

INSOMNIA

ARE YOU SUFFERING FROM INSOMNIA WITH TBI?

A new study is investigating a non-drug therapy program that you can receive from your computer or smartphone.

Protocol Title:

A Randomized, Controlled, Blinded Study of Internet-guided Cognitive Behavioral Therapy for Insomnia in Military Service Members with History of Traumatic Brain Injury.

Purpose:

To evaluate the feasibility and efficacy of Internet-guided Cognitive Behavioral Therapy for Insomnia (eCBT-I) in service members and veterans with history of Traumatic Brain Injury (TBI).

Principal Investigator:

Dr. David Brody, MD, PhD Director, Center for Neuroscience & Regenerative Medicine

Associate Investigator:

Dr. J. Kent Werner, MD, PhD LCDR, MC, USN
Director of Research WRNMMC Sleep Disorders Center



Risks/Benefits of Participation:

Traditional Cognitive Behavioral Therapy treatment (CBT) for Insomnia has been well validated as safe and effective. This study seeks to deliver the same treatment as would be completed in-person through the Internet using a computer or smartphone. The possible benefits to you as a research participant in this research study are an improvement in insomnia and insomnia-related impairments. The possible risks and discomforts include increased fatigue and anxiety following a brief period of mild sleep restriction during treatment.

Time commitment:

Your participation in this study is voluntary. Successful completion of the study will require approximately 1-2 hours involvement per week during a treatment period of 9 weeks with an approximately 2 hour long-term follow up occurring 3 months afterward. All study-related activities will take place via telephone or the Internet.

Although financial compensation is not being offered, all participants will be given an opportunity to receive free open-label eCBT-I treatment upon study completion.

(USUHS) IRB 1
IRB NUMBER: CNRM-02-9662
IRB APPROVAL DATE: 08/17/2020
IRB EXPIRATION DATE: 06/26/2021

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To participate or learn more about this study, contact the study team via email at cnrm-ecbti@usuhs.edu or telephone at 301-456-5474.