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**TITLE:** Regulating Mood and Suicidal Ideation with Morning Light Exposure Treatment

**PRINCIPAL INVESTIGATOR:** William D. “Scott” Killgore, PhD

**CONTRACTING ORGANIZATION:** University of Arizona, Tucson, AZ

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**PREPARED FOR:** U.S. Army Medical Research and Development Command
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**ABSTRACT:**
The present study examines the effects of morning light exposure on the mood and quality of sleep of active military members who report mild to moderate symptoms of depression. A total of 400 active military members including active duty, national guard, and reserves from all branches will participate in a fully remote, counterbalanced, cross-over study design for 46 days. We will track their daily mood and sleep quality through online assessments and wearable biodata devices such as a Dreem Headband (flexible at-home 5-channel EEG) and Fitbit watch (actigraphy tracker). Participants must complete daily assessments between the hours of 6 am and 11 am while wearing light-emitting glasses for 30 minutes. Assessments include scales of depression, anxiety, aggression, and stress, along with baseline measurements of sleepiness, personality, caffeine consumption and more. Participants will be randomly assigned to Condition 1, meaning active blue light first, then placebo red light next, or Condition 2, placebo red light first, then active blue light next. The timeline consists of three two-week blocks where the first and last block will be their light treatment, separated by a two-week washout period where daily online assessments are still completed but no glasses will be worn, and neither will the Dreem Headband. It is hypothesized that participants' mood and sleep quality will improve during the two-week active light segment in comparison to the placebo light segment.

| 16. SECURITY CLASSIFICATION OF: | | | 17. LIMITATION OF ABSTRACT | 18. NUMBER OF PAGES | 19a. NAME OF RESPONSIBLE PERSON |
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| Unclassified | Unclassified | Unclassified | Unclassified | 23 | 19b. TELEPHONE NUMBER *(include area code)* |

## TABLE OF CONTENTS

1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

Mental health issues remain a significant force limiting factor within the U.S. military. Suicide rates among active-duty members have gradually increased since 2011 but appear to be plateauing since the 2020 COVID-19 pandemic, although the suicide rate increased by 3% from 2021 to 2022. According to one study (Suitt, 2021), more military personnel died each year from suicide than from combat during the operations in Iraq and Afghanistan. Consequently, there continues to be a critical need for novel treatments for mental health concerns and suicidal ideation among military personnel. One factor that is often associated with poor mental health and mood is disruption of the circadian rhythm and consonant sleep difficulties. Military members are frequently faced with circadian misalignment and disrupted sleep patterns due to the requirements of service, placing them at particular risk for mental health issues, including depression and suicidal ideation. It is well established that precision targeted morning light exposure, particularly using blue wavelength light, is highly effective at resetting the daily circadian rhythm and promoting better quality sleep. We propose to conduct a large field trial of morning blue light therapy (BLT) in comparison to placebo light therapy (PLT) for improving mood and suicidal ideation in military personnel. Over a 3-year period, we aim to determine: 1) the effectiveness of daily morning BLT for regulating circadian alignment and sleep quality, 2) the effectiveness of daily morning BLT for sustaining or improving mental health outcomes including suicidal ideation, relative to PLT, and 3) the acceptability and "buy-in" from military personnel regarding use of a pair of light-emitting glasses for daily light exposure. This will be accomplished by recruiting 400 active military personnel within active duty, national guard, and reserves. Participants will complete a ransomized, double-blind, placebo-controlled, counterbalanced, crossover design study of the effects of 30-minute morning BLT sessions versus PLT on measured sleep and mental health outcomes. Participants will complete two weeks of morning blue light using AYO light-emitting glasses while completing daily online assessments to record their current mood, stressors, and sleep diaries. The same routine for two weeks will be carried out for each condition in a counterbalanced order, with an intervening two-week washout period where they continue to take morning online assessments but without completing light sessions. Throughout six weeks, participants will continuously wear Fitbit watches to capture actigraphy data and sleep and wake patterns. During the periods in which the light glasses are worn, a flexible 5-channel at-home EEG headband called Dreem will be worn nightly to measure sleep activity as well. This timeline is illustrated in the diagram below.

