TITLE OF RESEARCH:	**Effect of low carbohydrate versus low fat diet in the treatment of dyslipidemia in obese children**
IRB PROTOCOL:	**IRB-300002816**
INVESTIGATORS:	Dr. Bhuvana Sunil, Dr. Ambika Ashraf; Dr. Tanja Dudenbostel, Dr. Amy Miskimon Goss, Dr. Barbara Gower
Sponsor:	UAB Nutrition Obesity Research Center Pilot and Feasibility Grant

For Children (persons under 18 years of age) participating in this study, the term "You" addresses both the participant ("you") and the parent or legally authorized representative ("your child").

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to see how well changes in diet make-up will affect different health measures like lipids, insulin resistance and heart health in children between 10 – 18 years
Duration & Visits	You will be in this study for 8 weeks, and have 2 clinic visits at the beginning and the end of this time. The first visit will take about 5 ½ hours to complete and the return visit will take about 3 ½ hours to complete
Overview of Procedures	This study will include 2 clinic visits separated by 8 weeks, meeting with the doctor to get diet instructions, a blood draw of approximately 2 teaspoons at each visit, estimation of the resting energy usage at the first visit, a DXA scan to see of what the body is made at each visit, measurement of the blood pressure and other markers of blood vessel function at each visit
Risks	The most common risks include pain during the time of blood draw, pressure and pain during inflation of the blood pressure cuff, feelings of craving during eating the prescribed diet, feeling of claustrophobia during estimation of the resting energy usage, minimal radiation exposure during DXA scanning and loss of confidentiality

Benefits	You may or may not benefit from this study. You will receive information on blood samples and your body composition. Improvements in lipid levels, body composition and health may occur. While weight loss is not the primary goal in this research, it will likely be a side effect of these diets
Alternatives	The alternative is not to be a part of this research study.

Purpose of the Research Study:

We are asking you to take part in a research study. This research study will test how well changes in diet composition affect different health outcomes in children ages 10 -18 with abnormal lipids, insulin resistance and health of the blood vessels. Little is known about how change in diet composition can influence these in children and adolescents. It may be that simply changing the type of food you eat can greatly help these levels. That is what we are studying. This study will enroll 36 participants at the University of Alabama at Birmingham (UAB).

Study participation and Procedures:

You are eligible for this study if you are overweight or obese, have abnormal lipids, are 10-18 years of age, and your doctor told you that your lipid levels are abnormal. Other causes of abnormal lipids must be ruled out by your doctor and you cannot join the study if you take medications known to affect lipids, body weight, or the way your body uses the food you eat or you have a genetic or some other cause other than being overweight/obese to cause abnormal lipid levels.

If you enter the study, you will attend an individual meeting during the initial screening visit. You will be asked questions about your health, eating behaviors, typical diet, and use of medications. You will also have your height, weight, waist circumference and blood pressure measured and you will have a DXA scan to see what of what your body is composed. We will measure your energy expenditure at rest to calculate how many calories you need in a day. You will have a needle stick to get about two tablespoons of blood drawn. You will visit a hypertension laboratory where the health of your arteries will be measured. If the results of these tests are in the range that is required for the study, you will be eligible to complete the entire study. If you are entered and complete the entire study, you will be in the study for 8 weeks.

If you are eligible based on the first visit, the following tests will be conducted once before and after the diet intervention period requiring a total of 2 testing visits. At the first visit, a measurement of your energy expenditure at rest, a blood draw, a scan to measure fat and lean mass, body weight, waist circumference and height will be measured and you will be sent to the vascular hypertension lab where the health of your arteries will be measured by application of a sensor to your wrist pulse, and inflation of a blood pressure cuff and using ultrasound. At the return visit at 8 weeks – you will meet with the doctor, fill out a questionnaire to find out how well you liked the diet you were on and problems with the diet, a blood draw, a scan to measure fat and lean mass, body weight, waist circumference and height will be measured and you will be sent to the vascular hypertension lab where the health of your arteries will be measured by application of a sensor probe to your wrist pulse, inflation of a blood pressure cuff and using ultrasound.

If you qualify for the study, you will be randomly picked (like the flip of a coin) to participate in one of two groups: Carbohydrate-restricted Group or the Standard Diet Group. Recipes and a meal plan will be given to you and you will be advised on what types of foods can be eaten during the next eight weeks. You will also be taught how to write down what and how much you eat four times a week including one day of the weekend every week for the next eight weeks. Your doctor will call you every week to answer questions and address any difficulties you may be having with the diet.

