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CASE WESTERN RESERVE UNIVERSITY EST. 1826

INFORMED CONSENT DOCUMENT

Treatment of Stress-Related Psychopathology: Targeting Maladaptive and Adaptive Event Processing

You are being asked to participate in a research study about reducing maintained stressor-related psychopathology.

Researchers at Case Western Reserve University are conducting this study.

KEY INFORMATION

Purpose

The purpose of this research is to test a brief intervention that aims to provide relief for people who are suffering after experiencing a destabilizing life event, such as a sexual assault, loss of a job, divorce, or motor vehicle accident. We will explore whether or not this psychotherapy reduces stress related distress in comparison to an existing treatment, progressive muscle relaxation (PMR).

Procedures and Duration

Please refer to the Detailed Consent for a complete description of the study procedures.
Based on your completed telephone screening, you may be eligible for this study. You will then complete an in –person intake assessment that will last about 2 hours. Questions about life stress, mood, and anxiety will be asked by an interviewer and you will complete questionnaires. If the study is a good fit for you, meaning you are eligible and interested, you will receive 6 weeks of brief psychotherapy (90 minutes a session) followed by a post-treatment evaluation and 1 and 3 month follow-up assessments. Your study participation will end at this point and referrals will be provided if needed.

Reasons You Might Choose to Volunteer For This Study

You might choose to volunteer for this study if you have had stress-related symptoms that have not improved over time. We are testing a brief intervention that aims to provide relief for people who are suffering after experiencing a destabilizing life event. We will explore whether or not this psychotherapy reduces stress related distress. You may not benefit at all from this intervention. Your participation will help us determine if this brief talk therapy is tolerable and helpful for some.

Reasons You Might Choose Not to Volunteer For This Study

You may not want to volunteer for this study if you are uncomfortable disclosing details about destabilizing life events or answering questions about your mood and anxiety. You may not want to participate if you cannot attend weekly intervention sessions that last 90 minutes and assessments (pre, post, and 1 and 3 month follow-up) that will last approximately 2 hours.

Voluntary Participation:

If you decide to participate in the research, it should be because you want to volunteer. There is no penalty or loss of benefits for not participating or for discontinuing your participation.

DETAILED CONSENT

You were selected as a possible participant because you have experienced a destabilizing life event involving profound loss or threat and have associated mood or anxiety difficulties**.** If you are acutely suicidal or experiencing debilitating hallucinations or delusions, this study may not be appropriate for you. We hope to recruit a total of 135 people to volunteer for this research. Please read this form and ask any questions that you may have before agreeing to participate.

Procedures

If you agree to participate in this research, we would ask you to do the following things:

Based on your completed telephone screening, you may be eligible for this study. You will next complete an in –person intake assessment that will last about 2 hours. Questions about life stress, mood, and anxiety will be asked by a member of our study team and you will complete questionnaires. If the study is a good fit for you, you will be randomized to receive one of the two study treatments. This means you will not choose the intervention you receive and will be assigned at random, like the flip of a coin, to one of two study treatments: Positive Processes and Transition to Health (PATH) or PMR. The therapist will be aware of which treatment is received, the assessor will not. In both treatments, PATH and PMR, you will receive brief individual psychotherapy (90 minutes a session) via Zoom, each treatment includes learning skills to manage stress-related difficulties. The therapy will be weekly for six weeks, scheduled with your therapy provider (a member of our study team, who is either licensed or under the supervision of a licensed therapist). After you have completed the 6 week psychotherapy, you will again be assessed (i.e., posttreatment assessment) to determine if you have significantly benefited or not from the sessions. If not, you may be offered two additional sessions. Following the post-treatment evaluation, we will contact you for 1 and 3 month follow-up assessments. Your study participation will end at this point and referrals will be provided if needed. Each assessment will last about two hours. The study will not cost you anything. All study procedures including the 6 week intervention are provided to you at no cost.

All of your treatment visits and some of the assessment visits with the study psychologist and/or study psychiatrist will be audiotaped or videotaped. The tapes will be listened to by other research staff involved in the study to make sure you are getting adequate care and to help understand if the treatment works. These tapes will be stored for five years after the study is completed, after which they will be destroyed. Like all research information, these tapes will be stored in a secure location and will be kept confidential.

You can choose to stop participating for any reason at any time. However, if you decide to stop participating in the study, we encourage you to tell the researchers. You may be asked to complete some study termination activities (i.e., questionnaires/interviews), but you may choose not to participate in these activities.

Foreseeable Risks and Discomforts

All treatments and procedures may involve some level of risk to you, whether foreseeable or not.

There are no known risks, harms or discomforts associated with this study beyond those encountered in normal daily life. However, some of the activities we will ask you to complete might make you feel uncomfortable. You may refuse to answer any of the questions, take a break, or stop your participation in this study at any time. The possible risks and/or discomforts associated with the procedures described in this study include: distress during therapy sessions, a brief increase in trauma-related symptoms, or a lack of improvement.

We may also learn about the abuse of children or elders or that the individual intended to harm him or herself or others. In which case we will be mandated to inform the authorities.

