FLORIDA STATE UNIVERSITY
OFFICE *of the* VICE PRESIDENT *for* RESEARCH

APPROVAL

September 27, 2021

Danielle Morabito
dmorabito@fsu.edu

Dear Danielle Morabito:

On 9/27/2021, the IRB reviewed the following submission:

Type of Review:	Expedited (4) Noninvasive procedures; (7)(b) Social science methods
Title:	Development and Evaluation of a Tonic Immobility Focused Psychoeducational Intervention – Randomized Controlled Trial (RCT)
Investigator:	Danielle Morabito
Submission ID:	MOD00001686
Study ID:	STUDY00002518
Funding:	None
IND, IDE, or HDE:	None
Documents Reviewed:	• RCT Measures_updated 9.23.21.pdf, Category: Survey/Questionnaire/Instrument/Measure; • TIP Script_Updated 9.23.21.pdf, Category: Protocol; • TIP RCT Protocol, Category: IRB Protocol;

The IRB approved the modification, effective from 9/27/2021 .

COVID-19 Information for Research Involving Human Subjects: Note that the U.S. is operating under the national emergency Proclamation 9994 concerning the COVID-19 pandemic and that this national emergency remains in effect until rescinded or terminated by the President of the U.S. (go here for the Proclamation letter). Conditions are dynamic and related policies or guidance evolve accordingly; as applicable, refer to the U.S. Centers for Disease Control and Prevention website specific for universities or refer to our COVID-19 and Human Research Studies web page to learn more about how you

should or may protect persons (whether vaccinated or unvaccinated) involved in any of your in-person research activities.
Other Information:

This study meets the definition of a clinical trial as it involves the assignment of one or more human subjects to one or more interventions (procedure, device, or drug, including use of placebo or control) to evaluate the effects of the interventions on biomedical or behavioral health outcomes. Please note that the approved IRB consent form template must be posted by the awardee to a federal website to be disclosed. This document must be posted after the research has been closed and no later than 60 days after the last study visit of any subject.

You are advised that any modification(s) to the protocol for this project must be reviewed and approved by the IRB prior to implementation of the proposed modification(s).

Federal regulations require that the Principal Investigator promptly report any new information related to this protocol (see Investigator Manual (HRP-103)).

In conducting this protocol, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the IRB system.

Sincerely,

Human Subjects Research Office
humansubjects@fsu.edu

PROTOCOL TITLE: Development and Evaluation of a Tonic Immobility Focused Psychoeducational Intervention – Randomized Controlled Trial (RCT)

PRINCIPAL INVESTIGATOR:

Danielle Morabito
Psychology
850-645-1766
morabito@psy.fsu.edu

VERSION NUMBER/DATE: 1.2, 9/23/21

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	8/17/21	Requested modifications to consent and protocol as detailed in the response letter.	Yes
2	9/23/21	Added study personnel; added 2 additional measures; revised TIP intervention script.	No

Table of Contents

1.0 Study Summary

Study Title	Development and Evaluation of a Tonic Immobility Focused Psychoeducational Intervention - RCT
Study Design	Randomized Controlled Trial
Primary Objective	To evaluate the efficacy of a brief-web-based intervention (Tonic Immobility Psychoeducation; TIP) intended to educate about tonic immobility (TI) within a sample of those who experienced TI in the context of a traumatic event.
Secondary Objective(s)	(1) TIP will significantly reduce feelings of posttraumatic feelings of guilt and shame compared to control (2) TIP will significantly reduce PTSD symptoms across time relative to control (3) Reduction in trauma-related guilt and shame will mediate the association between condition and changed in PTSD symptoms at follow-up.
Research Intervention(s)/ Investigational Agent(s)	Tonic Immobility Psychoeducation Health Education Training
IND/IDE #	
Study Population	Adults who endorse prior TI during a traumatic event and elevated PTSD symptoms
Sample Size	120
Study Duration for individual participants	1 month
Study Specific Abbreviations/ Definitions	TI = Tonic Immobility TIP = Tonic Immobility Psychoeducation HET = Health Education Training PTSD = Posttraumatic Stress Disorder

2.0 Objectives*

2.1 A randomized controlled trial is planned to evaluate a brief, web-based intervention intended to educate about tonic immobility (TI) within a sample of those who experienced TI in the context of a traumatic event.

