedures as baseline data collection and participate in an interview to examine overall program impact and acceptability. **End of study**

If you take part in this study, you will have the following tests and procedures:

Procedures	Location	Time
Baseline data collection:		
1. Blood draw* (see details below)	CTSC outpatient clinic (525 East 68th St (F260-263))	15 minutes
2. Online survey on sociodemographic characteristics, Black identity scale, perceived stress, adultification, cooking skills/self-efficacy, grocery shopping practices, and physical activity	CTSC outpatient clinic (525 East 68th St (F260-263))	30 minutes
3. Training on completing diet records and using accelerometers	CTSC outpatient clinic (525 East 68th St (F260-263))	30 minutes
4. Measure height, weight, body fat percentage, waist circumference, and blood pressure	CTSC outpatient clinic (525 East 68th St (F260-263))	30 minutes
5. Measure dermal carotenoids	CTSC outpatient clinic (525 East 68th St (F260-263))	15 minutes
The week following baseline visit:		
1. Complete three 24-hr diet records	Home	3 hours
2. Wear accelerometer for 7 days	Home	NA
During program:		
1. Attend nutrition education lesson live every week**	Home	1 hour/week
2. Attend dance class live every week**	Home	1 hour/week
3. Prepare a dish following a recorded cooking experience lesson every week	Home	1 hour/week
4. Complete online surveys following each session	Home	0.5 hour/week
Endpoint data collection:		
1. Repeat all procedures from baseline data collection	CTSC outpatient clinic (525 East 68th St (F260-263))	3 hours
2. Audio-recorded interview	CTSC outpatient clinic (525 East 68th St (F260-263))	0.5 hour

*Details on blood draw:
The blood draw is a standard procedure to check for health status. When you come into the test, you will have your blood drawn by a certified phlebotomist (medical professional who has extensive experience of taking blood draws). We will measure your blood glucose, insulin, HbA1c, and lipid profiles. During waiting, you will be asked to complete online surveys and other measurements listed on the table above.

**The Wellness session and dance class will be live and will be video-recorded (with only the instructor visible during the dance class).

Please advise the researchers of any medications you are taking. In addition, if you are taking any over-the-counter drugs or herbal supplements which you have obtained from the drug store, grocery store, etc., you should advise the researchers.

HOW LONG WILL I BE IN THE STUDY?

If you participate in this study, the total study duration is up to 18 weeks. The first visit to CTSC can take up to 3 hours. The program will take 3.5 hours every week for 12 weeks. The second visit to CTSC can take up to 3 hours.

During the study, you can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first. If you choose to leave the study, your regular care will not be affected, nor will you lose any benefits to which you are entitled. In addition, your relations with WCMC, BMH, NewYork-Presbyterian Hospitals, your physicians, or other personnel will not be affected.

Withdrawal by investigator, physician, or sponsor

The investigators, physicians or sponsors may stop the study or take you out of the study at any time if they feel it is in your best interest, if you experience a study-related injury, if you need additional or different medication, or if you do not follow the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

WHAT ARE THE RISKS OF THE STUDY?

There is a change that you could feel uncomfortable during this program. We will help you with these feelings and you can **stop** at any time if you want. If you are in the study, you could experience any of the following:

- You could feel uncomfortable for the blood draw. We will try to minimize any discomfort you may feel.
- You may feel pain or develop a bruise or redness at the location of the needle stick during the blood draw. There may also be a risk of bleeding or infection at the location of the needle stick. But our staff are professionals who have a lot of experience in performing blood draws.
- You could feel uncomfortable with some of the questions in the survey and during the interview at the end of the program. If you do not want to answer any of the questions in the survey or during the interview, you can choose not to answer them.
- You may feel uncomfortable when we take your height, weight, and waist circumference. We will only collect these measurements from you in a private room at the clinic.
- You could get hurt during the cooking labs you complete at home with your caregiver. We will provide you with food/kitchen safety tips in the Black Girls for Wellness student workbook, and the information will be repeated each week. We also encourage your caregiver to participate in this program with you so that they can help you at home preparing the dish.
- You could get tired during the dance classes. The dance classes we offer are also developed specifically for adolescents that have zero to minimal prior experience in dancing.

While we will do our best to make sure your participation is kept confidential, there is always a risk that data from the interview and survey may be seen by other people. We will try our best to make sure that this does not happen by saving the interview files in a password-protected online storage space. Additionally, none of your personal information will be on the survey or in the interview. Since you will be participating in the nutrition education lesson live, other people who are participating in the program may see you. But we will emphasize to everyone to keep information on the program confidential.

If you have any questions on the potential risks of this study, you can contact Dr. Tashara M. Leak at 607-255-7664 or by email at leakreasearchgroup@cornell.edu. Your caregiver also has our information if you have questions.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

We cannot and do not guarantee that you will receive any personal benefits from this study. But we hope the information learned from this study will benefit other adolescents with prediabetes or type 2 diabetes. Some of the ways you could benefit from participating in Black Girls for Wellness is that you may: 1) increase your cooking skills, knowledge, and attitudes, 2) increase the amount of healthy foods you eat, 3) learn new ways to manage your stress, and 4) learn how to practice dance as a way to exercise.

WHAT OTHER OPTIONS ARE THERE?

You do not have to be in this study, and no one will be mad at you if you say no. You can also say yes now and change your mind later, just tell a member of the research team that you want to stop. If you want to stop, you will no longer attend the program's activities. Please talk about this with your caregiver before you decide if you want to be in the research study. If your caregiver says that it is ok with them if you are in the research study, you can still say **no**. If you choose not to participate in the study or if you decide that you do not want to be part of the study anymore in the future, your regular care will not be affected and you will not lose any of the benefits that belong to you. Also, your relations with WCMC, BMH, NewYork-Presbyterian Hospitals, your physicians, or other personnel will not be affected.

It's okay if you can't attend a Wellness session if you are sick, have to go to a doctor's appointment, etc. We do ask that you try to attend and actively participate in all 12 Wellness sessions and culinary sessions that you will complete at home.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Records of study participants are stored and kept according to legal requirements and may be part of your medical record. You will not be identified personally in any reports or publications resulting from this study. Organizations that may request to inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as:

- The WCMC Institutional Review Board (IRB)
- The Office of Human Research Protection (OHRP)
- Cornell University Institutional Review Board (IRB) at Ithaca, NY

By signing this consent form, you authorize access to this confidential information. You also authorize the release of your medical records to Cornell University and Weill Cornell Medicine by any other hospitals or institutions where you might receive medical care of any kind while you are participating in this study.

If information about your participation in this study is stored in a computer, we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage by requiring a unique ID and password to log into the database: All data is stored in password-protected computers that will be stored in a locked room. In addition, only researchers who are associated with the study will have access to the study-specific records in the database.

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 this website at any time.

HIPAA AUTHORIZATION TO USE or DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Purposes for Using or Sharing Protected Health Information: If you decide to join this study, Cornell University/Weill Cornell Medicine researchers need your permission to use your protected health information. If you give permission, Cornell University/Weill Cornell Medicine researchers may use your information or share (disclose) information about you for their research that is considered to be protected health information.

Voluntary Choice: The choice to give Cornell University/Weill Cornell Medicine researchers permission to use or share your protected health information for their research is voluntary. It is completely up to you. No one can force you to give permission. However, you must give permission for Cornell University/Weill Cornell Medicine researchers to use or share your protected health information if you want to participate in the study. If you decline to sign this form, you cannot participate in this study, because the researchers will not be able to obtain and/or use the information they need in order to conduct their research. Refusing to give permission will not affect your ability to get usual treatment, or health care from Cornell University/Weill Cornell Medicine or Brooklyn Methodist Hospital.

Protected Health Information To Be Used or Shared: Government rules require that researchers get your permission (authorization) to use or share your protected health information. Your medical information may be disclosed to authorized public health or government officials for public health activities when required or authorized by law. If you give permission, the researchers could use or share with the entities identified above any protected health information related to this research study from your medical records and from any test results, which includes the blood draw (which will give us results on your insulin levels, glucose levels, HbA1c, and lipid profiles.)

Other Use and Sharing of Protected Health Information: If you give permission, the researchers could also use your protected health information to develop new procedures or commercial products. They could share your protected health information with the study sponsor, the WCMC Institutional Review Board, inspectors who check the research, government agencies, and research study staff.

The information that may be shared with the sponsor and/or government agencies could include your medical record and your research record related to this study. They may not be considered covered entities under the Privacy Rule and your information would not be subject to protections under the Privacy Rule.

