University of Miami –Informed Consent to Participate in a Research Study

IRB Study Number: 20190760
Version: 2 Date: 09/17/2021
Title: Expressing Personal Recollections in English or Spanish to Alleviate Traumatic Emotions (Exprésate)
Protocol Number: 20190760
ICF Version: 2
Protocol Date: 09/17/2021
PI Name: Roger McIntosh, Ph.D.
NCT number: NCT05090839

NAME: _____

MRN: _____

AGE: _____ DOB: _____/_____/_____

University of Miami –Informed Consent to Participate in a Research Study

Title of Study: Expressing Personal Recollections in English or Spanish to Alleviate Traumatic Emotions (Exprésate)
Principal Investigator: Roger McIntosh Ph.D.
Department: Psychology
Phone Number: 305-243-2047
Email Address: r.mcintosh@miami.edu

Study Contact Name: Beatriz Yepes
Study Contact Telephone Number: 305-284-1266
Study Contact Email: bey7@med.miami.edu

Key Information:

The following is a short summary of this study. It will help you decide whether or not to take part. More information is given later in this form.

You are being asked to take part in a research study. Doing so is voluntary. The purpose of this study is to test if expressive writing about traumatic events has positive changes in women living with post-traumatic stress. You will spend about 6 weeks in this study**.** You will be asked to complete interviews, surveys, physical exams, blood tests and functional magnetic resonance imaging (fMRI) twice, at the beginning of the study and 6 weeks later. In between the tests, you will complete some expressive writing sessions with a trauma specialist on a weekly basis for 4 weeks.

Taking part in the study involves some risks. You may become sad and emotional with the interviews and writing sessions. Blood testing may cause a bruise. The fMRI generally does not have risks as long as you do not have medical reasons you cannot be in an MRI machine. You may benefit by learning creative writing and thinking about your experiences.

Detailed Information The rest of the form gives more information about the study.

Introduction. You are being asked to take part in a research study. Before you decide to take part, you can talk to anyone about the study. Please ask the researcher to explain anything you may not understand. If you have questions later, you can ask any researcher.

NAME: _____

MRN: _____

AGE: _____ DOB: _____/_____/_____

Many women have experienced traumatic events in their lives. These events can have longlasting effects on their mind and body. We want to learn more about these processes so that we can find ways to help women with the effects of the trauma.

Overall Procedures.

The full study will be done over 6 separate sessions. The first and sixth session will last about 45 hours. Then, between those sessions (sessions 2-5) you will engage in 4 online writing sessions that last 30 minutes, over the course of a month (one session per week). You will be asked to write about either a major traumatic life experience or what you did the previous day.

During the first and sixth session, you will have the following done: (1) a blood draw, (2) interview about traumatic or non-traumatic event where we will ask you to write about said events for 5 minutes on a computer, your written description will be used to generate an audio script of the event that you will hear while in the MRI scanner, (3) surveys about yourself that might ask about your thoughts, feeling and behaviors during the weeks and months leading up to the study in addition to your language preference, substance use and psychiatric history, (4) tests for memory and attention that evaluate certain aspects about your ability to remember information and direct your attention, and (5) an MRI to look at your brain function while remembering traumatic and non-traumatic information/events.

Pre-Screening. You already answered some questions about your trauma symptom severity. We also asked you to bring a copy of your most recent labs drawn within the last 6 months if you are HIV+. You are asked to do some more procedures to determine whether this study is a good fit for you. Once we determine your fit and receive your consent, we will make a copy of those labs, remove any identifiable information, and return the original copy to you.