2.2 It is hypothesized that the TIP intervention will show benefits in a sample of those who have experienced a traumatic event. Specifically, we hypothesize that: TIP will significantly reduce feelings of posttraumatic feelings of guilt and shame compared to control; TIP will significantly reduce PTSD symptoms across time relative to control; reduction in trauma-related guilt and shame will mediate the association between condition and changed in PTSD symptoms at follow-up.

3.0 Background*

3.1 Tonic Immobility (TI) is a common defensive response in situations involving extreme fear such as physical and sexual assault, and its occurrence is influenced by both situational and individual difference factors. Previous research has estimated the prevalence of TI among sexual assault survivors to be between 37 to 70% (Fusé et al., 2007; Galliano et al., 1993; Heidt et al., 2005; Möller et al., 2017). Additional research among urban violence victims and anecdotal reports from combat veterans suggest similar experiences among these groups (Gallup & Rager, 1996; Solomon & Mukulincer, 2006; Fiszman et al., 2008). Although TI is adaptive in certain circumstances, it has been shown to contribute to increases in negative emotion, particularly guilt and shame, along with posttraumatic stress disorder (PTSD) symptoms. Moreover, several studies have demonstrated an association between TI and poorer recovery from PTSD (Fiszman et al., 2007; Lima et al., 2010; Hagenaars & Hagenaars, 2020).

3.2 Among other cognitive-behavioral techniques, experts in the field of posttraumatic stress emphasize the importance of psychoeducation about common reactions during and after trauma exposure (Foa & Rothbaum, 2001; Herbert & Sageman, 2004; Resick et al., 2017). However, neither brief psychoeducational interventions nor the current frontline treatments for PTSD, have focused significant attention on the experience of TI (Foa et al., 2007; Resick et al., 2017). Thus, the interpretation of TI during a traumatic event and the potentially detrimental changes in cognition, emotion, and behavior that result from it, are not directly addressed in any of the current empirically informed intervention protocols. Therefore, the current study aims to evaluate the effects of a brief TI-focused psychoeducation intervention on negative emotions, cognitions, and PTSD symptoms.

3.3 The framework of this intervention was modeled after psychoeducation paradigms used in previous research and found to be effective (e.g. anxiety sensitivity focused psychoeducation intervention; Schmidt et al., 2014).

4.0 Study Endpoints*

4.1 Recruitment will stop after enrolling 120 participants. Data collection will continue until all enrolled participants have completed their Month 1 follow-up appointment, at which point data will be prepared for analysis

4.2 This is a minimal risk study. There are no safety endpoints given that there are no safety risks associated with the study.

5.0 Study Intervention/Investigational Agent

5.1 Tonic Immobility Psychoeducation (TIP; Active Condition)

TIP is a 45-minute computerized psychoeducation intervention aimed at addressing maladaptive cognitions and emotions associated with TI while using educational and behavioral techniques commonly used in the treatment of trauma-related disorders. Throughout the psychoeducation program vignettes will be presented to clarify concepts and promote participant engagement. In addition, practice exercises and rating scales will be integrated, where applicable, to increase the interactive nature of the program. The following modules will be addressed in the TI psychoeducation intervention: education, myth busting, and behavioral experiments.

Health Education Training (HET; Control Condition)

The Healthy Education Training intervention was developed as a 30-minute online intervention that provides education about physical health habits that can impact mental health, such as diet, exercise, and sleep. This intervention has been used in prior clinical trials to control for effects of general education, general coping techniques, and use of technology. Participants in past clinical trials have reported that HET is engaging and beneficial.

6.0 Procedures Involved*

6.1 The study adheres to a randomized controlled trial (RCT) design. Participants will be randomized to either the TIP or HET condition. Randomization will be stratified based on undergraduate vs. community member status. For each group, a random number table will be generated in Excel with either 1 = TIP or 2 = HET assigned to each participant ID. After completion of consent, the participant will receive their ID (assigned in sequential order) and the research assistant will prepare the corresponding treatment.

6.2 The study proposes to enroll 120 participants to test the efficacy of the TIP intervention, compared to a HET control condition. All data collection will be conducted using Qualtrics. The study will be comprised of a total of three time points: Baseline, Week 1 follow-up, and Month 1 follow-up.