CANCELING AUTHORIZATION

Canceling Permission: If you give Cornell University/Weill Cornell Medicine researchers permission to use or share your protected health information, you have the right to cancel your permission whenever you want. However, canceling your permission will not apply to information that the researchers have already used or shared.

If you wish to cancel your permission, you may do so at any time by writing to:

Privacy Office
1300 York Avenue, Box 303
New York, NY 10065
Email: privacy@med.cornell.edu

If you have questions about this and would like to discuss, call (646) 962-6930.

End of Permission: Unless you cancel it, permission for Cornell University/Weill Cornell Medicine researchers to use or share your protected health information for their research will never end.

ACCESS TO RESEARCH RECORDS

During the course of this study, **you will have access** to see or copy your protected health information as described in this authorization form in accordance with Cornell University/Weill Cornell Medicine policies. During your participation in this study, you will have access to your research record and any study information that is part of that record.

WHAT ARE THE COSTS?

You will not have to pay for anything in this study. All the materials for tests and program will be provided to you by the researchers.

POLICY/PROCEDURES FOR RESEARCH-RELATED INJURY

The Policy and Procedure for Cornell University/WCM are as follows:

We are obligated to inform you about Cornell University/WCM's policy in the event injury occurs. If, as a result of your participation, you experience injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available at the usual charge for such treatment. No monetary compensation is available from Cornell University/WCM. Further information can be obtained by calling the Institutional Review Board at (646) 962-8200.

COMPENSATION FOR PARTICIPATION

You will get paid for participating in this study. For the completion of surveys and measurements the first time you visit the CTSC outpatient clinic, you will receive $25 in cash. When you return the completed accelerometer data and diet records, you will receive another $25 in an electronic gift card. During your second visit to the CTSC outpatient clinic, you will receive $25 cash after completing activities. When you return the accelerometer and completed diet records to us, you will receive another $25 in an electronic gift card. Finally, you will receive $25 in cash after completing an interview during the second visit.

If total payments from us to you in a calendar year exceeds $600.00, your personal information, including name, address, and social security number, will be released to the Finance Department of WCM for the purpose of payment, as well as for reporting to the Internal Revenue Service.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose to not take part in the study or to leave the study at any time. If you choose to not participate in the study or to leave the study, your regular care will not be affected nor will your relations with Cornell University/WCM, BMH, your physicians, or other personnel. In addition, you will not lose any of the benefits to which you are entitled.

We will tell you about new information that may affect your health, welfare, or participation in this study. A Data Safety and Monitoring Board, a group of experts, will be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study, a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Dr. Tashara M. Leak at 607-255-7664, the Pediatric Endocrinology Clinic, the Adolescent Clinic at Cornell Weill Cornell Medicine, or Brooklyn Methodist Hospital. Be sure to inform the physician of your participation in this study.

If you have questions about your rights as a research participant, contact the WCMC IRB Office. Direct your questions to:

Institutional Review Board at:
(646) 962-8200
1300 York Avenue
Box 89
New York, New York 10065

RESEARCHER'S STATEMENT

I have fully explained this study to the subject. As a representative of this study, I have explained the purpose, the procedures, the benefits, and the risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____	_____	_____
Signature of person obtaining the consent (Principal Investigator or Co-investigator)	Print Name of Person	Date

FOLLOW UP STUDIES

We may ask you later if you want to be part of another study. Being part of any study is up to you and we will ask you to provide assent again if you would like to participate. May we contact you again to ask about your participation in a future study? **Yes/No**

If yes, please fill in at least one of the contact information below:

Phone number: _____

Email: _____

SUBJECT'S STATEMENT

I, the undersigned, have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way affect my future treatment or medical management and I will not lose any benefits to which I otherwise am entitled. I agree to cooperate with Dr. Tashara M. Leak and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

_____	_____	_____
Signature of Subject	Print Name of Subject	Date

WEILL CORNELL MEDICAL COLLEGE

Informed Parental Consent and HIPAA Authorization for Research

Project Title:	A telehealth lifestyle intervention for Black adolescent girls at risk for type 2 diabetes: a pilot study
Research Project/ Protocol #:	21-04023546
Principal Investigator:	Tashara M. Leak, PhD, RD
Subject MRN:	

Please note, are you currently or have been (within the last 6 months) a participant in any other research study at Weill Cornell Medicine, Brooklyn Methodist Hospital, NewYork-Presbyterian Hospital or elsewhere? If so, please inform the research team.

INSTITUTION: **Weill Cornell Medical College/College University**

KEY INFORMATION ABOUT THIS RESEARCH STUDY	
We are asking you and your child to choose whether to volunteer for a research study about a telehealth lifestyle intervention program to prevent type 2 diabetes in Black adolescent girls. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.	
Purpose: **What is the study about and how long will it last?**	By doing this study, we hope to learn whether a virtual program that focuses on wellness, cooking, and dancing can help prevent type 2 diabetes in adolescent girls and their primary female caregiver. The activities of the program are similar to activities that would be recommended to maintain general health. Your and your child's participation in this research will last about 18 weeks.
Benefits: **Key reasons you might choose to volunteer**	We hope to learn ways we can support Black adolescent girls improve their health and overall wellbeing. The study will not include a direct benefit to you nor your child. However, some participants appreciate knowing they have contributed to research that may benefit others in the future. For a complete description of benefits, refer to the Consent Document below.
Risks: **Key reasons you might choose NOT to volunteer**	In the beginning and end of the program, you and your child will be asked to doa blood draw. This may result in some discomfort. But we will try to minimize any discomfort you and your child may feel. For a complete description of risks, refer to the Consent Document below.

	Taking part in the study is entirely voluntary. You and your child may choose not to take part in this study.
Voluntary Participation: **Do you have to take part in the study?**	If you decide to take part in the study, it should be because you really want to volunteer. You and your child will not lose any services, benefits or rights or access to care you and your child would normally have if you choose not to volunteer.
What if you have questions, suggestions, or concerns?	The person in charge of the study is Tashara M. Leak**,** [PI]. If you have questions, suggestions, or concerns regarding this study or you want to leave the study her contact information is: 607-255-7664 or email at leakresearchgroup@cornell.edu If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Weill Cornell Medicine Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 646-962-8200 or send an e-mail to irb@med.cornell.edu
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INTRODUCTION

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We are inviting you and your child to participate because of your child's status as a patient in the Pediatric Endocrinology Clinic or Adolescent Clinic at Weill Cornell Medicine (WCM), or Brooklyn Methodist Hospital (BMH). We are working with these hospitals to invite any adolescent who is 12-18 years old, self-identify as Black or African American, and has a Body Mass Index ≥ 95th percentile, and their primary female caregiver to participate in the study.

It is important that you read and understand several general principles that apply to all who take part in our studies:

(a) Taking part in the study is entirely voluntary.

(b) If you and/or your child choose not to participate in the study or if your decision changes, your/your child's regular care will not be affected. In addition, you/your child will not lose any of the benefits to which you/your child are entitled.

(c) Personal benefit to you/your child may or may not result from taking part in the study, but knowledge gained from your and your child's participation may benefit others.

You can read more about the study below. Participation in this study is completely voluntary; meaning that the decision to participate or not to participate is yours. Please take your time to make your decision. If you decide to participate, please sign and date at the end of this form. If you give permission for your child to participate, please sign the permission form. If you choose not to participate in the study or if your decision changes, your/your child's regular care will not be affected. In addition, you/your child will not lose any of the benefits that belong to you both. Also, your/your child's relations with WCMC, BMH, NewYork-Presbyterian Hospitals, your physicians, or other personnel will not be affected.

If there is any new information that might affect your/your child's decision to participate or remain in the study, this information will be given to you and your child while you both are a participant in this study. If you have any questions about this information, you can discuss them with members of the research team.

The research study is being funded by the WCM Clinical and Translational Research Center (CTSC), Cornell Center for Health Equity, Cornell University: Schwartz Funds, and NIH NIMHD. Dr. Tashara M. Leak is the primary investigator.

You and your child will be asked to make a visit to the CTSC adult outpatient clinic (525 East 68th St) F260-263 at the beginning of the program and at the end of the program.

WHY IS THE STUDY BEING DONE?

The purpose of this study is to examine the efficacy of a 12-week lifestyle program on type 2 diabetes (T2D) related risk factors among Black adolescent girls who are 12-18 years old and who have obesity and their primary female caregiver.

