Study title: Enhancing Transdiagnostic Mechanisms of Cognitive Dyscontrol

Clinical trials identifier: NCT04912089

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University of California, San Diego
Consent to Act as a Research Subject

Enhancing transdiagnostic mechanisms of cognitive dyscontrol using computer-based training

Introduction

Dr. Jessica Bomyea is conducting this research and asking for your consent to participate. This section provides a summary of important information. The rest of the form provides additional details.

- Research is voluntary - whether or not you join is your decision. You can discuss your decision with others (such as family or friends)
- You can say yes but change your mind later.
- If you say no, we will not hold your decision against you.
- Your decision will not affect your health care or any other benefits you may be entitled to.
- Please ask questions or mention concerns before, during or after the research.

Study Purpose: This study is being conducted to examine the effects of a computer-based study treatment designed to improve thinking skills, emotional symptoms, and underlying brain systems. Participants will be individuals who experience difficulties with stress-related symptoms, anxiety, or depression. We are trying to find out if the computer-based study treatment is safe and effective in treating your condition. Participation in the study may or may not benefit you directly and may result in new knowledge that may help others.

Summary of Main Procedures. You will first undergo a visit with a clinical interview assessment and questionnaires to determine if you are eligible for the study (approximately 2.5 hours). If you are eligible, you will complete a visit with cognitive assessments (i.e., measurement of thinking skills like attention and memory) and an MRI scan (approximately 2.5 hours). Then, you will be randomly assigned to receive a computer-based cognitive training program or not over a period of 4 weeks. After 4 weeks, you will complete a visit with the interviews and questionnaires (2.5 hours) and a visit with the cognitive tasks and MRI (2 hours) again.

Summary of Risks and Alternatives: The most commonly expected risks of the study are temporary emotional discomfort while being asked personal questions or completing challenging cognitive tasks, or temporary discomfort while completing the fMRI task (e.g., lying still for one hour). The most serious risks of the study may include harm or injury due to unsafe metal in your body during the MRI. We will carefully screen you for any conditions that may present a risk or hazard for MRI scanning. Participation is voluntary, and you may choose not to participate. There are alternative treatments for stress-related, mood, and anxiety symptoms. These include talk therapy as well as medications.

Why have you been asked to participate, how you were selected, and what is the approximate number of participants in the study?
You have been asked to participate in this study because you have expressed stress-related, anxiety, or mood symptoms. There will be approximately 80 participants.

Detailed Description of the study visits and how long each visit will last:
This study has several parts. You will be asked to participate in one or more parts of the study. Some computer tasks and the brain imaging session will be conducted at the UCSD Keck Center for Functional MRI. Interview, questionnaire, and computer task portions of the study will be conducted using telehealth technology (i.e., "Zoom") for convenience and safety during the COVID-19 pandemic.

If you decide to participate in the study the following is a summary of what will happen to you:

Screening visit (~2.5 hours):
1. Clinical interview - To determine if you are eligible to participate, you will be asked to complete an interview assessment. This interview assessment is a tool that helps our team diagnose of a variety of potential psychiatric conditions. In the interview, a member of our research team will ask you questions about your current and past mental health symptoms as well as your psychological treatment history. The interview will take approximately one to two hours. The interview will be video recorded and later rated by a clinical research assistant to make sure that we conduct the interviews the same way with each participant.

2. Questionnaire measures - You will be asked to complete questionnaires that have items about your sociodemographic information, psychological symptoms, and history of head injuries. The questionnaire portion will take approximately 30 minutes.

3. Cognitive Tasks – You will be asked to complete computer-based tasks that test your memory and problem-solving. These tasks will take approximately 20 minutes.

If your responses indicate that you are eligible, you will be asked to participate in the remaining visits of the study. If you are not eligible for the study, your participation will be concluded at this point.

Baseline visit (~2.5 hours):
This session will take place at the UCSD Keck Center for fMRI. We will ask you questions about MRI safety (e.g., metal in your body) at the beginning of the visit to make sure it is safe to scan you. If you are a female and capable of child-bearing, a urine-based pregnancy test will be administered prior to your MRI scan in order to be as sure as possible that you are not pregnant. It is important to be as sure as possible that you are not pregnant, because it is currently unknown whether or not exposure to the magnetic fields from an MRI scanner is a risk to a fetus. Only those women who have a negative pregnancy test result may participate in the study. You will be given a pregnancy test by the researchers to self-administer prior to the MRI scan. We will ask about additional conditions that are relevant to MRI safety, for example, whether you have a cardiac pacemaker; metal fragments in your body, or prosthetic devices that may be unsafe for scanning. MRI may not be appropriate under some of these conditions.

1. Cognitive tasks - You will be asked to participate in several different computer-based tasks that measure your reaction time and response accuracy. These computer tasks will take approximately 1 hour. You may take breaks between the computer tasks. The task(s) will be explained to you in detail beforehand so that you will know how to perform the task.

