Fiscal Year:	FY 2020	**Task Last Updated:**	FY 02/10/2020
PI Name:	McKinley, Richard Ph.D.		
Project Title:	Effects of Transdermal Vagal Nerve Stimulation (tVNS) on Cognitive Performance Under Sleep Deprivation Stress		
Division Name:	Human Research		
Program/Discipline:			
Program/Discipline-- Element/Subdiscipline:			
Joint Agency Name:		**TechPort:**	No
Human Research Program Elements:	(1) **HFBP**:Human Factors & Behavioral Performance (IRP Rev H)		
Human Research Program Risks:	(1) **Sleep**:Risk of Performance Decrements and Adverse Health Outcomes Resulting from Sleep Loss, Circadian Desynchronization, and Work Overload		
Space Biology Element:	None		
Space Biology Cross-Element Discipline:	None		
Space Biology Special Category:	None		
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Zip Code:	45433-7951	**Congressional District:**	10
Comments:			
Project Type:	Ground	**Solicitation / Funding Source:**	2018 HERO 80JSC018N0001-Crew Health and Performance (FLAGSHIP, OMNIBUS). Appendix A-Flagship, Appendix B-Omnibus
Start Date:	12/17/2019	**End Date:**	12/15/2020
No. of Post Docs:		**No. of PhD Degrees:**	
No. of PhD Candidates:		**No. of Master' Degrees:**	
No. of Master's Candidates:		**No. of Bachelor's Degrees:**	
No. of Bachelor's Candidates:		**Monitoring Center:**	NASA JSC
Contact Monitor:	Whitmire, Alexandra	**Contact Phone:**	
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Flight Program:			
Flight Assignment:			
Key Personnel Changes/Previous PI:			
COI Name (Institution):	McIntire, Lindsey M.S. (Infoscitex, Inc)		
Grant/Contract No.:	80JSC020T0009 IAA		
Performance Goal No.:			
Performance Goal Text:			

Task Description:

Objective: To evaluate the efficacy of transdermal vagal nerve stimulation (tVNS) to mitigate the effects of fatigue induced by sleep deprivation on aspects of cognition including attention, arousal, multitasking, and memory in populations of Department of Defense (DoD) subjects.
Primary Objective: Demonstrate a >20% improvement in at least one cognitive skill during sleep deprivation stress when compared to the control population.

Secondary Objective: Assess effects of tVNS on subjective mood.

Methods: This study will utilize a single factor, between subjects, double blinded experimental design. The factor will be "stimulation type" and will be tested at two levels: active and sham. Participants will be randomly assigned to one of two experimental groups (n=20 for each group). Group 1 will receive active tVNS on the skin over the left and right cervical vagus nerve (neck) at 25 Hz for 2 minutes on each side (with a 2 minute break in between) at 1800. Group 2 will receive sham tVNS at 1800 on both the left and right cervical vagus. The sham will be conducted with a separate sham tVNS device provided by the manufacturer. The sham provides similar sensations (e.g., vibrations) without providing stimulation of the nerve.

After consenting to participate in the study, participants will fill out the medical screening questionnaire. Two days prior to their scheduled experimental trial, participants will be given an activity wrist monitor and instructed that their daily schedules should include a minimum of seven hours of sleep per night between the hours of 2300 and 0600. Also during this time participants will receive training on all four performance tasks to be utilized in the study. Participants will be trained to asymptote on the performance tasks to guard against learning effects during experimental testing. Therefore, more training may be administered if necessary. Participants will also become familiarized with the subjective questionnaires at this time.

On the day of their experimental trial, participants will be required to awaken at 0600 and perform their daily activities as normal. They will be instructed to not consume any caffeine or central nervous system (CNS)-altering medications/substances on the experimental test day. Each participant will arrive at the test facility at 1530 hours. Upon arrival, their activity data will be analyzed to ensure that proper sleep cycles were maintained. Starting at 1600 hours, participants will complete one session of the vigilance task (30 mins), one session of the working memory task (20 mins), one session of the psychomotor vigilance test (PVT) task (10 mins), one session of the Multi-attribute task battery (MATB) task (20 mins), and fill out the Profile of Mood States-Brief (POMS-B), Visual Analogue Scale (VAS), and side–effects questionnaire. Afterwards, participants will then be provided a break of approximately 90 minutes where they can talk, watch TV, walk, read, or play video games. The second session will begin at 1900 hours. These procedures will be repeated every three hours with the final session occurring at 1600 the following day (36 hours continuous wakefulness). At 1900, participants will be given active or sham tVNS depending on their experimental group.

Impact: High levels of performance at all times is a requirement for success in both military and space exploration populations. Non-invasive vagal nerve stimulation has been shown to augment cognitive performance such as learning, memory retention, attention, and arousal. The results from this research will help determine the feasibility of tVNS to limit the effects of fatigue stress on NASA and military operators. While there is no substitute for adequate sleep, this may substantially reduce errors and attention lapses caused by increased fatigue when rest is not an option.

Rationale for HRP Directed Research:

Research Impact/Earth Benefits:

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Task Progress:

New project for FY2020.

Bibliography Type:

Description: (Last Updated: 07/01/2021)