First, eligible participants will read and sign an informed consent that outlines all study procedures, details limits to confidentiality, and emphasizes that participants may discontinue participation at any time with no penalty.

The first appointment, baseline, will include pre-intervention self-report measures, the completion of one of the two interventions (TIP or PHET), and post-intervention self-report measures. The baseline appointment is expected to take 90 minutes. Participants will be compensated with a $30 gift card or 1.5 course credits. All baseline procedures will be conducted either in-person within the Anxiety and Behavioral Health Clinic research suite or virtually via HIPAA-compliant Zoom. For in-person sessions, all COVID-19 related federal, state, and local guidelines as well as FSU IRB regulations will be followed. See section 6.3 for further information on COVID-19 safeguards.

The second and third appointments, week 1 and month 1 follow-up, will be completed online. Participants will be contacted via email and asked to complete a battery of self-report measures via a Qualtrics survey link. The questionnaire is expected to last 30 minutes and participants will be compensated either a $10 gift card of 0.5 course credits for the completion of each appointment.

After the completion of the month 1 follow-up appointment, participants will be debriefed and individuals in the control condition will be given the opportunity to receive the active treatment condition.

6.3 The risks to human subjects in the proposed study are minimal. Nevertheless, precautions will be taken to minimize participants' risk in the proposed study. All individuals will be informed of the nature of the investigation and the types of assessments and procedures. Participants will be asked to fill out an informed consent statement prior to participating in the project. Should a participant experience emotional distress including strong emotional or physical reactions to the intervention, a graduate-level therapist supervised by Dr. Norman B. Schmidt will be called in to meet with the participant. Therapists will assist the participant in implementing coping skills to tolerate and reduce distress (e.g., deep breathing, self-soothing). Dr. Norman B. Schmidt or an alternate clinical supervisor with the FSU Psychology Clinic will be on call for consultation as needed at all times.

6.4 **Safeguards for Protecting Against COVID-19.** To reduce risk of COVID-19, our study team plans to follow standard COVID-19 precautions such as social distancing, mask wearing, and the sanitization of surfaces. However, participants will be informed that the voluntary disclosure of their full COVID-19 vaccination status is an alternative to COVID-19 related precautions, and they would be able to remove their masks during the baseline appointment. Staff will make a note in the study log of who has shown full COVID-19 vaccination documentation. The dialogue below will be said to participants when telling them about vaccination procedures:

- *"In order to protect against COVID-19 or Coronavirus, if you come to the lab we will follow certain precautions including social distancing and use of masks. However, we don't have to do this for persons who have completed a full COVID-19 vaccination. You may, if you'd like, share with us information about your COVID-19 vaccination, but this is your decision and is not required. You can still come to the lab and we will follow our usual COVID-19 precautions."*

6.5 The following self-report measures will be used throughout the study.

Demographic survey. A self-report questionnaire will be used to assess participant demographic information. Specifically, various demographic variables will be assessed including gender, ethnicity, race, sexual orientation, and educational/occupational level.

Adverse Childhood Experiences Questionnaire. (ACE; Felitti et al., 1998) The ACE is a self-report measure designed to assess abuse, neglect, and caregiver dysfunction experienced during childhood (i.e. before the age of 18). Participants were asked to respond "yes" or "no" to 10-items representing different categories of adverse childhood experiences.

Anxiety Sensitivity Index-3 (ASI-3; Taylor et al., 2007). The ASI-3 is an 18-item self-report questionnaire assessing levels of anxiety sensitivity. The ASI-3 is a widely used measure of fear of anxiety-related symptoms and sensations.

Childhood Harshness & Unpredictability (Maranges et al., Under Review). A brief self-report measure will be used to assess perceptions of harshness and unpredictability during childhood.

Credibility/Expectancy Questionnaire (CEQ; Devilly & Borkovec, 2000). The CEQ is a 6-item self-report measure of client's perceived expectations regarding the extent to which a treatment will reduce their symptoms.

Life Events Checklist (LEC-5; Weathers et al., 2013). The LEC-5 assesses the number and specific type of traumatic experiences an individual has experienced in their lifetime, as defined by Criterion A of the PTSD section of the DSM-5.

Positive and Negative Affect Schedule (PANAS; Watson et al., 1988). The PANAS is a 20-item self-report questionnaire assessing levels of positive and negative affect.

Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5; Weathers et al., 2013). The PCL-5 is a 20-item self-report questionnaire used to assess PTSD symptoms.

Posttraumatic Cognitions Inventory (PTCI; Foa et al., 1999). The PTCI is a 33-item scale designed to assess negative cognitions about the self, negative cognitions about the world, and self-blame occurring post-trauma.

Scale for Tonic Immobility Occurring Post-trauma (STOP; Lloyd et al., 2019). The STOP is a 30-item self-report questionnaire designed to assess TI experiences occurring post-trauma.

State Shame and Guilt Scale – 8 (SSGS-8; Cavalera et al., 2017). The SSGS-8 is a short version of the state shame and guilt scale designed to assess shame and guilt. This measure will be modified for the present study and participants will be asked to focus on their TI experience.

Tonic Immobility Questionnaire (TIQ; Taylor et al., 2007). The TIQ is a 12-item self-report questionnaire designed to assess TI experienced across a range of traumatic events.

World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0; Ustun, T.B. & World Health Organization, 2010). The WHODAS 2.0 is an assessment of difficulties due to health conditions in social, occupational, and daily life domains. A short version (21 items) of the WHODAS was compiled utilizing subscales that are relevant to mental health.

6.6 What data will be collected during the study and how that data will be obtained.

Data from self-report measures will be collected online using Qualtrics which is a safe and secure survey website platform previously used by Florida State University. Data will be coded and stored on a password-protected file.

7.0 Data and Specimen Banking*

7.1 If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.

All data that will be used for analysis. Safeguards include: (a) ensuring that all project staff and participants are well informed about regulations pertaining to confidentiality, (b) the use of study ID numbers as opposed to names on all data forms, (c) requiring that all subject files be password protected if online, and (d) any paper copies will be stored in locked file cabinets. All study personnel will have access to stored data.

7.2 List the data to be stored or associated with each specimen.

Data will include de-identified study ID numbers, self-report data, and qualitative written responses to open ended questions.

7.3 Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

N/A

8.0 Sharing of Results with Subjects*

8.1 Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how the results will be shared.

N/A

9.0 Study Timelines*

9.1 Participation is expected to last 1 month. We anticipate that it will take about **18 months** to enroll all participants

10.0 Inclusion and Exclusion Criteria*

10.1 Student participants who endorse prior TI experience during the subject pool screening process will be invited to complete a Qualtrics survey to determine eligibility. Interested participants will be asked to sign-up for the current study using the Sona-systems website. Community participants will be directed to the Qualtrics survey through flyers and online advertisements. Eligible community participants will be contacted via phone to schedule their initial appointment.

10.2 Eligible participants must be 18 years or older and have endorsed prior TI experience. Study participants will be selected for the

current investigation based on prior TI experience (TIQ items A & B) and elevated posttraumatic stress symptoms (PCL-5). Exclusion criteria includes individuals who have not endorsed past TI behavior and are not 18 years or older.

10.3 Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of the above populations as subjects in your research unless you indicate this in your inclusion criteria.)

- *Adults unable to consent:* Excluded
- *Individuals who are not yet adult:* Excluded
- *Pregnant women:* Excluded
- *Prisoners:* Excluded

11.0 Vulnerable Populations*

11.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

The current study will not involve pregnant women, prisoners, individuals under 18 years old, or cognitively impaired.

12.0 Local Number of Subjects

12.1 Indicate the total number of subjects to be accrued locally.

120 participants will be enrolled from Florida State University and the Tallahassee, FL area.

13.0 Recruitment Methods

13.1 Describe when, where, and how potential subjects will be recruited. If recruitment will involve a non-FSU site, describe whether site approval for recruitment is required, and attach documentation of site approval.

Participants will be recruited from the FSU undergraduate subject pool and the Tallahassee community. Student participants will be recruited from the psychology undergraduate research pool. Community participants will be recruited via online advertisements.

13.2 Describe the source of subjects.

All participants will be recruited from Florida State University and Tallahassee, FL.

13.3 Describe the methods that will be used to identify potential subjects.

Individuals will be identified as potential participants if they are 18 years or older and have endorsed past TI experience. Potential student participants who endorse prior TI experience during the subject pool screening process will be invited to complete a

Qualtrics survey to determine eligibility. Community participants will be directed to the Qualtrics survey to determine eligibility. Eligible participants will then be contacted via phone to schedule their initial appointment.

