

Georgia State University
Informed Consent

Title: Biphasic Effects of Acute Alcohol Intoxication on Bystander Intervention for Sexual Violence

Principal Investigators: Ruschelle M. Leone, PhD

Co-Investigators: Amanda Gilmore, PhD; Cynthia Stappenbeck, PhD

Sponsor: National Institutes of Health/National Institute of Alcohol Abuse and Alcoholism

Introduction and Key Information

- You are invited to take part in a research study. It is up to you to decide if you would like to take part in the study.
- The purpose of this study is to understand how gender and alcohol impacts people's views of social situations.
- Your role in the study will last up to 8 hours.
- You will be asked to do the following:
 - Complete one lab visit where you will answer questions online about alcohol use, social behavior, beliefs, and attitudes.
 - You will be asked to drink orange juice only or orange juice mixed with alcohol.
 - You will be asked to read about a social situation and talk aloud about your thoughts and feelings. You will answer questions on what you would do in the situation. The study will be over after this task. If you drank alcohol, you will be asked to stay in the lab until you pass a field sobriety test and your blood alcohol level decreases to .04%. This may take up to 8 hours.
 - The risks of being in this study include: 1) potential discomfort with drinking alcohol, 2) potential discomfort when reading about a social situation, and 3) leaving the lab after consuming alcohol.
 - This study is not designed to benefit you. Overall, we hope to learn more about how gender and alcohol influence the way people think in social situations that involve alcohol use.

Purpose

The purpose of this study is to understand the how alcohol and gender impacts people's views of social situations. You are invited to take part in this research study because you 1) are between the age of 21 and 30, 2) drink alcohol, 3) are not seeking treatment or in recovery for alcohol or substance disorder, 4) are not taking any medications that interact with alcohol, 5) do not have any psychiatric conditions, and 6) if female, have not had sexual intercourse in the last two weeks without protection. To participate, you cannot have taken any drugs or alcohol within the last 12 hours. You cannot have eaten food within the last four hours. We expect a total of 242 people to participate in this study.

Procedures

If you decide to take part, you will participate in one lab visit that lasts up to 8 hours.

- To confirm eligibility, you will be asked to show a photo ID, breathe into a breathalyzer, and answer a few questions about your history. If you are female, you will also self-administer a pregnancy test.
- You will take a 45-minute online survey to answer questions about your alcohol use, social behavior, beliefs, and attitudes.
- You may consume orange juice or a .71 g/kg dose (men) or .65 g/kg dose (women) of alcohol mixed with orange juice. This is about 2-3 mixed drinks. This dose should increase your blood alcohol level to about .08%, which is the legal limit for driving a car. It poses no health risk for a healthy drinker. You will be monitored via a live feed video after you receive your drink until the end of your time in the lab. After you are done drinking alcohol, we will wait for the alcohol in your system to take effect. You will be assigned to either wait about (1) 5 to 20 minutes or (2) 1 to 1.5 hours before beginning the next task. You will be given a breath test to determine the amount of alcohol in your system. These breath tests will be taken several times while you are in the lab to monitor the level of alcohol in your body.
- You will read about a social situation. This social situation involves sexual content. You will be asked to talk aloud during certain points. You will be asked to share your thoughts and feelings on the situation. This will be audio-recorded. You will also be asked to answer questions about this situation on the computer. This will take about 50 minutes.
- If you drank alcohol, you will still be drunk at that time. So, you will need to wait in the lab until you pass a field sobriety test and your blood alcohol level decreases to .04%. You will not be paid until you pass. This may take up to 8 hours. For your comfort, you will be seated in a room with a TV. You will be offered a full meal, nonalcoholic beverages, and other snacks.

Future Research

Researchers may use your data for future research. They will remove information that may identify you. If we do this, we will not ask for any additional consent from you.

Risks

Drinking alcohol may cause you to feel nauseous or dizzy. If you experience these effects, please tell the experimenter. You may also experience discomfort when reading or answering questions about social situations. There is the possibility of risks if you leave the lab after consuming alcohol.

No injury is expected from this study. If you believe you have been harmed, contact the research team as soon as possible. Georgia State University and the research team have not set aside funds to compensate for any injury.

Benefits

This study is not designed to benefit you. We hope to learn about how gender and alcohol impact what people do in certain social situations that involve alcohol.

Alternatives

The alternative to taking part in this study is to not take part in the study.

Compensation

You will receive \$15 per hour for participating in this study. You may earn up to \$120. Payments will be sent via digital Amazon gift cards.

