Study Title: Effects of a Wellbeing Intervention on Inflammation Through Reward and Threat Processes

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University of California, Los Angeles
CONSENT TO PARTICIPATE IN RESEARCH

UCLA SAVOR Neuroimaging Study:
A pilot study of savoring for UCLA undergraduates

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You were selected as a possible participant in this study because you are a UCLA undergraduate student who has low positive mood and expressed interest in a savoring intervention.

Key Information:

What is the purpose of this consent form?

The researchers involved in this study are seeking your consent to participate in this research. Your participation in this research study is voluntary.

Why is this study being done?

The purpose of this study is to evaluate the effects of savoring on psychological, neural and immune functioning.

How long will the research last and what will I need to do?

We expect that you will be in this research study for 9 weeks. You will be asked to complete a 7-week savoring intervention and 2 study visits. You will fill out questionnaires, give blood samples, and do an MRI scan.

If you are on medications, you will be asked to remain on a consistent dose/ regimen of your medication until after completion of the 7-week intervention and post-treatment assessment. You should always consult with your primary provider before making changes to medication, dose, or discontinuation of current medication Also, you will be asked to inform us if you seek other forms of medical or psychological treatment for depression, anxiety, or stress before completion of the 7-week intervention.

All 7 intervention sessions must be completed within 11 weeks. In addition, you may be removed from the study if you miss more than three treatment sessions without notifying study staff within 24 hours of your scheduled session. Further, we expect all participants to notify study staff within 24 hours before missing a physiological assessment. These assessments often require up to 5 researchers, and cancellations without notice are very inconvenient. We will work hard to schedule your appointments when convenient for you, so please let us know at least 24 hours in advance for any changes or cancellations.

What kinds of risks or discomforts should I expect?

The study includes blood collection, which may cause minor pain. It also includes an MRI scan in which you will be in a small, enclosed space lying still for 75 minutes, which can cause discomfort. Lastly, it includes questionnaires that ask about mood and emotional issues, which may make you feel uncomfortable.

Are there any potential benefits if I participate?

In initial studies, the savoring intervention has been shown to reduce depression, stress, and anxiety symptoms, as well as increase positive emotions. It is possible that you may experience these benefits after you complete the program.

What other choices do I have if I choose not to participate?

The other alternative is to not participate in this research study.

How many people take part in this study?

We plan to enroll approximately 20 participants.

What will happen if I take part in this study?

You will be assigned to meet with an experienced interventionist who will train you in savoring techniques. The one-on-one savoring sessions occur once a week for one hour for 7 weeks and will be held online. You will complete savoring-related homework between savoring sessions during the 7-week intervention. You will also complete in-person assessments at UCLA before and after the intervention. These will include completing questionnaires, providing blood samples, completing a behavior task, performing tasks assessing brain reactivity while lying in a MRI machine, and completing a daily diary. You will be paid after completing each study assessment. Savoring sessions are free for participants. The overall duration of this study will be approximately 9 weeks.

If you volunteer to participate in this study, we will ask you to do the following**:**

<u>Baseline (Pre-treatment) Visit</u>

1. During the pre-treatment visit, you will be asked to complete an online questionnaire. The survey questions will ask about demographic characteristics (ethnicity, gender), health behaviors (such as drinking alcohol and exercise), mood, and other personal characteristics. You may refuse to answer any questions that you do not want to answer and still remain in the study. The questionnaire will take up to 60 minutes to complete.

2. A small sample of blood (1/8 teaspoon) will be collected using a special device designed for easy, remote sample blood collection (TASSO device). The device is approximately the size of a credit card and attaches to your arm using a light adhesive. You will wipe the application site with alcohol, apply the device, and press a button that activates collection. Your sample will be used to look at aspects of your immune system. The blood sample is for research purposes only, and you will not receive the results. Any leftover study blood samples may be stored for future research studies.

3. You will complete a behavioral task involving viewing faces and responding to visual stimuli.

4. You will be asked to have a number of MRI pictures taken of your brain. These pictures are made with an MRI device that uses radio waves and a large magnet to create the images.

    a. The MRI scan will last up to 75 minutes. The MRI pictures will be made while you lie on a narrow bed placed inside of a large magnet. Throughout the scan, you will have at your disposal a squeeze ball that, if squeezed, will inform us that you want to discontinue your participation.

    b. During the MRI scan, you will be asked to perform various tasks that measure brain reactivity. The tasks include looking at images of people, objects, and nature scenes, and doing math problems. Some of the tasks are game-like and require you to make a response with a button box. The complete details will be explained prior to completing the scan. For scientific reasons, we may not give you all the information about the intent of the task, but there will be a complete debriefing at the end of the study.

    c. A comfortable head-stabilizing device (such as cloth, tapes, or pads on the sides of your head) will be used to reduce excess head motion. During the scan, you will be asked to remain very still for periods of up to 15 minutes (though most procedures will be much shorter). Should we detect an abnormality from your brain scan, a qualified physician or radiologist will assess the scan, speak to you regarding the abnormality, and provide you with referral information so that you may seek further testing.

5. At the end of the baseline visit (T1), you will be paid for your time and effort.

6. The entire visit will take approximately 3 hours.

7. For the week following the pre-intervention assessment before the savoring training begins, you will complete a daily diary every night. Each daily diary will take approximately 5 minutes to complete.

Intervention

Savoring sessions will be held once a week for 7 weeks online, for convenience. Each session will last one hour during which you will work with an experienced therapist. The purpose of this treatment is to increase your positive mood using various strategies and activities that target your thoughts, your behaviors, and your feelings. You will begin with a brief introduction to this therapy and the effects of low positive mood on your health and functioning. You then will work on scheduling more pleasant events in your daily life and enhance enjoyment of those events. Home practice is a key component of the savoring training. You will be instructed to practice savoring techniques on a daily basis and reflect on how different activities impact your mood. You will be asked to complete daily homework logs throughout the 7 weeks. All the intervention sessions will be audio-recorded for quality assurance.