13.4 Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)

Recruitment methods include flyers posted in the community and online advertisements via social media platforms (e.g. Facebook, twitter).

13.5 Describe as applicable whether and how subjects will be paid, earn course or other credits, reimbursed or provided with any financial or other incentive, token or gift for taking part in the research. Include a description and schedule of the total amount or value as well as the timing of any payments, credits, reimbursement or other incentive, token or gift. Indicate how if at all any amount is pro-rated for research visit or activity completion, and whether and how subjects' refusal to answer any question or subjects' withdrawal from or discontinuing taking part in the study or any study activity will reduce or preclude subjects from earning part or all of such any payment, credit, reimbursement or other incentive, token or gift.

Also describe the proposed method (how, by whom, form etc.) of payment/disbursement. While payment should not be contingent upon completion of the entire study, a proportion or progressive partial payment as an incentive for completion of the study is acceptable.

Student participants will receive 1.5 course credits for completion of the baseline appointment and 0.5 credits for each follow-up appointment. Thus, participants will receive 2.5 credits in total for completing all study appointments. Participants who refuse to answer any question or withdraw from the study will still receive compensation for their appointment.

Community participants will receive a $30 gift card for completion of the baseline appointment and a $10 gift card for each follow-up appointment. Thus, participants will receive $50 in total for completing all study appointments. Participants who refuse to answer any question or withdraw from the study will still receive compensation for their appointment.

14.0 Withdrawal of Subjects*

14.1 Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.

Possible reasons for removal include failure to complete the TIP intervention or self-report measures.

14.2 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

The participant will be told the can leave the research at any time and it will not be held against them. All data collected prior to withdrawal will be securely stored and analyzed unless otherwise requested. Participants will be able to contact the PI to request the removal of their data, if so desired.

15.0 Risks to Subjects*

15.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. For each of these risks, describe in detail how the risks will be minimized.

The risks to human subjects in the proposed study are minimal. Nevertheless, precautions will be taken to minimize participants' risk in the proposed study. All individuals will be informed of the nature of the investigation and the types of assessments and procedures. Participants will be asked to sign an informed consent statement prior to participating in the project. The specific potential risks involved in the proposed investigation are enumerated below:

<u>Self-report measures</u>

It is unlikely that participants will be at risk for emotional or physical harm as a result of study participation. However, there is a slight possibility that participants may experience emotional discomfort or distress while completing study tasks. Based upon our past research, any distress reactions due to completion of questionnaires is typically acute (i.e., few minutes in duration) and relatively minor.

<u>Interventions</u>

HET has been used in prior research studies with no adverse effects. Content is related to healthy living and stress management, and not expected to cause distress.

TIP has been modeled after a previous intervention which has been used in several studies and has a high level of acceptability as well as gold-standard evidence-based treatments for trauma. Although the information presented in the training should be no more anxiety-provoking than situations experienced in day-to-day life, it is possible that some participants may have strong emotional or physical reactions to information covered in the intervention. However, we believe prolonged distress is unlikely and feel that most participants will derive benefit from the interventions.

Protections against risk

Confidentiality will be described during the consent process. The process will reiterate the limits of confidentiality. Data entry personnel will download the data into a dedicated, password-protected computer database as an additional on-site back-up. Computer files will be maintained on the servers and backed up daily. Computers and databases will be password protected with independent passwords known only to the PI and data entry personnel. All data will be accessible only to trained study staff. Participants' data will be de-identified and coded with ID numbers. A link between participant names and ID numbers will be kept separately in a password protected computer file. All project staff are trained and certified in HIPAA regulations, responsible conduct of research and the protection of human research subjects via Collaborative Institutional Training Initiative (CITI) courses.

The risk of emotional discomfort will be minimized by informing participants that they are allowed to skip any sensitive areas on the assessment measure and may discontinue participation at any time. All research staff will be trained to deal with sensitive clinical issues and will be available should participants need assistance.

