Subject Name: _____ Date _____

Title of Study: The Nightmare Augmented Protocol (The NAP)

Principal Investigator: Jonathan Farrell-Higgins, Ph.D. VAMC: EKHCS

DESCRIPTION OF RESEARCH BY INVESTIGATOR

1. Purpose of study and how long it will last;
2. Description of study, including procedures to be used;
3. Description of any procedures that may result in discomfort or inconvenience;
4. Expected risks of study;
5. Expected benefits of study;
6. Other treatment available;
7. Use of research results;
8. Special circumstances.

Purpose of Study: The primary goal of this study is to determine whether the use of a new device, in addition to the use of established therapies, will reduce or eliminate the occurrence of nightmares.

Description of Study: You are being asked to volunteer for a research study looking at the helpfulness of treatments for long-lasting nightmares. The primary goal is to dramatically reduce or eliminate the occurrence of nightmares.

Inclusion Criterion Includes: 1) Experiencing nightmares related to a traumatic experience 2) Enrollment on the Stress Disorder Treatment Program (SDTP), which is a 7 week long inpatient treatment program.

Target Enrollment Size: 100 Participants total

The current study is a five-week protocol, consisting of 50 minute group sessions, once per week. All participants must remain on the SDTP unit during the duration of the protocol. If a participant chooses to withdraw from the SDTP program, they will be removed from the study.

After signing consent, the following will happen:

SUBJECTS IDENTIFICATION *(I.D. plate or give name-late, first, middle)*

Signature of Subject

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1. You will be assigned to one of 3 experimental groups. Assignment will be made randomly. This means that it will be made according to a previously determined scheme. The first subject to enroll will be assigned to Group 1, the second subject to Group 2, and so forth. Subjects in each Group will receive standard treatments for insomnia. Some subjects in each Group will be given a special headband, called the DREEM Headband, and will be asked to wear it during therapy sessions and during sleep. Subjects will be asked to complete the following tasks:
   - Members of group 1 will complete the Unit's existing therapies which are: Cognitive Processing Therapy and Cognitive Behavioral Therapy for Insomnia. Both of these are talked-based group therapies. Before each session, each member of this group will complete a brief weekly survey packet.
   - Members of Groups 2 and 3 will be asked to complete a 5-week "Nightmare Treatment Protocol" as well as Cognitive Processing Therapy. The Nightmare Treatment Protocol consist of weekly group meetings, nightmare exposure exercises and weekly surveys packets at the beginning of each session. All activities will take place during the inpatient treatment period of the Stress Disorder Treatment Program.
   - Members of Group 3 will hear tones from the DREEM Device during therapy sessions and during sleep. Tones will be played during sleep with a DREEM device. The DREEM device is a headband-like device used to improve sleep by playing tones while an individual is asleep. The DREEM device has been proven to be safe by the FDA and was designed to be as comfortable as possible. The tones played by the DREEM device have been proven to be unnoticeable during sleep by people wearing it.

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2. You will be asked to complete short surveys every morning upon awakening and every night prior to going to bed. These will be used to determine how you are doing or if you are improving. Depending on random assignment, you may be given a DREEM Headband to wear during sleep whether or not you are in the group assigned to have the device emit noise while you sleep. This is to prevent your survey responses from being impacted by whether you are given a headband to wear at night.
3. Each group is experimental as all are subjects who have given consent and are participating voluntarily. Data from each Group will be analyzed.

Risks of Participation: Participants may experience distress while in therapy or in the experimental group. The nature of this and other therapies for trauma disorders is to allow the client to experience their fears and anxiety. It is through this exposure process that distress ultimately decreases and new skills to cope with the anxiety and fear are leaned. In regard to the therapies used in this study (CPT, ERRT, & CBT-I), there have never been reports of client's worsening as a result of the therapy protocols. Additionally, no findings of clients worsening as a result of wearing the DREEM devices have been reported. Furthermore, no side effects are expected to occur as a result of the behavioral treatments or experimental protocols. In fact, previous studies using similar treatments report a reduction in the frequency and intensity of nightmares, improved sleep quality, and decreased daytime distress.

The only foreseeable risk of wearing the DREEM device is mild discomfort from wearing the headband. The participant will be allowed to discontinue wearing the device at any point without any repercussions and may still continue in the research study. Additionally, if I client decides to stop wearing the device and then later in the protocol wishes to resume wearing the headband, this will be permitted.

