Brief Title: Satiety and Alcohol Challenge
NCT Number: NCT06576674
Unique Protocol ID: 24-1095
Date: 06/26/2024

University of North Carolina at Chapel Hill
Consent to Participate in a Research
Study Adult Participants

Consent Form Version Date: 6/26/2024
IRB Study # 24-1095
Title of Study: Responses to alcohol and biomarkers of health

Principal Investigator: Jimikaye Courtney
Principal Investigator Department: Exercise and Sport Science
Principal Investigator Phone number: 919-445-1520
Principal Investigator Email Address: heallab@unc.edu

_____

CONCISE SUMMARY

This study is designed to measure responses to alcohol and health related biomarkers in the laboratory, as well as alcohol drinking behavior outside the lab using a breathalyzer and a wrist monitor to measure alcohol exposure through perspiration (aka transdermal alcohol concentration).

Participation will include two 5-6 hour visits to our lab, a 7-day field study, and a brief 30-minute follow-up study visit. The lab visits will involve taking a dietary supplement (green tea extract and a dietary fiber) or placebo followed by alcohol, questionnaires, and a cognitive task to measure your response to alcohol, and two blood draws and three finger pricks to measure biomarkers. The 7-day field study includes wearing an alcohol monitor on your wrist, completing daily surveys via your smartphone, and using a breathalyzer every 30 minutes while drinking. The follow-up visit will last 30 minutes and will include surveys, body composition measures, and return of the wrist monitor and breathalyzer. If you participate in the study, you may be compensated up to $230.00 for your time.

The risks involved with this study are minimal but may potentially include emotional stress related to survey questions and body composition measures, gastrointestinal discomfort related to a dietary supplement, bruising from the blood draw, risks related to drinking alcohol, or a loss of confidentiality. Participants will also be exposed to a small dose of radiation, less than a tenth of a chest X-ray.

If you are interested in learning more about this study, please continue to read below.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to evaluate responses to alcohol in and outside a laboratory setting among people with different alcohol drinking patterns and the potential role of appetite and inflammation related biomarkers as they relate to alcohol consumption. Results of this study may improve our knowledge of how health behaviors, like diet and alcohol use, interact with one another in impacting risk for obesity and inflammation.

You are being asked to be in the study because you are between the ages of 21-44 and reported recent alcohol use.fas

Are there any reasons you should not be in this study?

You should not be in this study if you are currently seeking or receiving treatment for alcohol use, or actively trying to quit drinking alcohol, pregnant or trying to become pregnant, currently use GLP-1 medication, have a history of diabetes, or are taking medication which you cannot take while drinking alcohol.

How many people will take part in this study?

Approximately 55 people will take part in this study.

How long will your part in this study last?

Your part in this study will last approximately two weeks. In the first week you will complete surveys at home that last about 20 minutes and two 5-6 hour long lab sessions. During the second week you will participate in a 7-day field protocol that requires approximately 6 minutes of your time per day, with some additional time on days you drink alcohol, and a final lab visit that requires about 30 minutes of your time. Overall, we estimate the study will require approximately 16 hours of your time.

What will happen if you take part in the study? If you decide to participate in this study, you be asked to come to the BAR Lab in medical school wing D for two 5-6 hour alcohol lab visits and an introduction to the 7-day field study (end of visit 2). For the follow-up visit, you will be asked to come to the HEAL Lab in Fetzer Hall (room G416) on UNC-Chapel Hill's campus for a DEXA scan. You will first be asked to sign a consent form (this form) before participation begins.

Baseline Surveys - ~20 minutes: Following enrollment, you will be asked to complete a series of electronic surveys at the time and location of your choice. A link to these surveys will be emailed to you.

BAR Lab Visits – ~5-6 hours/visit: Two lab visits are scheduled within the first week (ideally 2-3 days apart). The purposes of these visits is to examine potential effects of a dietary supplement (or control) on responses to alcohol. Participants will be asked to consume a beverage containing either a dietary supplement (10g Fibersol®-2 mixed with water and aspartame sweetener for taste + 725mg decaffeinated green tea extract capsule) or a calorically matched control supplement (Aspartame sweetener mixed with water + aspartame capsule). You have an equal chance of receiving the supplement first or placebo first.

