

The Impact of Pre-Exercise Meal Composition on Metabolic Heat Production and Thermal Strain During Exercise in a Hot Environment

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The Impact of Pre-Exercise Meal Composition on Metabolic Heat Production and Thermal Strain During Exercise in a Hot Environment

The present study is being conducted by Dr. Margaret Morrissey-Basler and Dr. Brett Ely from the *Department of Health Sciences* at Providence College. The purpose of this study is to examine whether a high-protein meal before exercise in the heat increases metabolic rate and heat productions during exercise, compared to a high-carbohydrate (low-protein) meal. We will also evaluate how urinary markers of hydration, kidney function, and acute kidney injury change based on meal type (high-protein vs. High-carbohydrate) and exercise timing (before and after exercise).

You have been asked to participate since you are a male or female between the ages of 18-45 years old.

If you agree to participate, you will be asked to visit the lab four times for:

1. *Visit 1: Screening (<30 min)*. An initial visit where you can see the equipment, ask questions, and complete a brief questionnaire to see if you qualify for the study.
2. *Visit 2: Metabolic Heat Production Test (<2hr)*. Researchers will measure your height, body mass, and body composition (i.e., bones, fat mass, lean mass) using dual-energy X-ray absorptiometry (DXA) and perform a metabolic heat production test in the lab's environmental chamber (set at 96.8°F (36°C), 40% relative humidity). The metabolic heat production test is an exercise treadmill test consisting of 6 x 4-min stages and will progressively increase in speed at each stage (2.5mph, 3.0mph, 3.5mph, 4.0mph, 4.5mph, and 5.0mph). During Visit 2, we will ask you to arrive having abstained from alcohol and food (24 and 4 hours, respectively). We will ask you to come dressed in loose clothing and bring exercise clothing (running shoes, shorts, and a T-shirt) to wear during exercise in the heat. You will provide a urine sample in a sterile urine cup in a private bathroom to assess hydration status. Following the urine sample, we will ask you to provide a nude body mass in a private curtain-changing area with a body weight scale inside. The scale's reading will come outside the private curtain area for the researchers to see. You will then dress and remove all metal from your body for the DXA scan. If you are female, you will be asked to complete a waiver stating that you are not pregnant. The DXA will measure your body composition and bone density (fat, lean tissue, and bone in your body). You will lie still on the padded table and breathe normally during the 5-min scan. We will provide towels and a private bathroom for you to change into your exercise clothing. For the exercise test (metabolic heat production test), we will measure your heart rate throughout the test to ensure you feel okay. At the end of the visit, in preparation for Visit 3, you will be given a food and fluid log to complete 24 hours prior to Visit 3 & Visit 4 (see below). Visit 2 and Visit 3 will be separated by at least 3 days.

3. *Visit 3 & 4: Experimental Trials (~2hrs each).* You will report to the laboratory after an overnight fast (eat dinner the night before but no food or drink other than plain water in the morning). You will log your food and fluid intake 24 hours before you arrive for your laboratory visit. You will be asked to maintain identical dietary habits before Visit 3 and Visit 4.

When you arrive, you will first be asked to provide a urine sample to ensure you are well hydrated. We will also perform a urinalysis using testing strips (test to analyze contents of urine) to test markers of kidney function. Your urine sample will be stored to measure a measure of acute kidney injury after the collection of the study. You will then swallow an ingestible temperature pill. The ingestible pill thermistor will measure your internal temperature during your exercise test. You will be given a “No MRI” bracelet to wear after you ingest the pill. You must wear this bracelet for 24 hours and do not undergo a MRI within the 24 hour timeframe or until the pill passes.

You will then consume a randomly assigned drink (HI-PRO or HI-CHO). Each beverage is mixed with 700mL (~22 oz) of water. Beverages will be similar in taste, color, and thickness. You will be blinded to condition, which means you will not know if you are drinking the HI-PRO or HI-CHO beverage. The HI-PRO condition will consume Premier Protein Chocolate protein powder (320 kcals: 8g carbohydrate, 60g protein, 6g fat) and the HI-CHO condition will consume Generation UCAN chocolate carbohydrate powder (320 kcals: 75g carbohydrate, 3g protein, <1g fat). You will be asked to consume the drink within 10 minutes. You will then rest for 30 minutes.

