Official title: Effect of Low Carbohydrate Versus Low Fat Diet in the Treatment of Dyslipidemia in Obese Children with Metabolic Syndrome
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Project design:
Two-arm, parallel design with participants randomized (15 per group) to reduced-carbohydrate diet or a reduced-fat diet for 8 weeks. Anthropometric evaluations, lab work for lipid levels, insulin and C peptide levels, resting energy expenditure evaluation, DXA scan and cardiovascular markers will occur at baseline during the initial clinic visit. Individual dietary counseling will be provided at baseline and as well as weekly diet-specific support will be provided with a phone call from the PI. Dietary intake will be assessed with weekly food records (weeks 1-8). The return visit on week 8 will include a visit identical to the initial visit except the resting energy expenditure will not be revaluated, and the participants will be asked to answer a questionnaire about the diet they were on.

Diet Interventions:
Participants will receive intense nutrition counselling including an individual meeting with PI to review food journals and ensure dietary goals at baseline and at week 8. They will also receive weekly phone calls for 8 weeks to provide feedback and support, and encourage adherence to dietary prescriptions. Caloric requirements will be calculated to be weight- maintaining by using calculations after measuring resting energy expenditure (REE). The number of CHO, protein, and fat servings will be determined based on total energy requirements and diet group assignment. Each diet group will receive a food list, sample menus, and recipes. The specific characteristics of the two diets are described below.

Carbohydrate restricted diet:
This diet is designed to minimize intake of carbohydrate sources such as added sugars, high glycemic grains, and fructose. It will provide a fixed amount of carbohydrate, and a total calorie goal – with proteins and fats to satiety. Dietary CHOs are not a required macronutrient for humans. Unlike essential fatty acids and essential amino acids, human metabolism does not have an analogous "essential CHO." Although the brain requires a small amount of glucose for fuel, this can readily be produced from hepatic metabolism of protein. Therefore, reducing CHO intake will provide all essential nutrients required by children for proper growth and development.

Standard Low-fat diet:
The control, low-fat diet will contain 55:25:20 % energy from CHO: protein:fats respectively based on the total energy expenditure.

Outcome measures:
All measurements will be done at Children's hospital. Subjects will be instructed to maintain their usual activity level throughout the intervention period. All blood draws will be performed in the Children's Hospital at UAB after an overnight fast of at least 10 h.

Initial visit:

- Anthropometric measures: Weight and height will be measured to determine whether BMI meets eligibility criteria. Waist circumference will be measured by the PI Waist circumference at the midpoint between the lower margin of the least palpable rib and the top of the iliac crest, using a stretch-resistant tape. The same calibrated scale with standardized stadiometer will be used for all weight measurements.
- Blood pressure (BP) and pulse. The PI will measure blood pressure (BP) using a standardized protocol with an automated BP measurement device (Omron HEM-907). At the beginning of the visit, participants will rest quietly for five minutes in the seated position with a back-rest. An appropriately sized cuff will be applied to the right arm after measurement of arm circumference. The Omron device will be activated, and a BP measurement recorded. A second reading will be obtained after a 30-second rest period.
- Food records: A 4-day food record will be distributed during screening and collected at baseline testing to determine typical dietary intake.
- Resting energy expenditure will be estimated by indirect calorimetry
- Initial blood draw: Nuclear magnetic resonance lipoprofile assay, fasting lipid profile, fasting insulin and glucose levels (to calculate HOMA IR), C peptide levels. Additionally - comprehensive metabolic panel, thyroid function studies, creatinine kinase levels as part of standard of care for a clinic visit for dyslipidemia
- Meet with Registered Dietitian/doctor: Once all testing at baseline has been completed, the participant will meet with the PI/ dietitian for initial diet instruction who will provide acceptable food lists, serving size instruction, and recipes/menus.
- Baseline evaluation of endothelial vascular dysfunction: flow mediated dilation and Augmentation index will be measured prior to initiation of the dietary intervention
- Baseline DXA scan: Body composition assessment through DXA scan

Interval 8 weeks:
Weekly calls from the PI to ensure compliance, answer any questions or concerns during the diet prescription. Participants will be asked to maintain a food record throughout the study period

8 week return visit:
- Anthropometric measures: Weight and height will be measured to determine whether BMI meets eligibility criteria. Waist circumference will be measured by the PI Waist circumference at the midpoint between the lower margin of the least palpable rib and the top of the iliac crest, using a stretch-resistant tape. The same calibrated scale with standardized stadiometer will be used for all weight measurements.
- Blood pressure (BP) and pulse. The PI will measure blood pressure (BP) using a standardized protocol with an automated BP measurement device (Omron HEM-907). At the beginning of the visit, participants will rest quietly for five minutes in the seated position with a back-rest. An appropriately sized cuff will be applied to the right arm after measurement of arm circumference. The Omron device will be activated, and a BP measurement recorded. A second reading will be obtained after a 30-second rest period.
- Maintained food records will be collected.

- Repeat blood draw: Nuclear magnetic resonance lipoprofile assay, fasting lipid profile, fasting insulin and glucose levels (to calculate HOMA IR), C peptide levels.
- Repeat evaluation of endothelial vascular dysfunction: flow mediated dilation and Augmentation index will be measured prior to initiation of the dietary intervention
- Repeat DXA scan: Body composition assessment through DXA scan