COVER PAGE

Official Study Title: Acute Use of Alcohol and Attentional Bias Towards Suicide: An Experimental Test of the Attention-Allocation Model

NCT number: NCT04276779

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CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research: The Effects of Alcohol and Mood on Attention
UAB IRB Protocol #: IRB-300004892
Principal Investigator: Caitlin Wolford Clevenger, Ph.D.
Sponsor: UAB Department of Psychiatry and Behavioral Neurobiology

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to examine the effects of alcohol and mood on attention. We are also interested in how people's beliefs and social and medical histories might influence the effects of alcohol and mood on attention.
Duration & Visits	You will be in this study for a total of two visits. The first visit will last approximately 1.5 hours. The second visit will last between one and ten hours.
Overview of Procedures	During the first visit, you will complete questionnaires on paper and a computer. You will also provide urine for a pregnancy test (if indicated) and height and weight measurements to ensure you can safely drink alcohol. You will also provide a sample for a drug screen. During the second session, you will complete a breathalyzer test, another pregnancy test (if indicated), and questionnaires to confirm your eligibility. You will then consume approximately 3-4 mixed alcoholic beverages and a task designed to induce positive or negative mood. You will then complete brief questionnaires about your mood and computerized measures of attention. After these tasks, you must remain in the lab until your breath alcohol concentration lowers to $\leq$ .03 and you pass a field sobriety test. This can take several hours. We will provide you a meal, snacks, nonalcoholic beverages, and access to entertainment (e.g., Netflix) for your comfort while you wait. When you are able to leave, you will be required to get a ride home from someone or take a cab home (for which we will pay) to ensure you arrive home safely.
Risks	You may experience discomfort when answering sensitive questions about yourself and when participating in the mood induction. These are temporary discomforts that will pass quickly. The second risk is discomfort from drinking alcohol, including feelings of nausea or dizziness. Third, your blood alcohol level will be above the legal limit. If you leave the study prior to your blood alcohol level decreasing, you may put yourself at risk for physical, emotional, or legal harm.
Benefits	You may or may not benefit from this study. At the end of the study, you will receive educational information about alcohol use and may be provided with referrals for alcohol and mental health treatment. The main benefit is to society, as this study will inform our understanding of the effects of alcohol on mood and attention.
Alternatives	You are not required to participate and there is no penalty for not participating. The only alternative to participation is to not participate.

Purpose of the Research Study

The purpose of this research study is to examine the effects of alcohol and mood on attention. We are also interested in how people's beliefs and social and medical histories might influence the effects of alcohol and mood on attention. You are being asked to participate because you are between the ages of 21 and 65, are generally healthy and without mental health problems or significant distress, and you are able to safely consume alcohol (i.e., not in treatment or recovery from drug or alcohol use disorders or abstaining from alcohol, have consumed alcohol before, and do not have any medical problems or are taking medications that would make drinking alcohol

unsafe). This is not a treatment study; you will not be receiving treatment as part of this study. We plan to enroll 260 participants at UAB.

Study Participation & Procedures

This study will involve two sessions, one that lasts about 1.5 hours and one that lasts up to ten hours.

Session 1

Session 1 will take place in our office at Chauncey Sparks Center Room 1001. Upon arrival to the lab, you will complete a pregnancy test (if you are assigned female sex at birth and have had penetrative sex with someone assigned male sex at birth) and provide weight and height measurements to ensure you can safely drink alcohol. You will also complete a urine drug screen so that we will know more about your medical history – if you test positive for any drug other than just cannabis (marijuana), you will be ineligible and will not be able to continue to Session 2. Following these tests, you will then complete questionnaires that ask questions about your thoughts, drinking patterns, and medical history. You will answer these questions on paper and on a computer. You will be paid $20 for this session. If eligible following Session 1, you will be scheduled for a second session. If you test positive on the pregnancy test or drug screen (excluding cannabis), you will not be eligible to continue in the study.

Session 2

Before Session 2, we will ask that you **not drink alcohol or use drugs in the 12 hours prior to the session or eat any food in the 4 hours prior to the session**. We will also ask that you arrange transportation to the second session, as you will not be able to drive yourself home following the study due to consuming alcohol. Session 2 will also take place in Chauncey Sparks Center Room 1001. If you are assigned female sex at birth and have had penetrative sex with someone assigned male sex at birth, you will have to complete another pregnancy test; if positive, you will be dismissed from the study. You will also be asked to compelte another urine drug screen. If you test positive for any drug other than just cannabis (marijuana), you will be dismissed from the study. You will complete brief questionnaires about your thoughts and feelings, any changes in your medical status, and whether or not you have eaten in the past four hours or used drugs or alcohol in the past 12 hours. We will also have you complete a breath alcohol test to ensure you have not been drinking that day. If you have consumed food within 4 hours, or alcohol or marijuana within 12 hours of Session 2, we will reschedule your appointment. Finally, you will complete a field sobriety test for comparision following the study procedures. These procedures will take approximately 30 minutes.

Next, you will consume .99 g/kg dose (assigned male sex at birth) or .90 g/kg dose (assigned female or intersex at birth) of alcohol mixed with club soda and flavored water mix (equal to 3-4 mixed drinks in a bar). This dose should increase your blood alcohol level to about .10%, which is above the legal limit for driving a car. However, it poses no health risk for a healthy drinker. After you are done drinking alcohol, we will wait about 5 to 20 minutes for the alcohol in your system to take effect. You will then 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. Then, you will complete brief, paper questionnaires about your feelings. Using a randomization scheme (like flipping a coin), you will be randomly picked to complete a task designed to induce positive or negative mood. In this task, you will listen to music and read statements that are designed to induce either positive or negative mood. This task will last about 10 minutes. You will then answer a few more brief questions on paper about your feelings, which will take about 5 minutes, followed by two visual speed computer tasks that will take about 10 minutes each. In one task, you will identify colors of words. Next, you will match paired words on a computer screen by pressing keys on a keyboard. After these tasks, you will complete a few more questionnaires about how you are feeling, which will take less than five minutes.

