

San Diego State University
INFORMED CONSENT FORM
Consent form version date: 2/25/20

Approved
Minimal Risk
03-Apr-2020

Ecological assessment of psychophysiological and mood-related variability

IMPORTANT THINGS TO KNOW ABOUT THIS STUDY:

We are inviting you to join this research study. The purpose of the research is to understand how your thoughts and emotion vary throughout the day. People's thinking and emotions respond to events differently throughout days, weeks, and months, and we are interested in understanding those changes.

We are asking some people who join this study to attend one visit, while other people will participate completely over the internet. The study involves answering questions through an app four times a day for 30 days. Some participants will also use a headset at home to record their brainwaves once a day during this period.

You do not have to join this study. These are the reasons you might want to join this study: by participating you are helping to provide information which may benefit science and society. These are the reasons you might not want to join this study: you may get tired or uncomfortable from completing the questionnaires, performing the tasks, and thinking about sad memories. During the EEG recording, there is a small possibility of temporary discomfort by wearing the EEG equipment, as it may put mild pressure on your head much like a baseball cap.

We will give you details about the purposes, procedures, risks and possible benefits related to this study. We will explain other choices you have. We will also give you any other information that you need to make an informed decision about joining this study.

The following information is a more complete description of the study. Please read this description carefully. We want you to ask us any questions that will help you decide whether you want to join this study. If you join the study, we will give you a copy of this form to keep for reference in the future.

WHO SHOULD I CONTACT IF I HAVE QUESTIONS or Concerns?

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WE ARE INVITING YOU TO JOIN THIS RESEARCH STUDY.

We are inviting you because you are an adult and we are interested in how adults' thoughts and emotions vary throughout the day.

Up to 1,000 participants will be included at San Diego State University. Up to 9,000 others will be included over the internet.

Research is not the same as treatment, or other medical or psychological care or therapy. The purpose of research is to answer scientific questions.

You do not have to be in this study. You are free to say "yes" or "no", or to drop out of the study after joining.

WHY ARE WE DOING THIS STUDY?

We are doing this study to find out if there are any patterns to how people's thoughts and emotions interact. We want to know if there are specific patterns that can tell us more about how thoughts and emotions affect each other, and how the brain is affected by these thoughts and emotions.

WHAT IS THE TIME COMMITMENT IF I JOIN THIS RESEARCH STUDY?

Your participation will last one month. You may come to the Center for Understanding and Treating Anxiety for one visit to pick up the headset and to learn how to use it, or you may participate entirely through the app. There are four surveys lasting about 2 minutes each day. Your total time spent on surveys will be about 8-10 minutes a day. The headset recording for participants that pick it up will last about 20-30 minutes once a day.

The research scientist could stop your participation in the research study at any time even if you want to still be in the study. This would happen if:

- They think it is in your best interest to stop being in the study.
- You are not willing or able to do all the things needed in the study.
- The whole study stops.

If you stop being in the study, your information collected before you stopped being in the study will be included in the study unless you ask us to remove it.

WHAT WILL I BE ASKED TO DO IN THIS RESEARCH STUDY?

If you wish to be part of this study, your participation will involve responding to questions on an app that you will download on your phone. You will answer the questions 4 times a day for 30 days, along with one EEG session at home once a day, if you are one of the participants using the headset to record brain activity. If you agree to use the headset you will need to pick up the headset from our lab but the rest of the study will be completed at home.

If you consent to participate, you will start by registering with your email address in the app, then you will receive instructions on how to pick up the headset if you are one of the participants using it. If not, you will be directed to your first survey. After that, you will be reminded by the app to complete the survey four times a day until the 30 days are over.

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Surveys: You will be asked to fill out surveys or questions about your mood (for example screenings for anxiety and depression), personality, and relationships. There will be one survey at the beginning with a few different short questionnaires (about 3 questions each). Then, you will be prompted by the app to respond to the same 21-item questionnaire 4 times a day for 30 days. Once you get the reminder, you'll need to fill out the questionnaire within the time window specified (e.g. one hour or two hours).

Brain Activity Recording Session: If you take home the headset, your brain activity and muscle activity will be recorded while you are making decisions about things we show on a mobile screen, playing some games on a mobile, hearing sounds, or just looking at pictures. Brain activity is recorded using an EEG. You will take home a portable EEG headset. The instructions are provided in the app to get it set up, but you will wear a band on your head with sensors on it. We ask that you complete the EEG once a day at the end of the day. All of these recordings are completely painless, nonintrusive, and safe. They are similar to heart rate recordings (i.e., electrocardiogram or EKG) that are typical during routine physical exams—the only exception is that EEG records electrical activity generated by the brain rather than the heart.

