NYU Human Research Protection Program

RESEARCH INFORMED CONSENT FORM

STUDY TITLE: Understanding the Associations between Romantic Relationship Conflict, Psychophysiological Responding and Alcohol Misuse among Emerging Adults (IRB-FY2023-7802)

INVESTIGATOR(S): Dr. Jasara Hogan, PhD

FUNDING SPONSOR: National Institute on Alcohol Abuse and Alcoholism (NIH-NIAAA)

INVITATION TO BE A PART OF A RESEARCH STUDY

You are invited to participate in a research study. This form has information to help you decide whether or not you wish to participate—please review it carefully. Your participation is voluntary. Please ask any questions you have about the study or about this form before deciding to participate.

PURPOSE OF THE STUDY

The purpose of this study is to learn more about how alcohol and romantic relationship conflict are linked among emerging adults.

ELIGIBILITY TO PARTICIPATE

You are eligible to participate in this study if

1. you are between the ages of 21 and 29 years old,
2. are in a committed romantic relationship of at least 3 months duration,
3. report at least two Heavy Episodic Drinking (HED) episodes in the past 30 days (5 or more drinks within 2 hours for males, 4 or more drinks within 2 hours for females), and
4. report that you have – at least three times in the last year – drank a quantity of alcohol that is equal to or greater than what you will be given as part of this study.

You should not participate if

1. you have been diagnosed with (aka, meet DSM-5 criteria for) a history of or current neurological, psychotic, or bipolar disorders.
2. have a history of self-reported head trauma requiring medical treatment.
3. your body weight exceeds 250 pounds.
4. are currently enrolled in treatment or seeking treatment for a substance or alcohol use disorder.
5. have current suicidal or homicidal intent.
6. have serious cardiovascular health conditions (e.g. pacemaker, cardiac arrhythmia, hypertension) that may alter normative cardiac functioning.
7. you have a current diagnosis of anorexia or bulimia.
8. use of medications such as lithium, methadone, alpha or beta blockers or cholinergic/anticholinergic medications likely to confound normative cardiovascular responding or response to alcohol administration (stimulant or benzodiazepine medication use is permissible provided participants do not take medication on the day of study participation).

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9. have severe and/or unilateral physical intimate partner violence with your current partner at any time.
10. have perpetrated severe and/or unilateral physical intimate partner violence with any partner at any time.
11. have sexual IPV with your current partner at any time.
12. have fear of your current partner.
13. are pregnant or breastfeeding.
14. have Severe Alcohol Use Disorder (as defined by the DSM-5).

When you arrive at the lab, we will have one more, short interview to confirm that you are eligible for the study and, if applicable, you will take a pregnancy test to make sure it is safe for you to participate.

DESCRIPTION OF STUDY PROCEDURES

If you agree to participate, you will be asked to

1. Complete one ~3-hour audio/video recorded session with your romantic partner at New York University and take part in the following activities with your partner
    a. Try to resolve some areas of disagreement with each other
    b. Play games where you are working with each other
2. Take part in an interview to confirm eligibility (15 minutes), and, if applicable, take a urine pregnancy test. You will also have to sign an agreement that you will not drive home following the study and will stay in the lab until you have returned to a .04 Breath Alcohol Content (BrAC) (10 minutes)
3. Take a breathalyzer test.
4. Complete self-report assessments asking about your alcohol use, mental health, and current relationship. (about 1 hour, dependent on individual reading speed)
5. Complete a physiological baseline where will measure your resting heart rate, skin conductance (a measure of your parasympathetic (i.e., the rest and digest) nervous system involving the sweat glands on your palm), and respiration rate. These sensors will stick to your torso, hands, and arms. (10 minutes)
6. Have a 5-minute neutral conversation with your partner.
7. Have a 10-minute conversation with your partner about yourself and your relationship. You will be asked to complete a brief questionnaire, measuring common areas in which you and your partner have disagreements. You will discuss a selected topic for ten minutes, trying to understand the topic as best as you can.
8. Complete a 5-minute puzzle task.
9. Drink alcohol. Participants will be given one drink consisting of an overall dose of 0.99 g/kg body weight of 95% ethanol USP (190 proof) mixed in a 1:5 ratio with orange juice (this is about 1-2 mixed drinks). You will use a breathalyzer to make sure your BrAC is 0.04% before the next tasks.
10. Have another 10-minute conversation with your partner about yourself and your relationship. This conversation is the same as Study Procedure #7 and, therefore, will also be based on answers from the brief questionnaire you filled out which measures common areas

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of disagreement in your partnership. You will discuss another selected topic for ten minutes, trying to understand the second topic as best as you can.

