Examining caffeine as a treatment for antidepressant-induced arousal dysfunction in women

NCT Number: Pending

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Consent for Participation in Research
Title: The Caffeine Study

Important Information about this Research Study

Things you should know:

- The purpose of the study is to examine the effect of caffeine on female sexual arousal.
- In order to participate, you must be female; fluent in English; experience regular menstrual periods; and have been stabilized on an antidepressant for at least three months. You must not have a history of panic attacks; a current or past STD; history of childhood sexual abuse; or history of any other medical conditions or procedures that would preclude participation in this study.
- If you choose to participate, you will be asked attend two laboratory sessions, complete questionnaires, ingest 300mg caffeine, and watch an erotic film while your mental and genital sexual arousal are measured. This process will take up to an hour per session.
- Risks or discomforts from this research may include embarrassment while viewing erotic films and nausea and/or anxiety symptoms (e.g., increased heart rate, sweating) after taking caffeine.
- There are no direct benefits to you for participating in this study; however, the results of this study will help us to better understand sexual functioning in females and inform future treatments for female sexual dysfunction.
- Taking part in this research study is voluntary. You do not have to participate, and you can stop at any time.

More detailed information is described later in this form. Please take time to read this entire form and ask questions before deciding whether to take part in this research study.

Introduction

The purpose of this form is to provide you information that may affect your decision to participate in this research study. The person performing the research will answer any of your questions. Please read the information below and ask any questions you might have before deciding whether or not to take part. If you decide to be involved in this study, this form will be used to record your consent.

Purpose of the Study

You have been asked to participate in a research study about female sexual arousal in response to erotic films. The purpose of this study is to examine the effect of caffeine on female sexual arousal.

What will you to be asked to do?

If you agree to participate in this study, you will be asked to:

- Attend two laboratory sessions, during both of which you will watch a short erotic film while your heart rate, physiological and psychological sexual arousal are measured
    - During one session, you will ingest a capsule containing 300 mg of caffeine
    - During the other session, you will ingest a placebo capsule

    - Abstain from caffeine use the day of each session prior to coming into the laboratory. Additionally, you will track your fat intake on the day of each session using MyFitnessPal.
- Complete questionnaires on demographics, mental and sexual health

Genital blood flow will be measured with an instrument called a vaginal photoplethysmograph, or vaginal probe, which is a tampon-shaped device that is about the size of a regular absorbency tampon. The probe is connected to a plastic cord that you will insert into your vagina in a private, locked room. The probe will measure the blood flow in your vagina with a light signal. You will insert the probe on your own after the researcher provides you with instructions.

The photoplethysmograph will be disinfected using Cidex Plus (Johnson & Johnson, Inc.) according to the manufacturer's guidelines. Cidex Plus is a 3.4% glutaraldehyde liquid solution that has been designated by the U. S. Food and Drug Administration as a "high level disinfectant" appropriate for the disinfection of reusable medical devices, such as endoscopes, that cannot be subjected to heat sterilization. Cidex Plus is known to be effective against infectious agents such as the tuberculosis bacterium, herpes simplex virus (Type 1 and 2), and HIV. Sterilization procedures have been reviewed and approved by Environmental Health and Safety of the University of Texas at Austin.

Heart rate will be measured with an electrocardiogram, or an ECG. To do this, you will be instructed on how to attach three electropads to your body: one on your right collar bone, one on your left abdomen, and one on your right ankle.

This study will take up to 2 hours total of your time, including up to one hour today and up to one hour during your second visit. In total, this study will enroll approximately 90 participants.

What are the risks involved in this study?

There are minimal risks to participating in this study. Vaginal photoplethysmography has been safely used to assess female genital sexual arousal in research studies like this for over 40 years. The vaginal probe is cleaned and sterilized between participants with hospital grade disinfectant, and our lab is overseen by the University of Texas at Austin's Environmental Health and Safety Office.

The FDA states that 400 mg is the maximum amount of caffeine adults can safely consume daily. To mitigate risks for physical health, our proposed dose of 300 mg is below this threshold. Additionally, we require participants to abstain from caffeine use for 24 hours prior to their session to ensure caffeine has been fully eliminated from their systems. Participants who have not abstained will be rescheduled. To mitigate risks for psychological well-being, we will exclude those who experience panic attacks given that caffeine can induce panic attacks.

