Project Determination

# **Nurse Fatigue-Mitigation Education Does it Change Nurse Sleep Behavior**

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| **Project ID:** | 0900f3eb81ce0f40 |
| **Accession #:** | NIOSH-SSTRB-3/30/21-e0f40 |
| **Project Contact:** | Beverly Hittle |
| **Organization:** | NIOSH |
| **Status:** | Pending Clearance |
| **Intended Use:** | Project Determination |
| **Estimated Start Date:** | 10/01/20 |
| **Estimated Completion Date:**  | 09/30/24 |
| **CDC/ATSDR HRPO/IRB Protocol#:**  |  |
| **OMB Control#:**  |  |
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| Description |
| Priority |
| Standard |
| Date Needed |
| 07/01/21 |
| Determination Start Date |
| 03/30/21 |
| Description |
| The NIOSH online training program, “Training for Nurses on Shift Work and Long Work Hours” published in 2015, provides information for nurses about health and safety risks associated with nonstandard work hours and strategies for improving sleep and reducing fatigue-related risks within the healthcare setting. The no-cost, publicly assessable training program training has been mentioned on over 45 different webpages, and over 6000 nurses have received credit from the CDC for taking this course. Our proposed project will evaluate the NIOSH Training for Nurses for dissemination reach since 2015 and improving registered nurse (RN) sleep health and well-being. Results of this project will be used to improve outreach efforts to the national nursing population and provide evidence of effectiveness about the online training on nurses’ sleep and wellbeing. |
| IMS/CIO/Epi-Aid/Chemical Exposure Submission |
| No |
| IMS Activation Name |
| Not selected |
| Select the primary priority of the project |
| Not selected |
| Select the secondary priority(s) of the project |
| Not selected |
| Select the task force associated with the response |
| Not selected |
| CIO Emergency Response Name |
| Not selected |
| Epi-Aid Name |
| Not selected |
| Assessment of Chemical Exposure Name |
| Not selected |
| Goals/Purpose |
| This purpose of this project is to evaluate an established NIOSH online training program, “Training for Nurses on Shift Work and Long Work Hours” for: 1) dissemination reach among the national nurse population and 2) improving nurse sleep and fatigue. Evaluation of this established online program can provide evidence the training improves nurses’ sleep and fatigue. Project results will identify: 1) if enhancements to the training are needed; 2) evidence of the training’s effectiveness at improving nurse sleep. |
| Objective |
| Primary Objectives: 1) Evaluate the effectiveness of the established online NIOSH “Training for Nurses on Shift Work and Long Work Hours” on objective and subjective sleep health (composite and separate components [i.e., duration, efficiency, timing, quality, daytime sleepiness]) and wellbeing from baseline over 1, 3, and 6-months post-training. 2a) Explore the relationship between nurse characteristics and behavioral intention, and 2b) Explore the relationship between behavioral intention and sleep health post-training (1-month, 3-months, and 6-months). Secondary Objectives: 1) Provide a descriptive characterization of RNs (e.g. educational background, type of healthcare workplace, geographic location) who have completed the online training (N≈6,000). |
| Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and/or decreasing disparities? |
| Not Selected |
| Project does not incorporate elements of health equity science |
| Not selected |
| Measuring Disparities |
| Not selected |
| Studying Social Determinants of Health (SDOH) |
| Not selected |
| Assessing Impact |
| Not selected |
| Methods to Improve Health Equity Research and Practice |
| Not selected |
| Other |
| Not selected |
| Activities or Tasks |
| New Collection of Information, Data, or Biospecimens; Secondary Data or Specimen Analysis |
| Target Population to be Included/Represented |
| General US Population; Healthcare Provider |
| Tags/Keywords |
| Sleep; Fatigue; Education; Actigraphy; Nurses |
| CDC's Role |
| Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided; CDC employees or agents will obtain data by intervening or interacting with participants; CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens; CDC employees will participate as co-authors in presentation(s) or publication(s); CDC employees will provide substantial technical assistance or oversight; CDC is providing funding; CDC is the sole institution conducting activity |
| Method Categories |
| Biomonitoring; Health Education; Prospective Cohort Study; Secondary Data Analysis; Survey |
| Methods |
| Study 1 is a secondary analyses of CDC administrative data of RNs (N = 6000) who have previously obtained CEs from the CDC for completing the online training. Study team will anonymize data prior to analyses. Characteristics of this cohort (employment type, education level) will be compared with the national nurse population to gain a better understanding of the online training program’s reach across all nursing populations (e.g. nursing specialty, worksite type). Study 2 will evaluate nurses' sleep health (i.e., duration, efficiency, timing, quality, daytime sleepiness) and wellbeing at 1-month, 3-month and 6-months post-training. Sleep will be measured subjectively with an online survey (see Appendix A), sleep diaries (see Appendix B), and objectively with actigraphy over 7-days at each follow-up period (1, 3 and 6-months post-training). Wellbeing will be ascertained with self-reported survey at post-training follow-up periods (see Appendix A). Post-training questions will be asked to provide descriptive evaluation of the training program, sleep behavior strategies adopted post-training, behavioral intention, and facilitators and barriers to change (see Appendix A). Data collection procedures: 1) Baseline measures: Participants will complete an online survey collecting demographics, workplace characteristics, sleep quality, daytime sleepiness, wellbeing, complete online daily sleep diaries, and activate actigraphy watches for 7-days. Actigraphy watches will be distributed via registered mail with training provided via videoconferencing. 