Then you will be asked to consume drinks which may or may not contain alcohol. On sessions where alcohol is consumed, the drinks will contain vodka and a cranberry juice mixer, using an amount intended to raise your blood alcohol concentration (BAC) to a target of .06g% (roughly 2-3 standard drinks for most people of average weight). Alcohol will be consumed in 5 mini-drinks paced out over a period of 2 hours. We will

monitor your breath alcohol level (using a breathalyzer) and ask you to complete questionnaires after each drink. After the drinking period is over, we will continue to monitor your breath alcohol level until your BAC reaches a safe level. During this time you will be provided with snacks, water, and allowed to use the things you brought with you to pass the time in private room.

Because you will be asked to consume alcohol at these visits, you will be asked to spend most of the day (e.g., 9am-3pm) on site. Therefore, we ask that you do not schedule any outside appointments or commitments on these days, and bring reading or other materials to keep busy during breaks. You will also be provided with options to watch movies.

We will ask you not to consume alcohol or use recreational drugs within 24 hours of these visits, and not to eat for 4 hours before arriving at UNC. Upon arrival, you will be asked to take a breath alcohol reading that morning to confirm recent abstinence from alcohol. For females, a urine pregnancy test will be conducted.

At the conclusion of the second lab visit, the researcher will orient you to the at home portion of the study.

Device-Training: You will be trained on how to use the devices and apps for the study. The first device is the BACtrack Skyn, which is an alcohol monitor that will be worn on your wrist like a wristwatch. The second device is the BACtrack S80, which is a breathalyzer that you will use when you are actively drinking alcohol. We will explain how to download and use two smartphone applications. The first is the BACtrack Skyn application and will be used to sync data from the BACtrack Skyn to the cloud. The second is LifeData, an application you will use to complete morning and drinking event surveys on your phone.

At-home portion of the study (7 days) - ~45 minutes: You will be asked to wear the BACtrack Skyn that will be attached to your wrist, except when showering/bathing/swimming. Complete a short, 3-minute questionnaire each morning that will ask about your past day alcohol use. On days you drink alcohol, you will be asked to use the BACtrack S80 breathalyzer to report your breath alcohol concentration every 30 minutes while drinking and for up to four hours after you start drinking. You will also be asked to complete brief phone surveys every 30 minutes while drinking.

Follow-Up HEAL Lab Visit - ~ 30 minutes: Following the 7-day field protocol, you will be asked to return to the lab to complete a single survey and to return the BACtrack Skyn and S80 devices. At this visit you will also undergo a dual energy x-ray absorptiometry (DEXA) scan: The DEXA uses two, low-dose x-ray beams to measure differences in composition of different tissues in the body such as bones, muscle, and fat. The scan is performed while you are resting on your back and takes approximately 5-15 minutes.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study, but you will be able to obtain the results of your body composition measurements and blood biomarkers. You may also learn more about your alcohol use behaviors due to answering daily surveys about those behaviors and monitoring your breath alcohol during drinking events.

What are the possible risks or discomforts involved from being in this study?

The risk of physiological or psychological harm is very minimal. However, a research study that measures alcohol use and body composition has the potential risk of emotional stress and/or embarrassment. Discussing the results in a private setting will minimize risk. Additionally, there is a minimal risk (< 1%) of infection due to the blood draws. Trained personnel will conduct all procedures and the site of blood draws will be cleaned appropriately prior to data collection. The risk of legal harm is very minimal. However, a research study that collects measures of alcohol use and illegal drug use has potential legal risks. We take

measures to maintain confidentiality of all data to minimize these risks and this study is protected by a Certificate of Confidentiality.

Alcohol consumption. There are potential risks related to the alcohol sessions. The effects of alcohol intoxication may lead to temporary symptoms such as dizziness or impairment in motor coordination. You could experience hangover-like symptoms (e.g., headache) after the alcohol session. It is important to remain at the study site until your BAC reaches 0 and the study team determines that it is safe to leave. If you arrive to an alcohol session with a positive breath alcohol reading, the visit will be postponed and you may be excluded from further participation. If you have driven to the session and arrive with a positive breath alcohol level, you will be asked to remain on site until your breath alcohol reading has reached zero.

Please initial below to indicate your agreement with these safety precautions for the alcohol sessions.

