

AWARD NUMBER:
CDMRPL-18-0-DM180286

TITLE: Using Personal Light Treatment Devices to Improve Performance of Submariners

PRINCIPAL INVESTIGATOR: Sarah Chabal, PhD

CONTRACTING ORGANIZATION:
Naval Submarine Medical Research Laboratory (NSMRL)

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14. ABSTRACT Navy submariners must contend with rotating schedules of shift work (8 hour watches) that are out of sync with the natural day/night cycle. As a result, they experience circadian misalignment and fatigue, which can lead to decreases in cognitive performance and health, and can result in dangerous or costly errors. One way to prevent or alleviate circadian misalignment is through the strategic management of light exposure. The present research effort will investigate whether the judicious scheduling of light exposure (through the use of personal light treatment devices; PLTDs) can help submariners maintain behavioral and physiological alignment with their operational schedules. Active duty submariners will be provided with PLTDs (blue-light goggles and blue-blocking glasses) designed to use light exposure to entrain the body's circadian rhythms. PLTDs will be worn at morning and night for the duration of a 15 day underway; a control group will not wear PLTDs. Assessments of objective sleep (actigraphy), circadian phase, cognitive performance, and self-report sleep and mood measures will be made at the beginning and end of the underway mission. Analyses will compare biochemical (circadian phase), sleep, cognitive, and self-report measures between groups. Use of PLTDs is expected to ease the circadian misalignment associated with changing and intense watch schedules, resulting in increased quality-of-life for sailors and increased efficiency and safety for Navy					
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1. INTRODUCTION: *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

Navy submariners must contend with rotating schedules of shift work (8 hour watches) that are out of sync with the natural day/night cycle. As a result, they experience circadian misalignment and fatigue, which can lead to decreases in cognitive performance (e.g., Dinges et al., 1997; Whitmire et al., 2009) and health (e.g., Davis & Mirick, 2006), and can result in dangerous or costly errors (e.g., Bourgeois-Bougrine, Carbon, Gounelle, Mollard, & Coblentz, 2003; Miller, Matsangas, & Shattuck, 2008). One way to prevent or alleviate circadian misalignment is through the strategic management of light exposure (e.g., Czeisler et al., 1990; Lahti, Terttunen, Lappamaki, Lonnqvist, & Partonen, 2007; Samel & Wegmann, 1997; Thompson et al., 2013). The present research effort will investigate whether the judicious scheduling of light exposure (through the use of personal light treatment devices; PLTDs) can help submariners maintain behavioral and physiological alignment with their operational schedules. Active duty submariners will be provided with PLTDs (blue-light goggles and blue-blocking glasses) designed to use light exposure to entrain the body's circadian rhythms. PLTDs will be worn at morning and night for the duration of a 15 day underway; a control group will not wear PLTDs. Assessments of objective sleep (actigraphy), circadian phase, cognitive performance, and self-report sleep and mood measures will be made at the beginning and end of the underway mission. Analyses will compare biochemical (circadian phase), sleep, cognitive, and self-report measures between groups. Use of PLTDs is expected to ease the circadian misalignment associated with changing and intense watch schedules, resulting in increased quality-of-life for sailors and increased efficiency and safety for Navy vessels.

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

Circadian misalignment; Circadian alignment; Watchstanding; Submarines; Fatigue; Blue light; Countermeasures

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?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

The main goals of this project are 1) determine whether personal light treatment devices (PLTDs) can be used to shift and maintain sailors' circadian rhythms; 2) determine whether PLTDs impact sailors' mood and fatigue; and 3) determine the operational feasibility of utilizing PLTDs onboard an operational Navy vessel.

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Major Task 1 – Obtain and Maintain Regulatory Approvals

- *Subtask 1: Prepare regulatory documents*
 - Institutional agreements were obtained between NSMRL and NHRC. COMSUBFOR granted approval for active data collection on a submarine.
 - **Milestone Achieved:** Approved Memorandum of Agreement (MOA) between NSMRL and NHRC for collaborative efforts
 - **Milestone Achieved:** COMSUBFOR approval for data collection
- *Subtask 2: Prepare research protocol*
 - A full study protocol was approved by NSMRL's Institutional Review Board (IRB) on 4 Sep 2019.
 - A protocol amendment was approved by NSMRL's IRB on 26 Mar 2020
 - **Milestone Achieved:** Local IRB approved at NSMRL
 - The study protocol was submitted to HRPO on 1 Apr 2020

Major Task 2 – Coordinate Staff and Prepare Study Materials

- *Subtask 1: Training of study staff*
 - Study staff attended a salivary data collection workshop hosted by Salimetrics, LLC on 23 APR 2019.
 - Study staff received a copy of the Automated Neuropsychological Assessment Metrics (ANAM) and received training on its usage
 - Written go-bys were completed for: the use of personal light treatment devices (blue-light goggles and blue-blocking glasses), the collection of saliva samples, and the set-up and use of actigraphy watches
 - **Milestone Achieved:** Written go-bys are complete for all study procedures
- *Subtask 2: Purchase supplies*
 - Personal light treatment devices have been purchased and received.
 - Handheld tablet devices for all cognitive assessments have been purchased and received.
 - Salivary sampling supplies have been identified and will be ordered once a date for data collection has been identified

Major Task 3 – Participant Recruitment and Data Collection

- *Subtask 1: Select boat for data collection*
 - We have reached out to military contacts at Naval Submarine Base Kings Bay and have provided initial briefings on our study aims and requirements.
- *Subtask 2: Data collection*
 - None

Major Tasks 4-5 (Data Analysis and Report Dissemination) will be initiated once all tasks within Major Tasks 1-3 are complete

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.