2) Online training (1 month after baseline measures): Participants will take the NIOSH online nurse training. The training is free, readily accessible online, and takes approximately 3.5-hours to complete. Participants can take the training at a location and time convenient to them. Following training completion, data will be collected via REDCap for two questions regarding behavioral intention and two open-ended questions requesting feedback on the training. 3) Post-training measures (1 month, 3 month and 6 month): At each follow-up period (1 month, 3 month and 6 month) study team members will distribute actigraphy watches via mail. Participants will follow the same sampling protocol completed at baseline, two behavioral intention questions, and three open-ended questions to describe strategies adopted to improve sleep, and facilitators and barriers to adoption. The 6-month follow-up will exclude behavioral intention measures. During all data collection periods, the study team will be in contact with participants via preferred method to schedule actigraphy delivery and answer any questions. For Recruitment, Inclusion/Exclusion Criteria, and Screening Procedures, please see attached file “Wong Methods Supplemental Information.” |
| Collection of Info, Data, or Bio specimens |
| Study 1: This study will not collect data but use existing CDC-collected data of RNs who have received credit for taking the online training. These data include: Name Address Employment type (i.e., CDC or uniformed service employee) Employer name Education level Work setting (multiple choice) Primary profession Two study team members (Drs. Hittle and Wong) will strip data of personally identifiable information prior to use. Data will be stored within an encrypted folder on secure CDC server accessible only by password protected CDC laptops/computers, with folder access limited to only three study team members (Drs. Caruso, Hittle, and Wong). Only aggregate statistics will be reported on: Employment type Education level Work setting Primary profession Study 2: Data collected will include survey, qualitative, and actigraphy. Study team will assign participants a unique study identifier. The study identifier will be used for all data collection platforms (i.e., REDCap, actigraphy). The key connecting participants to study identifiers will be stored on a government issued encrypted thumb drive, in a locked filing cabinet, in a locked office within continuously guarded and secure NIOSH premises. Survey and qualitative data (see Appendix A and B) will be collected via REDCap, a CDC approved online data collection and management system. Participants will be emailed a personalized, encrypted link for accessing the survey via a mobile device or web-browser. REDCap is password protected and data will only be accessed by study team members via a password protected CDC issued laptop. By default, REDCap presets data export as de-identified of any participant personal identifiers. Actigraphy data will be collected via an actigraphy watch, a wristwatch style device measuring sleep. Actigraphy are FDA approved devices for measuring sleep in the field and is recommended by the American Academy of Sleep Medicine for use with adult and pediatric populations. The device size and wearability is similar to wearing a wristwatch, posing minimal risks. Participants will wear actigraphy watches for the entire duration of each 7-day data collection period. Actigraphy watch data are stored in the watch and can only be extracted via computer software from the actigraphy watch manufacturer. This software will be stored on the study team’s CDC password protected laptop/computers. Participants will be identified in actigraphy data and software using study identifiers only. |
| Expected Use of Findings/Results and their impact |
| Evaluation findings will be used internally at NIOSH for improving the training content and dissemination. The findings will be presented at nursing and healthcare conferences and published in peer-reviewed and trade journals to 1) improve dissemination to targeted nurse groups, and 2) provide information of the value of the training, and potential benefits of integration of the training into existing organizational occupational health and safety programming. |
| Could Individuals potentially be identified based on Information Collected? |
| Yes |
| Will PII be captured (including coded data)? |
| Yes |
| Does CDC have access to the Identifiers (including coded data)? |
| Yes |
| Is an assurance of confidentiality in place or planned? |
| No |
| Is a certificate of confidentiality in place or planned? |
| No |
| Is there a formal written agreement prohibiting the release of identifiers? |
| No |

