STUDY TITLE: The Impact of Buoy on Hydration Status of Active Men and Women

IRB: STUDY22090018

NCT05768789

Consent Form: 06 FEB 2024

UPMC LIFE CHANGING MEDICINE

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: The Impact of Buoy on Hydration Status of Active Men and Women

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Locations: **(1.)** UPMC Presbyterian Hospital
200 Lothrop Street 15213
Pittsburgh, PA
(2.) UPMC Montefiore Hospital
3459 Fifth Avenue
Pittsburgh, PA 15213

Key Information:

You are being asked to take part in a research study. Research studies are voluntary and only include people who are eligible and choose to take part. The study team members are available to you to explain the study and will answer any questions you might have. You should take your time and ask questions before you decide.

The purpose of this study is to evaluate the use of Buoy in hydrating active adults. Buoy is an all-natural, organic, FDA-compliant dietary electrolyte supplement that can be dissolved in 8-12 ounces of water (or other liquid) and provide electrolytes in servings of 1/3 teaspoon.

This study is a prospective, cross-over, placebo-controlled clinical trial. All studies will be repeated in the same subject using either Buoy (intervention), water (control) or Nuun (intervention). Nuun is an electrolyte tablet added to water used to improve hydration.

Why is this research being done?
This research is being done to evaluate the use of Buoy in hydrating active adults, as compared to Nuun (intervention) and water (control).

Who is being asked to take part in this research study?
You are being invited to participate in this research study because you are a healthy volunteer who is physically active (can walk up a flight of stairs) and meets all other inclusion criteria.

What procedures will be performed for research purposes?
If you agree to take part in this study, you will participate in three separate visits, each using a different type of hydration supplement, including Buoy (intervention), Nuun (intervention), and water (control).

Prior to initiation of the study, you will complete a screening visit. The screening visit will be performed over the phone. . We will obtain your health history. The history for females will include your last date for menstruation and/or birth control method.

Prior to initiation of study procedures during the first study visit, a urine test will be performed for eligibility by looking at the results for blood, protein, glucose, creatinine, and electrolytes. Females will also be administered a urine pregnancy test. We will also measure your heart rate, blood pressure, height, and weight. These results will be used to confirm study eligibility.

For each study visit, you must refrain from vigorous exercise within 24 hours of study visit. Vigorous exercise is defined as exercise that raises your heartrate and causes you to breath heavy. This includes activities such as running, cycling and singles tennis. In the morning of each study visit, you will be asked to empty your bowel and bladder upon waking up. We will also ask you to fast, or not consume food, overnight for 10 hours prior to your study visit. You may consume one 8oz cup of coffee or tea (plain with no sugar or additives) prior to the study visit. Each study visit will begin at 8am and last approximately 6 hours. You will be asked to remain fasting throughout the study visit.

At the beginning each visit, your vitals will be measured, including blood pressure, heart rate, weight, and bioimpedance, which is a method to estimate body composition. We will also draw up to 1 ml of blood, which is equal to less than a quarter of a teaspoon.. The visits will be conducted with the study team and the assistance of a phlebotomist to complete blood draws. For Visit 2 and Visit 3, you will be asked to review your medical history and any change in status that may warrant an additional baseline creatinine and blood/protein test to confirm eligibility.

Each study visit will be repeated in the same way using either Buoy, water, or Nuun. Urine will be collected at four specific timepoints during the intervention and the volume will be recorded. If you need to urinate between scheduled collection times, your urine will be collected, volume recorded, and combined with the urine collection of the following timepoint. Your urine samples will be measured and sent to the lab to be tested for electrolytes. Urine creatinine will also be tested at these timepoints.

At Study Visit 1, you will be asked to drink Buoy over the course of 4 hours. At Study Visit 2, you will be asked to drink water over the course of 4 hours. At Study Visit 3, you will be asked to drink Nuun for the first 30 minutes of the visit and then water for the rest of the visit. Participants will be provided with a boxed lunch at the completion of the study procedures of each visit.

What are the possible risks, side effects, and discomforts of this research study?
There are risks associated with your participation in this research study.

