

Protocol #: 18-1086 Principal Investigator: Daniel Hernandez Altamirano, Version Date: 09/20/2018

**Principal Investigator: Daniel Hernandez Altamirano**

**COMIRB No: 18-1086**

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**Study Title: The Effect of Tablet Size on Cognitive Performance: A Randomized Controlled Trial Using Caffeine**

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

**Why is this study being done?**

This study plans to learn more about factors of designing drugs and the influence that the drug's size has on the desired outcome. This study assesses your performance on a series of cognitive tests after consuming caffeine.

You are being asked to be in this research study because we hope that the results of this study will provide better insight into more efficient drug designs.

Up to 120 people will participate in the study.

**Eligibility Criteria**

Eligibility includes:

Ages 18-40

Fluent in written and spoken English

No uncontrolled high blood pressure

Ability to see color

No allergies to caffeine or sucrose

No history of heart disease

No untreated anxiety or depression

Non-pregnant

No caffeine consumed the day of participation

## Consent Form

### What happens if I join this study?

If you join the study, you may or may not receive caffeine in an amount no greater than 90 milligrams (the same amount in an 8 ounce cup of coffee). After that, you will be presented with a series of four tasks. The fourth task is comprised of two parts. After completing the first part of the fourth task, you will be asked to complete a series of questionnaires to collect information on your weekly caffeine consumption habits and some demographic information. Lastly, you will complete the second component to the fourth task mentioned earlier. The trial will conclude with a short debriefing session where you will be thanked for your participation and reminded of appropriate contacts for questions regarding this study.

This trial will take approximately 90 minutes to complete.

### What are the possible discomforts or risks?

Discomforts you may experience while in this study include:

1. Increased anxiety (rare with higher doses, serious if individual has untreated anxiety disorder).
2. Increased blood pressure (common at higher doses, serious if individual has history of high blood pressure).

Other possible risks include:

1. Tachycardia (rapid heartbeat) from taking caffeine (rare, serious if individual has history of heart conditions).
2. Allergic reaction to caffeine or sucrose (rare, serious if individual is unaware of allergies and no epinephrine shot is available).

### What are the possible benefits of the study?

This study is designed for the researcher to learn more about effective physical drug designs for tablets using objective, cognitive measures - as opposed to previous, subjective research results and supporting existing research on the effects of caffeine on cognitive functioning.

Participants will likely not directly benefit from participation in this study. After the conclusion of the study, participants may gain a better understanding of the study's purpose. That is, they will be free to ask for a copy of the manuscript to see the results of the study; however, participants will not be able to access individual scores.

Investigating more efficient physical drug designs may lead to better outcomes when consuming medications (e.g. needing to consume less medication to achieve the same outcome). If one design is found to be better, and cheaper to manufacture, individuals may need to spend less on their medications.

## **Consent Form**

### **Who is paying for this study?**

This research is being paid for by the Undergraduate Research Opportunity Program (UROP) at the University of Colorado Denver

### **Will I be paid for being in the study? Will I have to pay for anything?**

You will not be paid to be in the study. However, extra-credit may be available upon agreement with course professors and completion of the research trial. An alternative assignment is also available for completion.

It will not cost you anything to be in the study.

### **Is my participation voluntary?**

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

### **What happens if I am injured or hurt during the study?**

The University has no plan to pay for a physical or psychological injury. If you are injured or hurt during this study, you may call Daniel Hernandez Altamirano at 303-315-7036

### **Who do I call if I have questions?**

The researcher carrying out this study is Daniel Hernandez Altamirano. You may ask any questions you have now. If you have questions later, you may call Daniel at 303-315-7036.

You may have questions about your rights as someone in this study. You can call Daniel Hernandez Altamirano with questions. You can also call the Multiple Institutional Review Board (IRB). You can call them at 303-724-1055.

### **What happens to data collected in this study?**

The data we collect will be used for this study but may also be important for future research. Your data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed from the data.

## Consent Form

### Who will see my research information?

We will do everything we can to keep your records a secret. It cannot be guaranteed.

Both the records that identify you and the consent form signed by you may be looked at by others.

- Federal agencies that monitor human subject research
- Human Subject Research Committee
- The group doing the study
- The group paying for the study
- Regulatory officials from the institution where the research is being conducted who want to make sure the research is safe

The results from the research may be shared at a meeting. The results from the research may be in published articles. Your name will be kept private when information is presented.

### Agreement to be in this study

I have read the above eligibility criteria and confirm that I meet all conditions listed.

Initial: \_\_\_\_\_ Date: \_\_\_\_\_

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary. I choose to be in this study: I will get a copy of this consent form.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Print Name: \_\_\_\_\_

Consent form explained by: \_\_\_\_\_

Date: \_\_\_\_\_

Print Name: \_\_\_\_\_

Investigator: \_\_\_\_\_

Date: \_\_\_\_\_