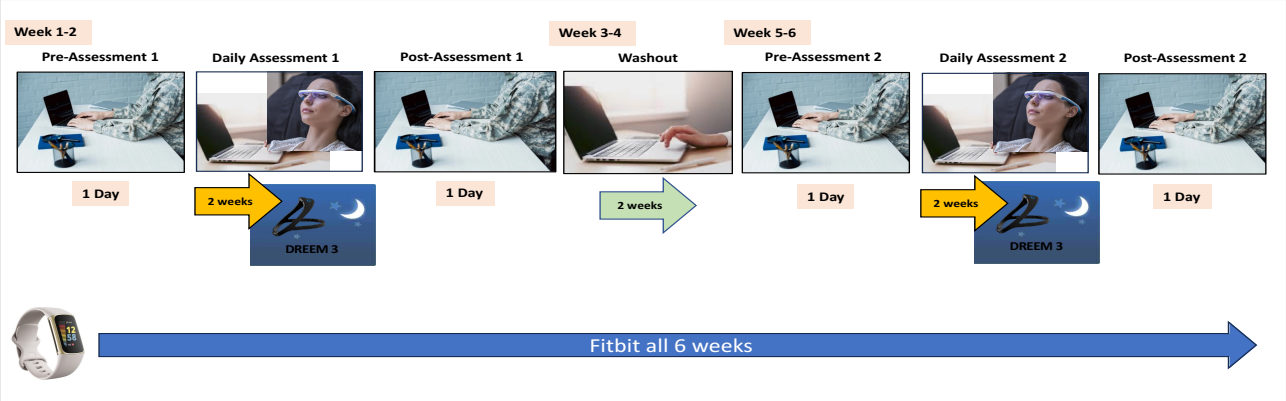


*Figure 1. Timeline of the 6-week remote study.*

The participation schedule includes 5 components: **1) Pre-Assessments:** Participants will be emailed an invitation to complete surveys on REDCap one day before starting the Daily Assessment Surveys as part of the Pre-Assessment 1. The Pre-Assessment surveys do not require the use of AYO glasses, but they will wear the Dreem Headband overnight before beginning the Daily Assessment 14-day block the following day. **2) Daily Assessments:** The following day, participants receive an email invitation to complete Daily Assessments on REDCap for 14 consecutive days. These are completed every morning and take approximately 10 minutes. Surveys must be completed within the time window of 6 am and 11 am while wearing the AYO glasses every morning. The light exposure sessions each last 30 minutes. The Dreem Headband is worn every night of the Daily Assessment. **3) Post-Assessments:** These occur one day after the two-week session of Daily Assessments and are the same surveys as the Pre-Assessment surveys. **4) Washout Period:** Participants will resume taking the Daily Assessment REDCap surveys every morning for 2 weeks during the Washout period, which means they will not wear any glasses or the headband. They will continue to wear the FitBit watch as normal. **5) Repeat the first 2-week schedule with alternate pair of glasses:** They will conduct the same timeline of events (Pre-Assessment, Daily Assessment, and Post-Assessment) for the final 2-week period, only this time they will wear the alternate pair of glasses (either active blue or placebo). All assessments must be completed in the mornings between the hours of 6:00 am and 11:00 am.

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

   **Light Exposure, Sleep, Circadian Rhythm, Mood, Suicidality, Active Military**

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*
   **What were the major goals of the project?**

   **Specific Aim 1:** Determine the effectiveness of daily morning light therapy for regulating circadian timing and sleep.

   **Specific Aim 2:** Determine the effectiveness of daily morning blue light therapy for sustaining or improving mental health outcomes relative to a placebo light therapy.

   **Specific Aim 3:** Determine the acceptability and "buy-in" from military personnel for using a daily light headset device.

| ***Major Tasks*** | ***Completion Percentage*** |
|---|---|
| • **Major Task 1:** Complete IRB/OHRO Approval, Train Staff and Procure Assessment Tests and Instruments.<br>  o **Subtask 1:** Prepare Regulatory Documents and Research Protocol | *Subtask 1* |

| | |
|---|---|
| ▪ Refine eligibility criteria, exclusion criteria, screening protocol | *Completed 10/30/22* |
| ▪ Finalize consent form and human subjects protocol | *Completed 01/06/23* |
| ▪ Submit for local UA IRB Review | *Completed 01/06/23* |
| ▪ Submit for Military 2nd level IRB review (ORP/HRPO) | *Completed 03/16/2023* |
| ▪ Submit amendments, adverse events and protocol deviations as needed | *90%* |
| ▪ Coordinate with sites for annual IRB report for continuing review | *NA* |
| o **Subtask 2:** Hire Staff and Procure Testing Materials | *Subtask 2* |
| ▪ Hire research staff to administer all tasks and carry out study procedures | *Completed 01/10/22* |
| ▪ Train research staff on study-related protocols | *Completed 03/30/23* |
| ▪ Acquire assessment tests and instruments | *Completed 03/13/23* |
| • **Major Task 2:** Data Collection<br>o **Subtask 1:** Set up online portal<br>▪ Create and set up any accounts necessary for the online portal | *Subtask 1*<br>*Completed 05/01/23* |
| ▪ Develop, test and launch all assessments using online portal | *Completed 06/21/23* |
| o **Subtask 2:** Begin data collection | *Subtask 2* |
| ▪ Place advertisements for participant recruitment | *90%* |
| ▪ Administer online baseline assessments (n=400) | *1% (6/400)* |
| ▪ Participants are randomly assigned to either the BLT-first (n=200) or the PLT-first (n=200) condition and begin at-home light therapy | *1% (6/400)* |
| ▪ Administer online post-treatment assessments (n=400) | *1% (6/400)* |
| • **Major Task 3: Analyze and Report Data**<br>o **Subtask 1:** Analyze data | *Subtask 1* |
| ▪ Compile and statistically analyze all data | *0%* |
| | *Subtask 2* |

| | |
|---|---|
| ○ **Subtask 2:** Submit Publications and Final Report<br>▪ Submit abstracts and manuscripts for publication<br>▪ Prepare final report describing primary outcomes | *0%*<br>*0%* |

**What was accomplished under these goals?**

During the first annual reporting period, this study has executed regulatory approval and planning, and it progressed fully to the data collection phase. By Y1Q1, we refined eligibility criteria, exclusion criteria, and the screening protocol. By Y1Q2 we received full regulatory approval from both the University of Arizona IRB and OHRO, completed all staff hiring and training of related research protocols, as well as acquired all assessment materials and instruments for data collection. In Y1Q3, we successfully set up all necessary online portals and accounts, developed and tested an abbreviated study run and initiated the distribution of advertisements for participant recruitment. These accomplishments led to the completion of Major Task 1 and steady start of Major Task 2. Another major task we accomplished within this year was enrolling our first six participants, with one of the participants fully completed by the end of the reporting period.

