

Consent to be a Research Subject

Research Study Title: Evaluating the Efficacy of a Self-Led Cognitive Processing Therapy (CPT) Workbook for PTSD

Principal Investigator: Melissa Goates-Jones, Ph.D.

Introduction

You are being invited to participate in a research study conducted by Melissa Goates-Jones, Ph.D. at Brigham Young University. Before you decide to participate, it is important for you to understand what the study involves, including potential risks and benefits. Please read this form carefully. Your participation is voluntary, and you can withdraw at any time without penalty. You are invited to participate so we can gather data about the efficacy of this PTSD intervention.

Purpose of the Study

The purpose of this study is to evaluate the effectiveness of an online course in reducing PTSD symptoms. The course is a self-led version of Cognitive Processing Therapy (CPT), which is based on well validated therapeutic interventions and has been specifically developed for individuals experiencing trauma-related symptoms. This research will help us understand how individuals interact with and benefit from this kind of self-guided intervention.

Study Procedures

1. If you agree to participate, you will:
 - Complete an initial eligibility screening, including questionnaires about your trauma history and PTSD symptoms.
 - Participate in a 12-week online course for about one hour per week
 - Completing brief weekly exercises and surveys.
 - Complete brief pre- and post-intervention evaluations of your psychological functioning.
2. All activities will be conducted online, and you can complete them at your own pace in a private location of your choosing.

Potential Benefits

You may gain insights into your trauma and coping mechanisms during this course. The CPT content has helped many people who experienced varying trauma reduce the severity of their PTSD symptoms. However, there is a chance you may not directly benefit from these interventions. The information obtained from this study may help improve interventions for PTSD, potentially expanding accessible treatment options for others.

Potential Risks

As with any therapeutic intervention, you may experience temporary discomfort or distress while engaging with the course content, especially when working through sensitive or emotional material. If you experience distress, please contact the support resources or the research team. Here is some more information about potential risks of participating in this study:

- **Emotional Distress:** Reflecting on trauma or completing assessments may cause temporary discomfort or distress. These responses are a natural part of working through difficult experiences and typically decrease over time.
- **Frustration or Fatigue:** We will frequently assess your symptoms and this may feel fatiguing. We have made an effort to ensure these assessments are concise and should take between 5-10 minutes.
- **Privacy Concerns:** Although we take every precaution to protect your data, we cannot completely guarantee that data will not be breached.
- **Mandatory Reporting:** By law, we are required to report concerns about current abuse to vulnerable populations:
 - Suspected abuse, neglect, or exploitation of a child or vulnerable adult.
 - Disclosures of sexual violence involving students subject to Title IX reporting.
 - Credible and imminent threats of harm to yourself or others, including suicidal or homicidal ideation with intent or a plan.

If such disclosures are made, we will contact the appropriate protective or emergency services to ensure safety. You will be informed if a report is made, except where it would increase risk to yourself or others.

Compensation

You will receive **\$100.00** in the form of an electronic Visa gift card upon completing all study requirements. Compensation is intended to offset the time and effort involved in participation. Partial compensation will not be provided for incomplete participation.

Privacy, Confidentiality and Data-Sharing

We take your privacy very seriously. Your name and other information that can directly identify you will be stored securely and separately from the rest of the information you provide or we collect. Here's how your information will be protected:

1. Your responses will be anonymized and stored securely on a password-protected, highly confidential server.
2. Personal identifiers (e.g., email address, mailing address) will be stored separately and only used for communication and compensation purposes.
3. Personal identifiers will be permanently deleted six months after the study concludes.
4. De-identified data may be retained for five years after conclusion of the study and may be used for research and publication purposes. If findings from this research are published or presented, they will be reported as general trends rather than individual scores in order to protect your privacy.

You can choose to participate in a private location and at a time that ensures your confidentiality.

Voluntary Participation and Withdrawal

- Your participation in this study is completely voluntary.
- You may skip any questions or exercises that make you uncomfortable.
- You may withdraw from the study at any time without penalty

Alternative Treatment Options

Participation in this study is voluntary, and there are other treatment options available for managing PTSD. If you choose not to participate, or if you choose to withdraw from the study, you may seek treatment such as therapy, counseling, or other mental health services. We will provide you with referrals to alternative treatment providers if needed.

Crisis Resources

If at any point you experience distress, we encourage you to use the following resources (more are included at the end of this document):

- **National Suicide Prevention Lifeline:** Dial 988
- **Crisis Text Line:** Text HOME to 741741
- **RAINN (Sexual Assault Hotline):** 1-800-656-HOPE (4673)
- **Substance Abuse and Mental Health Services Administration (SAMHSA):** 1-800-662-HELP (4357)

If you need immediate assistance, please call 911 or visit the nearest emergency room.

Questions about the Research

If you have questions, concerns, or complaints, you can contact the Principal Investigator by email:

- Melissa Jones, PhD: melissa_jones@byu.edu

Questions about Your Rights as a Research Participant

If you have any questions about the study or your rights as a participant, you may contact the Human Research Protections Program by phone or email:

- Human Research Protections Program: (801) 422-1461, BYU.HRPP@byu.edu

Consent

By signing below, you acknowledge that:

- You have read and understood the information provided in this consent form.

- You understand the risks, benefits, and your rights as a participant.
- You voluntarily agree to participate in the study.

If you agree to participate, please type your name and date below as an electronic signature.

Participant Signature:

Name (Printed): _____

Date: _____

Mental Health resources:

- **Suicidality:**
 - National Suicide Prevention Lifeline (988): provides immediate support for individuals in crisis or experiencing suicidal ideation
 - Crisis Text Line (text "HOME" to 741741): offers 24/7 support via text
 - crisistextline.org
- **Veterans Crisis Line** (dial 988, then press 1): specialized support for U.S. military veterans and their families.
 - veteranscrisisline.net
 - can also text: 838255
- **Substance Abuse and Mental Health Services Administration (SAMHSA)**: provides free, confidential, 24/7 treatment referrals and information for mental and substance use disorders
 - 1-800-662-HELP (4357)
 - samhsa.gov/find-help/national-helpline
- **National Alliance on Mental Illness (NAMI) HelpLine**: free information and support related to mental health conditions
 - 1-800-950-NAMI (6264)
 - nami.org/help
- **Trauma and Abuse Support:**
 - RAINN (Rape, Abuse & Incest National Network): 24/7 confidential support for survivors of sexual assault
 - rainn.org
 - 1-800-656-HOPE (4673)
 - National Domestic Violence Hotline: support for those experiencing domestic violence
 - 1-800-799-SAFE (7233) or text START to 88788
 - thehotline.org
- **PTSD-specific support:**
 - PTSD Coach App: mobile app offering tools for managing PTSD symptoms, developed by the U.S. Dept of Veterans Affairs
 - ptsd.va.gov/appvid/mobile/ptsdcoach_app.asp
 - Give an Hour: free mental health services from volunteer professionals, including trauma and PTSD support (does not provide emergency support)
 - giveanhour.org
- **General Health and Well-being:**
 - **United Way**: free, confidential assistance for a wide range of needs, including mental health, housing, and financial help
 - phone - dial 211
 - <http://www.211.org>
 - **mentalhealth.gov**
 - information and resources for mental health and mental illness