This research study is being done because lifestyle programs in adults have shown some benefits in preventing T2D. Currently, however, there are few programs available for adolescents to prevent T2D. Additionally, these programs are rarely done virtually. Thus, we want to evaluate whether a 12-week telehealth lifestyle program that consists of nutrition lessons, cooking experience, and dance classes can improve T2D-related risk factors, such as healthy eating and physical activity, in adolescents who are at risk for diabetes and their primary female caregiver. The knowledge gained from this study can help develop future programs to improve health and prevent diabetes in adolescents.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Participants in the study are referred to as subjects.
About 60 adolescent subjects and 60 caregiver subjects will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

Below are details of each of the study's activities that we will ask you and your child to complete if you take part in the study:

1. Make a visit to the CTSC adult outpatient clinic (525 East 68th St) F260-263. We will have an uber pick you up (if preferred) from your location. At the clinic, you/your child will:

a. **(YOU AND YOUR CHILD)** complete a blood draw. Then, when you and your child arrive, a trained nurse will collect blood samples. These blood samples will measure blood glucose, insulin, lipid profiles, and HbA1c.
b. **(YOU)** Complete an online survey that will ask you about your sociodemographic characteristics (age, sex, etc.), family medical history, household composition, food security survey, household food assistance received, cooking skills, grocery shopping practices, Black identity scale, perceived stress, and physical activity.
c. **(YOUR CHILD ONLY)** Complete an online survey that will ask them about their sociodemographic characteristics (age, sex, etc.), food security survey, cooking skills, grocery shopping practices, Black identity scale, perceived stress, adultification, and physical activity. **(YOU AND YOUR CHILD**) Be trained to complete 24-hr diet records (where you and your child will record everything they eat and drink in the past day) and use an accelerometer (which is a device you will clip on the wrist so that it can measure physical activity).
d. **(YOU AND YOUR CHILD)** Get your and your child's height, weight, body fat percentage, waist circumference, blood pressure, and dermal carotenoid levels measured. We will measure weight and body fat percentage with a scale and dermal carotenoid levels with a Veggie Meter, which involves placing a finger on a sensor pad for 10 seconds (this will not hurt or cause any physical discomfort).

2. **(YOU AND YOUR CHILD)** During the week after your visit, you and your child will be asked to complete three 24-hr diet records, where you will be asked to record everything you ate and drank in the past day.
3. **(YOU AND YOUR CHILD**) During the week after your visit, you and your child will also be asked to wear an accelerometer for 7 days at all moments, except for bathing. You and your child will be asked to send the accelerometers and both completed diet records in a stamped envelope after one week, at no cost to you.
4. You and your child will then participate in a 12-week lifestyle intervention program. One day per week will consist of:
    a. A virtual live-streamed Wellness Session: nutrition education lesson, a girl chat/reflection, and a virtual live-streamed dance class with Cumbe: Center for African and African Diaspora Dance (2 hr total). This session will be video-recorded (with only the instructor visible for the dance class).
    b. A cooking experience where you and your child will prepare a dish from a variety of cultures related to the nutrition education lesson (1 hr); the food ingredients will be delivered to your home.
5. Make another visit to the CTSC adult outpatient clinic to repeat everything in numbers 1-3. Participate in an interview, where you can talk about your experience in the program and how the program has impacted you. This interview will be done in-person, during the second clinic appointment and will be audio-recorded.

See the diagram below for a summary of all activities that you will be asked to participate in if you take part in this study.

Time	Activities
0 week	Recruitment, screen potential participants by inclusion and exclusion criteria using chart reviews. Schedule participants for baseline data collection.
3 weeks	**Consent/assent participants. Baseline data collection**. Adolescents: 1) survey on REDCap (sociodemographic characteristics, food cooking/shopper responsibilities, cooking equipment/supplies at home, cooking skills/self-efficacy, Black identity scale, perceived stress and adultification scale. 2) three 24-hr diet records. 3) dermal carotenoid levels using Veggie meter. 4) accelerometer to measure physical activity. 5) physical activity/screen time-survey. 6) body composition (height, weight, waistcircumference, body fat percentages using scales and stadiometers). 7) blood sample (blood glucose, insulin, lipid profiles, HbA1c will all be assessed). 8) blood pressure. Caregiver: 1) survey on REDCap (sociodemographic characteristics, household food security, family history of diabetes, household composition, food cooking/shopper responsibilities, household food assistance received, cooking skills/self-efficacy, Black identity scale, perceived stress, and physical activity. 2) three 24-hr diet records. 3) dermal carotenoid levels using Veggie meter. 4) accelerometer to measure physical activity. 5) physical activity/screen time survey. 6) body composition (height, weight, waist circumference, body fat percentages using scales and stadiometers). 7) blood sample (blood glucose, insulin, lipid profiles, HbA1c will all be assessed). 8) blood pressure.
12 weeks	12 weeks lifestyle intervention program
3 weeks	Endpoint data collection Adolescents: 1) same procedures as baseline data collection and participate in an interview to examine overall program impact and acceptability. Caregiver: 1) same procedures as baseline data collection and participate in an interview to examine overall program impact and acceptability. **End of study**

If you take part in this study, you and your child will have the following tests and procedures:

Procedures for your child	Procedures for you	Location	Time
Baseline data collection:			
1. Blood draw* (see details below)	1. Blood draw* (see details below)	CTSC outpatient clinic (525 East 68th St (F260-263))	15 minutes
2. Online survey on sociodemographic characteristics, family medical history, food security, Black identity scale, perceived stress and adultification, cooking skills/self-efficacy, grocery shopping practices, and physical activity.	2. Online survey on sociodemographic characteristics, family medical history, household composition, food security, Black identity scale, perceived stress, cooking skills/self-efficacy, grocery shopping practices, household food assistance received, and physical activity.	CTSC outpatient clinic (525 East 68th St (F260-263))	30 minutes
3. Training on completing diet records and using accelerometers	3. Training on completing diet records and using accelerometers	CTSC outpatient clinic (525 East 68th St (F260-263))	30 minutes
4. Measure height, weight, body fat percentage, blood pressure, and waist circumference	4. Measure height, weight, body fat percentage, blood pressure, and waist circumference	CTSC outpatient clinic (525 East 68th St (F260-263))	30 minutes
5. Measure dermal carotenoids (Veggie Meter)	5. Measure dermal carotenoids (Veggie Meter)	CTSC outpatient clinic (525 East 68th St (F260-263))	15 minutes
The week following baseline visit:			
1. Complete three 24-hr diet records	1. Complete three 24-hr diet records	Home	3 hours
2. Wear accelerometer for 7 days	2. Wear accelerometer for 7 days	Home	NA
During program			
1. Attend Wellness Session live every week**	1. Attend Wellness Session live every week**	Home	2 hours/ week
2. Prepare a dish following a recorded cooking experience lesson every week	2. Prepare a dish following a recorded cooking experience lesson every week	Home	1 hour/week
3. Complete online surveys following each session	4. Complete online surveys following each session	Home	0.5hour/week
Endpoint data collection:			

1. Repeat all procedures from baseline data collection	1. Repeat all procedures from baseline data collection	CTSC outpatient clinic (525 East 68th St (F260-263))	3 hours
2. Audio-recorded interview	2. Audio-recorded interview	CTSC outpatient clinic (525 East 68th St (F260-263))	0.5 hour

*Details on blood draw:
The blood draw is a standard procedure to check for dhealth status. When you come into the test, you will have your blood drawn by a certified phlebotomist (medical professional who has extensive experience of taking blood draws). We will measure your blood glucose, insulin, and lipid profiles. During waiting, you will be asked to complete online surveys and other measurements listed on the table above.

**The Wellness session will be live and will be video-recorded (with only the instructor visible during the dance class).

Please advise the researchers of any medications you are taking. In addition, if you are taking any over-the-counter drugs or herbal supplements which you have obtained from the drug store, grocery store, etc., you should advise the researchers.

HOW LONG WILL I BE IN THE STUDY?
We think you will be in the study for 18 weeks.

You/your child can stop participating at any time. However, if you/your child decide to stop participating in the study, we encourage you/your child to talk to the researcher and your regular doctor first. If you/your child choose to leave the study, your regular care will not be affected, nor will you/your child lose any benefits to which you are entitled. In addition, your relations with WCMC, BMH, NewYork-Presbyterian Hospitals, your/your child's physicians, or other personnel will not be affected.