Recruitment started in Y1Q3 (06/20/2023) and we enrolled our first participant in Y1Q4 (07/21/2023). The milestone for Major Task 2, Subtask 2 has progressed through our current participants who have completed baseline assessments and have been randomly assigned to BLT-first or PLT-first. Participant BLG_001 completed their full study participation and thus all post-assessments by 09/13/2023, marking another millstone in the study's progression.

Our primary method of recruitment has been through distributing flyers around the Tucson metropolitan area with a large focus on Davis Monthan Air Force Base since our study population must be actively serving in the military. We were able to establish contact with USAF Lt Col. Beth Zeiger, the Mental Health Flight Commander and Director of Psychological Health at DM-AFB, who agreed to post flyers in the Base Clinic. Aside from the flyers, several other methods have been effective in recruiting participants such as word of mouth and online representations through ads.

We have been exploring other broader avenues of advertising and recruiting as well. We are currently working with US Army LTC Michael Dretsch, Director of the US Army Research Directorate-West to assist in facilitating recruitment in the Joint-Base Lewis-McChord region. Additionally, we have discussed recruitment avenues with Dr. Dale Russell, and Dr. Rachel Markwald, from the US Navy Naval Health Research Center.

Our sources of study recruitment and overall progress are described below:

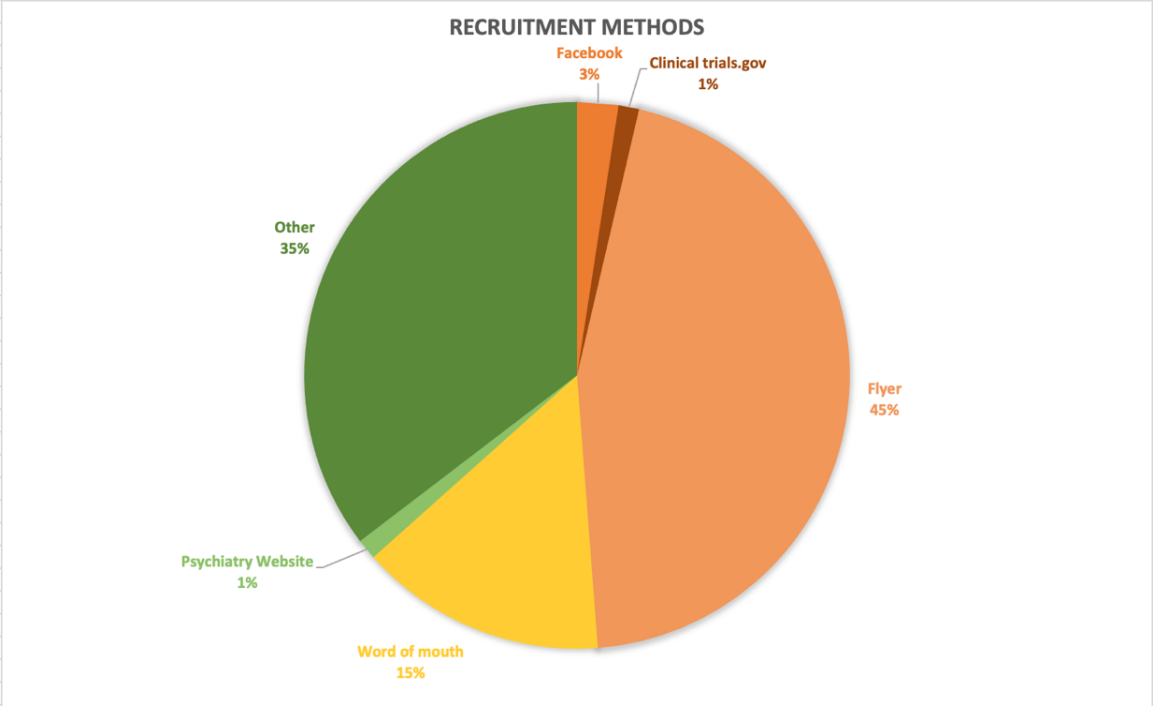


*Figure 2: Breakdown of Recruitment Methods*

By the end of Y1Q4 our most successful recruitment method was the flyer (*n*=37) and word of mouth (*n*=12). Of the other avenues that individuals reported were Facebook (*n*=2), the Clinical trials.gov (*n*=1), the University of Arizona Psychiatry website (*n*=1), and through other avenues (*n*=29).


*Figure 3: Breakdown of recruitment progress as of the end of this reporting period.*

During the annual reporting period a total of 82 individuals showed interest in this study by filling out our online REDCap survey for preliminary screening. Of the 82 entries, 76 individuals were

excluded (see Figure 4), six (6) were lost upon re-contact due to not consenting or not responding upon requested clarification.

Below is a figure illustrating the reasons for ineligibility/exclusion from the REDCap preliminary screening.

