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NCT # NCT06105138
Title: Cannabidiol Effects on Blood Alcohol Level and Intoxication

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ADULT PARTICIPANT INFORMED CONSENT

Department of Psychology

Participant Study Title: Exploring the Effects of Alcohol and Cannabidiol (CBD)

PRINCIPAL INVESTIGATOR: Hollis C. Karoly, PhD, Assistant Professor

SPONSOR: Colorado Clinical and Translational Sciences Institute (CCTSI), University of Colorado Anschutz Medical Campus

WHAT IF I HAVE QUESTIONS?

For questions or concerns about the study, you may contact **Dr. Hollis Karoly** at 970-491-3677**.** For questions regarding the rights of research subjects, any complaints or comments regarding the manner in which the study is being conducted, contact the CSU Institutional Review Board at: RICRO_IRB@mail.colostate.edu; 970-491-1553.

CONCISE STATEMENT OF STUDY

This research study is aimed at exploring how cannabidiol (CBD; a compound found in the cannabis plant) impacts alcohol use. You may be interested in the study because you regularly drink alcohol and have used cannabis products previously. The study will take about 15 hours total, across 3 study appointments. There are some risks to participating, such as risks associated with having your blood drawn and risks associated with consuming alcohol. We hope that this research will benefit society by providing new information regarding the impact of CBD on alcohol consumption. You can find more details on this study below, in the body of this consent form. If you are interested in continued discussion about the study, we would like to discuss more with you through this consent presentation.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to explore how cannabidiol (CBD) impacts alcohol consumption. We are interested specifically in how CBD impacts your blood alcohol level, as well as your level of alcohol-related intoxication, measured by your response to some questionnaires and performance on some tasks after drinking. Gaining a deeper understanding of these relationships can help people make informed decisions about their substance use habits and may be able to aid researchers in developing new treatments for alcohol use disorders.

WHY AM I BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being asked to participate in the study because you regularly drink alcohol and have used cannabis before, and you are between the ages of 21-60.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The study will take place in our on-campus laboratory (Clark 076) at CSU. You will come to our lab at CSU on three occasions. At each session, you will spend the full afternoon (approximately 5 hours) in our lab.

WHAT WILL I BE ASKED TO DO?

If you volunteer to participate in this study, you will be asked to do the following:

- Come to our lab at CSU for three full-afternoon (approximately 5 hour) sessions. Each session will be exactly the same, except that at two sessions you will receive either a high or low dose of oral cannabidiol (CBD) taken in a drink, and at the other session you will receive a placebo CBD drink which looks identical to the CBD drink but does not contain any CBD or any other active ingredients. You will not know which session you receive the CBD or which session you receive the placebo CBD.

- You will be asked to arrive for each session at approximately 11:15am. At the beginning of each session, you will take a breathalyzer test and a urine drug test. You must have a breath alcohol level of zero and must not test positive for any illicit drugs (e.g., sedatives, opiates, cocaine, amphetamines, etc.). Females will also take a pregnancy test, which must be negative in order to participate in each study session. You will then complete a short form asking about your age and gender identity, fill out some questionnaires about your psychological functioning and substance use patterns and have your blood drawn by our phlebotomist (three 10ml tubes of blood will be collected per session). You will then be given your CBD or placebo-CBD drink.

- You will need to wait in our lab for about 25 minutes after ingesting the CBD or placebo-CBD drink. During this time, you will be provided with internet access and movies/television. After the 25-minute wait period, you will have your blood drawn again. You will then complete a few tasks on the computer or iPad measuring things like attention, focus, motor skills and desire for alcohol.

- After completing the above tasks, you will be given several alcoholic drinks (vodka mixed with orange juice). You will be asked to consume the alcohol over a 20-minute timeframe. Over the next four hours, you will repeat the computerized tasks and questionnaires every 30 minutes, and will also be asked to blow into a breathalyzer device. One hour after alcohol consumption begins, your blood will be drawn one last time.

