Fiscal Year:	FY 2022	**Task Last Updated:**	FY 11/02/2021
PI Name:	Wood, Scott J. Ph.D.		
Project Title:	Optimizing the Combination of Intranasal Scopolamine and Sensory Augmentation to Mitigate G-Transition Induced Motion Sickness and Enhance Sensorimotor Performance		
Division Name:	Human Research		
Program/Discipline:			
Program/Discipline--Element/Subdiscipline:			
Joint Agency Name:		**TechPort:**	No
Human Research Program Elements:	(1) **HHC**:Human Health Countermeasures		
Human Research Program Risks:	(1) **Sensorimotor**:Risk of Altered Sensorimotor/Vestibular Function Impacting Critical Mission Tasks		
Space Biology Element:	None		
Space Biology Cross-Element Discipline:	None		
Space Biology Special Category:	None		
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Comments:	NOTE: PI returned to NASA JSC in January 2017. PI was at Azusa Pacific University from August 2013 – January 2017; prior to August 2013, PI was at NASA JSC.		
Project Type:	GROUND	**Solicitation / Funding Source:**	2019-2020 HERO 80JSC019N0001-HHCBPSR, OMNIBUS2: Human Health Countermeasures, Behavioral Performance, and Space Radiation-Appendix C; Omnibus2-Appendix D
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No. of Post Docs:	0	**No. of PhD Degrees:**	0
No. of PhD Candidates:	0	**No. of Master' Degrees:**	0
No. of Master's Candidates:	0	**No. of Bachelor's Degrees:**	0
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Flight Program:			
Flight Assignment:			
Key Personnel Changes/Previous PI:	November 2021 report: None		
COI Name (Institution):	Daniels, Vernie M.S. (KBR/NASA Johnson Space Center) Reschke, Millard Ph.D. (NASA Johnson Space Center)		
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Task Description:	Our primary aim is to evaluate a combination of intranasal scopolamine and sensory augmentation to both mitigate motion sickness and enhance crew performance. The current approach is to administer anti-motion sickness medications prior to landing. However, it is operationally challenging to optimize dosage levels. The intranasal form of scopolamine has several properties that should improve efficacy. It has increased bioavailability (i.e., plasma concentration) soon after administering the drug with minimal side effects. This formulation allows crewmembers to self-medicate in the operational environment even after the onset of symptoms. Water landings are expected to exacerbate reentry motion sickness severity. In addition to the unstable support surface, crewmembers will be deprived of a stable Earth visual reference inside the crew capsule. Sensory augmentation, e.g., vibrotactile feedback of an Earth vertical reference, has been effective as a spatial awareness and balance aid with vestibular impairment. We hypothesize that the combination of intranasal scopolamine and sensory augmentation of Earth vertical will be more effective to mitigate motion sickness and improve task performance than when administered separately. During this ground-based study, we will evaluate combining intranasal scopolamine and sensory augmentation as an integrated countermeasure on a multi-degree of freedom platform simulating capsule motion during water landings. We hypothesize that exposure to simulated capsule wave motion will induce motion sickness and impair performance on functional tasks. We also hypothesize that the combination of intranasal scopolamine and sensory augmentation of Earth vertical will be more effective to mitigate motion sickness and improve task performance than when administered separately. We will compare motion sickness symptom onset, severity, and recovery across four conditions: intranasal scopolamine (0.4 mg) and placebo control with and without sensory augmentation. Performance on a series of functional tasks (tilt motion tracking with and without a paced auditory serial addition test (PASAT) dual-task, eye-head-hand target acquisition)) will be performed pre, during, after capsule wave motion. The motion will continue until the subject reaches a motion sickness endpoint representing severe malaise on the Pensacola Diagnostic Index up to 45 min. The bioavailability of scopolamine for each session will be estimated from plasma concentrations every 15 min. Cognition (psychomotor vigilance task) and subjective reports of drug side effects will be obtained. Two additional specific aims are also proposed to further evaluate the efficacy of intranasal scopolamine to provide treatment (“rescue”) of symptoms following motion sickness onset. For specific aim 2, a laboratory-based study will be used to compare motion sickness symptom severity and recovery for intranasal scopolamine (0.4 mg) and placebo control subjects will self-administer during the simulated capsule wave motion following symptom onset. Finally, specific aim 3 will involve an operational clinical field study in which flight surgeons will administer intranasal scopolamine to astronauts and/or recovery operations personnel during SpaceX landings or Orion splashdown recovery simulations.