Further, a trained graduate-level therapist, supervised by Licensed Clinical Psychologist Norman B. Schmidt, will be available to assist participants experiencing emotional discomfort, including strong emotional or physical reactions to intervention materials, at all times. Standard procedures include implementation of coping skills (e.g., deep breathing, self-soothing) to reduce distress and referral to treatment, if desired. Dr. Noman B. Schmidt or an alternate clinical supervisor within the FSU Psychology Clinic will be on call and available during study sessions if consultation is needed.

15.2 – 15.4

N/A

16.0 Potential Benefits to Subjects*

16.1 Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be

useful for the IRB's consideration, the probability, magnitude, and duration of the potential benefits.

The primary benefits to participants include possible improvements to mental health.

16.2 Indicate if there is no direct benefit. Do not include benefits to society or others.

N/A

17.0 Data Management* and Confidentiality

17.1 Describe the data analysis plan, including any statistical procedures or power analysis.

Preliminary analyses and data screening will be conducted prior to the primary analyses. This will include checking equivalence of random assignment to treatment condition based on key baseline characteristics. Specifically, analyses will be conducted to ensure that there are not baseline differences between condition (active vs. control) in terms of age, gender, and TIQ total scores.

Hierarchical linear regression analyses will be conducted to examine the impact of intervention condition on early treatment outcomes including posttreatment guilt, posttreatment shame, and week 1 PTSD symptoms. Analyses will be conducted in SPSS version 27.0.

Latent difference score analyses will be utilized to examine the differential change in guilt, shame, and PTSD symptoms between intervention conditions, across all study timepoints. Analyses will be conducted in Mplus version 8.0 (Muthén & Muthén, 1998-2017). Full information maximum likelihood (FIML) with the adjusted Yuan-Bentler scaled chi-square index (Y-B χ^2) will be utilized when possible in order to account for missing data. To determine model fit, the S-B χ^2 statistic as well as several indices will be used.

Three separate models will be estimated for the impact of treatment condition on guilt, shame, and PTSD symptoms. The effects of treatment condition on changes in guilt from pre-intervention to post-intervention (change 1), from post-intervention to week 1 (change 2), and from week 1 to month 1 (change 3) will be examined using a multi-group latent difference score (LDS) approach (Mun et al., 2009). The same methods will be used to examine effects of treatment condition on shame from pre-intervention to post-intervention (change 1), from post-intervention to week 1 (change 2), and from week 1 to month 1 (change 3) and PTSD symptoms from pre-intervention to week 1 (change 1), and from week 1 to month 1 (change 2).

The indirect effects of treatment condition on PCL-5 scores at month 1 through week 1 guilt and shame will be examined in two separate

mediation models. Maximum likelihood and percentile bootstrapped CIs (with 5,000 resamples) will be used (Hayes & Scharkow, 2013; Preacher & Hayes, 2004).

17.2 Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.

All data will be coded by arbitrary participant numbers to ensure confidentiality and will be stored using password protected documents. Specifically, once the participant is consented, they will be assigned a unique study ID, which will be used instead of their name on subsequent surveys. The document linking participant names to study IDs will be recorded in a password-protected Microsoft Excel document, which will be stored on a password-protected server inside the Anxiety and Behavioral Health Clinic (ABHC) research suite. Only ABHC study staff (i.e., PI, graduate students, and project coordinators) who have been trained in data management procedures will be able to access the data via password.

17.3 Describe any procedures that will be used for quality control of collected data.

See 17.4

17.4 Describe how data or specimens will be handled study-wide:

Data entry personnel will download the data into a dedicated, password-protected computer database. Computer files will be maintained on the servers and backed up daily. Computers and databases will be password protected with independent passwords known only to the PI and data entry personnel. Other safeguards include: (a) ensuring that all project staff are well informed about regulations pertaining to confidentiality, (b) the use of ID numbers as opposed to names on all data forms, (c) utilizing computer-based assessments whenever possible.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

This section is required when research involves more than Minimal Risk to subjects.

N/A

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

All self-report data will be collected via Qualtrics, which is a secure website used by FSU to collect questionnaire data. Qualtrics data will be labeled only with participant IDs to ensure confidentiality. Data will be electronically communicated through password protected emails and password protected documents.

19.2 Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

Study participants will be able to withdraw from participation at any point without penalty. Any distress that a participant may feel is expected to be brief in duration (i.e., few minutes). In addition, should any lasting feelings of distress arise from an individual's participation, study participants are encouraged to contact the study PI. Each prospective participant will be notified through the consent that identifying information will not be tied to survey responses, except for the signed consent form.