Withdrawal by investigator, physician, or sponsor

The investigators, physicians or sponsors may stop the study or take you/your child out of the study at any time if they feel it is in your/your child's best interest, if you/your child experience a study-related injury, if you/your child need additional or different medication, or if you/your child do not follow the study plan. They may remove you/your child from the study for various other administrative and medical reasons. They can do this without your/your child's consent.

WHAT ARE THE RISKS OF THE STUDY?

You and your child will be asked to have blood drawn. This may result in a little bit of pain or discomfort. From the blood draw, you and your child may feel pain, develop a bruise or redness, bleeding, or infection at the location of the needle stick. We will try to minimize any discomfort you and your child may feel. Our staff are professionals who have a lot of experience in performing blood draws.

Throughout the study, there is also risk from performing the program's activities, for example injuries from handling knives and using heat while cooking, as well as tiredness or soreness from the dance classes. But we will provide lessons on kitchen safety and the information will be repeated each week. We also encourage you to participate in this program with your child so that you can help your child at home prepare the dish. The dance classes we offer are also developed specifically for adolescents that have zero to minimal prior experience in dancing.

Some of the questions in the survey and during the interview may be difficult to answer. If you/your child do not want to answer any of the questions in the survey or during the interview, you/your child can choose not to answer them. There are other risks of completing the interview including discomfort with some questions, revealing information, or boredom.

While we will do our best to make sure your participation is kept confidential, there is always a risk that data from the interview and survey may be seen by other people. We will try our best to make sure that this does not happen by saving the interview files in a password-protected online storage space. Additionally, none of your/your child's personal information will be on the survey or in the interview. Since you/your child will be participating in the nutrition education lesson live, other people who are participating in the program may see you. But we will emphasize to everyone to keep information on the program confidential. We will collect measures (e.g., height, weight, waist circumference) one-on-one in a private room in the clinic.

If you have any questions on the potential risks of this study, you can contact Dr. Tashara M. Leak at 607-255-7664 or by email at leakresearchgroup@cornell.edu

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

We cannot and do not guarantee that you/your child will receive any personal benefits from this study. But we hope the information learned from this study will benefit other adolescents with prediabetes or type 2 diabetes. While you and your child may not receive direct and personal benefits, they may experience improvements in: 1) diet; 2) weight status; 3) perceived psychological stress; 4) nutritional knowledge; 5) culinary skills, self-efficacy, and food attitudes; 6) social and emotional learning competencies; and 7) liking for dance as a mode of physical activity.

WHAT OTHER OPTIONS ARE THERE?

Taking part in the study is entirely voluntary. You/your child may choose not to participate in this study. If you/your child choose not to participate in the study or if you/your child decide that you/your child do not want to be part of the study anymore in the future, your/your child's regular care will not be affected and you/your child will not lose any of the benefits that belong to you both. Also, your/your child's relations with WCMC, BMH, NewYork-Presbyterian Hospitals, your physicians, or other personnel will not be affected.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to protect your/your child's medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Records of study participants are stored and kept according to legal requirements and may be part of your medical record. You/your child will not be identified personally in any reports or publications resulting from this study. Organizations that may request to inspect and/or copy your/your child's research and medical records for quality assurance and data analysis include groups such as:

- The WCMC Institutional Review Board (IRB)

- The Office of Human Research Protection (OHRP)
- Cornell University Institutional Review Board (IRB) at Ithaca, NY

By signing this consent form, you authorize access to this confidential information. You also authorize the release of your/your child's medical records to Cornell University and Weill Cornell Medicine by any other hospitals or institutions where you might receive medical care of any kind while you/your child are participating in this study.

If information about your/your child's participation in this study is stored in a computer, we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage by requiring a unique ID and password to log into the database: All data is stored in password-protected computers that will be stored in a locked room. In addition, only researchers who are associated with the study will have access to the study-specific records in the database.

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 this website at any time.

HIPAA AUTHORIZATION TO USE or DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Purposes for Using or Sharing Protected Health Information: If you/your child decide to join this study, Cornell University/Weill Cornell Medicine researchers need your/your child's permission to use your protected health information. If you/your child give permission, Cornell University/Weill Cornell Medicine researchers may use your information or share (disclose) information about you/your child for their research that is considered to be protected health information.

Voluntary Choice: The choice to give Cornell University/Weill Cornell Medicine researchers permission to use or share your/your child's protected health information for their research is voluntary. It is completely up to you/your child. No one can force you/your child to give permission. However, you/your child must give permission for Cornell University/Weill Cornell Medicine researchers to use or share your protected health information if you want to participate in the study and give permission for your child to participate in the study. If you decline to sign this form, you/your child cannot participate in this study because the researchers will not be able to obtain and/or use the information they need in order to conduct their research. Refusing to give permission will not affect your ability to get usual treatment, or health care from Cornell University/Weill Cornell Medicine or Brooklyn Methodist Hospital.

Protected Health Information To Be Used or Shared: Government rules require that researchers get your/your child's permission (authorization) to use or share your protected health information. Your/your child's medical information may be disclosed to authorized public health or government officials for public health activities when required or authorized by law. If you/your child give permission, the researchers could use or share with the entities identified above any protected health information related to this research study from your/your child's medical records and from any test results, which includes the blood draw (which will give us results on your/your child's insulin levels, glucose levels, HbA1c, and lipid profiles.)

Other Use and Sharing of Protected Health Information: If you/your child give permission, the researchers could also use your/your child's protected health information to develop new procedures or commercial products. They could share your/your child's protected health information with the study sponsor, the WCMC Institutional Review Board, inspectors who check the research, government agencies, and research study staff.

The information that may be shared with the sponsor and/or government agencies could include your/your child's medical record and your/your child's research record related to this study. They may not be considered covered entities under the Privacy Rule and your information would not be subject to protections under the Privacy Rule.

CANCELING AUTHORIZATION

Canceling Permission: If you give Cornell University/Weill Cornell Medicine researchers permission to use or share your/your child's protected health information, you have the right to cancel your permission whenever you want. However, canceling your permission will not apply to information that the researchers have already used or shared.

If you wish to cancel your permission, you may do so at any time by writing to:

Privacy Office
1300 York Avenue, Box 303
New York, NY 10065
Email: privacy@med.cornell.edu

If you have questions about this and would like to discuss, call (646) 962-6930.

End of Permission: Unless you cancel it, permission for Cornell University/Weill Cornell Medicine researchers to use or share your protected health information for their research will never end.

ACCESS TO RESEARCH RECORDS

During the course of this study, **you will have access** to see or copy your/your child's protected health information as described in this authorization form in accordance with Cornell University/Weill Cornell Medicine policies. During your participation in this study, you will have access to your/your child's research record and any study information that is part of that record.

WHAT ARE THE COSTS?

You/your child will not have to pay for anything in this study. All the materials for tests and program will be provided to you/your child by the researchers.

POLICY/PROCEDURES FOR RESEARCH-RELATED INJURY

The Policy and Procedure for Cornell University/WCM are as follows:

We are obligated to inform you about Cornell University/WCM's policy in the event injury occurs. If, as a result of your participation, you/your child experience injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available at the usual charge for such treatment. No monetary compensation is available from Cornell University/WCM. Further information can be obtained by calling the Institutional Review Board at (646) 962-8200.

COMPENSATION FOR PARTICIPATION

You and your child will receive compensation for participating in this study. For the completion of surveys and measurements the first time you and your child visit the CTSC outpatient clinic, you and your child will receive $25 in the form of cash. When you and your child return the accelerometers and completed diet records, you and your child will each receive another $25 electronic gift card. On the second visit to CTSC outpatient clinic, you and your child will receive another $25 in cash for completing surveys and other measurements. When you and your child return the accelerometers and completed diet records after the second visit, you and your child will each receive another $25 electronic gift card. Finally, you and your child will receive $25 in cash for completing an interview during the second visit to CTSC.

If total payments from us to you/your child in a calendar year exceeds $600.00, your personal information, including name, address and social security number, will be released to the Finance Department of WCM for the purpose of payment, as well as for reporting to the Internal Revenue Service.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You/your child may choose to not take part in the study or to leave the study at any time. You and your child will not be penalized for not being able to attend all the program's sessions if your child is unable to (e.g., being ill, doctor's appointment). We do ask that you and your child make the best effort to commit to the 12 weeks of the program. If you or your child want to leave the study before it is finished, please email or call Dr. Tashara M. Leak, the Principal Investigator for this study. If you or your child leave the study, you/they will no longer participate in the program's activities and there is no penalty to you/your child. If you/your child choose to not participate in the study or to leave the study, your/your child's regular care will not be affected nor will your/your child's relations with Cornell University/WCM, BMH, your physicians, or other personnel. In addition, you/your child will not lose any of the benefits to which you both are entitled.