WHAT ARE THE RISKS OR DISCOMFORTS INVOLVED IN THE RESEARCH?

Because we ask personal questions about you, you might remember unpleasant things when we ask you questions. You can refuse to answer any questions that you don't want to answer. You also can decide you want to stop participating.

Even though we will keep information collected in surveys/interviews private, there is a possible risk of loss of privacy.

The EEG recording is completely noninvasive. There is the possibility that you may experience mild, temporary pressure in response to the electrode cap no different than wearing a baseball cap. Finally, there is the risk of violating confidentiality as some of the information is personal and may be sensitive. You are free to terminate participation at any point in the study.

We may discover new information during this research study. This new information may affect whether or not you want to still be in the study. We will tell you so that you can decide if you still want to be in the research.

ARE THERE ANY BENEFITS TO PARTICIPATION?

There are no benefits for being in this study; however, by joining this research study, you are helping to provide information which may help science and society.

ARE THERE ANY ALTERNATIVES TO JOINING THIS RESEARCH STUDY?

The alternative is to not participate.

WILL MY INFORMATION BE PRIVATE?

Confidentiality will be maintained to the extent allowed by law. We will take steps to help make sure that all the information we get from you is kept private. We will do this by assigning you with a random number. In this way, all your information cannot be connected to you, except to your email address using that number.

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You have a right to privacy but the data we get about you in this study can be shared with the study team, San Diego State University's Institutional Review Board, and applicable institutional officials.

Research records will be stored on a secure database and will only be accessible to research staff associated with this study. Research data linking your email to your answers will be destroyed seven years after the end of this study.

The researcher may remove information that can identify you from the information that you provide in this research. This information could be used for future research studies or given to another researcher for another study. In this case, you won't be asked to consent to the future research.

We will use the information we learn to for published articles or for presentations to other scientists. But we will keep your information private. Others won't be able to identify you in those papers or presentations.

DO I HAVE TO JOIN THIS STUDY?

No, you do not have to join this research study. Even if you agree to join, you can decide later that you don't want to be in the research. If you choose not to join or later decide that you don't want to be in the study, there is no penalty or loss of benefits to which you are otherwise entitled

WILL I BE TOLD ABOUT THE RESEARCH RESULTS?

We will not contact you with results of this study after this study is completed.

WILL IT COST ME ANYTHING IF I JOIN THE RESEARCH?

It will not cost you anything to participate.

WILL I BE COMPENSATED OR PAID IF I JOIN THE RESEARCH?

If you are a SDSU undergraduate student, you may choose to be compensated with course credit. You will receive 3 credit hours for completing 75% or more of the daily surveys. You receive 2 hours for completing 50% or more. This amount covers the approximate hour of time spent doing surveys (over the course of the 30-day period), as well as the time it takes to download the app and respond to the initial questionnaires and sending the data via email to the investigators.

If you choose to not take course credit, you will be paid. You will receive a \$20 amazon gift card for participating in the study. This will be sent to your email address you provided upon completion of the 30-day period. Payment is contingent on 75% completion of the surveys. If less than 75% of the surveys are completed, the payment will be prorated. For example, if only 50% of the surveys are completed, you will receive \$13

WHOM DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS?

If you have questions later about the research, you may contact Nader Amir (619-229-3740) If you have any questions about your rights as a research participant, or in the event of a research related injury, you may contact the Division of Research Affairs at San Diego State University (telephone: 619-594-6622; email: irb@sdsu.edu). At any time during the research, you can contact the IRB for questions about research rights, to discuss problems, concerns, give suggestions, or to offer input.

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CONSENT TO PARTICIPATE:

The San Diego State University Institutional Review Board has approved this consent form, as signified by the Board's stamp. The IRB must review the consent form yearly. The IRB approval expires on the date indicated by the stamp in the upper right-hand corner of this document.

By checking and providing your first name or nickname and email address you understand what you have read about this study. You know how to contact researchers to ask any questions you have about the research. Later Please download or print a copy of this consent form, or a copy has been provided to you.

Please choose an option:

- I CONSENT to participating in this study.

Please enter the following:

First name or nickname: _____

Email Address: _____

- I DO NOT CONSENT.