Rationale for HRP Directed Research:	
Research Impact/Earth Benefits:	The significance of treating motion sickness with intranasal scopolamine is the ability to self-administer real-time dosage adjustments during crew launch, landing, and recovery operations. The combination of non-pharmaceutical sensory augmentation approach with intranasal scopolamine has the benefit to not only mitigate motion sickness but enhance crew performance of landing and egress tasks.
Task Progress:	Specific Aim 1: This aim will compare motion sickness symptom onset, severity, and recovery across four conditions: intranasal scopolamine (0.4 mg) and placebo control with and without sensory augmentation. The six degree-of-freedom (CKAS) platform was assembled in our laboratory space and the capsule wave pseudorandom motion stimuli consisting of combined pitch, roll, and heave motion centered around 0.2 Hz has been implemented. Defender Pharmaceuticals, Inc. (Tampa, FL) has provided the study medication (intranasal formulation of scopolamine hydrobromide, 0.4 mg dosage) including placebo control using a nasal pump delivery device. Engineering Acoustics, Inc (Orlando, FL) provided a wearable vibrotactile array to provide feedback about pitch and roll tilts. The functional and cognition tasks have also been implemented in the capsule cabin. We are conducting a preliminary pilot study with 10 subjects to verify the wave motion stimuli is sufficiently provocative to elicit symptoms and assess efficacy of the interventions. This pilot study data will also be used to complete and verify the data analysis scripts for the test battery. Specific Aim 2: This aim will compare motion sickness symptom severity and recovery for intranasal scopolamine (0.4 mg) and placebo control subjects will self-administer during the simulated capsule wave motion following symptom onset. We are currently evaluating moving this study arm to utilize the Disorientation Research Device (Kraken) located at the Naval Medical Research Unit – Dayton (NAMRU-D) at the Wright-Patterson Air Force Base in Ohio. This device has the capability to provide a greater range in levels of sea states for the capsule wave motion. Specific Aim 3: This aim is a clinical field study to examine the efficacy of intranasal scopolamine in various operational settings including SpaceX missions, Orion splashdown recovery simulations, and centrifuge training. The field test aim was initiated during the 3-day orbital free-flyer mission (Inspiration4) onboard the SpaceX Crew Dragon capsule this past year. Commercial crewmembers were trained in standardized self-administration of intranasal scopolamine for mild-to-moderate motion sickness (0.2 mg per nostril, 0.4 mg total dose). Each crewmember was supplied with one scopolamine nasal applicator, stowed in an accessible pocket of the IVA (intravehicular activity) suit. No restriction was placed upon the use of prophylactic anti-emetics, with decision for prophylactic use for each crewmember based on observed motion sickness susceptibility during training. Nausea levels (1 = no nausea, 20 = severe nausea) were recorded as a standard part of regularly scheduled Private Medical Conferences (PMCs). PMCs occurred shortly after initial orbital insertion, nightly prior to crew sleep, and post-splashdown. Two of four crewmembers utilized intranasal scopolamine during the hours of the spaceflight. Both Crewmembers reported a peak nausea level of 8 on the 0-20 scale prior to INSCOP (Intranasal Scopolamine) self-administration, reducing to 5 after 15 minutes. Side effects reported included drowsiness, dry mouth, and nasal irritation (n=1 for each). Duration of reported relief was 2.5 hrs. and 3.5 hrs. for each crewmember, respectively, later requiring more aggressive treatment for higher symptom scores. Nausea resolved by mission day 1, resulting in no further use of anti-emetics in flight. Despite the later need for anti-emetics, this novel tool effectively mitigated immediate symptoms of nausea and was easily self-administered by crewmembers with minimal training and did not impede flight operations by requiring unscheduled suit doffing or medical equipment access.
Bibliography Type:	Description: (Last Updated: 03/08/2024)