Official Title: Biology and Experience of Eating

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UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Biology and Experiences of Eating (BEE)

This is a clinical trial, a type of research study. This study is about brain responses to snack and dessert foods among people who report that they sometimes overeat. It is being run by **Ashley Mason, PhD** and **Frederick Hecht, MD**, of the Osher Center for Integrative Medicine, and **Elissa Epel, PhD,** of the UCSF Department of Psychiatry. One of the study staff or researchers will explain this study to you.

Clinical trials include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you can contact the study team using the information at the end of this form and you will receive a response from a team member or from the study doctor (Dr. Hecht).

You are being asked to take part in this study because you are female, meet criteria for obesity, and said that you binge eat.

Why is this study being done?

The purpose of this study is to understand the chemical and brain responses that lead to rewarding feelings after eating tasty food. In the future, this may help researchers understand how to develop treatments to help people stop binge eating.

Who pays for this study?

The National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health (NIH), pays for the conduct of this study.

What drug is used in this study?

Naloxone hydrochloride (Narcan) will be sprayed into your nose on one occasion during this study.

Naloxone hydrochloride is approved by the US Food and Drug Administration (the FDA) as a treatment for the effects of overdosing on heroin or other opiate drugs. In this study it will be used to help understand the effects of eating on the brain for people who are not taking opiates. This is considered an investigational use.

How many people will take part in this study?

About 40 people will take part in this study.

What will happen if I take part in this research study?

Study Overview:

In this study you will talk to a staff member on the phone, complete some questionnaires online, and purchase some of your favorite foods (which we will reimburse you for) before you attend each of two lab visits at the UCSF Osher Center. At these lab visits, you'll do some

computerized games, eat some snacks and rate them, and use a nasal spray. More details about each part of the study are below.

Phone screening

Time: 5-15 minutes

A study staff member will confirm some of your information, ask a few eligibility questions, and make sure that all your questions are answered. If you are eligible to continue the staff member will schedule your lab visits and email you the online questionnaires.

Online questionnaires

Time: 10 minutes each

You will fill out questionnaires the nights before each of your visits with us that you will receive by email. These questions ask about your eating behavior and demographic information. You can fill out the online questionnaires anytime before your scheduled lab visits.

Pre-Visit Food Shopping

Time: 60 minutes or less

You will purchase foods (up to $25 total) from nearby locations in the hour prior to your lab visit. You will save receipts from these purchases and study staff will reimburse you in cash for these purchases before you leave each lab visit.

Lab visits

Time: Visit One - 3 hours / Visit Two - 2.5 hours

Location: UCSF Osher Center for Integrative Medicine, 1545 Divisadero St., 3rd Floor

The lab visits will be in the afternoon, and must be at least 1 day apart. We will work with you to schedule a convenient day. At these visits you will:

- Provide a urine sample to ensure that you are not pregnant or using drugs or medications that may cause a reaction with the study medication (visit 1 only)
- Do some computerized games to measure things like attention and reaction speed
- Do a “taste test” with food of your choice
- Take a nasal spray
- Provide saliva samples
- Report on how you’re feeling physically and mentally

At one of the visits, the nasal spray will contain the FDA-approved dose of 4mg naloxone, the medication being studied. At the other visit it will contain placebo, an inactive substance (salt water). A computer random number generator will determine whether you get the placebo at the first visit and the naloxone at the second visit, or vice versa. Neither you or the study staff will know which nasal spray you are getting at each lab visit.

How long will I be in the study?

The two lab visits will be scheduled times that are convenient for you. They must be at least 1 calendar day apart. The researchers estimate that most participants will complete the study within 3 weeks of agreeing to participate, but this may vary depending on your schedule. The total time you spend on all study activities will probably be less than 7 hours (which includes 2 hours of food shopping: One hour before each visit).

Can I stop being in the study?

Yes. You can decide to stop at any time. Please tell the study staff or one of the study researchers if you would like to stop.

There are no risks caused by stopping the study. However, if you decide to stop shortly after taking the nasal spray you may wish to wait in the lab for 30 minutes to see if you experience any side effects.