Post-Treatment Assessment

This visit will be scheduled to occur approximately 1 week after the conclusion of the savoring training. For the week following the last savoring training session before the post-intervention assessment, you will complete a daily diary every night. Each daily diary will take approximately 5 minutes to complete.

You will be asked to complete a second online survey at your in-person visit, provide another 1/8 teaspoon of blood using the same collection device during the pre-intervention assessment, perform a behavioral task, and perform additional tasks while lying in a fMRI machine. This visit will take approximately 3 hours.

There are no plans to provide clinically relevant research results to you in this study.

Are there any potential risks or discomforts that I can expect from this study?

- The study questionnaires ask about mood and emotional issues. Answering some of these questions may cause discomfort. You may choose not to answer one or more of the questions on the study questionnaires.

- As with any blood collection, you may experience some pain, bruising, or bleeding during use of the Tasso device. You may also feel faint or nauseous, though these side effects are quite rare due to the small amount of blood drawn. There is also a rare risk of infection or allergic reaction. All blood samples will be performed using standardized collection procedures. You will watch a demonstration video so that you understand how to safely use the device before any blood samples are obtained.

- The MRI scan requires that you be confined in a small, partially enclosed space. Some individuals find this to be uncomfortable and may exhibit symptoms of claustrophobia including nervousness, sweating or other minor discomfort. The sound of the MRI scanner can be quite loud; you will be given special earplugs and headphones to minimize the noise. In addition, the magnetism of the machine attracts certain metals; therefore, people with metal within their bodies (such as pacemakers, infusion pumps, aneurysm clips, metal prostheses, joints, rods, or plates) will be excluded from the study. The "metal" in dental fillings is less responsive to magnetism and is therefore allowed. The investigators will ask you if you have any metals within your body. **You will be expected to notify the investigator conducting the study of any metal in your body, other than dental fillings**. **You must tell the technicians performing the MRI if there is any possibility that you are pregnant.** There are no other known side effects resulting from exposure to the MRI scan. The MRI scan does not involve exposure to radiation.

Will information about me and my participation be kept confidential?

You need to be aware that the investigator will need to disclose information including reporting to authorities to prevent harm to yourself or others. In the event that you tell the research or clinical staff that you are thinking about suicide, or if you answer yes to a question to having thoughts about suicide, the research staff will ask you more questions about the thoughts. Depending on how intense the thoughts are or how much you feel like hurting yourself, the research staff may provide you with referrals for treatment; work with

you to contact your personal physician, trusted family member, or therapist to discuss your thoughts of harming yourself; or work with you on a plan that may include getting you to a hospital for safety.

Otherwise, all information that is obtained in connection with this study and that can identify you will remain confidential. It will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of using only an identification number, and no other identifying information, on all questionnaires and samples that are collected as a part of this study. The data and samples are stored in a locked file cabinet or a password protected computer in the research office or lab. Only members of the research team and the study investigators have access to the data collected. When results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

Will I be paid for participating?

You will be paid $100 for completing the pre-intervention assessment and another $100 for completing the post-intervention assessment. There are opportunities for earning additional payments during the MRI scans during each assessment. You will also receive $1 for each day that you complete the daily diary for the week following the pre-intervention assessment and preceding the post-intervention assessment, for a total of $14 possible dollars. You will be paid $10 for attending your first savoring session plus $15 dollars for each savoring session attended after that for a total of $100.

What other things should I consider before participation?

Biospecimens: Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations (e.g. to comply with data sharing policies at the National Institute of Health). You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them. Any specimens (e.g., tissue, blood, urine) obtained for routine lab testing will be discarded or destroyed once they have been used for the purposes described in the protocol.

Disclosure: You are responsible for informing investigators of current mental and physical health conditions throughout the study. If your scores on depression or anxiety measures fall into a clinically significant range, the investigators may follow up with additional questions about your mental health and ask the UCLA Counseling and Psychological Services Center (CAPS) to follow up with you to assess and provide appropriate support and resources that are available on campus.

Removal from the study: The investigator may withdraw you from this study to protect your health and safety.

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

Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from UCLA.
- If you decide to take part, you can leave the study at any time.
- If you decide to stop being in this study you should notify the research team right away. The researchers may ask you to complete some procedures in order to protect your safety.
- If you decide not to take part, you can still receive medical care from UCLA.
- You may refuse to answer any questions that you do not want to answer and still remain in the study.
- You have the right to refuse storage and future use of blood samples.

Who can I contact if I have questions about this study?

If you have any questions, comments, or concerns about the research, you can talk to the one of the researchers. Please contact:

Robin Blades (Co-Investigator/Study Coordinator)
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How do I indicate my agreement to participate?

If you agree to participate in this study, you should sign and date below. You have been given a copy of this consent form and the Research Participant's Bill of Rights to keep.

SIGNATURE OF STUDY PARTICIPANT

_____
Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____ _____
Name of Person Obtaining Consent Contact Number

_____ _____
Signature of Person Obtaining Consent Date

UCLA Office of the Human Research Protection Program (OHRPP):
If you have questions about your rights as a research subject, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

Public Information about this Study:

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

FUTURE CONTACT
Please check and initial the appropriate box below and initial:

☐ _____I agree to be contacted by the study team to be asked if I would like to take part in additional research.

☐ _____I do not want to be contacted for future research.

SAMPLES FOR FUTURE STUDIES
The researchers also would like your permission to use your blood samples for future research.

☐ _____I agree to have my blood samples stored for future use by the study investigators.

☐ _____I do not want my blood samples stored for future use by the study investigators.