If you are assigned to the Standard Diet Group, you will be asked to change your diet and eat low fat, high carbohydrate foods such as fruits, vegetables, grains and cereals. You will attend an individual meeting during the initial screening visit with a Registered Dietitian or one of the doctors. You will also be asked to record the food you eat each week for four days including one typical day of the weekend. One parent will be required to attend individual meetings with a dietitian/doctor. We will call you every week to ask how you are doing and help answer any questions you may have about the diet during this call.

If you are assigned to the Carbohydrate-restricted Group, you will participate in the same activities as those who were assigned to the Standard Diet Group except this diet will limit sugars and starches rather than fat.

Both diets will provide all essential nutrients for children in this age range.

Testing Schedule and Procedures:

Test	1st visit	1st visit	1st visit	1st visit	Return visit (week 8)	Return visit	Return visit
Visit Duration	*3 hours*	*1 hour*	*30 mins*	*1 hour*	*2 hours*	*30 mins*	*1 hour*
Visit Location	Children's Park Place		Webb building of Nutrition Sciences	Vascular hypertension lab	Children's Park Place		Vascular hypertension lab
Resting energy expenditure		X					
Height, weight and waist circumference	X				X		
4-day Food Record and 24h recall	X						
Blood pressure, pulse and clinic visit	X				X		

DXA (Body composition)			X			X	
Post study questionnaire					X		
Medical History Questionnaire	X						
Medication Usage Form	X						
Fasting blood draw	X				X		
Meeting with Registered Dietitian & Doctor	X				X		
Measurement of Augmentation Index and flow-mediated dilation				X			X

If you join the study, you will be asked to participate in one screening visit and one return visit. The visit schedule and brief description of each test are provided below.

First visit:

Resting Energy Expenditure: REE is placing a large plastic bubble over your head, while a plastic sheet covers your upper body. Oxygen flows into the bubble from a valve at the top. We measure the amount of oxygen consumed and the amount of carbon di oxide produced while at rest. This procedure takes about an hour to complete.

Weight, Height and Waist Circumference: Weight, height waist circumference will be measured to determine if you are eligible for the study.

Blood pressure and pulse: After being seated and resting for five minutes, your blood pressure and pulse will be measured. A second reading will be measured after a 30-second rest period.

Food Record: You will be given a four-day food record and instructed on how to complete this at home before your next visit. You and your parent will also complete an online 24-hour dietary recall with help from the study staff. This will help us understand what you and your parent normally eat.

Medical History Questionnaire: You will be asked to fill out a form detailing your medical history. This will be used to determine eligibility and will also provide us a complete picture of your health.

Medication Usage Form: You will be asked to fill out a form detailing your medication usage. This will be used to determine eligibility and will also provide us a complete picture of your health.

DXA Scan: DXA is a method that uses a small amount of radiation to test body composition. This also requires a minimum 8-hour fast prior to the scan. In this procedure, you will lie on your back on a padded table while a measuring device moves back and forth over your body from head to foot, taking about 30 minutes. You will be asked to lie still, but there is no discomfort in this procedure. The DXA is located in the Webb Nutrition Sciences Building at UAB and will take about 15 minutes.

If you are a female who can have children, you will have a pregnancy test prior to the DXA scan. The results of that test must be negative for you to continue being in this study. The results of the pregnancy test will be given to you and if you are under 18 years of age the results will also be given to your parents.

Blood draw (insulin level, fasting glucose level, C- peptide and lipid level): You will be asked to fast for 8 hours prior to the blood draw. Blood samples (approximately 2 tablespoons) will be obtained to measure insulin level, fasting glucose level, glucose, C peptide and lipid levels. These samples will be obtained using a needle stick. Measurements will be performed in UAB's research core laboratory and at the UAB Outreach laboratory.

Meet with Registered Dietitian/doctor: Once all testing at baseline has been completed, you will meet with a dietitian or doctor for initial diet instruction. They will provide acceptable food lists, serving size instruction, and recipes/menus.

Measurement of Augmentation Index and Flow Mediated Dilation: These are used to measure the stiffness of your arteries. You will be asked to rest for ten minutes. Augmentation index will be measured by applying pressure to the pulse of your wrist and taking measurements. Flow-mediated dilation will be measured using a blood pressure cuff with ultrasound.

Return visit (all as previously described)
Weight, Height and Waist Circumference
Blood pressure and pulse
Four Day Food Record
DXA Scan
Blood draw (insulin level, fasting glucose level, C-peptide and lipid level)
Meet with Registered Dietitian/doctor
Measurement of augmentation index and flow-mediated dilation
Filling out a post study questionnaire

Post study questionnaire: A brief questionnaire on what and how long you were on the diet for and feedback on the diet.

