Permission to Take Part in a Human Research Study

Title of the Study: Breathwork Treatment for Post-Traumatic Stress Disorder

Principal Investigator: Adam Hanley, PhD, Associate Professor, Florida State University

What is this study about?

Researchers at Florida State University are studying different ways to manage Post-Traumatic Stress Disorder. We are interested in finding out how a 2-hour breathwork training impacts PTSD symptoms. You are invited to take part in the study because you have symptoms of Post Traumatic Stress Disorder. You are one of 30 individuals to take part in this study. All study procedures are expected to take less than 3.5 hours over the course of 6 weeks.

What will happen during this research?

If you choose to participate, you will attend a 2-hour training, in which you will learn a new breathing technique designed to help you better manage your PTSD symptoms. You will complete your 2-hour training in a single group meeting with Vivian Rosenthal, a certified breathwork facilitator, and Dr. Adam Hanley. Training sessions will occur at the Diamond Rose Sanctuary. Immediately before and after your training you will be asked several questions about your experience while breathing.

When you first join the study, 2-weeks later and 6-weeks later, you will also be asked to complete a set of surveys. This set of surveys will take about 10 to 15 minutes to complete. We will collect the following information in these surveys:

- Information about your exposure to stressful events in the past and current PTSD symptoms PTSD effects on your daily life
- Information about sleep, pain, anxiety, and depression
- Information about your substance use
- Information about how you experience your sense of self

All of the information gathered in these surveys will be used for research purposes only. No study information (e.g., pain, mental health, substance use) will be added to your medical record or disclosed to your medical provider(s).

What will you do to protect my privacy?

The results of the study may be published or presented, but no information that may identify you will ever be provided or released in publications or presentations. We will take steps to protect your privacy and confidentiality. These steps include 1) assigning you a unique study identification number and removing any personally identifying information from your study data, and 2) storing your study data on password protected computers or in locked cabinets or offices.

Despite taking steps to protect your privacy or the confidentiality of your identifiable information, we cannot guarantee that your privacy or confidentiality will be protected. For example, if you tell us something that makes us believe that you or others have been or may be physically harmed, or if we are likely to uncover abuse, neglect, self-injury or injury to others, and/or reportable diseases, that information may be disclosed or reported to appropriate hospital or care providers as well as authorities such as law enforcement.

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Individuals and organizations responsible for conducting or monitoring this research may be permitted access to and inspect the research records. This includes the Florida State University Institutional Review Board (FSU IRB), which reviewed this study.

If you later change your mind and no longer wish to have us share your data, contact the investigator. We will do our best to honor your request and to retrieve any data that have been shared with other researchers. However, there may be times we cannot. For example, if we do not have a way to identify your data, we will not be able to retrieve the shared data. In addition, if the shared data has already been used for new research, the information from that research may still be used.

We will do our best to protect your data when the data is shared. However, even if we remove any information that may identify you, such as your name, there is a possibility that someone could or might try to identify you. There is also the possibility that unauthorized people might try to access your data. In either case, we cannot reduce the risk to zero.

At the end of this study, we may share your data with other researchers so that future studies may be done. Those studies may be done by researchers here or at other places. Those studies may be about health or other conditions like those in this study, or different conditions. Before we share data, your name and other information that might identify you will be removed. Also, before we share your data, other researchers must promise that any shared data will only be used for genuine research purposes. These researchers must also agree not to make any attempts to identify you.

What are the risks of harms or discomforts associated with this research?

In a recent analysis of 12 studies examining breathwork, no breathwork-related adverse effects were reported. However, anecdotally, side effects of breathwork may include nausea, vomiting, dizziness, tetany, body temperature changes, intense emotions, dry mouth/throat, coughing, and uncomfortable bodily sensations. Events of this type are very uncommon and transient. If you experience any significant discomfort, please inform the research assistant and/or trainer.

How might I benefit from this research?

You may experience decreases in PTSD symptoms and improvement in well-being as a result of this breathing training. These improvements may assist in your recovery and return to activities.

What is the compensation for the research?

You will be compensated up to $50 for participating: $10 for the baseline assessment, $20 for the 2-week follow-up assessment, $20 for the 6-week follow-up assessment.

What will happen if I choose not to participate?

It is your choice to participate or not to participate in this research. Participation is voluntary. There are no consequences from choosing not to participate.

Is my participation voluntary, and can I withdraw?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. Your decision whether to participate will not affect your relationship with the researchers or FSU. If you do not participate, there are no penalties, consequences, or losses of benefit to which you are otherwise entitled.

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You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or consequence. If you withdraw from the study, the data collected to the point of withdrawal will be kept and analyzed unless you request in writing that your data be withdrawn as well.

Can I be removed from the research without my OK?

We may remove you from the research study without your approval. Reasons we would do this include: 1) if the study team believes it is in your best interest, 2) if you do not follow the study rules, or 3) if you miss study visits and/or procedures.

Who do I talk to if I have questions?

If you have questions, concerns, or have experienced a research-related injury, contact the research team at:

Dr. Adam Hanley
850-644-2647
adam.hanley@fsu.edu

The Florida State University Institutional Review Board (IRB) is overseeing this research. The FSU IRB is a group of people who perform official independent review of research studies before studies begin to ensure that the rights and welfare of participants are protected. If you have questions about your rights or wish to speak with someone other than the research team, you may contact:

Florida State University IRB
2010 Levy Drive, Suite 276
Tallahassee, Florida 32306
850-644-7900
humansubjects@fsu.edu

STATEMENT OF CONSENT

I have read and considered the information presented in this form. I confirm that I understand the purpose of the research and the study procedures. I understand that I may ask questions at any time and can withdraw my participation without prejudice. I have read this consent form. My signature below indicates my willingness to participate in this study.

I consent to participate in this study. Y / N

_____

Printed Name of Adult Participant

_____

Signature of Adult Participant Date

Researcher's Signature

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I have fully explained the research study described by this form. I have answered the participant and/or parent/guardians' questions and will answer any future questions to the best of my ability. I will tell the family and/or the person taking part in this research of any changes in the procedures or in the possible harms/possible benefits of the study that may affect their health or their willingness to stay in the study.

Printed Name of Research Team Member Obtaining Consent

Signature of Research Team Member Date