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Title of Study: **Using CBT to Probe Psychobiobehavioral Resilience to Post-trauma Psychopathology**
Sponsor: **National Institute of Health**

RUSH

Subject Information Sheet and Consent Form

Introduction

You are being invited to take part in this research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the information in this form carefully, as it may contain words you do not understand. You may wish to discuss it with your doctor, family, and/or friends. If there is anything that you do not understand or you would like more information, please ask questions and the study doctor or study staff will try their best to answer them. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate. Before anything is done for this study, you must sign this form. A copy of this signed form will be given to you.

You do not have to take part in this study. You are free to withdraw from this study at any time you choose without giving a reason. This will not affect any future care you will receive. No promises can be made about the outcome of this as far as your current condition, either positive or negative. People who take part in research are called "subjects" instead of "patients".

Why are you being invited to participate in this study?

You are being asked to take part in this study because you experienced one or more traumatic events early in life. This traumatic event may be causing difficulties that are currently affecting your ability to manage the stressors in your life.

What is the purpose of this study?

The purpose of this study is to examine the impact of two health and wellness programs on resilience to current and future stress among individuals with a history of trauma. Being resilient means being able to adapt and overcome in the face of difficult or challenging life experiences. We will also examine whether the health and wellness programs affects psychological symptoms associated with trauma (anxiety, depression, and substance use).

One program focuses on teaching you ways to improve your mood; the other program focuses on teaching you ways to improve your general health. These health and wellness programs have been shown to help people improve their mental and physical health; however, these particular programs have not been investigated as a way to prevent future distress among individuals with a history of trauma. Based on the information that we gather from this study, we may be able to improve psychological care of individuals who have gone through a traumatic experience.

How many study subjects are expected to take part in the study?

Approximately 90 subjects are expected to participate at Rush University Medical Center.

What will you be asked to do?

Screening Visit

After your written consent has been obtained and you receive a copy of this consent, you will be asked to participate in screening tests and procedures to determine if you are eligible for participation in this study.

The screening visit will last about 2.5 hours:

- We will explain the study to you and answer any questions you have.
- You will fill out questionnaires and talk to our clinician. We will be asking about your demographics (gender, age, ethnicity), medical and psychiatric history, any medications you have been taking, any illnesses that you may be experiencing, any current psychotherapy you have been receiving, any traumatic events you have experienced, major life events, and present and past psychological symptoms. We hope you will answer all questions but you can skip over any you do not want to answer.
- These assessments will be video-recorded to ensure that it is being done in a consistent manner; the recordings will be labeled by subject number only (not name), and will be deleted 5 years after the end of the study
- You will be asked to complete a urine drug test to help us determine whether you are using any drugs

If you qualify for the study based on the outcome of the screening assessments, you will be enrolled in the study. Once eligible, you will be asked to come in for a baseline visit.

Baseline Visit

The Baseline Visit will last about 2 hours:

- You will fill out questionnaires. We will be asking about factors related to resilience (things that help you cope with stress) and current psychological symptoms. We hope you will answer all questions but you can skip over any you do not want to answer.
- You will complete a task on the computer where you will be asked to watch a series of pictures and respond to the images that appear using the keypad.
- You will take part in a procedure that assesses extinction learning. See below for more specifics of this procedure. This task will be video-recorded to ensure that it is being done in a consistent manner; the recordings will be labeled by subject number only (not name), and will be deleted 5 years after the end of the study.
- About 1 tablespoon of blood (20 mL) will be drawn before and after the extinction learning task. Specifically, we will assess the part of the blood associated with biological resilience factors.

Extinction Learning Task:

The aim of this task is to determine whether or not the health and wellness program will help extinguish (turn off) a fear response that will be learned in the lab. This task will last around an hour and any distress experienced while participating in the task is not likely to continue beyond completion of the task. During this task, there is a possibility that you will receive a mild electrical current on two fingers of your non-dominant (less favored) hand. Prior to this task, you will determine what level of electrical current is "**highly annoying**" to you, "**but not painful**." Generally, this is in the 3-4 milliamps range and the current only occurs for 250 milliseconds. It

is important to note that this is in the range that chiropractors and physical therapists use, but for a much shorter duration. During this task, there is a possibility that you will receive a blast of air to your larynx (the upper area of your neck). This airblast will come at an intensity of 140 p.s.i. and is meant to be uncomfortable but not painful. During this task, you may also occasionally hear brief, loud tones. These tones appear loud, but they do not cause any hearing damage.

