Title: Dismantling MBRP: Identifying Critical Neuroimmune Mechanisms of Action

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University of Colorado Boulder

Title of the research study: Mindfulness Based Relapse Prevention

Principal Investigator: Kent Hutchison, Ph.D

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are an adult between the ages of 21 and 60 years old who drinks alcohol.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.
- You will be offered a copy of this document.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at the CU CHANGE Lab at **303-735-1304** or by email at AIM.CUstudy@gmail.com.

You can also reach the PI, Dr. Kent Hutchison directly at **303-492-8662.**

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (303) 735-3702 or irbadmin@colorado.edu if:

- The research team is not answering your questions, concerns, or complaints.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

Mindfulness Based Relapse Prevention (MBRP) and Relapse Prevention (RP) have been shown to help regular alcohol users curb their drinking habits. In order to determine the effectiveness of using MBRP versus RP, we will look at the mechanisms that have shown to be affected by regular alcohol consumption. These mechanisms are predicted to cause certain adaptations to the brain's structure and function. By monitoring these mechanisms, we will be able to characterize how MBRP or RP is working and determine their effectiveness. We will address these questions by 1) implementing an 8-week long MBRP or RP therapy program once per week for one hour,

2) conducting questionnaires and surveys that ask about alcohol use and other psychological and health factors. It is our hope that this research will help in the development of treatment and prevention programs for the improvement of health and quality of life among people with Alcohol Use Disorders.

How long will the research last?

We expect that the total time this research study will last from start to finish is approximately 15 hours. You will attend twelve individual sessions via Zoom (or other computer interface application).

How many people will be studied?

We expect that about 40 adults between the ages of 21 and 60 will be in this research study.

What happens if I say yes, I want to be in this research?

Due to the **COVID-19 situation**, this study will be conducted remotely through contact with a research assistant. Therefore, you will need access to the internet whether by computer, smartphone, or other device such that you can complete this study. A research assistant will send unique links to you that you will simply click on in order to participate, applications such as: Zoom (an internet application that allows us to see and talk with you), Qualtrics and REDCap (online survey platforms), and DocuSign (an internet application that allows us to send you forms to sign).

The first study appointment is an orientation and consent session, also referred to as your Baseline session. For this appointment, you will meet with a trained member of the study team who will take you through the informed consent procedures and give you an opportunity to ask any questions you may have about your participation in the study. You will complete some computerized questionnaires asking about your substance use, psychological functioning and health behaviors. You will be assigned to receive either MBRP or RP for an 8-week long program, and you will be compensated with at $30 Amazon gift card for completing this appointment.

You will then be given some instructions about how to prepare for your next study session, which is called your Goal-setting Session. Before you start your 8-week long program, you will meet with your therapist for a 1 hour Goal-setting Session, resulting in a total of 9 individual therapy sessions. This will be an informational session where you will be introduced to your therapist, talk about your goals for treatment, and learn about what you will be doing over the next 8 weeks.

For your therapy sessions, you will meet with a therapist via Zoom once a week for 1 hour individual therapy sessions. Your therapist will guide each session by engaging you in an exercise and a discussion. You will be compensated $15 in Amazon gift cards for every therapy session you attend. This compensation will be totaled for therapy sessions 1-3 and 5-7, and given to you at the end of your End of Treatment Session, at week 8 (see table and compensation charts below).

At your Intermediate Session, 4-week therapy session, you will have your regular meeting with a therapist, and complete some computerized questionnaires. You will be compensated with a $30 Amazon gift card for this appointment.

At your End of Treatment Session, week 8, you will have your final session with your therapist and fill out questionnaires. You will be compensated for all therapy sessions and receive an additional $30 Amazon gift card at the completion of this appointment. At the end of this week 8 session, you will schedule your final two follow-up appointments with the research team member. We will schedule them at 20 weeks (3 months post-treatment) and 32 weeks (6 months post-treatment). At these two appointments, you will fill out questionnaires, and will be compensated with a $50 Amazon gift card for completing surveys at each of these two follow-up appointments. After this 32-week appointment, your participation in this study will be complete.