Some people may feel uncomfortable or embarrassed while watching the erotic film or completing the questionnaires about sexuality. We would like to remind you that you are free

to decline to participate in our study with no penalties, and that you can withdraw your participation from the study at any time for any reason.

There is a risk for emotional discomfort as this study asks questions about your mood and past experiences that may be sensitive. You are free to skip any questions that make you feel uncomfortable, and resources will be provided upon request.

What are the possible benefits of this study?

There are no direct benefits to you for participating in this study; however, the results of this study will help us to better understand sexual functioning in females and inform future treatments for female sexual dysfunction.

Do you have to participate?

No, your participation is voluntary. You may decide not to participate at all or, if you start the study, you may withdraw at any time. Withdrawal or refusing to participate will not affect your relationship with The University of Texas at Austin (University) in anyway.

If you would like to participate, please sign and date both copies of this form. You will also receive a copy of this form for your records.

Will there be any compensation?

If you are a SONA participant, you will receive 3 hours total of research credit for PSY 301 at the end of the second experimental session. As per Sona's policies, students in the PSY 301 subject-pool who do not complete the study will not receive course credit.

If you are not a SONA participant, you will receive $20 cash at the conclusion of your second laboratory session. If you decide to discontinue your participation before the end of the study, which is your right, you will receive full compensation ($20) at that time.

What if you are injured because of the study?

The University has no program or plan to provide treatment for research related injury or payment in the event of a medical problem. If you are an eligible University student and incur injuries as a result of study activity, you may be treated at the usual level of care with the usual cost for services at the Student Health Center. In the event of a research related injury, please contact the Principal Investigator, Leah McMahon, B.S.A., at mestonlab@utexas.edu.

What are my confidentiality or privacy protections when participating in this research study?

This study is confidential and all data is de-identified, which means that all of your data will only ever be labeled with a participant number and never with your name. That number will be used to aggregate your physiological and self-report data but will never be connected to your name or identity. Study findings will be published in a group format, such that no information would be individually identifiable. Data and consent forms will be kept (in separate, locked files) for 10 years, beginning when data collection is complete. Data collected during the phone screen will not be kept. Your name, e-mail address, and phone number will be kept in a locked file on UT's secure server until you have participated in this

study (or until you choose to withdraw from this study). Upon your personal study completion, all contact information will be erased.

If it becomes necessary for the Institutional Review Board to review the study records, information that can be linked to you will be protected to the extent permitted by law. Your research records will not be released without your consent unless required by law or a court order. The data resulting from your participation may be made available to other researchers in the future for research purposes not detailed within this consent form. In these cases, the data will contain no identifying information that could associate it with you, or with your participation in any study.

A description of this study will be available on http://www.ClinicalTrials.gov as required by U.S. law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

Texas Education Code, Chapter 51, Subchapters E-2 and E-3, requires reporting incidents of sexual assault, sexual harassment, dating violence, or stalking committed by or against a person who was a student enrolled at or an employee of UT Austin at the time of the incident. However, the researchers working on this study have been designated as confidential employees. This means that if we learn about any incidents of sexual assault, sexual harassment, dating violence, or stalking, we are only required to report the type of incident reported and the date we learn about the incident. We will not report any information that could identify you.

Whom to contact with questions about the study?

Prior, during or after your participation you can contact the researcher the Primary Investigator, Leah McMahon, B.S.A., at mestonlab@utexas.edu for any questions or if you feel that you have been harmed.

Whom to contact with questions concerning your rights as a research participant?

For questions about your rights or any dissatisfaction with any part of this study, you can contact, anonymously if you wish, the Institutional Review Board by phone at (512) 232-1543 or email at irb@austin.utexas.edu. Data collected from this study will be kept for 10 years.

Participation

If you agree to participate, please print your name, sign, and date both copies of the consent form and then alert the experiment over the intercom that you are ready to move on.

Signature

You have been informed about this study's purpose, procedures, possible benefits and risks, and you have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time. You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

_____
Printed Name

_____ _____
Signature Date

As a representative of this study, I have explained the purpose, procedures, benefits, and the risks involved in this research study.

_____
Print Name of Person obtaining consent

_____ _____
Signature of Person obtaining consent Date