

Neurogenic Tremors Training (TRE) for Stress and PTSD: A Controlled Clinical Trial

Principal Investigator: KENT, MARTHA

Institution Receiving Award: CARL T. HAYDEN MEDICAL RESEARCH FOUNDATION

Program: PH-TBI

Proposal Number: 12030006

Award Number: W81XWH-15-1-0054

Funding Mechanism: Broad Agency Announcement

Partnering Awards:

Award Amount: \$494,859.00

TECHNICAL ABSTRACT

Although trauma is first responded to and stored in the body, the dominant best practice therapies of cognitive behavior therapy or exposure reprocessing therapy attempt to change the mind in order to affect changes in the mind. Approaches to effect somatic changes in order to modify traumatic emotional functions are beginning to emerge, among them Levin's somatic experience therapy, Ogden and Minton's sensorimotor psychotherapy, and Berceli's neurogenic tremors training. Animal research has found innate neurogenic trembling responses that discharge tensions experienced during sympathetic fight/flight/freeze responses. This potential innate survival mechanism has human counterparts. Although the use of tremors to improve emotional functions is very recent, its use to enhance physiological functions has a longer history in sports medicine and rehabilitation where results demonstrate improved strength, range of motion, coordination, increased rate of healing injuries, and hormonal changes evident in increased growth hormones and testosterone, and decreased cortisol.

The trauma release exercises (TRE) developed by Berceli in his current work on mass trauma in many parts of the world are an at-will self-help method to manage and reduce the effects of stress and post-traumatic stress disorder (PTSD) in an efficient, short, and inexpensive intervention that appears to have broad effects on physical and emotional functioning. This study proposes to test the efficacy of a brief TRE training program with a psychiatric population diagnosed with PTSD at the Phoenix VAMC (Department of Veterans Affairs Medical Center). It is hypothesized that this natural biological capacity to release stress has wide-ranging effects that restore capacities diminished by stress and trauma. We propose to test the efficacy of TRE in a randomized clinical trial that will compare three treatment conditions: standard TRE with tremors, TRE without tremors, and a wait-list control. We hypothesize that standard TRE with tremors will reduce self-reported PTSD and depression; reduce physical symptoms of pain, insomnia, somatic symptoms; show gains in self-reported well-being and physical health; and show improved cognitive functions.

The specific aim of this study is to confirm the efficacy of neurogenic tremors training as an adjunctive treatment for PTSD and stress. The training of Veterans in an at-will self-help method to manage stress and reduce the effects of PTSD through the induction of neurogenic tremors will be associated with a broad range of beneficial effects that reduce subjective symptoms of stress and trauma and increase sense of well-being and improve thinking.

The efficacy of TRE will be examined in a randomized clinical trial that will compare three treatment conditions: TRE with tremors, TRE without tremors (a "placebo" condition), and a wait-list control. Participants will undergo 4 weeks of training, meeting twice weekly in small exercise groups of 10. Pre- and post-test outcome measures will assess self-reported PTSD and depression, emotional well-being,

physical symptoms and well-being, and neurocognitive functions. Participants will be 35-69 years of age, meet PTSD criteria confirmed by CAPS (Clinician-Administered PTSD Scale), be US Veterans, and meet inclusion/exclusion criteria. The study is a 3 (Treatment: TRE standard, TRE minus trembling, and wait-list control) by 2 (Time: Pre- versus Post-testing) factorial design. We will examine group effects on primary outcomes with a series of 3x2 repeated measures multivariate analysis of variance (MANOVA). A series of ANOVA will identify the measures contributing to the significant multivariate findings. All analyses will be intent to treat. The sample size of 90 was arrived at by calculating the effect size for a 3x2 ANOVA. With $n=90$, $\alpha=.05$, and $\text{power}=.80$, the effect size is $f=.17$, a small to moderate effect size.

This study is particularly relevant in testing a somatic therapeutic approach to PTSD. It is particularly valuable, since there is such a dearth of body-based approaches to a psychiatric condition that is expressed in major sympathetic, hypothalamic-pituitary-adrenal axis, and endocrine dysregulation. Also significant is the fact that PTSD is associated with increased morbidity and mortality. TRE promises to be a very "user friendly," easy to learn, widely applicable, inexpensive, and very portable approach for a condition that remains remarkably difficult to treat in Veterans and the general population.