2. MRI scan - A picture of your brain will be obtained using a magnetic resonance imaging (MRI) scanner. The scan will take approximately 1 hour. During the MRI scan, you will be placed in a

large donut-like machine. Your head will be placed in a helmet-like holder that allows us to take images of your brain. The MRI technician will position you in the scanning machine, provide hearing protection including ear plugs and headphones, ensure that you can fully view the display screen, and give you the response device (i.e., button box or joystick).

During the scanning session, you will be asked to complete computerized tasks. These tasks will include doing one or more of the following: (1) looking at emotional stimuli (for example, negative words like death"), (2) solving puzzles, (3) resting awake, and/or (4) remembering pieces of information for a short period of time. The task(s) will be explained to you in detail before you enter the scanner so that you will know how to perform the task.

Computerized training treatment visits (approximately 4-8 hours):
This is the treatment part of the study. You will be randomly assigned by chance to one of two study treatment groups or a waitlist group. The random group assignment ensures that each participant has the same probability (~33% chance) of being assigned to any group. Neither you nor the researcher(s) can choose the group to which you will be assigned.

Study Treatment Groups:
If you are assigned to one of the study treatment groups, you will attend either 8 or 16 computer-based training study treatment sessions via Zoom, which last ~30 minute each, over the course of 4 weeks. During each session you will be presented with memory tasks and puzzles designed to engage and train your thinking skills.

Waitlist Group: If you are assigned to the waitlist group, you will not complete any exercises for a 4-week duration. You will be asked to complete a set of questionnaires 3 weeks after your previous appointment (approximately 15 minutes).You will be given the opportunity to complete the study treatment protocol after you have completed all study assessments.

Post Visit 1 (~2 hours):
Within approximately 1 week after completing the study treatment visits or waitlist period, you will attend an assessment session during which you will complete the same assessments that you completed during the Screening Visit.

Post Visit 2 (~2.5 hours):
Shortly after your Post Visit 1 you will attend a final assessment session during which you will complete the same tasks as the Baseline Visit (cognitive assessments and MRI).

What risks are associated with this study?
Participation in this study may involve some added risks or discomforts. In addition to the risks described at the beginning of this form,

a. Temporary discomfort including restlessness, anxiety, or fatigue in some people while filling out questionnaires, temporary discomfort while being asked personal questions about anxiety, depression, and negative life experiences (for example: "Have you ever experienced a traumatic or life-threatening event?"), or temporary discomfort or frustration while being asked to complete challenging computer tasks that ask you to remember many items at a time. These experiences occur in a small portion of individuals and are generally mild. You will also be asked to view words, sentences, or pictures that are negative (for example: read the word "embarrassed" or "stupid") that may cause temporary discomfort. We will do everything possible to minimize any risks or

discomfort you may experience as a result of the study. If you feel any discomfort as a result of participating in this study, you may stop at any time, and you should also contact the investigator for further consultation. The investigator will also provide you with a referral list with contact information for mental health resources in the community.

b. There is a risk of loss of confidentiality. To minimize this risk, all of your data will be anonymized and kept in locked cabinets or in databases with secured passwords.

c. Risk of MRI procedures. Some people experience a 'closed-in' feeling due to the relatively restricted space within the MRI machine. You may not be able to have the MRI procedure if you have certain metal, surgical clips, or implants, including a brain aneurysm clip or a pacemaker, in your body, because during the MRI procedure metal can heat up and move, or clips and implants can stop working. Other possible risks include muscle aches due to lying on your back for 1 hour in the scanner, emotional discomfort or agitation while in the scanner due to tasks that may be emotional in nature or challenging. You may experience muscle twitches during the scanning procedure. A small number of people experience vertigo related to the scan (i.e., sensations of dizziness or motion sickness). You may terminate the scan if you become overly emotionally or physically affected. You may experience discomfort due to banging noises that the MRI scanner makes while taking pictures. You will be asked to wear earplugs to minimize the risks of these loud noises to your hearing.Sometimes over the course of a research study, research personnel may encounter incidental findings. An incidental finding is a previously undiagnosed medical or psychiatric condition that is discovered unintentionally. Research personnel are not trained to diagnose potential abnormalities. In such a case, a qualified medical professional will be consulted. If this condition requires further medical evaluation or treatment, you will be notified.

d. You will be assigned to a study group at random (by chance). Your assignment is based on chance rather than a medical decision made by the researchers. The study group you are assigned to might not be the group you would prefer to be in. Your assigned study group might also prove to be less effective or have more side effects than the other study groups(s), or other treatments available for your condition.

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

What are the alternatives to participating in this study?
The alternative to participation in this study is to not participate. There are alternative treatments available for psychological symptoms. These include cognitive behavioral and talk therapy, as well as medications that have been shown to reduce symptoms.

What benefits can be reasonably expected?
There may or may not be any direct benefit to you from participating in this study. All participants will also be given information on community clinics offering mental health services on a sliding fee scale. You may experience a decrease in symptoms or improvement in thinking skills as a result of these procedures. The investigators may learn more about new treatments to benefit individuals experiencing elevated levels of stress-related, anxiety, or depression symptoms.