Visit/Session	***Procedures/Tools***	***Location***	***Time to Complete***
Baseline Session	Informed consent; Study orientation; Questionnaires.	Remote/Zoom	1 hours and 30 minutes
Goal-setting Session	An introduction and goal-setting session with your therapist.	Remote/Zoom	1 hour
MBRP or RP, Individual Therapy Sessions (weeks 1-3 and 5-7)	Mindfulness Based Relapse Prevention or Relapse Prevention therapy session with a trained therapist.	Remote/Zoom	1 hour sessions (6 hours total)
Intermediate Session (at 4 weeks)	MBRP or RP therapy session; Questionnaires.	Remote/Zoom	2 hours
End of Treatment Session (at 8 weeks)	MBRP or RP therapy session; Questionnaires.	Remote/Zoom	2 hours
Follow-up Session I (at 20 weeks)	Questionnaires	Remote/Zoom	1 hour
Follow-up Session II (at 32 weeks)	Questionnaires	Remote/Zoom	1 hour
TOTAL TIME			***Approximately 15 hours***

What happens if I do not want to be in this research?

You can leave the research at any time and it will not be held against you. You have the right to withdraw your consent or stop participating at any time.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. You have the right to withdraw your consent or stop participating at any time. You have the right to refuse to participate in any procedure for any reason. Refusing to participate in this protocol will not result

in any penalty or loss of benefits to which you are otherwise entitled. If you choose to withdraw from the study, all data collected up to that point may be retained and analyzed.

Is there any way being in this study could be bad for me?

Risks associated with breach of confidentiality. Every effort will be made to protect the information you give us. Any personal identifying information and any record linking that information to study ID numbers will be destroyed when the study is completed. Information resulting from this study will be used for research purposes and may be published in summary form; however, you will not be identified by name in any publications.

If you are injured as a result of participating in this protocol or for questions about a protocol-related injury, call **Dr. Kent Hutchison, at 303-735-1304**. The cost for any treatment will be billed to you or your medical or hospital insurance.

Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include getting a chance to examine your alcohol use patterns. You will have the opportunity to examine your own alcohol use behavior in the context of completing these measurements, and will have the opportunity to work with a trained therapist over the course of the 9-week long study. You will receive the benefit of a treatment (either MBRP or RP) that has demonstrated efficacy in the treatment of Alcohol Use Disorder (AUD). These studies are expected to add to the knowledge base of information on the development and treatment of Alcohol Use Disorder.

What happens to the information collected for the research?

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. This certification means that the researchers cannot be forced to tell people who are not connected with the study, such as the court system, about your participation in this study. But, if you request that we do so, we will release information that is unique to you.

There are three exceptions to this promise of confidentiality:

1. If we see or are told information that makes us reasonably suspect that a child or at-risk adult is being or has been abused, mistreated, or neglected, we will immediately report that information to the county department of social services or a local law enforcement agency.
2. If we learn of a serious threat of imminent physical violence against a person, we will report that information to the appropriate legal authorities and make reasonable and timely efforts to notify the potential victim.
3. This promise of confidentiality does not include information we may learn about future criminal conduct.

Strict standards of confidentiality are maintained. All data will be electronically stored and analyzed using numerical identification codes. Data collected during this study may be used for future undetermined research; however, the record linking your name to your study ID number will be destroyed when the study is completed. If the data are published you will remain anonymous in all publications. Data will be stored indefinitely and will not be shared with other investigators without your permission.

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot

promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Can I be removed from the research without my OK?

It is possible that you might be removed from the study without your ok if you fail to comply with the explicit study instructions. If, upon completion of psychometric tests, the study clinician(s) deem it necessary that you are in need of a form of treatment that we are unable to provide, you will be dropped from the study and referred to another provider.

What else do I need to know?

This study is neither designed nor intended to find health problems. If you think that you might be suffering from injury or illness, you should not rely on this research study as a way to determine your health status.

If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. The University of Colorado has no program to pay for medical care for research-related injury.

You will be paid up to $280 in Amazon gift cards if you complete all aspects of this study. If you leave the study early, or if we have to take you out of the study, you will receive a pro-rated payment, depending on which aspects of the study you have completed. You will be paid for all therapy sessions you completed at your End of Treatment Session, at week 8. For all other appointments, you will be compensated at the end of the session.

Compensation (via Amazon gift cards) for each study appointment goes as follows:

- Baseline session: $30
- Therapy sessions (weeks 1-3, 5-7): $15 per session ($90 total given at week 8)
- Intermediate session (week 4): $30
- End of treatment session (week 8): $30
- Follow-up session I (week 20): $50 for surveys
- Follow-up session II (week 32): $50 for surveys

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	2 July 2020 IRB Approval Date