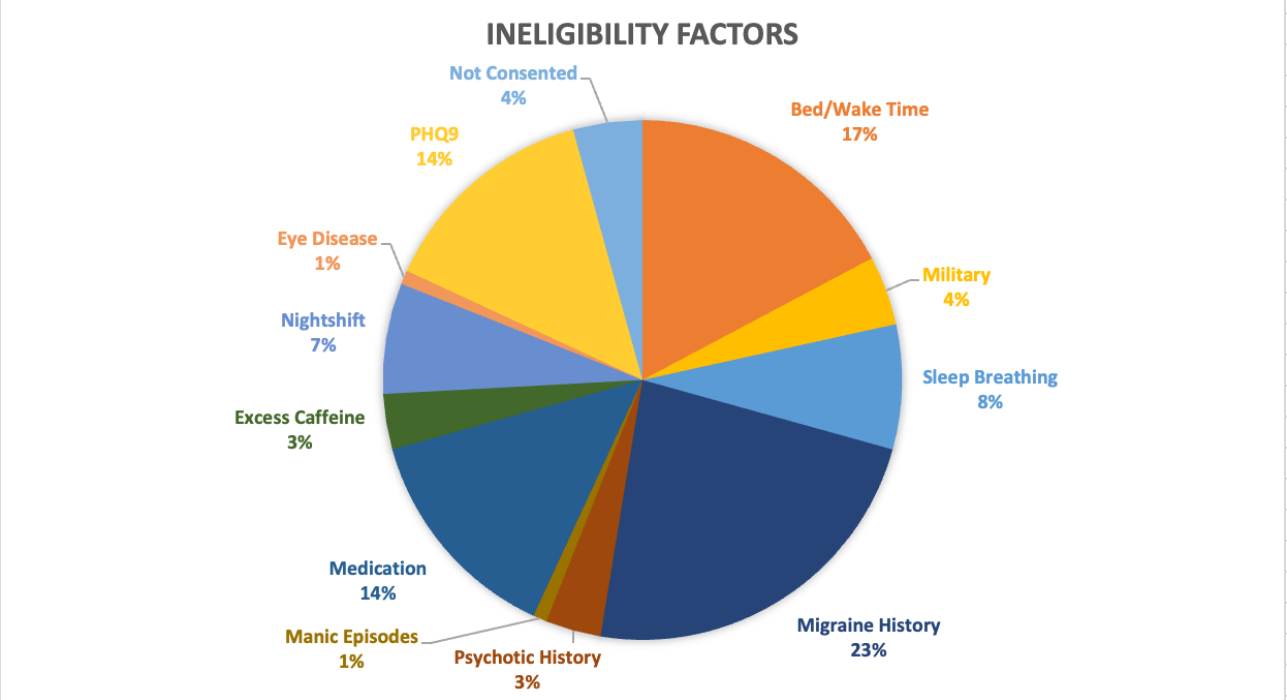


*Figure 4: Exclusion factors for the 76 excluded individuals as of 09/30/2023.*

As Figure 4 illustrates, the primary exclusion factor for ineligible participants has thus far been due to health-related issues such as reported migraine history (*n*=27), taking sleep medications (*n*=16), and self-reported sleep breathing disorders (*n*=9). As these reflect important health concerns that would potentially place participants at increased risk of discomfort or medical condition complications, and/or contaminate the results, we have excluded such volunteers. The next most common reasons for ineligibility include unusual bed and wake times (i.e., they sleep outside of regular morning and night circadian pattern (*n*=20), scoring below the mild depression threshold on the Patient Health Questionnaire (PHQ9) for depression (*n*=16), reported plans to conduct night shift during the study (*n*=8), not actively serving in the military (*n*=5), not completing the consent process after passing screener (*n*=5), reporting a daily average greater than 500 mg of caffeine (*n*=4), self-report of psychotic history (*n*=4), self-report of history of manic episodes (*n*=1), and having a history of eye disease (*n*=1). These exclusion criteria were maintained to minimize potential harm to participants and/or to ensure that the findings validly represent the constructs of interest.

Several individuals met more than one exclusionary criterion, accounting for 30% of the entries in this reporting period. Criteria commonly reported together were migraine history and sleep medication use (*n*=8) as well as reports of less than 5 hours of sleep on average and sleep breathing related disorders (*n*=7).

After reviewing the data regarding exclusions, our team had several meetings to discuss potential minor criteria that could be modified/eliminated to reduce exclusions without compromising the integrity of the final results. Several factors were considered. We attempted to discern whether a particular exclusionary criterion might make it difficult to generalize the findings to active military personnel. For example, the issue of daily caffeine intake appeared to be a major source of lost participants, yet high caffeine use is endemic throughout the military. Therefore, we decided to stop excluding participants who exceeded a particular threshold of caffeine up front and to simply document their caffeine use so that it could be included in the statistical analysis, which would then enhance our ability to generalize the findings to the wider military population and to determine the potential effects of caffeine use on responses to the treatment. Similar logic was applied to a number of exclusionary criteria. Thus, after this reporting period, exclusionary criteria have been adjusted to no longer screen out applicants if they report excessive habitual caffeine use, non-light sensitive migraine headaches, and possible evidence of sleep breathing related disorders, all of which may be commonly encountered among active-duty military personnel. Instead, our approach going forward is to collect data regarding details of habitual and daily caffeine intake and capture risk of sleep breathing disorders within the baseline assessments, as individuals with these factors are not at increased risk in participating in our study. With less stringent exclusion criteria and increased recruitment efforts, the number of study applications and eligible participants have greatly increased.