What happens if you change your mind about participating?
Participation in this study is voluntary. Your choice of whether or not to participate will not influence your current or future relations with UCSD. If you decide to participate, you are free to

withdraw your consent and to stop your participation at any time without penalty or loss of benefits to which you are allowed. If you decide that you no longer wish to continue in this study, you will be requested to notify the Investigator, Dr. Bomyea, or another member of the study team. If you withdraw from the study, your data up to the point at which you withdraw will continue to be used for study analysis but no further information will be collected or added to the study database. If you do not wish for any of your data to be used you may notify the investigator or another member of the study team and your data will not be used.

Can you be withdrawn from the study without your consent?
There may be conditions under which the Investigator, Dr. Bomyea determines that your participation in the study should end. These include any signs of change in your health status that may jeopardize your well-being (e.g., significant worsening of anxiety or mood symptoms). You can be withdrawn from the study if you do not follow instructions from the study team. You can also be withdrawn if the investigator believes it is in your best interest. If your study participation is ended for these reasons, you will be referred to clinical resources in your community.

Are there any costs associated with participating in this study?
The only costs associated with this study are transportation costs to UCSD and the time required to complete the study procedures. You or your insurance will not be billed for the study procedures, such as the pregnancy testing or MRI.

Will you be compensated for participating in this study?
If you complete the baseline clinical assessment but are then deemed ineligible to participate, you will be compensated $30. Otherwise, you will be compensated $100 per completed set of assessments visits (maximum $200), $10 for each week of completed study treatment or wait time (maximum $40), and a $10 completion bonus for all parts, for a total of up to $250.

You will be reimbursed for parking costs associated with visiting the UCSD campus.

What if you are injured as a direct result of being in this study?
If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research subject or to report research-related problems.

What about your confidentiality?
Research records will be kept confidential to the extent allowed by law. Your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office. Consent forms with identifying information will be kept in a separate locked filing cabinet from research materials. Any research records that identify you will be kept only as paper records in a secure UCSD location, or as files behind a secure computer firewall. None of the presentations or publications based on the data collected through this study will identify you.

Information about you is protected by a federal Certificate of Confidentiality. This means that we cannot be forced to release information about you for any legal proceeding, even if a court of law asks. The Certificate allows us to use information about you for purposes of this research,

or to disclose it for other research when allowed by law. The Certificate requires other researchers to also protect information we share with them.

There are limits to this protection. The Certificate does not protect your information when:

• You or your family voluntarily release information about yourselves.

• You consent to release of information (for example, the uses described in this form, or if you sign release forms for employment, insurance or medical care).

• A federal agency audits or evaluates research that it funds.

• Researchers are required to report possible intent to harm yourself or others, child abuse, elder abuse, or infectious disease cases."

. During the course of your participation in this study, if our research team is given information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect we must report this information to the appropriate authorities under California Law. Our team is also legally required to report serious threats of physical violence against a reasonably identifiable victim or victims to law enforcement and the victim(s). In the event that you report intention to injure or harm yourself (e.g., thoughts of suicide) the Investigator may also report this to appropriate medical or law enforcement personnel as required to assure your safety.

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) because the study is funded by the National Institute of Mental Health (NIH). NDA is a large database where deidentified study data from many NIMH studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about mental health and substance use more quickly than before. During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA. Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity. You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about mental health and substance use and how to help others who have problems with mental health and substance use. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA. You may decide now or later that you do not want your study data to be added to the NDA. You can still participate in this research study even if you decide that you do not want your data to be added to the NDA. If you know now that you do not want your data in the NDA, please tell the study researcher before leaving the clinic today. If you decide any time after

today that you do not want your data to be added to the NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of the NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, this is available on-line at http://nda.nih.gov.

Consent to be contacted for future studies and to contact an alternative person
Please **check** a box below to indicate whether or not you would like to be informed about other studies you may be eligible to participate in:

☐ **YES**, you agree to be contacted about other studies. _____ (initial here)

☐ **NO,** you do not wish to be contacted about other studies. _____ (initial here)

In the case that the research team is not able to contact you via your primary telephone number, would you be willing to provide information for an alternative contact person?

☐ **YES**

☐ **NO**

_____ Alternate Contact Person

_____ Alternate Contact Number

May we leave a message?

☐ **YES**

☐ **NO**

Will you receive any results from participating in this study?
If you would like to receive study results, we will share a copy of the publication once it is available.

Who can you call if you have questions?
This study has been explained to you and your questions have been answered. If you have other questions or research-related problems, you may reach Dr. Jessica Bomyea at (858) 534-9446.

You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) to inquire about your rights as a research subject or to report research-related problems.

Your Signature and Consent
You have received a copy of this consent document and a copy of the “Experimental Subject's Bill of Rights” to keep.

By initialing here, you agree to complete the consent in electronic format: _____

You agree to participate.

Subject's signature	Date
Signature of the person conducting the informed consent discussion	Date