11. Complete another 5-minute puzzle task.
12. Be provided two drinks consisting of your choice of liquor and mixer mixed in a 1:3 ratio above for you to drink if you want over 20 minutes. This will be equal to about 2-3 standard mixed drinks total. Depending on how much you choose to drink, this dose could increase your blood alcohol level to about .12%, which is above the legal limit for driving a car. It poses no serious health risk for a drinker with no known medical issues. After you are done drinking alcohol, you will be given a breath test periodically to check 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.
13. Complete a detox session. You will have to stay in the lab until you have a BrAC of .04, or below. We will provide you with snacks, drinks, and a meal. Additionally, you will have access to entertainment (games, media, etc.). We will breathalyze you periodically to check your BrAC.
14. Once your BrAC is at .04, we will ask you some questions about your participation in the study. Then you will be paid for your participation and the study will be completed. This will take about 5 minutes.
15. One, three, and seven days after your lab visit, we will call you on the phone. You will be asked questions about your participation in the study such as your feelings of distress and safety leaving the lab. These phone calls will be about 5 minutes long.

Please note that time in the lab depends on individual participant factors and participants will be compensated for the total time they spend in the lab. Participation in this study will involve up to 6-8 total hours in one day.

RISKS OR DISCOMFORTS

This study involves the following risks or discomforts:

1. You may experience discomfort associated with alcohol consumption.
    a. You may feel nauseous or dizzy from drinking alcohol in this study. To minimize this risk, we will provide you snacks, water, and a meal during the detox session. We will also not offer you more alcohol than you report that you drink on your own. As stated, we will follow the alcohol administration guidelines outlined by NIAAA.
    b. If you do experience nausea or dizziness, please tell the study staff. If at any time you feel alcohol-related physical discomfort, you may stop drinking and quit the study.
    c. If you feel sick, you will be allowed to remain in a quiet, private room until you feel well enough to leave and your BrAC is below 0.04%. You will be given access to a bathroom if you feel nauseated. Additionally, if you feel unwell and need to stop the study, we will provide you food and drinks while you are resting.
2. You may experience mild skin irritation from the sensors attached to the body.
3. You will not be able to use tobacco for 4 hours before the study begins and the 6-8 hours that you are completing the study procedures in the lab. If you regularly use tobacco then you may experience symptoms of nicotine withdrawal. You will be offered the use of a nicotine

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patch to help prevent nicotine withdrawal symptoms. Use of a nicotine patch is completely voluntary and not a requirement of participating in the study.

4. Intoxicated participants may try to leave the lab before your BrAC is at .04%.
    a. You will not be allowed to leave the laboratory until your BrAC has fallen to 0.04% (in accordance with NIAAA guidelines). You will be walked to your choice of transportation, the subway, pre-arranged transportation, or your home if it is close to the lab.
    b. You will be required to give up your keys and valid ID (e.g., driver's license) upon entering the laboratory to decrease risk of leaving the lab before your BrAC reaches 0.04%.
    c. If you leave before your BrAC reaches 0.04%, police may be contacted if Dr. Hogan (the principal investigator) or other research staff considers you a danger to yourself or others. Laboratory staff will make contact with you when you arrive home (on the day of the study) to confirm your safety.
5. You may experience mild psychological distress/aggression.
    a. To minimize this risk, you will only be asked questions that have been tested for use with study participants and are regularly used in these types of studies.
    b. If you experience discomfort when reading or answering questions today about sensitive subjects, you can skip any questions you do not want to answer or withdraw from participation at any time.
    c. It is possible that you may experience conflict with your partner while discussing areas of disagreement or working together to complete the puzzle task.
    d. If you become distressed after participation, you may contact Dr. Hogan (PI). The PI is able to help participants manage distress and to evaluate conditions in which participants need additional assistance.
    e. If you become significantly distressed, the PI will contact you later that day to check-in and the following day to make sure you have received necessary resources, and to assess your safety and wellbeing. If called by participants, the PI will attempt to address all participant concerns and set up a referral for treatment for those who desire it.
    f. Study staff will check with you after you finish the study to make sure that you do not feel distressed or unsafe before you leave the laboratory.
    g. Out of an abundance of caution, study staff will also check in 1, 3, and 7 days after your participation to ensure that you do not feel distressed or unsafe.
6. Loss of confidentiality. Any time personally identifiable information is collected, there is a risk of a breach of confidentiality. Procedures for the potential loss of confidentiality are outlined in the Privacy & Data Confidentiality section below.