19.3 Indicate how the research team is permitted to access any sources of information about the subjects.

All research staff team will have access to password protected documents.

20.0 Compensation for Research-Related Injury

20.1 If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

N/A

20.2 Provide a copy of contract language, if any, relevant to compensation for research-related injury.

N/A

21.0 Economic Burden to Subjects

21.1 Describe any costs that subjects may be responsible for because of participation in the research.

N/A

22.0 Consent Process

22.1 Indicate whether you will you be obtaining consent, and if so describe:

This study will follow SOP: Informed Consent Process for Research HRP-090. The consent process will take place in-person in our research lab or via Zoom for participants taking part in the study

online. In the case of online participation, subjects will be asked to provide an electronic signature in place of their hand-written signature.

Non-English Speaking Subjects - N/A

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception) - N/A

Subjects who are not yet adults (infants, children, teenagers) - N/A

Cognitively Impaired Adults - N/A

Adults Unable to Consent - N/A

23.0 Process to Document Consent in Writing

23.1 Describe whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not, describe whether and how consent of the subject will be documented in writing.

This study will be following SOP: Informed Consent Process for Research HRP-091.

23.2 If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.

N/A

23.3 (If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach a consent script. Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)"to create the consent document or script.)

See attached consent form.

24.0 Setting

24.1 Describe the sites or locations where your research team will conduct the research.

The research team will identify and recruit potential subjects from the FSU psychology undergraduate research pool and Tallahassee community. The research study will take place in person or online via HIPAA compliant Zoom. For in-person appointments, measures will be taken to safeguard against COVID-19 (e.g., social distancing, mask wearing, thoroughly cleaning surfaces).

25.0 Resources Available

25.1 Describe the resources available to conduct the research: For example, as appropriate:

- *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*
  There are approximately **1,500** students screened through the undergraduate psychology research pool in 1 year and 159,426 people in the Tallahassee area. Thus, recruitment for our sample size ($N = 120$) is highly feasible.

- *Describe the time that you will devote to conducting and completing the research.*

  We anticipate completing the research study in 18 months.

- *Describe your facilities.*

  Our research suite includes four individual, private research rooms that each contain a password protected computer and locked file cabinets. The research suite is locked via swipe access that only research staff have access to.

- *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.*

  Although the study is expected to cause no more than minimal distress, a resource sheet will be provided to participants with local emergency & referral numbers.

- *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*

  All research staff are given protocols that outline duties for each job that is part of the study. These protocols are available on an online computer drive which staff members have access to.

26.0 Multi-Site Research*

N/A

Permission to Take Part in a Human Research Study

Title of research study: Development and Evaluation of a Tonic Immobility Focused Psychoeducational Intervention – Randomized Controlled Trial (RCT)

Investigator: Danielle M. Morabito

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

- Consent is being sought for research for the study described in detail below, participation in which is completely voluntary.
- The purpose of this research is to examine whether a brief web-based intervention reduces negative thoughts, feelings, and symptoms associated with trauma.
- Duration of participation is expected to be no longer than 1 month, during which time participants will complete an initial appointment consisting of a brief online intervention and self-report measures, as self-report measures at 1-week and 1-month follow-ups after the initial appointment. The initial session will be conducted either in-person or via HIPAA compliant Zoom. The follow-ups can be completed online through Qualtrics survey software.
- While we think one intervention condition will reduce trauma-related symptoms, we do not think that the second will. We do not know and cannot guarantee whether you will receive the active intervention. You will be randomized based on student status and participant ID# to complete one of these two interventions. There is a 50/50 chance that you will receive the active intervention.
- Potential risks include feelings of discomfort when answering self-report measures and the possibility of an unexpected breach in confidentiality.
- Potential benefits include improvement in mental health.
- If you did not receive the intervention that we think will improve symptoms during the first appointment, it will be offered to you after the 1-month follow-up is complete.
- Total compensation for completion of all parts of the study is 2.5 course credits (for undergraduate students enrolled through the subject pool) or $50 in gift cards.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you endorsed a previous experience where you felt frozen or paralyzed with fear.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Permission to Take Part in a Human Research Study

Why is this research being done?

