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

Study Title: Transcutaneous Vagal Nerve Stimulation in Romantic Relationships

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This is a research study about romantic relationships. The Principal Investigator, who is the person in charge of the study, or another member of the study team from the UCSF Department of Psychiatry and Behavioral Sciences will explain this study to you.

DETAILED STUDY INFORMATION

Research studies include only people who choose to take part. Please take your time to make your decision about participating and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you are a healthy adult who is in a committed romantic relationship between the ages of 18 and 39 and have indicated interest in participating.

Why is this study being done?

The purpose of this study is to examine the role of vagus nerve in changing how you feel and behave during different types of interactions. The vagus nerve is one of the largest nerves in our body that connects our brain to various organs including the heart, lungs, and stomach. It serves many functions, some of which can affect how we interact with other people such as regulating our facial expressions. This study is sponsored by the Emotional Well-Being Network funded by the National Institute on Aging.

How many people will take part in this study?

About 80 couples (i.e., 160 people) will take part in this study.

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

If you agree, the following procedures will occur:

- You will complete a questionnaire at home before attending a laboratory session with your partner.
- You will come to the laboratory (Nancy Pritzker Building, 675 18th Street, San Francisco) with your partner at a scheduled time.
- You will take part in a series of conversation tasks with your partner while being videotaped and wearing equipment to track changes in your physiology. Specifically, the experimenter will attach these sensors in the following manner:
  1. Sensors will be attached to your upper and lower torso in order to measure heart rate.
  2. We will apply four pieces of tape onto your body, two loosely encircling your neck and two loosely encircling your torso (one around your chest and another closer to your belly button), in order to measure the amount of blood pumped by your heart on each beat. You will have to lift your shirt approximately 3 inches above your belly button to allow placement of the tape. These sensors are disposable and are discarded after use.
  3. A blood pressure sensor will be placed on your non-dominant upper arm.
- We will also attach electrodes to either your outer auditory canal or ear lobe through which you will receive stimulation (which you will not be able to sense) during the conversations.
- In between the conversations, you will complete a series of short questionnaires.

We do not provide individual results of the study including your physiologic activities.

How long will I be in the study?

Participation in the study will take a total of about 2.5 hours – you will complete a questionnaire prior to coming to the lab (about 30 minutes) and a lab visit (about 2 hours).

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.

If you withdraw from the study, any data we have already collected from you will remain part of the study records. Also, the study researcher may stop you from taking part in this study at any time if they believe it is in your best interest, if you do not follow the study rules, or if the study is stopped.

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

- You may feel uncomfortable answering some of the questions about yourself and your relationship or while engaging in conversations with your partner in the lab. However, you will be able to skip any questions you do not want to answer and withdraw participation at any point during your lab visit.

- You may experience physical discomfort when we attach sensors on your skin to measure physiological changes. The sensors that we use are similar to adhesives used in band-aids. Some people experience minor redness upon removal of the sensors, which generally goes away within an hour.
- We will deliver stimulation through either your outer ear canal or ear lobe and the stimulation will be adjusted to be at the intensity you cannot perceive. However, there are potential local side effects of the stimulation, including itching, burning or prickling sensation on the ear, pain, redness, pressure marks and skin lesion at the stimulation site. You might also experience headache or nausea. Among epilepsy patients, an increased number of seizures has also been reported.
- In any case of discomfort, you can let the experimenter know and we will make adjustments or remove the device immediately. The side effects typically disappear soon after stopping the stimulation.
- For more information about risks and side effects, ask one of the researchers.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study.

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

You are free to choose not to participate in the 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 your care from our institution the way you usually do.

How will my information be used?

Researchers will use your information to conduct this study. Once the study is done using your information, we may use the information collected for future research studies or share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information. We cannot guarantee that this will prevent future researchers from determining who you are. We will not ask you for additional permission to share this de-identified information.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. For recordings, you will be asked again at the end of the study if you consent to our use of the data for analysis and/or for sharing at scientific meetings. All data from the study, including the recordings, will be kept in locked files, secure servers or encrypted computers at UCSF by the principal investigator of the study, with access restricted to study staff.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Health
- Representatives of the University of California

This research is covered by a Certificate of Confidentiality. It prevents State and Federal courts, legislatures, and administrative agencies from requiring researchers to reveal information (by subpoena/court order or otherwise) about research participants.

The Certificate DOES NOT:

- stop legally required reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.
- stop a sponsoring United States federal or state government agency from reviewing research records to monitor or evaluate programs.
- stop disclosures required by the federal Food and Drug Administration (FDA).
- prevent your information from being used for other research if that is allowed by federal regulations.

The Certificate does not stop you:

- from releasing information about your involvement in this research.
- from having access to your own medical record information.

Are there any costs to me for taking part in this study?

No. The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed.

Will I be paid for taking part in this study?

In return for your time and effort, you will be paid $125 for completing the entire study. You will be paid in full in cash at the end of your laboratory visit. In case you complete only a portion of the study, you will be paid per your time ($25 per 30 minutes).

Will I be reimbursed if I pay expenses related to my participation in this study?

You will not be reimbursed for expenses if you take part in this study.

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

It is important that you tell your study doctor, Dr. Wendy Berry Mendes or Dr. Yoobin Park, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call them at 415-476-7409 (email: Wendy.Mendes@ucsf.edu) or 628-946-1325 (email: yoobin.park@ucsf.edu).

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 Institutional Review Board 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 in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

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 at Yoobin Park (Yoobin.park@ucsf.edu) or Professor Wendy Berry Mendes at 415-476-7409 (email: Wendy.Mendes@ucsf.edu). 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 Institutional Review Board 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. The National Clinical Trial (NCT) number for this study is NCT05899413.

CONSENT

You have been given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point 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
Date	Person Obtaining Consent