We will tell you/your child about new information that may affect your/your child's health, welfare, or participation in this study.

A Data Safety and Monitoring Board, a group of experts, will be reviewing the data from this research throughout the study. We will tell you/your child about the new information from this or other studies that may affect your/your child's health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study, a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Dr. Tashara M. Leak at 607-255-7664, the Pediatric Endocrinology Clinic, or the Adolescent Clinic at Cornell Weill Cornell Medicine, or Brooklyn Methodist Hospital. Be sure to inform the physician of your participation in this study.

If you have questions about your rights as a research participant, contact the WCMC IRB Office. Direct your questions to:

Institutional Review Board at:
(646) 962-8200
1300 York Avenue
Box 89
New York, New York 10065

RESEARCHER'S STATEMENT

I have fully explained this study to the subject. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____	_____	_____
Signature of person obtaining the consent (Principal Investigator or Co-investigator)	Print Name of Person	Date

FOLLOW UP STUDIES

We may contact you again to request your participation in a follow-up study. As always, your participation will be voluntary, and we will ask for your explicit consent to participate in any of the follow-up studies. May we contact you again to request your participation in a follow-up study? **Yes/No**

If yes, please fill in at least one of the contact information below:

Phone number: _____

Email: _____

SUBJECT'S STATEMENT

I, the undersigned, have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time.

I voluntarily agree to participate in this study and I confirm that I share the same household as my adolescent child, and am their primary caregiver. I am free to withdraw from the study without need to justify my decision. This withdrawal will not in any way affect my/my child's future treatment or medical management and I/my child will not lose any benefits to which we otherwise are entitled. I agree to cooperate with Dr. Tashara M. Leak and the research staff and to inform them immediately if I/my child experience any unexpected or unusual symptoms.

_____	_____	_____
Signature of Subject	Print Name of Subject	Date

WEILL CORNELL MEDICAL COLLEGE
Informed Parental/Caregiver Permission and HIPAA Authorization for Resear

Project Title:	A telehealth lifestyle intervention for Black adolescent girls at risk for typ diabetes: a pilot study
Research Project/ Protocol #:	21-04023546
Principal Investigator:	Tashara M. Leak, PhD, RD
Subject MRN:	

INSTITUTION:Weill Cornell Medical College/College University

KEY INFORMATION ABOUT THIS RESEARCH STUDY	
We are asking your child to choose whether to volunteer for a research study about a telehealth lifestyle intervention program to prevent type 2 diabetes in Black adolescent girls. This page is designed to give you key information to help you decide whether you would give permission for your child to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.	
Purpose: **What is the study about and how long will it last?**	By doing this study, we hope to learn whether a virtual program that focuses on wellness, cooking, and dancing can help prevent type 2 diabetes in adolescent girls and their primary female caregiver. The activities of the program are similar to activities that would be recommended to maintain general health. Your child's participation in this research will last about 18 weeks.
Benefits: **Key reasons you might choose to volunteer**	We hope to learn ways we can support Black adolescent girls improve their health and overall wellbeing. The study will not include a direct benefit to your child. However, some participants appreciate knowing they have contributed to research that may benefit others in the future. For a complete description of benefits, refer to the Consent Document below.
Risks: **Key reasons you might choose NOT to volunteer**	In the beginning and end of the program, your child will be asked to do a blood draw. In this test, your child will be asked to have their blood drawn. Some of these may result in some discomfort. But we will try to minimize any discomfort your child may feel. For a complete description of risks, refer to the Consent Document below. Taking part in the study is entirely voluntary. Your child may choose not to take part in this study. You may choose not to give permission for your child to participate.
Voluntary Participation: **Do you have to take part in the study?**	If you decide to give permission for your child, it should be because you really want to. You and your child will not lose any services, benefits or rights or access to care you and your child would normally have if you choose not to give permission.
What if you have questions, suggestions, or concerns?	The person in charge of the study is Tashara M. Leak**,** [PI]. If you have questions, suggestions, or concerns regarding this study or you want to

	leave the study her contact information is**:** 607-255-7664 or email at leakresearchgroup@cornell.edu If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Weill Cornell Medicine Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 646-962-8200 or send an e-mail to irb@med.cornell.edu
This overview does not include all the information you need to know before deciding whether to take part in the study. Much additional detail is given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.	

INTRODUCTION

Dr. Tashara M. Leak, PhD, RD, Associate Professor at Cornell University and Weill Cornell Medical College is conducting a study titled "A telehealth lifestyle intervention for Black adolescent girls at risk for type 2 diabetes: a pilot study." In this study, we're interested in learning about how participating in a 12-wk telehealth lifestyle program with nutrition lessons, cooking experience, and dance classes may affect the diet and health of Black adolescent girls who are at risk for type 2 diabetes and their primary female caregiver.

We are inviting your child to participate because of your child's status as a patient in the Pediatric Endocrinology Clinic or Adolescent Clinic at Weill Cornell Medicine (WCM), or Brooklyn Methodist Hospital (BMH). We are working with these hospitals to invite any adolescent who's 12-18 years old, self-identify as Black or African American, and having Body Mass Index ≥ 95th percentile, and their primary female caregiver to participate in the study.

It is important that you read and understand several general principles that apply to all who take part in our studies:

(a) Taking part in the study is entirely voluntary.

(b) If your child chooses not to participate in the study or if your decision changes, your/your child's regular care will not be affected. In addition, you/your child will not lose any of the benefits to which you/your child are entitled.

(c) Personal benefit to your child may or may not result from taking part in the study, but knowledge gained from your and your child's participation may benefit others.

You can read more about the study below. Participation in this study is completely voluntary; meaning that the decision to participate or not to participate is yours and your child's. Please take your time to make your decision. If you decide to give permission for your child to participate, please sign and date at the end of this form. If you choose not to or if your decision changes, your/your child's regular care will not be affected. In addition, you/your child will not lose any of the benefits that belong to you both. Also, your/your child's relations with WCMC, BMH, NewYork-Presbyterian Hospitals, your physicians, or other personnel will not be affected.

If there is any new information that might affect your child's decision to participate or remain in the study, this information will be given to you and your child while they are a participant in this study. If you have any questions at all, you can discuss them with members of the research team.

The research study is being funded by the WCM Clinical and Translational Research Center (CTSC), Cornell Center for Health Equity, Cornell University: Schwartz Funds, and NIH NIMHD. Dr. Tashara M. Leak is the primary investigator.

Your child will be asked to make a visit to the CTSC adult outpatient clinic (525 East 68th St) F260-263 in the beginning of the program and at the end of the program.

WHY IS THE STUDY BEING DONE?

The purpose of this study is to examine the efficacy of a 12-week lifestyle program on type 2 diabetes (T2D) related risk factors among Black adolescent girls who are 12-18 years old and who have obesity and their primary female caregiver.

This research study is being done because lifestyle programs in adults have shown some benefits in preventing T2D. Currently, however, there are few programs available for adolescents to prevent T2D. Additionally, these programs are rarely done virtually. Thus, we want to evaluate whether a 12-week telehealth lifestyle program that consists of nutrition lessons, cooking experience, and dance classes can improve T2D-related risk factors, such as healthy eating and physical activity, in adolescents who are at risk for diabetes and their primary female caregiver. The knowledge gained from this study can help develop future programs to improve health and prevent diabetes in adolescents.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Participants in the study are referred to as subjects.
About 60 adolescent subjects and 60 adult subjects will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

Below are details of each of the study's activities that we will ask your child to complete if your child takes part in the study:

1. Make a visit to the CTSC adult outpatient clinic (525 East 68th St) F260-263. We will have an Uber pick your child up (if preferred) from your location. At the clinic, your child will:
    a. complete a blood draw. A trained nurse will collect a blood sample from them. This blood samples will measure blood glucose, insulin, lipid profiles, and HbA1c.
    b. Complete an online survey that will ask them about their sociodemographic characteristics (age, sex, etc.), food security survey, cooking skills, grocery shopping practices, Black identity scale, perceived stress,adultification, and physical activity.
    c. Be trained to complete 24-hr diet records (where they will record everything they eat and drink in the past day) and use an accelerometer (which is a device that clips on your wrist so that it can measure their physical activity).
    d. Get height, weight, body fat percentage, waist circumference, blood pressure, and dermal carotenoid levels measured. We will measure weight and body fat percentage with a scale and dermal carotenoid levels with a Veggie Meter, which involves placing one's finger on a sensor pad for 10 seconds (this will not hurt or cause any physical discomfort).
2. During the week after the visit, your child will also be asked to wear an accelerometer for 7 days (not during bathing). Your child will be asked to send the accelerometer and their completed diet records in a stamped envelope after one week, at no cost to you.
3. Your child will then participate in a 12-week lifestyle intervention program. Each week will consist of:
    a. A virtual live-streamed Wellness Session: nutrition education lesson, a girl chat/reflection, and a dance class with Cumbe: Center for African and African Diaspora Dance (2 hr total). This session will be video-recorded (with only the instructor visible for the dance class).

b. A cooking experience where they will prepare a dish from a variety of cultures related to the nutrition education lesson (1 hr); the food ingredients will be delivered to your home and you are encouraged to participate.