The purpose of this study is to examine whether a brief web-based intervention reduces negative thoughts, feelings, and symptoms associated with trauma.

How long will the research last and what will I need to do?

We expect that you will be in this research study for 1 month. The initial appointment will take approximately 1.5 hours and you will be compensated with either a) 1.5 course credits (for undergraduate students enrolled through the subject pool) or b) a $30 gift card. You will be asked to complete self-report measures before completing the intervention. After completing the intervention, you will be asked to complete more self-report measures. Additionally, you will receive surveys to complete at 1-week and 1-month after the initial appointment. We expect these surveys to take approximately 30 minutes each. You will be compensated with 0.5 credits or $10 gift card for each of these surveys.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

If you choose to take part in this study, there is a risk of feeling uncomfortable, frustrated, tired, or upset while answering the questionnaires. You do not have to answer any question that makes you uncomfortable, and you may stop your participation at any time.

Although the information presented in the training should be no more anxiety-provoking than situations experienced in day-to-day life (e.g., watching the news), some individuals may experience strong emotional or physical reactions. In the event that you experience any strong emotional or physical reactions, a trained graduate-level therapist, supervised by Licensed Clinical Psychologist Dr. Norman B Schmidt, will be available to assist you.

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you. There may also be other risks of taking part in this study that we do not yet know about.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Safeguards against COVID-19:

For in-person study activities, we are required to follow certain COVID-19 precaution such as social distancing and the use of masks. However, we do not have to do this for persons who have completed a full COVID-19 vaccination. You may voluntarily share with us this information about your COVID-19 vaccination, but this is your decision and is not required. If you do share this information with us, we will make a note of it in our records.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include possible improvements to mental health. Others may benefit in the future from the information learned during this study.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

Permission to Take Part in a Human Research Study

If you are a part of the undergraduate psychology subject pool and choose not to participate, you may enroll in different research studies and/or complete an alternative assignment to earn course credit. You are encouraged to discuss these options with your course instructor.

There are other options for managing symptoms associated with a traumatic experience. Alternative treatments and/or procedures that may be available to you include: psychotherapy and/or medication offered outside of this study. A list of some potential resources/providers in the area will be provided to you. You should also talk with your personal physician (if applicable) about these options.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, please contact Dr. Norman B. Schmidt at (850) 644-1707 or the principal investigator Danielle Morabito at (973)907-3914 or morabito@psy.fsu.edu

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at 850-644-7900 or humansubjects@fsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 120 people here will be in this research study out of 120 people in the entire study nationally.

What happens if I say "yes" to being in this research?

We expect that you will be in this research study for 1 month. The initial appointment will take approximately 1.5 hours and you will be compensated with either a) 1.5 course credits (for undergraduate students enrolled through the subject pool) or b) a $30 gift card. After completing this consent form, you will receive a participant ID# which corresponds to one of the two treatment conditions (randomly assigned prior to participation). There is a 50/50 chance that you will receive the active treatment. You will be asked to complete self-report measures before completing the intervention. After completing the intervention, you will be asked to complete more self-report measures. Additionally, you will receive surveys to complete online using Qualtrics Survey Software at 1-week and 1-month after the initial appointment. The survey links will be sent to you via email. We expect these surveys to take approximately 30 minutes each. You will be compensated with 0.5 credits or $10 gift card for each of these surveys.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to complete all self-report measures, your assigned intervention, and all follow-up appointments.

Permission to Take Part in a Human Research Study

What happens if I say "yes," but I change my mind later?

You can leave the research at any time it will not be held against you.

Is there any way being in this study could be bad for me? (Detailed Risks)

There is a risk of feeling uncomfortable, frustrated, tired, or upset while answering the questionnaires. You do not have to answer any question that makes you uncomfortable, and you may stop your participation at any time. Additionally, some information presented in the training may trigger strong emotional or physical reactions. There may also be other risks of taking part in this study that we do not yet know about. In addition to these risks, this research may hurt you in ways that are unknown.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations.

Procedures to protect the confidentiality of the data in this study include but are not limited to: Assignment of a random numeric ID that will be linked to participants' name only in a password-protected file stored on a secure server.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

By signing this document, you give your permission for information gained from your participation in this research study to be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified; all information will be presented as anonymous data.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	