    - 4 hours after you consume the alcohol, the study session will be complete, and you will be allowed to leave as soon as your breathalyzer reading is below .03. You need to either have arranged for someone to pick you up after the study, or we will

call a Lyft to take you home. We will cover the cost of the Lyft for you. If you are hungry, there will be snacks available, which may also help your BAC to decrease faster.

ARE THERE ANY BENEFITS FROM TAKING PART IN THIS STUDY?

This study may benefit the public by increasing our understanding of how cannabidiol (CBD) impacts the brain and body when used in combination with alcohol. This information may help people who use alcohol and/or cannabis to make decisions about their use, and may help clinicians advise patients regarding cannabis and alcohol use.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The risks associated with participating in this study are low, however you could experience discomfort associated with several study procedures. During the alcohol consumption portion of the study, you may experience intoxication, mood shifts (e.g., feelings of depression or sadness) and some changes in how you perceive the world around you. You may also experience discomfort or embarrassment associated with filling out questionnaires related to medical conditions, health-related behaviors, drug use and psychiatric history. You may also experience some discomfort or mild bruising related to the three blood draws.

WILL I RECEIVE ANY COMPENSATION FOR TAKING PART IN THIS STUDY?

You will be compensated for participating in this research. The maximum you can earn for completing all portions of the study is $297. You will receive $99 for your participation in each session.

WHO WILL SEE THE INFORMATION THAT I GIVE?

All information gathered in this study will be kept as confidential as possible and stored in a manner that information cannot be traced back to you. Your privacy is important to us and we take every measure to protect it. For this study, we will assign a code to your data so that the only place your name will appear in our records is on the consent and in our data spreadsheet which links you to your code. Only the research team will have access to the link between you, your code, and your data. Your information may be given out if required by law; however, the researchers will do their best to make sure that any information that is released will not identify you. No reference will be made in written or oral materials that could link you to this study. All records will be stored in a restricted access folder at CSU and after study completion, the information linking your data to your code will be destroyed.

There are organizations that may inspect research records that may include yours. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The CSU financial management team may request an audit of research expenditure, in which only your participating in the research may be shared, but not your research data.
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.

Your identity/record of receiving compensation (NOT your data) may be made available to CSU officials for financial audits.

The research team works to ensure confidentiality to the degree permitted by technology. It is possible, although unlikely, that unauthorized individuals could gain access to your responses because you are responding online. However, your participation in this online survey involves risks similar to a person's everyday use of the internet.

If you choose to take part in this study, your private information and blood will be collected. Any identifiers linking you to your private information and biospecimens will be removed. After we remove those identifiers, the information and blood could be used for future studies or distributed to another research for future research studies without your permission.

DO I HAVE TO TAKE PART IN THE STUDY?

Your participation in this study is voluntary. You may refuse to participate in this study or in any part of this study. You may withdraw at any time without prejudice to your relations with CSU. You are encouraged to ask questions about this study at the beginning or any time during the research study.

RETENTION OF BLOOD SAMPLES:

You should understand that we plan to keep any extra blood that is not used in the analysis of this study in a freezer in our lab. It is very possible that we will use all of the blood obtained in this study and will have none left, but in the event that we do, we would like your permission to keep the samples so that they can be used for further research. We will use these samples in the future solely for the additional research on the health effects of alcohol and CBD. Your stored samples will be coded in such a way that your confidentiality will be maintained (you will be identified as a number rather than a name). Only the Principal Investigator (Dr. Karoly) and members of the research team will have access to the coding system for your samples.

By checking 'YES' below and signing the accompanying line, you are agreeing to allow the investigators to retain any blood samples obtained during this study. If you do not wish the investigators to retain your samples, please check the box marked 'NO' and also sign on the accompanying line:

The investigators may keep any blood samples obtained during the course of this study for future research

YES ☐ NO ☐ Signature: _____ Date:_____

Participant Consent:

Your signature acknowledges that you have read the information stated and voluntarily wish to participate in this research. Your signature also acknowledges that you have received, on the date signed, a copy of this document containing 5 pages.

_____ _____

Signature of person agreeing to take part in the study Date

_____

Printed name of person agreeing to take part in the study

_____ _____

Name of person providing information to participant Date

_____

Signature of Research Staff