We have listed all the risks of which we are aware, but there may be unforeseeable risks to participation. If we are made aware of new risks, we will communicate these to you. Please tell the researchers if you believe you are harmed from your participation in the study.

NYU will not provide you with medical treatment or compensation for any injury that you may experience form participating in this study. By agreeing to participate in the study, you do not give up any legal rights to seek compensation for potential injury.

BENEFITS

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We hope that this study will contribute to knowledge about understanding how alcohol misuse and romantic relationship conflict are linked among emerging adults.

You are not expected to directly benefit from participation in the study.

COMPENSATION

The compensation for participating in this study would be $160 for completion of all study activities and compensation will be in the form of cash. For interviews, questionnaires, or surveys, you have the right to skip or not answer any questions you prefer not to answer. You may be withdrawn from the study without your consent if you or your partner become physically aggressive or overly intoxicated. You may also be withdrawn from the study if you attempt to consume your partner's drinks or if your partner attempts to consume your drink. You will only receive compensation upon successfully completing all aspects of the lab components of the study. You will not receive compensation for completing phone surveys one, three, and seven days after your lab visit.

Participants departing from the lab upon completion of the study via subway will have their transportation home covered.

VOLUNTARY PARTICIPATION

Participating in this study is completely voluntary. You may choose not to take part in the study or to stop participating at any time, for any reason, without penalty or negative consequences. If you wish to end your participation, let the researchers know.

If you withdraw from the study early, you will not be allowed to leave the laboratory until your BrAC has fallen to 0.04% (in accordance with NIAAA guidelines).

We may end your participation in the study if there are any changes in your study eligibility, if you become physically aggressive or overly intoxicated, or if you attempt to drink your partner's drinks.

If you withdraw or are withdrawn from the study early, we will retain the data collected up to that point unless you ask us to destroy your data.

PRIVACY & DATA CONFIDENTIALITY

In this study, you may be asked to give information that could be used to identify you personally. This information will be kept confidential. Only researchers and others that will keep the information confidential (e.g., regulatory agencies or oversight groups) may access information that could personally identify you.

Confidentiality of your research records will be strictly maintained and all digital data collected will be numerically coded, kept in locked filing cabinets and password-protected computers within NYU's encrypted data server. A code key which links participant names to the unique ID number and any hard copies of participants' data will be kept in a separate secure database. When each participant completes the study, the code key that links his or her identity to their data will be destroyed. Information not containing identifiers may be used in future research, shared with other researchers, or placed in a data repository without your additional consent. Participants will be audio and video

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recorded. They may review these recordings and request that all or any portion of the recordings be destroyed.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers with this Certificate will not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, even if there is a court subpoena.
Exceptions include:

- A federal, state, or local law requires disclosure.
- Your explicit approval for the researchers to release your name or any other personally identifiable information.

Future Use of Data

Information about you collected for this study may be shared with other researchers, used for other research studies, or placed in a data repository. These studies may be similar to this study or completely different. All information that could identify you will be removed before sharing the data or using it for other research studies. We will not ask you for additional permission before sharing the information.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website may include a summary of the results, but will never include information that can identify you. You can search this website at any time.

ACCESS TO YOUR STUDY INFORMATION

We will not give you access to the information that is collected about you in this study, with two exceptions. If you have a positive pregnancy test, that information will be shared with you privately. Also, if we observe anything abnormal while monitoring your heart beats, we may tell you so that you can follow up with a physician. Please note that we are not medically trained to identify abnormalities while monitoring heart rates, so if you have any concerns about your heart than you should contact a physician.

CONTACT INFORMATION

You are encouraged to ask questions at any time during this study. For information about the study, contact Dr. Jasara Hogan at (646) 655-9863, relationshipresearch@nyu.edu.
If you have questions about your rights as a research participant or if you believe you have been harmed from the research, please contact the NYU Human Research Protection Program at (212)998-4808 or ask.humansubjects@nyu.edu.

AGREEMENT TO PARTICIPATE

Participant: By signing this document, you are agreeing to participate in this study. Make sure you understand what the study involves before you sign. If you have any questions about the study after you agree to participate, you can contact the research team using the information provided above. You may keep a copy of this form.

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Name of Participant (print) _____

_____ _____

Signature of Participant Date

Person Obtaining Consent: Your signature below means that you have explained the research to the participant/participant representative and have answered any questions they may have about the research.

Name of Person Obtaining Consent (print) _____

_____ _____

Signature of Person Obtaining Consent Date

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