At every session, participants will be clinically monitored for suicidal risk or serious depression, and withdrawn from the study if these conditions are present and preclude participation. If necessary, procedures are in place for imminent at risk patients to be escorted to local emergency rooms. If a patient calls their treatment provider or the research coordinator in crisis, an emergency session will be scheduled immediately. If you choose to withdraw from the study, you will do so by contacting the local investigator (Norah C. Feeny, Ph.D.).

Anticipated Benefits

The possible benefits you may experience from the procedures described in this study include improvements in functioning, including reduced symptoms of PTSD, depression, and functioning. However, this cannot be guaranteed.

Compensation

There will be no costs to you for study participation.
You will receive the following compensation/reimbursement: Participants will be compensated $50 per assessment completed after treatment (post, 1 and 3-month follow-up assessments) and up to $35 (from 5 assessments) for completion of a laboratory paradigm task. Parking or transportation assistance will also be provided to defray costs, as necessary.

Alternative(s) to Participation

Individuals are free not to participate in this study, free to not answer questions, and free to stop being in the study at any time. As an alternative to this study, individuals may choose to receive counseling or therapy from another community provider. If individuals choose to do this, we will provide them with contact information for other counselors who work with survivors of trauma. This therapy will be at the individual's own cost.

Voluntary Nature of the Study

Your participation is voluntary. If you choose not to participate, it will not affect your current or future relations with the University. There is no penalty or loss of benefits for not participating or for discontinuing your participation.

You are free to withdraw from this study at any time. If you decide to withdraw from this study you should notify the research team immediately. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, or if your safety or welfare are at risk.

If you withdraw or are removed from the study, the researcher may ask you to complete some study termination activities (i.e. questionnaires/interviews), but you may choose not to participate in these activities**.**

If you elect to withdraw or are withdrawn from this research study, you may choose to terminate the continued use or disclosure of your protected health information (PHI) for research purposes. The request to end the use or disclosure of your PHI must be made in writing to the Responsible Investigator.

Confidentiality

The records of this research will be kept confidential. Any time information is collected, there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

In any sort of report we might publish, we will not include any information that will make it possible to identify a participant. Research records will be kept in a locked file and access will be limited to the researchers, the University review board responsible for protecting human participants, regulatory agencies, and The National Institutes of Health. However, you should understand that in cases where we suspect elder or child abuse or

neglect or imminent harm to self or others, we will take the necessary action in an effort to prevent such harm or injury, including reporting to authorities.

Certificate of Confidentiality

For Adults
We will apply for a Certificate of Confidentiality (CC) from the National Institutes of Health. This CC adds special protection for the research information about you. The CC will protect the investigators from being forced, even under a court order or subpoena, to release information that could identify you. We may release identifying information in some circumstances, however. One example is if you agree that we can give out research information with your name on it. Other examples may include, disclosing medical information in cases of medical necessity related to your care, or taking steps (including notifying authorities) to protect you or someone else from serious harm, including child abuse or neglect, or disclosing auditing information required by the agency or entity funding the research. In addition, we may use certain information in future research as permitted by law.

Subject Identifiable Data –
All information that identifies you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. Personal identifiers will be retained for follow-up assessment contact.

Data Storage –
Research data will be maintained in a secure location at CWRU. Only authorized individuals will have access to it.
Research data will be stored electronically in an encrypted file and is password protected.

The audio/video recordings that can identify you will be:
- Stored in a secure location;
- Transcribed and erased as soon as possible.
- The recordings will be retained with the other research data for 5 years after the study is completed.

Data Retention –
The researchers intend to keep the research data: Indefinitely, or until it is no longer needed for research purposes.

Your identifiable information which are collected for this research may have the identifiers removed and be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Sharing of Data

Sharing of de-identified data

This study is collecting data from you. We would like to make these available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study, but it could also be unrelated. These studies may be done by researchers at this institution, other institutions, including commercial entities. Our goal is to make more research possible.

Your deidentified information may be shared with other researchers or databases. If your identifying information is removed from the data you provided, they may be shared without your additional consent. We cannot guarantee anonymity of your personal data even if identifying information is removed.

Significant Financial Interest
The responsible investigator and other key members of the research team are funded for their time conducting this research study. No individuals are receiving financial benefits beyond this. If you have any questions about this interest, please discuss it with the responsible investigator.

Contacts and Questions

The researcher conducting this study is Norah C. Feeny, Ph.D. You may ask any questions you have now. If you have any additional questions, concerns or complaints about the study, you may contact her at (216) 368-2695.

If the researcher cannot be reached, or if you would like to talk to someone other than the researcher(s) about: (1) questions, concerns or complaints regarding this study, (2) research participant rights, (3) research-related injuries, or (4) other human subjects issues, please contact Case Western Reserve University's Institutional Review Board at (216) 368-4514 or write: Case Western Reserve University; Institutional Review Board; 10900 Euclid Ave.; Cleveland, OH 44106-7230.

You will be given a copy of this form for your records.

Statement of Consent

Your signature below certifies the following:

- You are at least 18 years of age.
- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.

_____
Printed Name of Participant

_____ Date: _____
Signature of Participant:

_____ Date: _____
Signature of Person Obtaining Consent*:*

Statement of Consent to Share Deidentified Data with the National Institute of Mental Health Data Archive (NDA)

Do you consent to your information being shared with the National Institute of Mental Health Data Archive (NDA)?

☐ Yes ☐ No