The task involves the following steps:

- Step 1: attachment of psychophysiological equipment
- Step 2: choosing the level of electric current you will receive/confirming the level of airblast is not painful
- Step 3: testing procedure

Step 1: A member of the research staff will attach one set of wires with sticky pads to the index and middle fingers of your dominant (favored) hand, another set of wires with hook and loop fasteners to the index and middle fingers of your non-dominant (less favored) hand, and attach a third set of wires with sticky pads to your face.

Step 2: In this study, we will use mild electric current (lasting about 250 milliseconds each) or a blast of air. You will decide the level of current we use during your testing sessions. At first, we will send current at a level that you should not even feel. Then we will increase the current in small steps, with your permission. We will ask you to tell us when you feel the level of current is highly annoying, but not painful. We will stick to the level of current that you select. The level of current will not be increased without your consent. The level of the blast of air will also be shown. This level is predetermined but if it is too uncomfortable, you should inform us and the study will be stopped.

Step 3: The purpose of the electric current/airblast is to create a situation in which emotional learning may occur. In this study, you will see a series of pictures of different shapes on a computer monitor and you will hear brief, loud tones through the headphones. You will notice that some, but not all, of the pictures presented to you will be followed by the electric current at the level you chose before the test began. We will measure your body's physical responses to the images through wires attached to your fingers and face with sticky pads. We will also ask you to indicate whether you expect to receive the electrical current/airblast on a keypad. Although you may experience some distress during the task, it is not likely to continue after the task has ended.

Health and Wellness Program Phase (Weeks 1 through 8)

These visits will last around 60 minutes:

- You will be randomized or selected/assigned by chance, like a flip of a coin or roll of a dice, to one of the two health and wellness programs described below.
- These sessions will be video-recorded to ensure that they are being done in a consistent manner; the recordings will be labeled by subject number only (not name), and will be deleted 5 years after the end of the study.
- You will fill out questionnaires about any changes you have made in your psychological treatment, factors related to your resilience (things that help you cope with stress), symptoms related to anxiety and mood, and your feedback on the program. We hope you will answer all questions but you can skip over any you do not want to answer.
- At Weeks 3 and 6, about 1 tablespoon of blood (20 mL) will be drawn. Specifically, we will assess the part of the blood associated with biological resilience factors.

Healthy Mind Program
You will meet with your trainer for 8, 60-minute sessions. These sessions will focus on developing a personalized resilience plan, identifying your current strengths, building 3 new resilience and coping strategies, and discussing how to use these techniques in your daily life.

Healthy Body Program
You will meet with your trainer for 8, 60-minute sessions. These sessions will focus on important health-related topics including exercise; nutrition; proper hydration; alcohol / tobacco; and sleep. Each session is spent providing discussing these topics and strategies and how to make changes in these areas.

Post-Health and Wellness Program Visit (Week 9)
The Post-Health and Wellness Program Visit will last around 2 hours.

- You will fill out questionnaires about any changes you have made in your psychological treatment, factors related to your resilience (things that help you cope with stress), life events, any traumatic events that occurred during the study, symptoms related to anxiety and mood, and your feedback on the program. We hope you will answer all questions but you can skip over any you do not want to answer.
- You will complete a task on the computer where you will be asked to watch a series of pictures and respond to the images that appear using the keypad.
- You will take part in a procedure that assesses extinction learning. This is the same task you completed during the Baseline Visit. This task will be video-recorded to ensure that it is being done in a consistent manner; the recordings will be labeled by subject number only (not name), and will be deleted 5 years after the end of the study.
- About 1 tablespoon of blood (20 mL) will be drawn before and after the fear conditioning task. Specifically, we will assess the part of the blood associated with biological resilience factors.
- If you were in the healthy body program, you will be given the option of completing the healthy mind program at this time. If you choose to complete the healthy mind program, you will be asked to repeat the post- program visit (Week 9) at the end of the healthy mind program.

2 Month Follow-up and 6 Month Follow-up
The 2 month and 6 month follow-up visits will each last around 2 hours. This visit is important for us to understand whether the health and wellness program had lasting effects.

- You will fill out questionnaires about any changes you have made in your psychological treatment, factors related to your resilience (things that help you cope with stress), life events, any traumatic events that occurred during the study, and symptoms related to anxiety and mood. We hope you will answer all questions but you can skip over any you do not want to answer.
- You will complete a task on the computer where you will be asked to watch a series of pictures and respond to the images that appear using the keypad.
- You will take part in a procedure that assesses extinction learning. This is the same task you completed during the Baseline Visit. This task will be video-recorded to ensure that it is being done in a consistent manner; the recordings will be labeled by subject number only (not name), and will be deleted 5 years after the end of the study.
- About 1 tablespoon of blood (20 mL) will be drawn before and after the extinction learning task. Specifically, we will assess the part of the blood associated with biological resilience factors.