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Monitoring: Your mental health will be monitored continuously throughout this study. This continuous monitoring consists of daily meetings with a psychologist, daily class attendance, routine meetings with your assigned nurse and medication provider (their PA), and weekly self-report surveys. Through these steps we have a system that allows us to continually monitor your mental well-being. If your symptoms become worse, adjustments may be made, which can include changes to therapy type/frequency, more frequent assessments of well-being, addition or removal of psychoeducation classes, and medication changes. Additional, if the treatment team or you deem it necessary, you may also be removed from participating in the study at any time without any consequences. Overall, your well-being comes first.

Benefits of participation: The standard STDP therapies will be provided to all enrollees in the qualifying program. No charges will be made for any additional experimental procedures involved in the study. Future patients with similar conditions may benefit from knowledge gained in this study. There will be no compensation for participating in this study.

Experimental Procedures: The DREEM Headband is considered an experimental procedure given that the noise created by the DREEM Headband is not standard-of-care treatment for the condition being studied. If the participant does not want to participate in this study, they will still have access to all services usually provided by the VA.

Participant Assurances

Conditions of Participation: If you are eligible, your participation in this study is completely voluntary. If you don't participate, there will be no penalty. You have the right to stop being in the study at any time with no repercussions.

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Contacts: If you have any questions or concerns about this study, please feel free to speak to Dr. Jonathan Farrell-Higgins (Jonathan.Farrell-Higgins@va.gov) or Westley Youngren (way946@ku.edu) Monday through Friday between the hours of 8 a.m. & 4:30 p.m. For emergencies, you can contact these investigators by phone: (785) 350-3111, Ext. 52118 or should call 911.

RESEARCH SUBJECTS' RIGHTS: You have read or have had read to you all of the above. You have been told the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You will be informed of any new significant findings that may occur during the course of the study that may be related to your willingness to continue participation.

Your participation in this study is voluntary and you may refuse to participate or withdraw at any time without jeopardizing your future care at this Medical Center. There will be no penalty or loss of rights or other benefits to which you are entitled. Circumstances may arise which might cause the research investigator to terminate your participation before completion of the study.

Every effort will be made to maintain the confidentiality of any data that is collected during the course of the study. Your name will not be disclosed to any source unless required by applicable State laws and FDA regulations, nor will it be revealed in the event the data are published. There are times when we may have to show your records to other people. For example, personnel from the Food and Drug Administration, the Office of Human Research Protections, The General Accounting Office, the VA Office of Research Oversight, the Kansas City VA Institutional Review Board (IRB), the VA Research and Development Committee, the Research Compliance Officer, and the study monitors may look at or copy portions of records about you.

It is the policy of the VA to provide necessary medical care for any eligible veteran patient, non-eligible veteran or non-veteran participant who incurs an injury as a result of participation in an authorized research project conducted by a VA employee, unless the injury is a result of not complying with the research study procedures. In addition to medical care, an injured person may also seek compensation under Title 38 USC 1151, and in some circumstances, under the Federal Tort Claims Act.

If you should have medical problems, questions, concerns or complaints about the research or need to report an adverse event, **you may contact the Principal Investigator, Jonathan Farrell-Higgins, Ph.D. at (785} 350-3111 extension 52118 or the VA operator at (785) 350-3111 after hours.** If you have any questions regarding your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Kansas City VA Medical Center (KCVAMC) Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study.

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Also, you may call the KCVAMC IRB if you have questions, complaints or concerns about the study, 816-861-4700 Ext. 57255. If you want to speak to individuals who are independent of the research team you may also contact the Associate Chief of Staff for Research for the Eastern Kansas Healthcare System at (913) 682-2000 extension 52658.

You will be given a signed copy of this consent form prior to entering the study.

_____

Subject's Signature

Any questions that I may have had concerning this study have been answered to satisfaction. I hereby volunteer and consent to participate in this research study.

_____

Subject's Printed Name

_____

Signature of Person Obtaining Consent Date

Printed Name of Person Obtaining Consent: _____

Note: If subject is not competent to consent, then a legal authorized representative must be used to complete a Surrogate Consent Form.