Informed Consent Form

Title of Study: Neural Mechanisms of Enhancing Emotion Regulation in Bereaved Spouses

ClinicalTrials.gov Identifier: NCT04822194

Principal Investigator: Bryan Denny

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Consent Form for Participation in Research

Study Title: Neural Mechanisms of Reappraisal Training in Bereaved Romantic Partners

Principal Investigator: Bryan Denny, PhD
Assistant Professor
Phone number: 713-348-8257
Email: bryan.denny@rice.edu

Subtitle: Consent for Bereaved Romantic Partner

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Participant Name Participant ID Number

This consent and authorization form explains why this research study is being conducted and what your role will be if you choose to take part. This form also describes the possible risks connected with being in this study. After reviewing this information with the person responsible for your enrollment, you should know enough to be able to make an informed decision on whether you want to take part in the study.

You are being asked to take part in this study because you are a bereaved romantic partner.

Purpose of this Study

The goal of this research study is to find out more about how people cope with the bereavement experience and how bereavement impacts negative affect in response to various stimuli. The long-term goal of this work is to inform future interventions that can reduce suffering (physical and mental). This study seeks to include approximately 84 participants.

Procedures

If you agree to take part in this study, you will have a total of 7 study visits, which will span the course of 2-3 weeks. Additionally, you will be sent a follow-up via email one- and two-months after your initial appointment.

Visit 1 & 7: Blood Draws and Cognitive Assessments

At the first and seventh visit, you will have your blood drawn. At the first visit only, you will also go through a series of cognitive assessments. Some parts of the cognitive testing will be recorded for quality control purposes; you will be given the option to consent/object to audio recording.The first visit will take approximately 60-90 minutes and the seventh visit will take approximately 30 minutes or less. Both visits will take place either in the Rice University Bioscience Research Collaborative Building or in the Clinical Pathological Laboratories at Baylor College of Medicine in the Texas Medical Center. For blood draw purposes, you will be

asked to drink plenty of water and to avoid certain foods (including deep fried products, coffee, etc) the morning of your visit.

Visit 2 & 6: Brain Imaging Sessions, Oral Interview, Questionnaires, Health Assessments
At the second and sixth visit, you will 1) fill out questionnaires about general health and mood, 2) wear a device on your finger that measures your heart rate, 3) undergo an oral interview (more details below), 4) do a social image response task, and 5) undergo this task while being scanned by a functional magnetic resonance imaging (fMRI) machine. These visits will take approximately 2.5-3 hours and will take place at Rice University's BioScience Research Collaborative building and the Translational Imaging Center at the Houston Methodist Research Institute.

Visit 3, 4, 5: Behavioral Sessions
The third, fourth, and fifth visit will take place at Rice University's BioSciences Research Collaborative (BRC). At these visits, you will 1) complete one brief questionnaire and 2) do the social image response task at a computer. These visits will take approximately 30-60 minutes.

Follow-up Sessions
One- and two-months after your initial appointment, you will be sent an email containing a link to the same questionnaires you completed during the first and fifth appointments. You will complete these assessments remotely.

Oral Interview
During visits 2 and 6, participants will be orally interviewed with a trained experimenter and asked to discuss their relationship with the deceased romantic partner for six minutes while being recorded. Specifically, the participant will respond to the prompt, "Please tell me about your relationship with (deceased romantic partner's name)."

Participant Requirements
To be included in this study, you must have recently lost a romantic partner (within the last 5-7 months), and be able to speak, read, and write in English. Further, you must be eligible to safely complete MRI scanning and be at least 18 years of age.

Risks, Side Effects, and Discomforts to Participants
The possibility of harm or discomfort from this research is minimal. This study involves brain imaging using functional magnetic resonance imaging (fMRI). As MRI involves strong magnetic fields which are always present during scanning, participants with non-removable metal on or in the body may not be able to participate in this study. Participants will be screened for MRI eligibility both initially and later on the scheduled day of fMRI participation. This will involve

screening for the presence of any non-removable metal on or in the body, implanted medical devices, tattoos, medication patches, orthodontic braces or permanent retainers, hearing aids, and history of claustrophobia or breathing disorders.