You will be asked to complete a urine test to see if you are actively using illicit drugs. You will also need to perform a COVID screening. After this is confirmed, you may proceed with the activities of Session 1 and 6, beginning with this consent form. Since we are taking a urine sample and are studying important markers in your blood, you must not have taken caffeinated beverages, over the counter medications, alcohol, street drugs and exercise, and to fast from 10 pm the night before you arrive at the Cox Neuroscience Annex. If you test positive for any of these, you will be rescheduled for a later date

Session 1 & 6 (Assessment Sessions):

These sessions will last about 4-5 hours. During these sessions you will first be asked to complete a physical exam. We will measure your height, weight and blood pressure. Next, you will see a phlebotomist, a person who draws blood from your arm. We will be collecting blood and saliva over three timepoints: first blood draw will be approximately 40ml, the second draw 20ml, and third draw 20ml for a total of 80ml or approximately 5 tablespoons of blood over 90 minutes. The purpose of the blood draw is to look at levels of inflammation in your blood. Following the blood draw you will go to a separate room where a mock scanner is located, so that you can better adjust to the real thing. You will then meet with a trained Spanish-speaking technician who will assist us with your MRI. You will be given a personal salivette to collect saliva before and after the MRI. The saliva test will measure stress hormones and inflammation.

An MRI is an imaging procedure that uses a very strong magnetic field and radio waves to take pictures of your brain. Functional MRI allows us to see what parts of the brain become active at different times. The MRI scanner is a metal tube surrounded by a strong magnet. During the MRI you will lie on a table that can slide in and out of the tube. A device called a "coil" will be placed over your head. This coil looks like a helmet but will not touch your scalp. A mirror will be attached to the coil so that you can see a computer screen to read and follow instructions. You will be given a button you can press to stop the scan at any time.

During the MRI procedure you will be asked to either lay quietly with your eyes open, follow written instructions on a screen, or listen to portions of your description of the traumatic and nontraumatic events. To limit your movement in the scanner your written descriptions will be narrated by a study team member. The total scan will last 30 minutes. We will collect a small amount of saliva, using a cotton swab and plastic tube directly before the scan and again 1, 15, and 30 minutes after the scan. We will use the saliva to measure stress hormones and inflammation. During the MRI we will monitor your heart rate, breathing rate, and blood pressure. We will do so by attaching sticky pads to your chest, fingers and/or feet. In order to safely attach these pads, we may need to clean your skin with some gel and/or use surgical tape. The tape can be easily removed, and the gel washed off with water. You will also be asked to refrain from wearing hair products, wigs, heavy facial make-up or any metallic based jewelry during the scan. While in the scanner, you will hear loud knocking noises and so you will be given earplugs or headphones to reduce the noise. You will be able to speak with the MRI technician at all times. You may ask to come out of the scanner at any time for any reason.

NAME: _____

MRN: _____

AGE: _____ DOB: _____/_____/_____

Sessions 2-5 (Writing Sessions):
You will be assigned by chance, like the flip of a coin, to one of three writing styles. All writing sessions will occur during the 4 writing days. You will be asked to write about upsetting experiences of your life in either English or Spanish or write about your daily events. You will be asked to explore your thoughts and emotions. The researcher will guide you on what to do. You will be asked to write without stopping for about 20 minutes. After the 20 minutes, you will talk about what you wrote with the researcher. In total, the session will take about 30 minutes.

Please note that none of the study procedures are a substitute for regular medical care. For example, if you are HIV+ you must see your doctor about your HIV care.

WHAT ARE THE RISKS OF THE STUDY?

The risks of taking your blood include fainting, temporary discomfort and/or a bruise at the site of puncture; rarely, infection or the formation of a small clot or swelling to the area may occur.

The surveys will ask about negative experiences that happened in the past or negative feelings and emotions you may be living with. We understand that some of these survey questions might make you feel uncomfortable, and you may refuse to answer any question.

The interview and writing sessions may evoke some emotional stress. Study staff will be present to help. The trauma writing will be done with a trained trauma therapist. You will be debriefed after each trauma writing. You will also be given support and information about possible reactions and about how to help you get support.

Because the risk of MRI to pregnant women and/or fetus is not known, those who are pregnant cannot take part in this study. However, we will not be screening for pregnancy so women who are of child-bearing age are encouraged to take a pregnancy test before consenting to take part in the study. While in the scanner, you may experience discomfort from hearing MRI-related sounds or when asked to recall unpleasant emotional events. You may close your eyes or ask to have the headphones removed, if needed. You may experience some discomfort due to the equipment that records your bodily responses. If you experience any irritation, please notify us immediately and any equipment causing the irritation will be removed.