Incidental Findings

DXA scans will be conducted at the Webb building in the Dept. of Nutrition Sciences. DXA scans will be read by study physician.

If you want your scan to be reviewed by a physician so that the physician can look for medical issues, you can request a copy of your scan. We will provide a copy at no charge.

Risks and Discomforts

There may be minor risks involved in changing dietary intake. With either diet, there may be risk of hunger, weakness, constipation, cravings for certain foods, or fatigue. There may be risks that are unknown at this time. More information will be given to participants if risks are found.

Blood collection: During this procedure there is a risk of a bruise, slight pain, inflammation of the vein, bleeding at the site of puncture. There is also the rare possibility of infection.

DXA is a method that uses a small amount of radiation to test body composition. In this procedure, you will lie on your back on a padded table while a measuring device moves back and forth over your body from head to foot. You will be asked to lie still, but there is no discomfort in this procedure. The DXA will take about 30 minutes. The amount of radiation dose that you receive from each DXA scan is comparable to approximately 2 days of background radiation. Background radiation is radiation normally received from sources such as cosmic rays and natural radioactivity in building materials and the ground. A small risk of cancer and other radiation effects, which may not be known at this time, may develop from each imaging exam received. To ensure correct function of the equipment, quality assurance testing is performed daily by trained personnel.

During the measurement of blood vessel and heart health, you may experience slight discomfort and/or bruising due to inflation of the blood pressure cuff

You will be assigned to a group by chance, which may prove to be less effective or to have more side effects than the other study group(s) or alternatives.

During measurement of the resting energy expenditure, a clear plastic bubble will be placed on our head. This may cause some claustrophobia or fear of being in a confined space. Your doctor will be with you during this test and will stop the testing if this happens.

Benefits

You may not benefit directly from taking part in this study. You will receive information on blood samples and your body composition. Improvements in fat levels, body composition and health may occur. While weight loss is not the primary goal in this research, it will likely be a side effect of these diets in some individuals. You will be assigned to a group by chance, which may prove to have more or less benefits than the other study group.

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

Alternatives

The alternative is not to be a part of this research study. There are other dietary plans, commercial programs, and drugs that may improve your health. These options will not be a part of this research

study; however, they may be an alternative course of treatment for you depending on your overall health status.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with the UAB Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research like the Office for Human Research Protections (OHRP). The information from the research may be published for scientific purposes; however, your identity will not be given out.
Information relating to this study, including your name, medical record number and date of birth may be shared with the billing offices of UAB and UAB Health System affiliated entities, along with Children's of Alabama and its billing agents so that the costs for clinical services can be appropriately paid for by the study account.

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

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?

All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

Your consent form will be placed in your medical record at UAB Health System or Children's of Alabama. This may include either a paper medical record or electronic medical record (EMR). An EMR is an electronic version of a paper medical record of your care within this health system. Your EMR may indicate that you are on a clinical trial and provide the name and contact information for the principal investigator.

If you are receiving care or have received care within this health system (outpatient or inpatient), results of research tests or procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing medical record.

Results of research tests or procedures may be placed in your medical record. All information within your medical record can be viewed by individuals authorized to access the record.

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

Who may use and give out information about you?

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?

All Individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, University of Alabama Health Services Foundation, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the UAB IRB and its staff
- The billing offices of UAB and UAB Health Systems affiliates and/or Children's of Alabama and its billing agents

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the *UAB Nutrition Obesity Research Center* which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

What if I decide not to give permission to use and give out my health information?

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?

You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?

Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal

Your taking part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution.

You may be removed from the study without your consent if the sponsor ends the study, or if the study doctor decides it is not in the best interest of your health.

Costs of Participation

There will be no cost to you from taking part in this study. All exams and tests will be provided to you at no cost.

Payment for Participation in Research

You will be paid $50 per visit for participation in this study maximally two times.

Payment for Research-Related Injuries

UAB does not provide any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Significant New Findings

You will be told by study staff if new information becomes available and might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact Dr. Bhuvana Sunil at (205) 638 6456

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures:

Signature of Participant 14 Years of Age and Older Date

Signature of Parent or Guardian Date

Signature of Person Obtaining Consent Date

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____
Research Protocol: ***Effect of low carbohydrate versus low fat diet in the treatment of dyslipidemia in obese children***
UAB IRB Protocol Number:
Principal Investigator: **Bhuvana Sunil, MD**
Sponsor:

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date:

or participant's legally authorized representative: _____ Date:

Printed Name of participant's representative: _____

Relationship to the participant: _____