Potential risks include:

- Drinking Buoy and Nuun: dislike of the taste and nausea.
- Fasting: headaches, dizziness, hunger and fainting.
- Water intoxication may occur if consuming 4-5 L of water in a few hours. Symptoms include headache, cramping, weakness, nausea, vomiting, drowsiness, and fatigue. To avoid this, we will limit free water intake to no more than 1 L per testing day.
- Blood draws: bruising, hematoma and fainting.
- Your medical record will be accessed by the study team. All your medical record and study-related information will be considered protected health information and will be kept confidential per HIPAA privacy act. There is, however, a possibility of breach of confidentiality. That is, in very rare cases, people not associated with this research study may inadvertently see your identifiable research results. We will do everything in our power to prevent this from happening by keeping all research records in locked files and identify all medical information by a research record number, rather than by your name or social security number. The codebook containing your name and number will be kept secure by the study team.

You can speak with the study team if you have questions or concerns regarding the implications and frequencies of each risk.

What are possible benefits from taking part in this study?
There are no intended potential benefits to taking part in this study.

If I agree to take part in this research study, will I be told of any new risks that may be found during the study?
You will be promptly notified if, during the conduct of this research study, any new information develops which may cause you to change your mind about continuing to participate.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?
Neither you, nor your insurance provider, will be charged for the cost of the procedures performed only for the purposes of this research study.

Will I be paid if I take part in this research study?

You will receive a compensation of $300 following the completion of three visits.

Payment to participants is considered taxable income regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a "Form 1099 – Miscellaneous" with the IRS and provide a copy to the taxpayer. We are required to give your name and social security number to the Accounting Office. Participants who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 76% of the expected payment.

Who will pay if I am injured as a result of taking part in this study?
University of Pittsburgh researchers and their associates who provide services at UPMC recognize the importance of your voluntary participation in their research studies. These individuals and their staff will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research.

If you believe you are injured as a result of the research procedures being performed, please contact the Principal Investigator listed on the first page of this consent form immediately. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

Who will know about my participation in this research study?
Any information about obtained from this research will be kept as private as possible. All records related to your involvement in this research study will be stored in a locked file cabinet. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of the research results. We will make every attempt to protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University

Will this research study involve the use or disclosure of my identifiable medical information?
As part of this research study, we are asking your permission to use your medical records to see if you are eligible to be in this study, as well as to support other data collected in the study. This permission does not expire. We will collect the following information: age, BMI, past medical history, and results of any blood and/or urinalysis tests that were already done as part of your standard medical care.

As part of this study, some research results from testing we do with you will be placed into your medical records held at UPMC. These tests include: urinalysis.

This medical record information, which includes your name, is available to members of the research team for an indefinite period.

You can withdraw your permission to allow the research to team use your information from your medical records. You can do this by sending a request in writing to Dr. Subramanian listed on the first page. If you do so, you will be withdrawn from this study since your medical information is a critical part. The research team will continue to use information collected from you or your records up to that point.

De-identifiable data, meaning data that does not include identifying information such as your name or MRN, may be shared with others inside and outside of the University who are conducting similar research.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US 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 will have access to identifiable information related to my participation in this research study?

In addition to the investigators listed on the first page of this authorization (consent form) and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study.

- Authorized representatives of the study team, who are also part of the Department of Anesthesiology and the Acute Interventional Perioperative Pain Service, will review and/or obtain identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data.
- Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for the purpose of ensuring the appropriate conduct of this research study.
- Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (e.g., quality assurance).

- In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.
- Your data and specimens used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?
The investigators may continue to use and disclose, for the purposes described above identifiable information (which may include your identifiable medical information) related to your participation in this research study for an indefinite period of time.

Also, per the University of Pittsburgh policy all research records must be maintained for at least 7 years following final reporting or publication of a project.

May I have access to my medical information that results from my participation in this research study?
The results of testing performed under this research study will not be included in your medical record. You have the right to access information that is in your medical record. However, results from testing done purely for research purposes may not be put into your medical record and will not be provided to you because it is only being conducted for research purposes..

Is my participation in this research study voluntary?
Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the UPMC.

May I withdraw, at a future date, my consent for participation in this research study?
You may withdraw, at any time, your consent for participation in this research study. Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that your formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh or UPMC.

VOLUNTARY CONSENT

The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during this study, and that such future questions will be answered by a qualified individual or by the principal investigator listed on the first page of this consent document at the telephone number given. I understand that I may always request that my questions, concerns, or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations if the research team is unavailable.
By signing this form, I agree to participate in this research study and to authorize Dr. Subramanian and the members of his research team to access my medical records and extract research data from them, as described in this document. A copy of this consent form will be given to me. Also, I further certify that no research component of this protocol was begun until after the consent form was signed.

_____
Participant's Signature

_____ _____
Printed Name of Participant Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____
Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date