Data repository

- You are invited to donate your blood to a data repository for research purposes. Your decision to donate your blood for future research is entirely voluntary. The *repository*, or storage bank, consists of a freezer where your blood will be stored and a computer database.
- The specimens will be in the locked laboratory of the Department of Psychiatry. We will collect the samples during the blood draws for the study you are already participating in. There will not be any additional blood draws beyond what you are already giving for the *Using CBT to Probe Psychobiobehavioral Resilience to Post-trauma Psychopathology* study.
  - To protect confidentiality, each subject is assigned a unique code for these blood samples. No data sources will contain information that will personally identify subjects. Only study personnel will be able to link your name to the identification number. All information and data collected in the study will be kept in a password protected computer file on the Department of Behavioral Sciences secure server or in a secure locked cabinet in the Department of Behavioral Sciences. Blood samples will be kept in a freezer in a locked room in the Department of Psychiatry. Only approved study staff will have access to this data.
  - Whether or not you donate to the blood repository will have no effect on your eligibility for this study or your relationship with Rush University Medical Center or the quality of your care.

I agree to the use of my specimens for the data repository.
____Yes ____No Initial_____

  - *Genetic research*: The cells of your body contain deoxyribonucleic acid, or DNA for short. DNA is passed down from your parents. DNA carries the genes that determine physical features such as the color of your hair and eyes. Differences in our genes help explain why we all look different. They may also determine how different people get certain diseases and respond to drug treatments. The use of genetic material in research to study the causes of disease and to help understand how individuals respond to drug treatments is called genetic research.

    Since your samples and information are collected as part of a repository, they may be used for future genetic (hereditary) research. In the case that an investigator uses your samples for genetic analysis you will not be notified of the results. These results will not be labeled with any identifying information. However, you may choose to be excluded from participating in future genetic studies below. Your response will not impact your participation in the repository.
  - A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:
    - Health insurance companies and group health plans may not request your genetic information that we get from this research.
    - Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
    - Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

- Be aware that this new Federal law does *not* protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

I agree to the use of my specimens for future genetic research.
____Yes ____No Initial_____

If you change your mind and wish to withdraw your tissue or specimen at a later time, you may do so, in writing, by addressing a letter to the research coordinator or repository manager (Dr. Michelle Kaufman – contact information at the top of Page 1).

How long will you be in the study?

If you choose to take part, your participation in this study will be for approximately 9 months.

You may be removed from this study without your consent. Possible reasons may be that the study doctor decides that continued participation in the study will be harmful to you, you will need a treatment not allowed during the study, your symptoms become worse, you are unable to complete the health and wellness program as directed, or the study is canceled.

What are the possible risks of the study?

Health and Wellness Program Risks

The two programs have not been shown to cause any harm. It is possible that learning new coping skills may be difficult; however, this distress is usually very mild and decreases with further practice. It is possible that changes in health behaviors may lead to injury. Study subjects with any medical conditions that would affect their diet, exercise, and sleep should speak with their primary care doctor prior to making any significant changes to their routine.

Emotional Risks

We expect risks to you to be minimal. There is a risk that discussing traumatic experiences and current symptoms may cause temporary discomfort or emotional distress. Research shows that individuals generally report lower distress as a result of being asked about these experiences. However, you do not have to answer any questions that make you feel uncomfortable.

Please notify the study staff immediately if your psychological symptoms get much worse or you are having any harmful thoughts. Michelle Kaufman, PhD will be available to answer any questions or concerns you may have by calling Dr. Kaufman at 312-563-0224.

Blood Drawing Risks

You may feel some pain associated with having blood drawn through a vein. You may experience pain or discomfort, and/or bleeding, and bruising at the site the needle enters the body, and in rare cases, fainting or infection, which can be treated.

Extinction Learning Risks

The risk associated with the extinction learning task is minimal. During the study, the electric current/airblast you receive will be uncomfortable but not painful or dangerous. You may experience temporary mild anxiety in response to the procedure. Additionally, some people may

experience mild allergic reactions to adhesives used in attaching wires to the skin or may experience redness and drying of the skin as a result of gels used in cleaning and preparing the skin for the study procedures. Any reaction to these chemicals is expected to be mild and temporary. Any distress experienced while participating in the study is unlikely to continue beyond completion of the study procedures.