NAME: _____

MRN: _____

AGE: _____ DOB: _____/_____/_____

MRI is an imaging procedure which uses a very strong magnetic field and radio waves to capture images of your brain. Absolutely no x-rays are used to produce the image. People are at risk for injury from the MRI magnet if they have certain types of metal in their bodies. You will be screened for these conditions before having each scan. If there are any findings, for your safety, you will not receive an MRI scan. Items that may cause harm include any electrical devices implanted anywhere in your body, some types of dental implants, metal clips, pins and rods holding body parts in place, heart valves, permanent eyeliner, piercings, or any other metal fragments in your body. In addition, all magnetic objects (for example, watches, cell phones, coins, jewelry, and credit cards) must be removed before entering the MRI scan room.

The noise from the scanner is loud enough to damage hearing, especially in people who already have hearing loss. Everyone having an MRI scan will be fitted with hearing protection. Participants will be asked to wear earplugs or headphones to reduce the sound. Sometimes, people report being uncomfortable during an MRI scan. For example, people that fear tight spaces may become nervous during an MRI. Those with back problems may have back pain or discomfort from lying in the scanner. Because of the strong magnetic forces of the scanner, some people might have brief periods of muscle twitching, eye discomfort, dizziness, mild nausea, headache, or a sensation of flashing lights. Participants will be informed that the best way to minimize these events is to not cross one's arms and legs during scanning. Should you feel discomfort you may stop the scan at any time and for any reason.

The MRI facility is a research facility, not a medical facility. The MRI scans obtained at the imaging facility are research scans, to be used for scientific purposes. The scientists who review the scans are not physicians and they cannot provide any medical advice or diagnose those images. These scans are not meant to provide medical information for you. Also, the facility has no medical staff to provide medical information or advice. If you are worried or have any concerns about anything that a scan might reveal, you should talk to your doctor about it.

The first research scan will be read by a radiologist. If any clinically important results are found, we will let you know and help you follow-up with a scan for medical purposes. The University of Miami will not pay for any costs relating to your standard medical care. You or your insurance company will be responsible for such costs. Should your scan be identified, receiving medical information may cause you some distress.

There are no known long-term risks of MRI scans

NAME: _____

MRN: _____

AGE: _____ DOB: _____/_____/_____

Catheter: Part of this study involves having a catheter (thin tube) inserted into one of your blood vessels. There may be slight discomfort while the study team inserts the catheter. Occasionally,

a bruise or small lump may form at the insertion site. A small amount of bleeding may occur around the catheter site. Rarely, a local infection may occur around the catheter site.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

A potential benefit of you taking part in this study is that you may practice expressive writing techniques shown to help manage symptoms of post-traumatic stress.

WHAT ABOUT CONFIDENTIALITY?

All your information will be coded by a special study ID code, not your name. We will keep any linking ID codes to names in a location that is separate from all the rest of the information. In all cases, paper records will be stored in a locked filing system. When data are entered into computer files for analysis, those files will also be kept safe by passwords so that only authorized persons can reach them. Access will be limited to project staff for only those purposes related directly to the study. Research staff who will have access to data will include UM faculty, graduate students and the project manager. Summaries and results from this research may be reported. We will not use your personal records in any scientific report without your permission.

The investigators and their assistants will consider your records confidential to the full extent permitted by law. The U.S Department of Health and Human Services (DHHS) may request to review and obtain copies of your records. Your records may also be reviewed by authorized University officials or other agents who will also make sure to keep your info confidential. You have the right to have your data destroyed at any time following completion of the study.

You may be contacted by one of our research staff members for follow-up. This means you will have to provide us with updated contact information. When we contact you or leave messages we will not discuss the study in order to make sure of your privacy.

A Certificate of Confidentiality (CoC), issued by the NIH, covers this research. A CoC helps protect your identifiable information and biological samples. A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study

that identifies you will not be shared outside this research except as described above. No one can be forced to share your identifiable information or biological samples for a lawsuit. Your information can't be used as evidence even if there is a court subpoena.