After the 30-minute rest period, you will be asked to void your bladder (urinate) in the private bathroom to empty your bladder. You will then have your nude body mass measured, and you will be asked to wear a heart rate monitor and four skin temperature sensors placed on your chest, shoulder, thigh, and calf with adhesive tape. You will have your resting metabolic rate measured by laying on your back, still, and quiet outside of the chamber on a comfortable, padded table. Researchers will place a ventilated hood over you that is attached to a hose. It will not limit oxygen delivery. You will lay under the hood for 30 minutes. After the resting metabolic rate assessment, you will perform the one-hour exercise protocol in an environmental chamber.

Immediately upon entering the environmental chamber (set at 96.8°F (36°C), 40% relative humidity), you will perform a seated 10-minute passive equilibration period. This means you will sit in a chair and rest for 10 minutes. You will then walk briskly at 6 W/kg (2.5-4.5 MPH) for 60 mins. Your exact walking speed will be determined from the metabolic heat production test performed in the previous visit. During exercise, core temperature, heart rate, and skin temperature will be continuously monitored. **Fluids will not be permitted during exercise.** You will not be permitted to drink fluids because doing so will alter your sweat loss, which is a variable we are measuring. After completing the exercise protocol, you will provide a urine sample for hydration assessment, urinalysis, and acute kidney injury assessment. Your nude body mass will then be measured. Following Visit 3, you will be given another food and fluid log to log your food and fluid intake 24 hours prior to Visit 4. Visit 3 and Visit 4 will be separated by at least 3 days.

There are some minor risks associated with participation in this study. These risks include a chance of muscle soreness or fatigue from exercise (treadmill walking), feeling slightly uncomfortable during exercise in the heat (i.e., heat-related symptoms), possible stomach discomfort from the high-protein drink, and skin irritation from the adhesive tape or heart rate strap. You will be removed from the chamber and be given ice packs for cooling if your core temperature reaches 104°F (40°C). You may be uncomfortable swallowing the ingestible pill thermistor. You cannot receive an MRI within 24 hours of swallowing the pill. We will give you a “No MRI” to wear for 24 hours after swallowing the pill or until the pill passes through your gastrointestinal tract.

In your DXA scan, you will be exposed to very low amounts of x-ray radiation. A typical DXA scan results in radiation exposure between 0.01-0.07 mSv, less than what you would be exposed to during a roundtrip transatlantic flight or a chest x-ray. The amount of radiation exposure you will experience in your scan is well below the regulatory limit for radiation exposure to the public and well below levels thought to result in any significant risk of harmful effects. There is no data to suggest that lactating women are more susceptible to radiation exposure than the general public.

There are no direct benefits from participating in this study. The outcomes of this study will be a necessary first step to determine whether nutrient composition influences metabolic heat production/rate and thermoregulatory outcomes. The study’s results will help inform nutrition recommendations before exercising in the heat. You will have the option to review your results after completing the study. The data will provide you with information regarding your body composition and thermoregulatory responses. The benefits of the study outweigh the minimal risks.

You will earn \$100 for completing the study, as compensation for your time and inconvenience. You will receive \$20 dollars for completing Visit 2 and \$40 each for completing Visit 3 and 4.

Your responses during the study are anonymous. Each participant is assigned a number and the names are in no way associated to the numbers. We do not collect any information about your personal identity. All responses are confidential and are stored on a password-protected computer. Only the Principal Investigators and students working on the project will have access to data. Finally, we are only interested in participants’ responses in aggregate and therefore do not analyze individual responses.

Your decision to participate is entirely voluntary. You are free to end your participation (i.e., stop the experiment) at any time without penalty (i.e., you will still be paid a pro-rated amount). The experimenter also reserves the right to end your participation in the study at any time. Finally, you have the right to request that your data not be used.

You are free to ask questions at any time during the study. If you have concerns about your experiences in the study and/or your rights as a participant, please contact the Providence College IRB via e-mail at irb@providence.edu or you may contact the Principle Investigators (Margaret Morrissey-Basler, mmorris17@providence.edu; Brett Ely, bely@providence.edu) or phone (*Margaret Morrissey-Basler, 401-865-1209; Brett Ely, 401-865-2632*).

Your signature on this form indicates that you have read and understand the form, the general procedures of the study, and agree to participate in the study. You will be given a copy of this form to keep for your records.

Participant's Name: _____

_____ I confirm I am 18 years of age or older and can consent to participation in this study.

Participant's Signature: _____ Date: _____