NSMRL Study staff attended a salivary data collection workshop hosted by Salimetrics, LLC on 23 APR 2019.
NSMRL and NHRC study staff attended a DoD Sleep Workshop on 5-6 FEB 2020.

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.

Plans for this research study were presented at the 2020 Department of Defense Sleep Workshop, which was attended by researchers across the DoD with interests in sleep researcher and how to overcome the challenges of operational research in a military context.

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.

Major Task 1 – Obtain and Maintain Regulatory Approvals

- *Subtask 1: Prepare regulatory documents*
 - None. All milestones for this subtask have been achieved.
- *Subtask 2: Prepare research protocol*
 - Receive approval from HRPO at USAMRMC Office of Research Protections before human subject enrollment and testing commences.

Major Task 2 – Coordinate Staff and Prepare Study Materials

- *Subtask 1: Training of study staff*
 - None. All milestones for this subtask have been achieved.
- *Subtask 2: Purchase supplies*
 - Purchase supplies required for the collection of salivary samples (purchase will be made when date of data collection is known).

Major Task 3 – Participant Recruitment and Data Collection

- *Subtask 1: Select boat for data collection*
 - Coordinate with NSMRL Senior Enlisted Leader to identify new contacts at potential submarine home-port locations
 - Continue to communicate with military contacts at Naval Submarine Base Kings Bay regarding submarine selection
 - Send official recruitment letter from NSMRL commanding officer (CO) to the CO of the submarine selected for data collection
- *Subtask 2: Data collection*
 - Coordinate travel schedules for military riders
 - Coordinate schedule of study ombudsman to ensure proper consenting process is followed
 - Ship all study equipment to home port of submarine
 - Will be initiated once Major Task 3 – Subtask 1 is complete

Major Tasks 4-5 (Data Analysis and Report Dissemination) will be initiated once all tasks within Major Tasks 1-3 are complete.

4. **IMPACT:** Describe 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 (data collection and results are pending)

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 (data collection and results are pending)

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 (data collection and results are pending)

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 (data collection and results are pending)

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.

Nothing to report

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.

COVID-19 and associated DOD travel restrictions may delay data collection for this effort. We will update as the situation unfolds and more information is known. Communications about boat selection can occur during COVID-19 operations, but data collection will not be possible (as travel to the data collection site will not be permitted and research riders will not be allowed onboard the submarine).

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.

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 (data collection and results are pending)

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.

1. Chabal, S. (2020, February). The importance of sleep and circadian optimization in submarine operations. Invited talk presented to leadership and staff at the Naval Leadership and Ethics Center (NLEC). Newport, RI.
2. Chabal, S., Markwald, R., & Chinoy, E. (2020, February). Challenges with field sleep assessments: Lessons learned from a submarine-based data collection. Invited talk presented at the 2020 Department of Defense Sleep Workshop. Arlington, VA.
3. Chabal, S. (2019, April). Accelerated adaptation to changing work schedules. Invited talk presented at the United States-Israel Conference on Military Medicine (Shores). Tel Aviv, Israel.

- **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:	Sarah Chabal, Ph.D.
Project Role:	Principal Investigator (NSMRL)
Researcher Identifier:	0000-0002-6258-481X
Nearest Person Month Worked:	4
Contribution to Project:	Dr. Chabal managed efforts at NSMRL and held regular teleconferences with the collective study team across both sites. She directed the regulatory approval efforts, including submission of research protocol to NSMRL IRB and ensuring that all equipment to be used in the study adhere to all SUBFOR policies for electronic device usage.

Name: Rachel Markwald, Ph.D.
Project Role: Associate Investigator (NHRC)
Researcher Identifier: 0000-0002-0432-3937
Nearest Person Month Worked: 4
Contribution to Project: Dr. Markwald managed efforts at NHRC and participated in regular teleconferences with the collective study team. She assisted with protocol development, and led efforts to determine the best way-forward for the collection of circadian phase information.

Name: Evan Chinoy, Ph.D.
Project Role: Associate Investigator (NHRC)
Researcher Identifier: 0000-0001-6613-6654
Nearest Person Month Worked: 2
Contribution to Project: Dr. Chinoy managed efforts to determine the best way-ahead for the collection of circadian phase estimation data.

Name: Kristin Peterson, B.G.S.
Project Role: Research Coordinator (NSMRL)
Researcher Identifier: 0000-0003-3403-5984
Nearest Person Month Worked: 1
Contribution to Project: Ms. Peterson attended regular in-person and teleconference meetings. She had a lead role in completing revisions to the NSMRL IRB protocol and maintaining contact with all vendors and collaborators.

Name: Emily Moslener, B.A.
Project Role: Research Assistant (NSMRL)
Researcher Identifier: 0000-0002-8034-3139
Nearest Person Month Worked: 1
Contribution to Project: Ms. Moslener attended regular in-person and teleconference meetings. She had a lead role in drafting the protocol for SRB/IRB submission.

Name: Alexia Bohnenkamper, B.A.
Project Role: Research Assistant (NSMRL)
Researcher Identifier: 0000-0003-4538-6763
Nearest Person Month Worked: 2
Contribution to Project: Ms. Bohnenkamper attended regular in-person and teleconference meetings. She had a lead role in completing revisions to the NSMRL IRB protocol and lead the development of all study go-bys.

Personnel changes:

1. Dr. Reinhart (NSMRL Co-I) has left NSMRL. A hiring process is underway to fill his position. Hiring can continue in spite of COVID-19, as interview processes are being conducted via video teleconferencing and work can begin from off-site.
2. LT Brian Vaught (NSMRL Co-I) and LT Dale Hirsch (NHRC Co-I) have rotated to different military duty stations. Their roles will be filled by equivalently-trained military members.

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://ers.amedd.army.mil> for each unique award.*

Nothing to report

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

Attached with submission

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.*

Nothing to report