Voluntary Participation and Withdrawal

You do not have to be in this study. If you decide to be in the study and change your mind, you have the right to drop out at any time. You may skip questions or stop participating at any time. You may refuse to take part in the study or stop at any time. This will not cause you to lose any benefits to which you are otherwise entitled.

Confidentiality

We will keep your records private to the extent allowed by law. The following people and entities will have access to the information you provide:

- Dr. Leone and her research staff
- GSU Institutional Review Board
- Office for Human Research Protection (OHRP)
- National Institute on Alcohol Abuse and Alcoholism

We will use a study number rather than your name on study records. The information you provide will be stored a locked filing cabinet as well as password- and firewall-protected computers. The questions you fill out will also be stored on Qualtrics. Data sent over the Internet may not be secure. However, no information that links your name to your answers will be recorded on this website. Your interview will be audio recorded. This will be kept in a password-protected file. We will type out your interview and remove any personal information. Once we do this, your audio recording will be deleted. When we present or publish the results of this study, we will not use your name or other information that may identify you.

Deidentified data from this study will also be submitted to the National Institute on Alcohol Abuse and Alcoholism Database (NIAAADA) at the National Institutes of Health (NIH). Deidentified data means that all personal information about you (such as name and phone number) is removed and replaced with a number. Other researchers will be able to request access to the data; however, your identifying information will not be connected to the data, and anyone with access to the data must promise to keep your data safe, and they must not try to learn your identity. Although researchers and NIH will make every attempt to protect your identity, your data could be accidentally shared with someone without approval who may attempt to learn your identity.

You may decide now or later that you do not want your deidentified data to be added to the NIAAADA. You can still take part in this research study even if you decide that you do not want your data to be added to the NIAAADA. If you know now that you do not want your data in the NIAAADA, you may opt out on the next page. If you decide any time after today that you do not want your data to be added to the NIAAADA, please call or email the study staff. They will tell NIAAADA to stop sharing your data. Once

your data is part of the NIAAADA, the study researchers cannot take back the data that was shared before they were notified that you changed your mind. For more information about NIAAADA, visit <https://nda.nih.gov/niaaa>.

To help us protect your privacy, we have a Certificate of Confidentiality from the NIH. With this Certificate, we cannot be forced by a court order or subpoena to disclose information that could identify you in any civil, criminal, administrative, legislative or other proceeding.

There are circumstances where the Certificate does not protect against disclosure of your personally identifiable information:

- When the US government is inspecting or evaluating federally-funded studies
- When information must be disclosed to meet FDA requirements
- If you give someone written permission to receive research information or voluntarily disclose your study information
- If the researcher reports that you threatened to harm yourself or others
- In cases of child abuse reported by the researcher
- If the investigator reports cases of contagious disease (such as HIV) to the state

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 Web site will include a summary of the results. You can search this Web site at any time.

Contact Information

Contact Dr. Leone at 404-413-1537 or rleone1@gsu.edu

- If you have questions about the study or your part in it
- If you have questions, concerns, or complaints about the study
- If you think you have been harmed by the study

The IRB at Georgia State University reviews all research that involves human participants. You can contact the IRB if you would like to speak to someone who is not involved directly with the study. You can contact the IRB for questions, concerns, problems, information, input, or questions about your rights as a research participant. Contact the IRB at 404-413-3500 or irb@gsu.edu.

Consent

Please initial each statement below with which you agree:

I have not consumed drugs or alcohol within the last 12 hours

I have not eaten food within the last four hours

*I have not engaged in unprotected vaginal sex within the last two weeks, that is, sex without an effective form of contraception.**

**Effective forms of contraception include hormonal birth control (e.g., pill, ring) or non-hormonal birth control (e.g., natural cycles, condoms)*

I understand that drinking alcohol while also taking any drugs or unreported medications is a health risk

Deidentified data from this study will also be submitted to the National Institute on Alcohol Abuse and Alcoholism Database (NIAAADA) at the National Institutes of Health (NIH). Deidentified data means that all personal information about you will be removed and replaced with a number. Your name, birthdate, birth city, and phone number will be used to generate a study number

Legal First Name: _____

Legal Middle Name: _____

Legal Last Name: _____

Date of Birth: _____

Birth City: _____

If you do not want to provide the information above for the NIAAADA, you can leave this section blank. Your data will still be included in the database, but this information will not be used to create a code for your data.

If you would like to opt out of providing your information to the NIAAADA, initial here: _____

We will give you a copy of this consent form to keep. If you are willing to volunteer for this research, please sign below.

Printed Name of Participant

Signature of Participant

Date

Principal Investigator or Researcher Obtaining Consent

Date