**What opportunities for training and professional development has the project provided?**
*If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.*

All team members on this study have been trained on all relevant areas of this study. Members include four (4) full time research technicians and a team of five (5) undergraduate research assistants and two postdoctoral research trainees. All members have completed training certificates for good clinical research practice, HIPAA compliance, responsible conduct of research and more. This project has provided opportunities for professional development such as implementing skills in REDCap data manager. Data management is extremely important for a study of this size, and researchers have used this skill in all aspects of the study. Researchers have also benefitted from opportunities in communicating with participants in a professional manner and providing virtual assistance with enrollment and onboarding processes.

**How were the results disseminated to communities of interest?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.*

Nothing to Report

**What do you plan to do during the next reporting period to accomplish the goals?**
*If this is the final report, state "Nothing to Report."*

*Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.*

During the next reporting period we will continue to focus on increasing recruitment efforts and the amount of completed participants. There are currently sixteen (16) confirmed participants to begin enrollment/onboarding during the next quarterly reporting period, likely bringing the total enrolled participants to twenty-two (22) in the beginning of Y2Q1. We expect this number to double by the next quarterly reporting date, which will be achievable with templated modifications to increase participant compensation and the addition of recruitment material distribution through military social media ad placements. Once we receive IRB approval for our latest modification submission, which includes increasing the participant compensation amount, we will submit the modification to eBRAP for OHRO approval.

***4.*** **IMPACT:** D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

**What was the impact on the development of the principal discipline(s) of the project?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).*

Nothing to Report

**What was the impact on other disciplines?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.*

Nothing to Report

**What was the impact on technology transfer?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:*

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report

**What was the impact on society beyond science and technology?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:*

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report

**5. CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

**Changes in approach and reasons for change**
*Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.*

| Type of amendment: | UA IRB Submission Date | UA IRB Approval Date | UA IRB Approval Submitted to HRPO | Approved by HRPO |
|---|---|---|---|---|
| New Project | 01/06/2023 | 03/14/2023 | 03/16/2023 | 05/08/2023 |
| New Project Initial Approval | | | | |
| Minor | 04/25/2023 | 05/09/2023 | N/A | N/A |
| Amendment #1<br><br>1. Recruitment flyers: all recruitment flyers received an additional statement to the bottom of the page that says, "Approved by the Department of Defense Office of Human Research Oversight OHRO Protocol: E03759.1a".<br>2. Created an info card: added a new place for instructions about uploading sleep recording data, which will be attached to the Dreem Headband box when delivered to participants.<br>3. Tutorial Video: created a video tutorial for how to upload a sleep recording when using Dreem Headband that will be accessible via google drive, in the same place as the other instructional videos. | | | | |

4. New surveys: we added pre-post measures such as the PTSD Check List 5 (PCL5), Invincibility Belief Index (IBI), abbreviated Stressful Life Events Screening Questionnaire (SLESQ), and Buss-Perry Aggression Questionnaire (BPAQ), and added a new daily measure, Daily Inventory of Stressful Events (DISE).
5. Modifications to already present daily surveys: made abbreviated versions of PHQ9, displayed as PHQ3, GAD7, displayed as GAD2, and BPAQ, displayed as BPAQ2. These modifications include reducing the number of questions for each of these surveys, as well as changing the wording so it can measure daily responses in participants. For example, the full versions of these surveys ask questions relating to "over the past week" or responses that address a period of time greater than one day. We changed these to ask, "since yesterday…" or "yesterday I…". We decreased the number of questions asked to better fit our major aims of the study in the daily measures portion and to be conscience to not overwhelm participants with too many questions on a daily basis.
6. Updates to Sleep Diary located inside the Daily Instruments survey: added 5 questions, 1)"How long did it take you to fall asleep?", 2)"I woke up __ times during the night", 3)"How would you rate your quality of sleep?", 4)"How many alcoholic drinks (beer, wine, liquor) did you have yesterday?", 5)"I consumed alcohol yesterday: Not applicable, Morning, Afternoon, Evening." We also removed "AM/PM" in answer choices since they will be answering in a 24-hour clock format.
7. Updates to Screener survey: added question #5 and #6 to the Screening Questionnaire survey, "On average, what time do you go to bed on weeknights (Sunday-Thursday)?" and "On average, what time do you wake up in the morning on weekdays (Monday-Friday)?" As well as question #14, "Do you have a history of Bipolar Disorder?"
8. Updates to Demographics survey: added 9 questions which ask active duty members about their deployment information: 1) "What is your military occupational specialty?" which means to provide their occupational code (job title), 2) "Have you deployed? (select choice)", 3) "Total number of deployments (both combat and noncombat)", 4) "How many months did you spend deployed across all deployments?", 5) "Have you ever been combat deployed?", 6) "Total Number of Combat Deployments?", 7) "Mark which campaigns you deployed under:", 8) "How long was your longest combat deployment?", 9) "How many months did you spend deployed across all combat deployments?" Our rationale for adding these questions to the demographics survey is to be able to covary or address any correlations in type and duration of deployment. None of these questions ask personally identifiable information or any sensitive content. The question of location of deployment was intentionally excluded, as this would potentially ask sensitive information.
9. Updated scripts: attached scripts with track changes. The two scripts that were updated are "BL_PhoneEquipmentConfirmScript" and "BL_EmailEquipmentConfirmScript". The minor updates made to these two scripts include additional instructions for handling equipment. For example, "Once you receive all of the devices, please charge them and try going through the pairing instructions. We will contact you again when you get the study equipment to confirm that all items are working properly." As well as adding additional helpful information like a visual timeline (inputted in email version and addressed/referenced in phone version) of their participation and ways to upload their data. We also just rearranged the order of already pre-existent informational content for reading ease and semantic flow.
10. Updated ICF: added two links for participants to access information about their confidentiality and what the Certificate of Confidentiality covers for them.
11. Updated IRB Protocol: added one item to inclusion criteria, "Average 6-9 hours of sleep on weeknights between 10 pm and 10 am" to match the added screening questions.