The long-term effects of MRI procedures on the body are unknown. However, there is no evidence of harmful or adverse effects. The Food and Drug Administration (FDA) has set recommendations for exposure in MRI studies and this study satisfies those criteria. The MRI procedure is painless and not uncomfortable. However, it does require participants to lie still with the head and part of the body confined in a tunnel-like device. Therefore, some participants may experience claustrophobia. If this is the case, the participant may terminate the study immediately. Additionally, we will pre-screen for claustrophobia to reduce the risk that participants will find the enclosed space intolerable. We make a point of exposing participants to the scanner environment before an fMRI scan and explain the procedure in detail.

Some participants find the loudness of the oscillating gradients during image acquisition to be discomforting. Thus discomfort due to acoustic noise is an additional possibility. We will provide foam earplugs and foam padding to mitigate the acoustic noise and to increase participant comfort.

There is also a risk of heating in the scanner. The guidelines from the Bureau of Radiological Health by the FDA will be followed in regard to specific absorption rate (SAR) of radiofrequency energy and time varying magnetic fields (dB/dt). Precautions will be maintained so that SAR will be less than 8watts/kg in any 1 gram of tissue. This is the estimated power required to raise the temperature 1 degree centigrade. The maximum dB/dt will be set at 20T/sec for > 120us or 200T/sec for < 12usec. At these levels, any peripheral nerve stimulation will be minor, if any at all, and akin to light touching of the skin. If you feel any discomfort during scanning, you will be able to press the emergency squeeze button immediately to terminate the scan.

Any request to terminate the study because of any of the above reasons will be accommodated immediately. Additionally, in the MR scanner we can communicate with the participant via intercom so the participant can receive instructions and check in between scanning runs. Participants will be removed from the scanner immediately if they request to end the scan. They can communicate their desire to exit the scanner by speaking with experimenters between scans, or by squeezing a ball device (near the participant's left hand) while the scanner is running. Participants will be assured that they can terminate the experiment at any time for any reason, without penalty.

The final risk associated with the fMRI scanner is the possibility of an incidental MRI finding. Structural and functional images of the brain will be collected during the fMRI scanning session, raising the possibility of detecting a brain abnormality not otherwise known to the participant. Scanning parameters used in this study are not optimized for the identification of brain abnormalities. Additionally, researchers analyzing the data collected in this study are not trained to identify abnormalities. Participants will be informed of these facts prior to providing informed

consent. However, in the event that a researcher or scanner technician happens to note something potentially concerning when collecting a MRI scan, a neuroradiologist associated with Houston Methodist Hospital will perform a reading. In the event that the neuroradiologist deems follow-up care necessary, the neuroradiologist will contact the participant and provide referrals for appropriate care and will notify Drs. Denny and Fagundes. Medical expenses associated with the neuroradiologist's reading will not be reimbursed by study personnel but will be billed to the participant's insurance company. There is a minimal risk of undue stress or concern and costs for treatment, if referred to the participant and/or his or her insurance company. In addition, it is possible that participants could be unnecessarily worried if a problem were suspected, but not actually found.

Viewing loss and grief-related pictures may be upsetting to some participants, and the questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you experience any psychological discomfort as a result of the study, you are encouraged to contact the Mental Health and Mental Retardation Authority (MHMRA) of Houston through their crisis hotline: (713) 970-7000. This line is open 24 hours a day and can provide immediate crisis intervention, assess for risk, and recommend further resources. If the study staff thinks that any of your responses while on study suggest signs of depression or that you are thinking of harming yourself, you will be contacted by a member of the study staff who will give you a list of resources for mental health services.

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. We ask participants to drink their normal intake of water the day before and the day of each visit. We especially recommend a glass of water the morning of your visit.