Are there any anticipated pregnancy risks?

We do not anticipate that any procedures will pose risks to pregnant women or fetuses above and beyond those already described. Other studies have not excluded pregnant women. If you have any concerns, you should consult with your doctor prior to starting the study.

Are there benefits to taking part in the study?

There may be no direct benefit to you for participating in this study. All subjects will be offered an health and wellness program as part of this study, however, the success of programs cannot be guaranteed for any particular individual. The potential benefit to others is that the study may advance our understanding of underlying risk and resilience processes linked to post-trauma symptoms, allowing researchers to develop improved preventive health and wellness programs**.**

What other options are there?

Taking part in this study is completely voluntary. You do not have to take part in this research study to receive psychological care. There are routine treatments available for psychological distress. You should discuss treatment options with your doctor so that you have enough information to decide if you want to participate in this study.

What about confidentiality of your information?

Records of participation in this research study will be maintained and kept confidential as required by law. To help protect confidentiality, each subject is assigned a unique code. No data sources will contain information that will personally identify subjects. Only study personnel will be able to link your name to the identification number. All information and data collected in the study will be kept in a password protected computer file on the Department of Behavioral Sciences secure server or in a secure locked cabinet in the Department of Behavioral Sciences. The video recordings will only be kept for 5 years after the end of the study and then they will be erased. Blood samples will be kept in a freezer in a locked room in the Department of Psychiatry. Only approved study staff will have access to this data.

If you withdraw from this study, the data already collected from may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you.

Your identity, including video recordings, will not be revealed on any report, publication, or at scientific meetings. Your data may be reported, anonymously, to provide examples of the extinction learning task.

In order to conduct the study, the study investigators will use and share personal health information about you. This includes information already in your medical record, as well as information created or collected during the study. Examples of the information that may be shared include your medical history, physical exam and laboratory test results. The study doctor will use this information about you to complete this research.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is titled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects.

A description of this study 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.

What are the costs of your participation in this study?

There will be no cost to you for taking part in this study. All clinic fees, professional fees, diagnostic and laboratory fees are part of this study at no cost to you.

The cost of your ongoing routine medical care, which is not part of this research study, will be billed to you or your health insurance in a normal way.

Will you be compensated or paid?

Your parking or public transportation costs will be reimbursed at each visit. In addition, study subjects will be compensated $30 for the screening visit, $50 for the baseline visit, $15 for both blood draws done at sessions 4 and 7, $50 for the post-health and wellness program visit, and $50 for each of the follow-up visits. You will not receive any additional compensation beyond transportation for the Health and Wellness visits. You will only be paid for activities you complete. If you complete the entire study, you will be paid a total of $260.

You have the option of receiving gift cards as you complete the study visits or a single check at the end of the study that may take up to 4 weeks to arrive. The payment will be reported to the Internal Revenue Service. We will collect your social security number when you begin the study in order to process your payment.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. Please check with your insurance company regarding coverage.

If you have any medical problems during the study, please contact the study doctor. She will explain your treatment options to you and/or help you find a place to get treatment.

Neither Rush University Medical Center nor the National Institute of Mental Health (NIMH) has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

What happens if you need emergency care?

If you need emergency care while you are participating in this study, it is important that you tell emergency personnel of your participation in this study and notify the study doctor as soon as possible.

Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: Michelle Kaufman, 312-563-0224. Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 1-800-876-0772.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

SIGNATURE BY THE SUBJECT:

Name of Subject	Signature of Subject	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:

I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge. I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the subject and the person signing the form has done so voluntarily.

Signature of Individual Obtaining Consent	Date of Signature

☐ *Check here if the Individual Obtaining Consent observed the signing of this consent document and can attest, to the best of their knowledge, the person signing the consent form is the subject or the subject's legally authorized representative and the person signing the form has done so voluntarily. By checking this box, the Individual Obtaining Consent does not need to sign on the Witness signature line (below).*

SIGNATURE BY WITNESS/TRANSLATOR
(for use if this consent is being used as a written summary of the research along with a short form consent OR when the person obtaining consent is not the witness):

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the subject or the subject's legally authorized representative and the person signing the form has done so voluntarily.

Signature of Witness/Translator	Date of Signature

Check here if a separate witness signature is not necessary.

SIGNATURE OF THE PRINCIPAL INVESTIGATOR:
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

_____ _____
Signature of the Principal Investigator Date of Signature
Check here if Principal Investigator obtained consent and a separate signature is not required.