| | | | | |
|---|---|---|---|---|
| Minor | 04/25/23 | 04/27/23 | N/A | N/A |
| Amendment #2<br>Study personnel updated | | | | |

| | | | | |
|---|---|---|---|---|
| Minor | 05/04/2023 | 05/05/2023 | N/A | N/A |
| Amendment #3<br>Study personnel updated | | | | |
| Minor | 06/13/2023 | 07/11/2023 | N/A | N/A |

Amendment #4

1. Made updates and edits to the study enrollment script. (Please see comments which highlight specific changes on document and track changes) – Some of these changes include updating a diagram for study timeline for participants to be aware of, updating scripts for how and when we will respond to their inquiries, specifying instructions for getting started with the devices after shipment and asking that they respond to our emails. Other major updates include overall clearer instructions for participation. This is shown through the highlighted areas with comments and dates in the document.
2. Made updates and edits to the non-compliance script – There were substantial changes, making the first non-compliance *warning* email say, "Hello [demorand_arm_1][demo_first_name], You have unfinished surveys on RedCap. As a reminder, this is part of your study compliance. Please click the link below to complete these surveys as soon as possible. [survey-link:SurveyName] (include whatever name of survey they are being reminded about) Sincerely, The SCAN Lab"
and we added the *withdrawal* script for full non-compliance. At the end of this script is the optional attachment of instructions to send participants if they must return the Fitbit watch which would involve un-pairing the device from their phone. They would get the instructions to return the watch if they were non-compliant to the point that they did not earn the compensation of keeping the device. This would be calculated prior to sending them this set of instructions based on the compliance and compensation tracker.
3. Edits to Screening questionnaire – 1) We added contact info questions ("Email address" and "phone number") at the top of the questionnaire to contact the potential participant if they stop halfway through screening process, which will allow us to resend them the survey link if they choose to resume the screening questionnaire. 2) We added a blurb at the beginning of this survey that says the screening questionnaire's data will not be used in the study and only the data collected after their consent is given will be collected for data. 3) We removed the following demographics questions: "Do you consider yourself to be Hispanic or Latino? (Meaning of Mexican, Puerto Rican, Cuban, Caribbean, or of Latin American descent?)" and "Race" because we ask this in the Demographics survey after screening and found it redundant. 4) Added the question, "On average, how many hours of sleep do you get?" to ensure our exclusion criteria of "have a sleep schedule outside of normal day and night circadian sleep cycle" is screened for.
4. Added a new document – This is the email script to send potential participants that provides them with the access link to finish filling out the screening questionnaire.
5. Updated Informed Consent Form – Now it says that participants are to wear the Dreem Headband the night prior to starting the AYO session the following day: "You will only wear the Dreem Headband during the two-week periods when you wear light glasses in the morning, as well as the night before starting your light glasses period." This only adds two nights to their entire Dreem Headband use since there are two separate sets of 2-week daily assessments, i.e. two glasses conditions that participants will conduct.
6. Updated "All Devices Instructions Packet" – Updates include adding an interactive table of contents to help participants navigate through the packet more easily. We also included a new video link, "DREEM Headband Tutorial: How to record your sleep" in the cover page, added cover pages for 3, 8, 14, 17, 19, and 36, added the AYO app and login instructions (Page 3-4), and the FitBit Quick start guide (Page 21-35).

7. Updated all flyers and social media posts to have the correct QR code – Previous version had an old QR code which was a broken link when scanned. Now the updated flyers and social media posts have the updated QR codes that work. Also updated flyers and social media posts to include a blurb at the bottom that lets applicants know that if they are eligible to participate, they must "perform study tasks outside of work/duty hours".
8. Updated Recruitment Email – This is the 'StudyRecruitmentScriptEmail' document, which we made edits to for clarification about participant eligibility and study timeline and tasks. Specific changes include, clearing up the wording for participants to seek approval from their supervisors, recommending that they perform study tasks outside of work hours, and clarifying the timeline of using devices and taking online assessments for the entire study.
9. Protocol – Added the sentence, "If participants do not score at least 80% on the comprehension quiz, they will be required to retake the comprehension quiz. Otherwise, they will be ineligible to move forward with participation."
10. Contact information form – Added the Contact Information Form for study enrollment.
11. Volunteer Comprehension Assessment – Changed question #3 in the VCA to say, "I will complete online surveys every day during:" instead of "during today's evaluation I will:" and changed the answer options for question #7 to be "these can enhance vision, these may cause blindness, these may cause mild eyestrain, and there is no chance of side effects". Please check older version of VCA to see changed questions. We slightly edited the wording/question structure to keep each question in same tense/format.