4. Make another visit to the CTSC adult outpatient clinic to repeat everything in numbers 1-3. Participate in an interview, where you can talk about your experience in the program and how the program has impacted you. This interview will be done in-person, during the second clinic appointment and will be audio-recorded.

See the diagram below for a summary of all activities that your child will be asked to participate in if you give them permission to participate.

Time	Activities
0 week	Recruitment, screen potential participants by inclusion and exclusion criteria using chart reviews. Schedule participants for baseline data collection.
3 weeks	**Consent/assent participants. Baseline data collection**. 1) survey on REDCap (sociodemographic characteristics, food cooking/shopper responsibilities, cooking equipment/supplies at home, cooking skills/self-efficacy, Black identity scale, perceived stress and adultification scale. 2) three 24-hr diet records. 3) dermal carotenoid levels using Veggie meter. 4) accelerometer to measure physical activity. 5) physical activity/screen time-survey. 6) body composition (height, weight, waist circumference, body fat percentages using scales and stadiometers). 7) blood sample (blood glucose, insulin, lipid profiles, HbA1c will all be assessed). 8) blood pressure.
12 weeks	12 weeks lifestyle intervention program
3 weeks	Endpoint data collection Same procedures as baseline data collection and participate in an interview to examine overall program impact and acceptability. **End of study**

If you take part in this study, you and your child will have the following tests and procedures:

Procedures for your child	Location	Time
Baseline data collection:		
1. Blood drawt* (see details below)	CTSC outpatient clinic (525 East 68th St (F260-263))	15 minutes
2. Online survey on sociodemographic characteristics, family medical history, food	CTSC outpatient clinic (525 East 68th St (F260-263))	30 minutes

security, Black identity scale, perceived stress and adultification, cooking skills/self-efficacy, grocery shopping practices, and physical activity.		
3. Training on completing diet records and using accelerometers	CTSC outpatient clinic (525 East 68th St (F260-263))	30 minutes
4. Measure height, weight, body fat percentage, blood pressure, and waist circumference	CTSC outpatient clinic (525 East 68th St (F260-263))	30 minutes
5. Measure dermal carotenoids	CTSC outpatient clinic (525 East 68th St (F260-263))	15 minutes
The week following baseline visit:		
1. Complete three 24-hr diet records	Home	3 hours
2. Wear accelerometers for 7 days	Home	NA
During program		
1. Attend Wellness Session live every week**	Home	2 hours/ week
2. Prepare a dish following a recorded cooking experience lesson every week	Home	1 hour/week
3. Complete online surveys following each session	Home	0.5 hour/week
Endpoint data collection:		
1. Repeat all procedures from baseline data collection	CTSC outpatient clinic (525 East 68th St (F260-263))	3 hours
2. Audio-recorded interview	Home	0.5 hour

*Details on blood draw:
The blood draw is a standard procedure to check for health status. Your child will have their blood drawn by a certified phlebotomist (medical professional who has extensive experience of taking blood draws). We will measure their blood glucose, insulin, and lipid profiles. During waiting, they will be asked to complete online surveys and other measurements listed on the table above.

**The Wellness session and dance class will be live and will be video-recorded (with only the instructor visible during the dance class).

HOW LONG WILL YOUR CHILD BE IN THE STUDY?
We think your child will be in the study for 18 weeks.

Your child can stop participating at any time. However, if your child decides to stop participating in the study, we encourage your child to talk to the researcher and their/your regular doctor first. If your child chooses to leave the study, their regular care will not be affected, nor will you/your child lose any benefits to which you are entitled. In addition, your relations with WCMC, BMH, NewYork-Presbyterian Hospitals, your/your child's physicians, or other personnel will not be affected.

Withdrawal by investigator, physician, or sponsor

The investigators, physicians or sponsors may stop the study or take your child out of the study at any time if they feel it is in your child's best interest, if your child experience a study-related injury, if your child needs additional or

different medication, or if your child do not follow the study plan. They may remove your child from the study for various other administrative and medical reasons. They can do this without your child's consent.

WHAT ARE THE RISKS OF THE STUDY?

Your child will be asked to have their blood drawn. This may result in a little bit of pain or discomfort. From the blood draw, your child may feel pain, develop a bruise or redness, bleeding, or infection at the location of the needle stick. We will try to minimize any discomfort your child may feel. Our staff are professionals who have a lot of experience in performing blood draws.

Throughout the study, there is also risk from performing the program's activities, for example injuries from handling knives and using heat while cooking, as well as tiredness or soreness from the dance classes. But we will provide lessons on food/kitchen safety and the information will be repeated each week. We also encourage you to participate in this program with your child so that you can help your child at home prepare the dish. The dance classes we offer are also developed specifically for adolescents that have zero to minimal prior experience in dancing.

Some of the questions in the survey and during the interview may be difficult to answer. If your child does not want to answer any of the questions in the survey or during the interview, your child can choose not to answer them. There are other risks of completing the interview including discomfort with some questions, revealing information, or boredom.

While we will do our best to make sure your child's participation is kept confidential, there is always a risk that data from the finterview and survey may be seen by other people. We will try our best to make sure that this does not happen by saving the interview files in a password-protected online storage space. Additionally, none of your child's personal information will be on the survey or in the interview. Since your child will be participating in the nutrition education lesson live, other people who are participating in the program may see you. But we will emphasize to everyone to keep information on the program confidential. We will collect measures (e.g., height, weight, waist circumference) one-on-one in a private room in the clinic.

If you have any questions on the potential risks of this study, you can contact Dr. Tashara M. Leak at 607-255-7664 or by email at leakresearchgroup@cornell.edu

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

We cannot and do not guarantee that your child will receive any personal benefits from this study. But we hope the information learned from this study will benefit other adolescents with prediabetes or type 2 diabetes. While your child may not receive direct and personal benefits, they may experience improvements in: 1) diet; 2) weight status; 3) perceived psychological stress; 4) nutritional knowledge; 5) culinary skills, self-efficacy, and food attitudes; 6) social and emotional learning competencies; and 7) liking for dance as a mode of physical activity.

WHAT OTHER OPTIONS ARE THERE?

Taking part in the study is entirely voluntary. Your child may choose not to participate in this study. If your child chooses not to participate in the study or if you/your child decide that you do not want your child to be part of the study anymore in the future, your/your child's regular care will not be affected and you/your child will not lose any of the benefits that belong to you both. Also, your/your child's relations with WCMC, BMH, NewYork-Presbyterian Hospitals, your physicians, or other personnel will not be affected.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to protect your child's medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Records of study participants are stored and kept according to

legal requirements and may be part of your medical record. Your child will not be identified personally in any reports or publications resulting from this study. Organizations that may request to inspect and/or copy your/your child's research and medical records for quality assurance and data analysis include groups such as:

- The WCMC Institutional Review Board (IRB)
- The Office of Human Research Protection (OHRP)
- Cornell University Institutional Review Board (IRB) at Ithaca, NY

By signing this consent form, you authorize access to this confidential information. You also authorize the release of your child's medical records to Cornell University and Weill Cornell Medicine by any other hospitals or institutions where you might receive medical care of any kind while your child is participating in this study.

If information about your child's participation in this study is stored in a computer, we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage by requiring a unique ID and password to log into the database: All data is stored in password-protected computers that will be stored in a locked room. In addition, only researchers who are associated with the study will have access to the study-specific records in the database.

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 this website at any time.

HIPAA AUTHORIZATION TO USE or DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Purposes for Using or Sharing Protected Health Information: If your child decides to join this study, Cornell University/Weill Cornell Medicine researchers need your/your child's permission to use your protected health information. If you/your child give permission, Cornell University/Weill Cornell Medicine researchers may use your child's information or share (disclose) information about your child for their research that is considered to be protected health information.