The CoC does not prevent some disclosures. You can still share information about yourself. You can also freely discuss your involvement in this research, but this is your choice. The information you share will no longer be protected by the CoC. The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local laws. If information is revealed that you are at risk to harm yourself or others, to abuse or neglect a child or elderly person, or you are experiencing abuse, we are required by law to report this immediately to the proper authorities.

This trial will be registered and may report results on www.ClinicalTrials.gov.

WILL YOU SHARE MY INFORMATION WITH OTHERS?

We will remove identifiable information from the Data we collect about you. After we remove all of the identifiers, we will place a code on the information. The code will be linked to your identity but the link will be kept in a location that is separate from your study data. We will also maintain your study data on encrypted computers and access to the information will be limited to only members of the research team who need the access to properly conduct the study.

We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

We may use the data and samples we collect from you for future research studies. We may also provide the data and samples to another researcher for future research. We will remove information that can identify you if we use or share the data and samples for future research. Once identifiers have been removed, we will not ask for your consent for the use or sharing of your Data or specimens for future research.

The following is a list of individuals who may access your records:

- Members of the research team

- Offices and committees responsible for the oversight of research

COMPENSATION

Schedule of Assessments for Visit			
	Procedures	**Locations**	**Compensation**
Session 1	Blood draw, personal trauma interview, psychological surveys, cognitive tests, MRI	Cox Neuroimaging Suite (NIS) 5151 San Amaro Drive, Coral Gables, FL	$100
Session 2	30-minute writing session	Online	$20
Session 3	30-minute writing session	Online	$20
Session 4	30-minute writing session	Online	$20
Session 5	30-minute writing session	Online	$20
Session 6	Blood draw, personal trauma interview, psychological surveys, cognitive tests, MRI	Cox NIS 5151 San Amaro Drive, Coral Gables, FL	$100

Participants will be compensated through Zelle ™.

* Note: Sessions 1 – 5 must be completed to be eligible to participate in and be compensated for Session 6.

WHAT ABOUT COMPENSATION FOR INJURY?

Although injury is unlikely, if injury should occur, treatment will in most cases be available. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay. Funds to pay for pain treatment, medical expenses, lost wages and other damages caused by injury are not routinely available. You do not give up or waive any of your legal rights by signing this consent form.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

NAME: _____

MRN: _____

AGE: _____ DOB: _____/_____/_____

Taking part in this study is voluntary. You may say no or leave the study at any time. You will be told about any new information that may affect your health or how much you are willing to continue taking part in the study. If you cancel your permission after you have started in the study the study staff will stop collecting your data. Although they will stop collecting new information about you, they may need to use the information they have already collected to evaluate the study results.

FUTURE RESEARCH:

The blood samples taken from you may be used for future studies about inflammation and posttraumatic stress. This portion of the study is optional. You can indicate below if you do or do not want the researchers to keep the blood stored. If you change your mind in the future, please contact the study team at the numbers below.

____ Yes, my blood samples may be stored for future research.

____ **No**, my blood samples may **NOT** be stored for future research.

WHO DO I CALL IF I HAVE QUESTIONS?

Roger McIntosh, PhD, is the principal investigator. He can be reached at **305-243-2047** and will answer any questions. If you prefer to a Spanish speaker **Beatriz Yepes** can be reached at **305284-1266.** Questions regarding your rights as a research participant you may contact the University of Miami**, Human Subjects Research Office** (HRSO) at **305-243-3195.**

AGREEMENT OF DECISION TO PARTICIPATE

You will receive a copy of this signed informed consent form. *I have read this form, which is printed in English (a language which I read and understand). This form has been explained to my satisfaction and all of my questions have been answered. If I have any further questions*

NAME: _____

MRN: _____

AGE: _____ DOB: _____/_____/_____

regarding this study, or in the event of a study-related injury, I should contact the person named above. Based on this information, I agree to give permission to take part in this study.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

NAME: _____

MRN: _____

AGE: _____ DOB: _____/_____/_____