Benefits

Future bereaved romantic partners may benefit from what is learned from the research. There may be no individual benefits for you in this study.

Compensation & Costs

You will be financially compensated for the time, effort, and inconvenience associated with participating in this study. For the pre-scan initial visit and the final visit (visit 6), you will receive $25 for each session. For visits 1 and 5, you will receive $30 per hour (pro-rated). For visits 2, 3, and 4, you will receive $25 per hour (pro-rated). For remote follow-up assessments, you will receive $10 for each follow-up survey you complete (there will be a total of 2 follow-up surveys). In total, you will earn approximately $270.00 for completing this study. All compensation will be in the form of Amazon gift cards. After completing all 7 sessions, you will receive an Amazon gift card reflecting your participation during all in-person visits. Once you have completed the 1-month and 2-month online follow-up surveys, you will receive a second Amazon gift card for your participation in the follow-ups. There will be no cost to you if you participate in this study. You will also receive parking validations for all visits.

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Ending Your Participation

Your participation in this study is entirely voluntary. You are free to refuse to be in the study and your refusal will not influence current or future relationships with Rice University and participating sites. You are free to discontinue your participation at any point in the study.

Confidentiality

By participating in the study, you understand and agree that Rice University may be required to disclose your consent form, data and other personally identifiable information as required by law, regulation, subpoena or court order. Otherwise, your confidentiality will be maintained in the following manner: Your data and consent form will be stored separately. Your consent form will be stored in a locked location on Rice University property and will not be disclosed to third parties. By participating, you understand and agree that the data and information gathered during this study may be used by Rice University and published and/or disclosed by Rice University to others outside of Rice University. De-identified data and other study results may be posted on ClinicalTrials.gov. However, your name, address, contact information and other direct personal identifiers in your consent form will not be mentioned by Rice University in any such publication or dissemination of the research data and/or results.

We will take the following steps to protect your identity during this study: (1) You will be assigned an ID number; (2) We will record any data collected during the study by number, not by name; (3) Your name and other identifying information will be kept in a password protected computer file that can be accessed only by authorized personnel of this project; (4) All original recordings or data files will be stored in a secured location accessed only by authorized personnel of this project.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen. All study data will be stored in password-protected computers and/or locked file cabinets. There will be no personal identifying information connected to your questionnaire answers. Identifying information such as your name and address will not be stored in the same location as the data files from the study. All data will be held for up to 10 years after study completion.

Rights

Your participation is voluntary. You are free to stop your participation at any point. Refusal to participate, withdrawal of your consent or discontinued participation in the study will not result in any penalty, loss of benefits or rights to which you might otherwise be entitled. The Principal Investigator may at his/her discretion remove you from the study for any of a number of reasons. In the event that this happens, you will not suffer any penalty or loss of benefits or rights which you might otherwise be entitled.

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Right to Ask Questions & Contact Information

This research study (IRB-FY2017-90) has been reviewed and approved by Rice's Institutional Review Board. If you have any questions about this study, you should feel free to ask them now. If you have questions later, desire additional information, or wish to withdraw your participation please contact the Principal Investigator, Dr. Bryan Denny, by mail, phone, or e-mail in accordance with the contact information listed on the first page of this consent form.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, you should contact the:

> Compliance Administrator at Rice University.
> Email: irb@rice.edu
> Telephone: 713-348-3586

By signing below, you agree that the above information has been explained to you and all your current questions have been answered. You understand that you may ask questions about any aspect of this research study during the course of the study and in the future. By signing this form, you agree to participate in this research study.

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PARTICIPANT SIGNATURE DATE

I certify that I have explained the nature and purpose of this research study to the above individual and I have discussed the potential benefits and possible risks of participation in the study. Any questions the individual has about this study have been answered and any future questions will be answered as they arise.

_____ _____

SIGNATURE OF PERSON OBTAINING CONSENT DATE