| | | | | |
|---|---|---|---|---|
| Minor | 06/13/2023 | 07/18/2023 | N/A | N/A |

Amendment #5
Study personnel updated

| | | | | |
|---|---|---|---|---|
| Minor | 07/26/2023 | 08/18/2023 | N/A | N/A |

Amendment #6

1. Updated AYO App Download Instructions that is located within the All Devices Instructions.pdf on page 3 – These updates are shown in the "All Devices Instructions Packet" pdf. The updates included adding instructions for running a light session to help users with the app. We also included instructions to support pairing the second light glasses which occurs near the end of their participation in the 6-week study.
2. Created a new script that notifies the participant that they will be starting their Assessment 2 portion of the study – This script includes the reminder to let them know that they will be starting Assessment 2 and provides them with instructions for Assessment 2, as well as the AYO App document to remind them of the clear steps for successfully pairing Assessment 2 glasses.
3. Modified Email_ScriptEnrollment document – Added clarification about setting up all devices upon receipt except for Assessment 2 glasses. We also reorganized the structure of the "It is very important that you:" section in Email #2 to increase participant comprehension, and we made minor wording adjustments to point #1 and #3.
4. Updated our flyers – We created new flyers to increase variety of our paper and social media flyers. These changes included visual changes and minor changes of wording. All necessary information is still present in the new flyers.

| | | | | |
|---|---|---|---|---|
| Minor | 08/23/2023 | 09/25/2023 | N/A | N/A |

Amendment #7:

1. Caffeine question – Removed caffeine question from screener and added the caffeine consumption questionnaire (CCQ) to pretx1 as a baseline survey. It only takes ~2 minutes on average to complete. This addition

will not strain participants, as they will still be below the max amount of time for participants' morning tasks as described in the protocol.
2. Screener survey edit – Added branching logic that will specify migraine history. We need to clarify participant eligibility while ensuring their safety. Thus, if they report having infrequent and non-light sensitive migraines, then they will still be eligible for the study. These edits include: "Have you received migraine headaches in the past 6 months?", "Do you receive migraines more than once a week?", and "Are you sensitive to light when receiving migraines?".
3. Updates to protocol – Along with removing the caffeine question from the screener we are updating the exclusion criteria in the protocol to reflect this change. We will no longer exclude for caffeine consumption but will still use the baseline CCQ to check for covariates between caffeine and sleep quality. This is so that we do not exclude otherwise eligible participants because our study population tends to have a higher intake of caffeine on average and removing the caffeine exclusion criteria will not affect the participant's safety.
4. Updates to protocol – We updated the inclusion criteria from "Average 6-9 hours of sleep on weeknights between 10 pm and 10 am" to be "Average 5-9 hours of sleep on weeknights between 9 pm and 9 am". This change is necessary because our study population is active military servicemembers and they tend to sleep earlier and wake up earlier. This does not put participants at any additional risk.
5. Daily Instrument Survey - We repeated the question, "Did you use any of the following: melatonin supplements, sedative hypnotic sleep medication, or any other form of sleep medication?" from the screener to also be in the Daily Instruments survey, specifically within the Sleep Diary. This is so that we may keep track of their use of sleep meds throughout their participation.
6. Eye color - We included the question of eye color to the Demographics survey to collect general demographic data for light color on different eye colors.
7. Sleep-related breathing disorder – We deemed this a non-exclusion criterion and moved it out of the Screening Questionnaire and into the Demographics survey so that we may control for participants who have sleep disorders instead of excluding them from participating. We have also updated this in the protocol, removing it from the list of exclusion criteria. This will not affect participant safety as this study does not not interfere with sleep breathing disorders nor does it suggest to have any correlation.
8. Updated "Incomplete Screener Entry" Script - Now it is called Screener Follow Up Script. We added to the script to follow up for screener responses that we require clarification on. The reason we will ask for this clarification is to see if there was a mistake in filling out the screener in which they would be eligible. However, if they are not deemed eligible after correspondence, we would use the REDCap script (already approved) to notify them of their ineligibility. This information will not be used or kept since it is just used for screening for eligibility. Any information collected prior to consent is not kept for data collection.
9. New Flyers - We added new social media flyers and physical format flyers for distribution. We included our contact details in these versions as well as changed the title and background designs to add variety. All crucial study details have remained the same.

**Actual or anticipated problems or delays and actions or plans to resolve them**
*Describe problems or delays encountered during the reporting period and actions or plans to resolve them.*

During this annual reporting period devices for data collection such as the AYO light-emitting glasses and the 5-channel EEG Dreem Headbands had device development setbacks that slowed the early progression of the study. As reported in Y1Q2 (04/30/2023), the glasses and headband required

dashboard modifications for bug fixes on the user and study researcher side. These adjustments were important for the validity of the study. This slight delay was mitigated by diligent preparation of communications for successful participant-use of the equipment. Rapid response from device developers and consistent device testing allowed us to resolve all technical device issues. Aside from adjustments to the data collection tools, recruitment was an aspect that significantly delayed study progression as well, which was reported in Y1Q3 (07/30/2023). This slowness occurred during our first distribution of the recruitment materials in local areas of Tucson, solely focusing on Davis-Monthan Air Force Base and local National Guard units. However, rates of enrollment significantly increased once we expanded recruitment outreach to military bases outside of Tucson, such as bases in other states including California, Washington, Missouri, Minnesota, and others. We have found successful recruitment to be correlated with collaborators' efforts to share the purpose of our research study. To increase interest and ensure a consistent and ample flow of volunteers, we have submitted an IRB modification (to be reported on the next quarterly report) to increase the participant compensation. By increasing the compensation, we expect to have a meaningful increase in volunteer interest and to maintain a consistent influx of people wanting to participate. Our updated flyers with the compensation adjustment will be distributed physically throughout the greater Tucson area and Phoenix, and virtually across the country. We are currently working with Military Media to post our study ads in their expansive newsletters and will provide updated materials to our collaborators in other states, all to ensure a steady increase in eligible volunteers for the study.