Voluntary Choice: The choice to give Cornell University/Weill Cornell Medicine researchers permission to use or share your child's protected health information for their research is voluntary. It is completely up to you/your child. No one can force you/your child to give permission. However, you/your child must give permission for Cornell University/Weill Cornell Medicine researchers to use or share your protected health information if you want to participate in the study and give permission for your child to participate in the study. If you decline to sign this form, your child cannot participate in this study because the researchers will not be able to obtain and/or use the information they need in order to conduct their research. Refusing to give permission will not affect your ability to get usual treatment, or health care from Cornell University/Weill Cornell Medicine or Brooklyn Methodist Hospital.

Protected Health Information To Be Used or Shared: Government rules require that researchers get your/your child's permission (authorization) to use or share your protected health information. Your child's medical information may be disclosed to authorized public health or government officials for public health activities when required or authorized by law. If you/your child give permission, the researchers could use or share with the entities identified above any protected health information related to this research study from your child's medical records and from any test results, which includes the blood draw (which will give us results on your child's , insulin levels, glucose levels, HbA1c, and lipid profiles.)

Other Use and Sharing of Protected Health Information: If you/your child give permission, the researchers could also use your child's protected health information to develop new procedures or commercial products. They could share your child's protected health information with the study sponsor, the WCMC Institutional Review Board, inspectors who check the research, government agencies, and research study staff.

The information that may be shared with the sponsor and/or government agencies could include your child's medical record and your child's research record related to this study. They may not be considered covered entities under the Privacy Rule and your information would not be subject to protections under the Privacy Rule.

CANCELING AUTHORIZATION

Canceling Permission: If you give Cornell University/Weill Cornell Medicine researchers permission to use or share your child's protected health information, you have the right to cancel your permission whenever you want. However, canceling your permission will not apply to information that the researchers have already used or shared.

If you wish to cancel your permission, you may do so at any time by writing to:

Privacy Office
1300 York Avenue, Box 303
New York, NY 10065
Email: privacy@med.cornell.edu

If you have questions about this and would like to discuss, call (646) 962-6930.

End of Permission: Unless you cancel it, permission for Cornell University/Weill Cornell Medicine researchers to use or share your child's protected health information for their research will never end.

ACCESS TO RESEARCH RECORDS

During the course of this study, **you will have access** to see or copy your child's protected health information as described in this authorization form in accordance with Cornell University/Weill Cornell Medicine policies. During your child's participation in this study, you will have access to your child's research record and any study information that is part of that record.

WHAT ARE THE COSTS?

Your child will not have to pay for anything in this study. All the materials for tests and program will be provided to your child by the researchers.

POLICY/PROCEDURES FOR RESEARCH-RELATED INJURY

The Policy and Procedure for Cornell University/WCM are as follows:
We are obligated to inform you about Cornell University/WCM's policy in the event injury occurs. If, as a result of your participation, your child experiences injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available at the usual charge for such

treatment. No monetary compensation is available from Cornell University/WCM. Further information can be obtained by calling the Institutional Review Board at (646) 962-8200.

COMPENSATION FOR PARTICIPATION

Your child will receive compensation for participating in this study. For the completion of surveys and measurements the first time your child visits the CTSC outpatient clinic, your child will receive $25 in the form of cash. When your child returns the accelerometers and completed diet records, your child will receive another $25 electronic gift card. On the second visit to CTSC outpatient clinic, your child will receive another $25 in cash when your child completes all surveys and measurements. When your child returns the accelerometer and completed diet records after the second visit, your child will receive another $25 electronic gift card. Finally, your child will receive $25 in cash for completing an interview during the second visit to CTSC.

If total payments from us to your child in a calendar year exceeds $600.00, your personal information, including name, address and social security number, will be released to the Finance Department of WCM for the purpose of payment, as well as for reporting to the Internal Revenue Service.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You do not have to give permission, your child may choose to not take part in the study, or to leave the study at any time. Your child will not be penalized for not being able to attend all the program's sessions if your child is unable to (e.g., being ill, doctor's appointment). We do ask that you and your child make the best effort to commit to the 12 weeks of the program. If you or your child want to leave the study before it is finished, please email or call Dr. Tashara M. Leak, the Principal Investigator for this study. If your child leaves the study, they will no longer participate in the program's activities and there is no penalty to you nor your child. If your child chooses to not participate in the study or to leave the study, your/your child's regular care will not be affected nor will your/your child's relations with Cornell University/WCM, BMH, your physicians, or other personnel. In addition, you/your child will not lose any of the benefits to which you both are entitled.

We will tell you/your child about new information that may affect your child's health, welfare, or participation in this study.

A Data Safety and Monitoring Board, a group of experts, will be reviewing the data from this research throughout the study. We will tell you/your child about the new information from this or other studies that may affect your child's health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study, a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Dr. Tashara M. Leak at 607-255-7664, the Pediatric Endocrinology Clinic, the Adolescent Clinic at Cornell Weill Cornell Medicine, or Brooklyn Methodist Hospital. Be sure to inform the physician of your participation in this study.

If you have questions about your rights as a research participant, contact the WCMC IRB Office. Direct your questions to:

Institutional Review Board at:
(646) 962-8200
1300 York Avenue
Box 89
New York, New York 10065

RESEARCHER'S STATEMENT

I have fully explained this study to the subject. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____	_____	_____
Signature of person/investigator obtaining consent	Print Name of Person	Date

FOLLOW UP STUDIES

We may contact you again to request your participation in a follow-up study. As always, your participation will be voluntary, and we will ask for your explicit consent to participate in any of the follow-up studies. May we contact you again to request your participation in a follow-up study? **Yes/No**

If yes, please fill in at least one of the contact information below:

Phone number: _____

Email: _____

SUBJECT'S STATEMENT

I, the undersigned, have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time.

I allow my adolescent child to participate in the study. I am free to withdraw this permission at any time without need to justify my decision. This withdrawal will not in any way affect my/my child's future treatment or medical management and I/my child will not lose any benefits to which we otherwise are entitled. I agree to cooperate with Dr. Tashara M. Leak and the research staff and to inform them immediately if my child experiences any unexpected or unusual symptoms.

_____
Print name of adolescent child

_____	_____	_____
Signature of Caregiver	Print Name of Caregiver	Date

WEILL CORNELL MEDICAL COLLEGE

Assent Form for Minors for Clinical Investigation (Age 12-17)

Project Title: A telehealth lifestyle intervention for Black adolescent girls who are at risk for type 2 diabetes: a pilot study

Research Project #: 21-04023546

Principal Investigator: Tashara M. Leak, PhD, RD

INSTITUTION: **Weill Cornell Medical College/Cornell University**

KEY INFORMATION ABOUT THIS RESEARCH STUDY

We are asking you to choose whether to volunteer for a research study about a telehealth lifestyle intervention program to prevent type 2 diabetes in Black adolescent girls. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

Purpose: **What is the study about and how long will it last?**	By doing this study, we hope to learn whether a virtual program that focuses on wellness, cooking, and dancing can help prevent type 2 diabetes in adolescent girls and their primary female caregiver. The activities of the program are similar to activities that would be recommended to maintain general health. Your participation in this research will last about 18 weeks.
Benefits: **Key reasons you might choose to volunteer**	We hope to learn ways we can support Black adolescent girls improve their health and overall wellbeing. The study will not include a direct benefit to you. However, some participants appreciate knowing they have contributed to research that may benefit others in the future. For a complete description of benefits, refer to the Consent Document below.
Risks: **Key reasons you might choose NOT to volunteer**	In the beginning and end of the program, you will be asked to do a blood draw. This may result in some discomfort. You also may experience some discomfort during the program. But we will try to minimize any discomfort you may feel. For a complete description of risks, refer to the Consent Document below. Taking part in the study is entirely voluntary. You may choose not to take part in this study.

Voluntary Participation: **Do you have to take part in the study?**	If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care you would normally have if you choose not to volunteer.
What if you have questions, suggestions, or concerns?	The person in charge of the study is Tashara M. Leak**,** [PI]. If you have questions, suggestions, or concerns regarding this study or you want to leave the study her contact information is**:** 607-255-7664 or email at leakresearchgroup@cornell.edu If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Weill Cornell Medicine Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 646-962-8200 or send an e-mail to irb@med.cornell.edu
This overview does not include all the information you need to know before deciding whether to take part in the study. Much additional detail is given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.	