One of the study researchers may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, if he/she believes that you are not an appropriate participant for the study, or if the study is stopped.

What side effects or risks can I expect from being in the study?

Medication side effects

You may have side effects after taking the nasal spray. Everyone taking part in the study will be watched carefully for any side effects. For healthy people who are not taking opiate drugs, all of the known side effects of naloxone are mild and go away within about an hour.

You should talk to the study staff about any side effects you experience while taking part in the study. The staff member may contact the study doctor, or you can ask to speak to the study doctor if you wish.

Side effects related to naloxone nasal spray can include:

- Increased blood pressure
- Musculoskeletal pain (pain in bones, muscles, or joints)
- Headache
- Nausea
- Nasal dryness
- Nasal edema (swelling)
- Nasal congestion
- Nasal inflammation

Reproductive risks: Pregnant women are excluded from this study as it is not known whether naloxone has any risks for developing fetuses. If you think you might be pregnant, please tell the researchers.

Unknown Risks: Naloxone may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

For more information about risks and side effects, please contact the study doctor, Dr. Hecht, at Rick.Hecht@ucsf.edu or (415) 476 4082, extension 431.

Privacy risks

Your information could be disclosed in a security breach. This might lead to embarrassment or to others learning about your health, medication use, or pregnancy status. The study uses industry-standard encryption and multiple layers of data security to minimize this possibility, and security breaches are extremely rare.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, this study will help doctors and scientists learn more about *the biological and psychological experiences of eating tasty foods.* In the future, this information might help create treatments for people who binge eat or have food cravings.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in this study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get care the way you usually do.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy.

Research records will be kept as confidentially as possible. All specimens and data collected will be coded (your name will not be stored in the same file as your study data). The study will protect your data from unauthorized access using physical and electronic security protocols. All information that is sent over the internet will use industry-standard encryption and authentication methods.

No information will be shared with your doctor or insurance provider, or anyone else not directly involved with the study. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Your personal information may be given out if required by law. Additionally, organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The University of California
- The National Heart, Lung, and Blood Institute
- Government agencies, e.g., the Food and Drug Administration (FDA), involved in keeping research safe for people.

What are the costs of taking part in this study?

You will not be charged for any of the study activities.

Will I be paid for taking part in this study?

In return for your time and effort, you will be paid in amazon.com giftcards at each study visit for each part of your participation in this study:

- $10 in Amazon.com giftcards for completing the online questionnaires ($5 each at visit 1 and visit 2)
- $75 in Amazon.com giftcards for completing the first lab visit (visit 1)
- $125 in Amazon.com giftcards for completing the second lab visit (visit 2)

You will be reimbursed in cash at each visit for the cost of the foods you bought before each study visit, up to $25 per visit; you will be required to provide receipts so that we can reimburse you.

You will be reimbursed for $4.50 for round trip MUNI transportation or will be provided with parking stickers for the UCSF Mt. Zion Garage for each visit.

What happens if I am injured because I took part in this study?

It is important that you tell the Principal Investigator, Dr. Mason, or the study doctor, Dr. Hecht, if you feel that you have been injured because of taking part in this study. You can reach Dr. Mason at (415) 514 6820 or ashley.mason@ucsf.edu. You can reach Dr. Hecht at (415) 476 4082, extension 431.

> **Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at (415) 476 1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can contact the study team with any questions, concerns, or complaints you have about this study. You will receive a prompt response from a staff member, the lead researcher, or the study doctor, as appropriate.

- **Email**: BeeStudy@UCSF.edu
- **Phone**: (415) 476 7634

If you wish to contact the principal investigator directly, you can reach Dr. Mason at (415) 514 6820 or ashley.mason@ucsf.edu.

If you wish to contact the study doctor directly, you can reach Dr. Hecht at Rick.Hecht@ucsf.edu or (415) 476 4082 extension 431.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Committee on Human Research at (415) 476 1814.

A description of this clinical trial 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.

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CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____ _____
Date Participant's Signature for Consent

_____
Print name of Participant

_____ _____
Date Person Obtaining Consent

_____
Print name of Person Obtaining Consent