**Changes that had a significant impact on expenditures**

*Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.*

Nothing to Report

**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

*Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.*

**Significant changes in use or care of human subjects**

Nothing to Report

**Significant changes in use or care of vertebrate animals**

Nothing to Report

**Significant changes in use of biohazards and/or select agents**

Nothing to Report

6. **PRODUCTS:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**
  *Report only the major publication(s) resulting from the work under this award.*

  Nothing to Report

  **Journal publications.** *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

  Nothing to Report

  **Books or other non-periodical, one-time publications.** *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

  Nothing to Report

  **Other publications, conference papers and presentations**. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

  Nothing to Report

- **Website(s) or other Internet site(s)**
  *List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.*

  Nothing to Report

- **Technologies or techniques**
  *Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.*

Nothing to Report

- **Inventions, patent applications, and/or licenses**
  *Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.*

  Nothing to Report

- **Other Products**
  *Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:*
  - *data or databases;*
  - *physical collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other.*

  Nothing to Report

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

**What individuals have worked on the project?**
*Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".*

Name: Dr. William "Scott" Killgore
Project Role: Principal investigator
Researcher Identifier:
Nearest person month worked: 4.800
Contribution to project: Dr. Killgore assisted with project development and oversight with the present study.

Name: Dr. Michael Grandner
Project Role: Co-Investigator
Researcher Identifier:
Nearest person month worked: 0.600
Contribution to project: Dr. Grandner assisted with study design issues.

Name: Dr. Julia Fisher
Project Role: Co-Investigator
Researcher Identifier:
Nearest person month worked: 0.449
Contribution to project: Dr. Fisher was available for statistical consultation.

Name: Lindsey Hildebrand
Project Role: Research Operations Manager
Researcher Identifier:
Nearest person month worked: 5.400
Contribution to project: Ms. Hildebrand assisted in procurement of materials, hiring and training of staff, and coordination with outside organizations involved in the project.

Name: Alisa Huskey
Project Role: Postdoctoral Fellow
Researcher Identifier:
Nearest person month worked: 1.991
Contribution to project: Dr. Huskey assisted with training of lab staff and development/maintenance of the REDCap study projects.

Name: David Negelspach
Project Role: Postdoctoral Fellow
Researcher Identifier:
Nearest person month worked: 2.520
Contribution to project: Dr. Negelspach assisted with project modeling.

Name: Gabriela Franca
Project Role: Research Technician
Researcher Identifier:
Nearest person month worked: 2.700
Contribution to project: Ms. Franca assisted with recruitment efforts, screening and enrolling participants, data management, and conducting study data collection.

Name: Kymberly Henderson
Project Role: Research Technician
Researcher Identifier:
Nearest person month worked: 0.720
Contribution to project: Ms. Henderson assisted with recruitment efforts and conducting study data collection.

Name: Melissa Reich-Fuehrer
Project Role: Research Technician
Researcher Identifier:
Nearest person month worked: 1.200
Contribution to project: Mrs. Reich-Fuehrer assisted with recruitment efforts and conducting study data collection.

Name: Camryn Wellman
Project Role: Research Technician
Researcher Identifier:
Nearest person month worked: 1.200
Contribution to project: Ms. Wellman assisted with recruitment efforts, screening participants, and conducting study data collection.

Name: Ryan Hassan
Project Role: Research Technician
Researcher Identifier:
Nearest person month worked: 1.080
Contribution to project: Mr. Hassan assisted with recruitment efforts and conducting study data collection.

Name: Shivani Desai
Project Role: Research Technician
Researcher Identifier:
Nearest person month worked: 3.000
Contribution to project: Ms. Desai assisted with recruitment efforts, screening and enrolling participants and conducting study data collection.

Name: Palmer Grabner
Project Role: Research Assistant
Researcher Identifier:
Nearest person month worked: 2.520
Contribution to project: Mr. Grabner assisted with screening and enrolling participants and conducting study data collection.

Name: Darby Wolocko
Project Role: Research Assistant
Researcher Identifier:
Nearest person month worked: 1.500
Contribution to project: Ms. Wolocko assisted with conducting study data collection.

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.*

Nothing to Report

**What other organizations were involved as partners?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.*

*Provide the following information for each partnership:*
*Organization Name:*
*Location of Organization: (if foreign location list country)*
*Partner's contribution to the project (identify one or more)*

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Nothing to Report.

## 8. SPECIAL REPORTING REQUIREMENTS

**COLLABORATIVE AWARDS:** *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ebrap.org/eBRAP/public/index.htm*** *for each unique award.*

**QUAD CHARTS:** *If applicable, the Quad Chart (available on https://www.usamraa.army.mil/Pages/Resources.aspx) should be updated and submitted with attachments.*

9. **APPENDICES:** *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*