INTRODUCTION

Dr. Tashara M. Leak, PhD, RD, Associate Professor at Cornell University and Weill Cornell Medical College is conducting a study titled "A telehealth lifestyle intervention for Black adolescent girls who are at risk for type 2 diabetes: a pilot study" In this study, we're interested in learning about how participating in a 12-week telehealth lifestyle program with nutrition lessons, cooking experience, and dance classes may affect the diet and health of Black adolescent girls who are at risk for type 2 diabetes and their primary female caregiver.

We are inviting you to participate because of your status as a patient in the Pediatric Endocrinology Clinic or Adolescent Clinic at Weill Cornell Medicine (WCM), or Brooklyn Methodist Hospital (BMH). We are working with these hospitals to invite any adolescent who's 12-18 years old, self-identify as Black or African American, and has Body Mass Index ≥ 95th percentile.

You can read more about the study below. Participation in this study is completely voluntarily, meaning that the decision to participate or not to participate is yours. Please take your time to make your decision. If you decide to participate, please sign and date at the end of this form. If you choose not to participate in the study or if your decision changes, your regular care will not be affected. In addition, you will not lose any of the benefits that belong to you. Also, your relations with WCMC, BMH, NewYork-Presbyterian Hospitals, your physicians, or other personnel will not be affected.

If there is any new information that might affect your decision to participate or remain in the study, this information will be given to you while you are a participant in this study. If you have any questions at all about the question, you can discuss them with members of the research team. The research study is being funded by the WCM Clinical and Translational Research Center (CTSC), Cornell Center for Health Equity, Cornell University: Schwartz Funds, and NIH NIMHD. Dr. Tashara M. Leak is the primary investigator.

PROCEDURES
If you take part in this study, you will be asked to do a couple of things:

1. Make a visit to the CTSC adult outpatient clinic (525 East 68th St) F260-263. We will order an Uber to pick you up from your location, if preferred. At the clinic, you will:
    a. Complete a blood draw that will measure your blood glucose, insulin, lipid profiles, and HbA1c.
    b. Complete an online survey that will ask you about your sociodemographic characteristics (age, sex etc.), cooking equipment at home, cooking skills, Black identity scale, perceived stress and adultification, and physical activity.
    c. Be trained to complete 24-hr diet records (where you will record everything you eat and drink in the past day) and use an accelerometer (which is a device you will clip on your wrist so that it can measure your physical activity).
    d. Get your height, weight, body fat percentage, waist circumference, blood pressure, and dermal carotenoid levels measured. We will measure weight and body fat percentage with a scale and dermal carotenoid levels with a Veggie Meter, which involves you placing your finger on a sensor pad for 10 seconds (this will not hurt or cause any physical discomfort).
2. During the week after your visit, you will be asked to complete three 24-hr diet records where you will be asked to record everything you ate and drank in the past day.
3. During the week after your visit, you will also be asked to wear an accelerometer for 7 days at all moments except during bathing. You will be asked to send the accelerometer and your completed diet records in a stamped envelope after one week.
4. You will then participate in a 12-week lifestyle intervention program. Each week will consist of:
    a. A virtual live-streamed Wellness Session: nutrition education lesson, a girl chat/reflection, and a dance class with Cumbe: Center for African and African Diaspora Dance (2 hrs total). This session will be video-recorded (with only the instructor visible during the dance class).
    b. A cooking experience where you will prepare a dish from a variety of cultures related to the nutrition education lesson (1 hr); the food ingredients will be delivered to your home.
5. Make another visit to the CTSC adult outpatient clinic to repeat everything in numbers 1-3. Participate in an interview, where you can talk about your experience in the program and how the program has impacted you. This interview will be done in-person, during the second clinic appointment.

DURATION
If you participate in this study, the total study duration is up to 18 weeks. The first visit to CTSC can take up to 3 hours. The program will take 3.5 hours every week for 12 weeks. The second visit to CTSC can take up to 3 hours.

During the study, you can stop participation at any time. However, if you decide to stop, we encourage you to talk to the researcher first (see the end of the document for contact information). If you choose to leave the study, your regular care will not be affected. You will not lose any benefits to which you both are entitled to. Also, your relations with Cornell University, WCMC, BMH, NewYork-Presbyterian Hospitals, your physicians, or other personnel will not be affected.

RISKS (Including risks associated with confidentiality)
There is a change that you could feel uncomfortable during this program. We will help you with these feelings and you can **stop** at any time if you want. If you are in the study, you could experience any of the following:

- You may feel pain or develop a bruise or redness at the location of the needle stick during the blood draw. There may also be a risk of bleeding or infection at the location of the needle stick. But our staff are professionals who have a lot of experience in performing blood draws.
- You could feel uncomfortable with some of the questions in the survey and the interview at the end of the program. If you do not want to answer any of the questions in the survey or during the interview, you can choose not to answer them.
- You may feel uncomfortable when we take your height, weight, and waist circumference. We will only collect these measurements from you in a private room at the clinic.
- You could get hurt during the cooking labs you complete at home with your caregiver. We will provide you with food/kitchen safety tips in the BGW student workbook, and the information will be repeated each week. We also encourage your caregiver to participate in this program with you so that they can help you at home preparing the dish.
- You could get tired during the dance classes. The dance classes we offer are also developed specifically for adolescents that have zero to minimal prior experience in dancing.

While we will do our best to make sure your participation is kept confidential, there is always a risk that data from the interview and survey may be seen by other people. We will try our best to make sure that this does not happen by saving the interview files in a password-protected online storage space. Additionally, none of your personal information will be on the survey or in the interview. Since you will be participating in the nutrition education lesson live, other people who are participating in the program may see you. But we will emphasize to everyone to keep information on the program confidential.
If you have any questions on the potential risks of this study, you can contact Dr. Tashara M. Leak at 607-255-7664 or by email at leakresearchgroup@cornell.edu. Your caregiver also has our information if you have questions.

BENEFITS
We cannot and do not guarantee that you will receive any personal benefits from this study. But we hope the information learned from this study will benefit other adolescents with prediabetes or type 2 diabetes.
Some of the ways you could benefit from participating in Black Girls for Wellness is that you may: 1) increase your cooking skills, knowledge, and attitudes, 2) increase the amount of healthy foods you eat, 3) learn new ways to manage your stress, and 4) learn how to practice dance as a way to exercise.

ALTERNATIVES TO PARTICIPATION (Including the option not to participate)
You do not have to be in this study, and no one will be mad at you if you say no. You can also say yes now and change your mind later, just tell a member of the research team that you want to stop. If you want to stop, you will no longer attend the program's activities. Please talk about this with your caregiver before you decide if you want to be in the research study. If your caregiver says that it is ok with them if you are in the research study, you can still say **no**. If you choose not to participate in the study or if you decide that you do not want to be part of the study anymore in the future, your regular care will not be affected and you will not lose any of the benefits that belong to you. Also, your relations with WCMC, BMH, NewYork-Presbyterian Hospitals, your physicians, or other personnel will not be affected.

It's okay if you can't attend a Wellness session if you are sick, have to go to a doctor's appointment, etc. We do ask that you try to attend and actively participate in all 12 Wellness sessions and culinary sessions that you will complete at home.

COSTS / REIMBURSEMENT (Ages 12-17 only)

You will get paid for participating in this study. For the completion of surveys and measurements the first time you visit the CTSC outpatient clinic, you will receive $25 in cash. When you return the accelerometer watch and diet records, you will receive another $25 in an electronic gift card. During your second visit to the CTSC outpatient clinic, you will receive $25 cash after completing activities. When you return the accelerometer watch and completed diet records to us, you will receive another $25 in an electronic gift card. Finally, you will receive a $25 in cash after completing an interview during the second visit.

FOLLOW UP STUDIES

We may ask you later if you want to be part of another study. Being part of any study is up to you and we will ask you to provide assent again if you would like to participate. May we contact you again to ask about your participation in a future study? **Yes/No**

If yes, please fill in at least one of the contact information below:

Phone number: _____

Email: _____

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions about the study at any time or encounter any problems (unexpected research-related physical or psychological discomforts), you can call Dr. Tashara M. Leak at 607-255-5967 or email her at leakresearchgroup@cornell.edu. If you have questions about your rights as a research participant, contact the WCMC IRB Office.

Direct your questions to:

Institutional Review Board at:

(646) 962-8200
1300 York Avenue Box 89
New York, New York10065

_____	_____	_____
Signature of Minor	Print Name of Person	Date / Time
_____	_____	_____
Signature of Investigator	Print Name of Person	Date / Time