___ At alcohol sessions I agree to remain on site until the study team decides it is safe to leave.

Alcohol can cause birth defects if you are pregnant. Additionally, alcohol can be transferred via breastmilk to infants/toddlers. Therefore, you should not take part in this study if you are potentially pregnant, trying to conceive, or currently lactating.

All data collection methods carry the risk of loss of privacy or confidentiality. We will take steps to minimize risk to you. Our data collectors are trained in the importance of protecting confidentiality. Your data will be kept in a storage cabinet in a locked laboratory or stored on a secure computer database. We do not expect any breach of patient confidentiality since your record will not be shared with anyone outside the research team. No one will be identified in any report or publication resulting from this study.

This research study involves exposure to radiation from one dual energy X-ray absorptiometry (DEXA) scan. Please note that this radiation exposure is not necessary for your medical care and is for research purposes only. For comparison, the average person in the United States receives a radiation exposure of 0.3 rem (or 300 mrem) per year from natural background sources, such as from the sun, outer space, and from radioactive materials that are found naturally in the earth's air and soil. The dose that you will receive from participation in this research study is less than amount you receive from these natural sources in one year. The amount of radiation you will receive in this study has a minimal risk and is below the dose guideline established by The University of North Carolina Radiation Safety Committee for research subjects.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

Safety Precautions: Several safety precautions will be in place while you participate. On days involving alcohol we will verify that your breath alcohol level reaches a safe level before you leave the lab. We will ask that you do not drive to the study site on alcohol session days, and will help you to determine alternative ways to get home. If you choose to drive we will ask that you sign an acknowledgment indicating that the study team will be in possession of your car keys until your BAC reaches 0 and it's safe to drive.

Pregnancy Test (for women only): As a safety precaution, women will be asked to complete a pregnancy test at the beginning of the study, and at scheduled study visits. Participants will not be charged for the pregnancy tests. If you are planning to become pregnant during the next 6 months, or if you are sexually active and not using a reliable birth control method, you should notify the research team, and you will not be eligible to participate. There are no risks associated with the pregnancy tests. However, if your pregnancy test is positive, you will no longer be eligible to participate in the study. The results of your pregnancy test will

remain confidential; no one else will receive the results of your pregnancy test.

What if we learn about new findings or information during the study?
You will also be informed of any significant new findings that become available during the study.

Will I receive any other clinical results?

Other clinically relevant results of this research will be communicated with you. We will share your lean mass and fat mass results at the end of your study visit.

How will information about you be protected?
Your data will be kept in a storage cabinet in a locked laboratory or stored on a secure computer database. We do not expect any breach of patient confidentiality since your record will not be shared with anyone outside the research team. You and your associated information will be identified by a 4-digit alpha-numerical identification code. You will be identified by this code only when labeling any data collection sheets or computer printouts. Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

Your biospecimens will not be used for commercial profit.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

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 an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you self-report becoming pregnant, you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?
You will be receiving up to $230 for taking part in all components of this study. Details on study payment information are below:

$20 for baseline surveys, $50 for lab visit one, $50 for lab visit two, $70 for all 7-day EMA study procedures ($8/day for Skyn wear, $2/day for morning surveys), $10 for device return, $10 for follow-up questionnaires, $10 for DEXA scan, and $10 study completion bonus.

Partial completion of a study requirement may be prorated at $10/hr. for study visits, $0.25 for each daily survey you complete, or $0.50 for each day the BACtrack Skyn wrist monitor is worn.

Payment will be in the form of an electronic gift card. Any payment provided for participation in this study may be subject to applicable tax withholding obligations.

Will it cost you anything to be in this study?

Participants may experience a cost of transportation to and from study visits, loss of time at work and/or childcare. All procedures included in the study (i.e., body composition, blood biomarkers) are for research only purposes and not for clinical purposes. There will be no cost to participants for the research procedures.

What if you are a UNC student?

You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades at UNC-Chapel Hill. You will not be offered or receive any special consideration if you take part in this research.

What if you are a UNC employee?

Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

___ I agree to participate in this study.

___ I do not agree to participate in this study.

_____
Signature of Research Participant

_____
Date

_____
Printed Name of Research Participant

_____
Signature of Research Team Member Obtaining Consent

_____
Date

_____
Printed Name of Research Team Member Obtaining Consent

_____
Signature of Witness, if applicable (e.g., literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form)

_____
Date

_____
Printed Name of Witness