After completing these final questionnaires, the study will be over. However, you will still be drunk at that time. You will need to wait in the lab, and will not be paid, until you pass a field sobriety test and your breath alcohol level decreases to .03%. This may take up to 7 hours. For your comfort, you will be seated in a room with access

to internet, media, and magazines. You will be offered a full meal, nonalcoholic beverages, and snacks. You will receive $20 per hour for Session 2 (up to $200). We will not tell you everything about the study purposes in advance. When the study is over, we will tell you everything about the study procedures and purposes. We will pay your cab fare home or you can arrange to have a friend or family member pick you up.

For Session 2 Only: To participate, you should not have consumed any drugs or alcohol within the last 12 hours, and you should not have not eaten food within the last four hours. Drinking alcohol while also taking illicit substances or unreported medications is a health risk. If you are seeking treatment or in recovery for an alcohol use disorder or other mental health disorder, you should not participate.

Additional Information

Your de-identified private information (private information with all identifiers, such as name, are removed) may be used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Risks and Discomforts

There is the possibility that participation in this study may cause you to feel uncomfortable due to answering sensitive questions. Furthermore, you are being randomized (like flipping a coin) to one of two groups (negative mood induction task or positive mood induction task), which comes with different risks. If you are randomly assigned to the negative mood induction task, you may also experience some emotional discomfort from this mood induction task. These risks are occasional and this discomfort is temporary. If the mood state remains after the study is complete, please inform research personnel. If you are randomized to the positive mood induction task, you are unlikely to experience emotional discomfort.

Drinking alcohol may cause you to feel nauseous or dizzy; this risk is rare. If you experience these effects, please tell research personnel. If you are given alcohol, your blood alcohol levels will be above the legal limit. If you leave the study prior your blood alcohol level decreasing, you may put yourself at risk for physical, emotional, or legal harm. It is important that you remain in the lab until your blood alcohol concentraion decreases.

Benefits

Participation in this study will not benefit you personally. You will receive educational information about alcohol use upon study completion. Referrals for alcohol use treatment or other mental health problems will also be provided at the end of the study. The main benefit is to society. Overall, we hope to gain information about alcohol and thoughts and behaviors.

Alternatives

You are not required to participate and there is no penalty for not participating. The alternative is to not participate in the study.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?

Medical information, including but not limited to information of any diagnosis or treatment of disease or condition, which may include drug/alcohol dependency, etc.; personal identifiers, including but not limited to your name, social security number, date of birth; any other information related to or collected for use in the research study.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. 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 may use and give out this information?
Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?
All individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:
- the Office for Human Research Protections (OHRP)
- Department of Health and Human Services (DHHS) agencies
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, as necessary for their operations; the UAB IRB and its staff

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants may be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

This research will be covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate 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 action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). 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 you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal
Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

If you decide to be in the study, you have the right to drop out at any time and will be paid for the time you have spent. You may skip questions or stop at any time. You will not lose any benefits to which you are otherwise entitled. While you have the right to drop out at any time, we ask you to stay in the lab until your breath alcohol level has dropped to 0.03%. For your safety, you will not be paid until this occurs. We will call the police if you leave before your breath alcohol reaches this level.
You may be removed from the study without your consent if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation
There will be no cost to you for taking part in this study.

Payment for Participation

You will receive $20 per hour for Session 1 (up to $20) and Session 2 (up to $200). If you withdraw from the study early, we will pay you for your time up to that point ($20 per hour). We will pay your cab fare (e.g., using Lyft or Uber services) for transportation home. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit). Please note that payment can take up to three business days to be approved. If you do not finish the entire study, you will be paid at the time you decide to stop taking part in the study.

Payment for Research-Related Injuries

UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Optional: Future Research Use of De-identified Private Information

Data from this study will be submitted to the National Institute on Alcohol Abuse and Alcoholism Database (NIAAADA), a large database where de-identified study data from many NIAAA studies are stored and managed. De-identified study data means that all personal information about you (such as name and phone number) is removed and replaced with a code number. Sharing your de-identified data helps researchers learn about alcohol problems more quickly than before. Other researchers can then request your de-identified study data for other research and must promise to keep your data safe and promise not to try to learn your identity. Sharing your study data does have some rare risks. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity. You may not benefit directly from allowing your study data to be shared with NIAAADA. You will not be contacted directly about the study data you contributed. You may decide now or later that you do not want your study data to be added to the NIAAADA. You can still participate 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, please tell the study researcher. If you decide any time after today that you do not want your data to be added to the NIAAADA, contact the study staff, and they will tell NIAAADA to stop sharing your study data. Once your data is part of the NIAAADA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. For more information see https://nda.nih.gov/niaaa.

Initial your choice below:

___ I agree to allow de-identified private information to be kept and used for future research.

___ I do not agree to allow my de-identified private information and identifiable biospecimens to be kept and used for future research.

Questions

To discuss information, comments, or concerns about this research, please contact the primary PI: Caitlin Clevenger at (205) 975-9943. If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Signature of Participant Date

Signature of Person Obtaining Consent Date