| ****Funding**** |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Funding Type | Funding Title | Funding # | Original Fiscal Year | # of Years of Award | Budget Amount |
| CDC Funding Intramural | NIOSH Small NORA | 9390FZW | 2020 | 4 |  |

| ****HSC Review**** |
| --- |
| HSC Attributes |
| Program Evaluation |
| Yes |
| Additional Ethical Considerations |
| The purpose of this project is to evaluate an established NIOSH online training program. This is an evaluation activity determined to be non-research. Ethical guidelines will be followed. |

| ****Regulation and Policy**** |
| --- |
| Do you anticipate this project will be submitted to the IRB office |
| No |

| ****Institutions**** |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Institution | FWA # | FWA Exp. Date | IRB Title | IRB Exp. Date | Funding # |

| ****Staff**** |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Staff Member | SIQT Exp. Date | Citi Biomedical Exp. Date | Citi Social and Behavioral Exp. Date | Citi Good Clinical Exp. Date | Staff Role | Email | Phone # | Organization/Institution |
| Beverly Hittle | 07/31/2023 |  | 11/11/2023 |  | Co-Investigator | nnx3@cdc.gov | 513-533-8355 | SOCIAL SCIENCE AND TRANSLATION RESEARCH BRANCH |
| Claire Caruso | 04/30/2023 |  | 08/06/2022 |  | Co-Investigator | zhl1@cdc.gov | 513-533-8535 | SOCIAL SCIENCE AND TRANSLATION RESEARCH BRANCH |
| Imelda Wong | 07/30/2023 |  | 06/25/2022 |  | Principal Investigator | kwn0@cdc.gov | 513-533-6847 | SOCIAL SCIENCE AND TRANSLATION RESEARCH BRANCH |
| Rebecca Guerin | 03/27/2023 |  | 12/22/2021 |  | Co-Investigator | hlb3@cdc.gov | 513-533-8435 | SOCIAL SCIENCE AND TRANSLATION RESEARCH BRANCH |

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| ****DMP**** |  |
| ****Proposed Data Collection Start Date**** | **11/01/21** |
| ****Proposed Data Collection End Date**** | **05/31/23** |
| ****Proposed Public Access Level**** | **Non-Public** |
| ****Reason for not Releasing the Data**** | **Other- 1.“Other” - Data use agreement(s) or other formal agreement(s) prevent sharing the data- Data set for study 1 is owned by the CDC Training and Continuing Education Online system. 2. “Other” - Direct** |
| ****Public Access justification**** | **1.“Other” - Data use agreement(s) or other formal agreement(s) prevent sharing the data- Data set for study 1 is owned by the CDC Training and Continuing Education Online system. 2.“Other” - Direct reading sensor and other monitoring data are large, need specialized software and require expertise to interpret - Actigraphy data obtained for study 2 requires specialized software for analyzing data.** |
| ****How Access Will Be Provided for Data**** | **The data collected will be used to inform the internal development of NIOSH products. Every attempt will be made to publish results in peer-reviewed journals. It is CDC/NIOSH policy that the results of the activities that it funds should be made available to the public, if possible. The study staff will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and security for data dissemination and reuse. Plans for archiving and long-term preservation of the data will be implemented, as appropriate. This study will comply with the CDC Data Management and Sharing Policy.** |
| ****Plans for archival and long-term preservation of the data**** | **Optional- N/A** |

| ****Spatiality (Geographic Location)**** |  |  |
| --- | --- | --- |
| Country | State/Province | County/Region |
| United States |  |  |

| ****Determinations**** |
| --- |
| Determination | Justification | Completed | Entered By & Role |
| HSC: Does NOT Require HRPO Review | Not Research / Other*45 CFR 46.102(l)*Program Evaluation | 04/27/21 | MacMahon\_Kathleen (kqm1) Division HSC |
| PRA: PRA Applies |  | 04/27/21 | Sawyer Deloney\_Tamela (tqs7) OMB / PRA |