Nurse Fatigue-Mitigation Education: Does it Change Nurse Sleep Behavior?

Supporting Statement- Section B

OMB No.

New

Request for Office of Management and Budget (OMB) Review and Approval for a Federally Sponsored Data Collection

Project Officer:

Imelda S. Wong, PhD

Centers for Disease Control and Prevention (CDC)

National Institute for Occupational Safety and Health (NIOSH)

Division of Science Integration

Phone: 513-533-6847

E-mail: kwn0@cdc.gov

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B. Collections of Information Employing Statistical Methods

B.1. Respondent universe and sampling methods

Part 1 will use CDC administrative data collected from individuals (N = ~6,000) who have completed the NIOSH “Training for Nurses on Shift Work and Long Work Hours” since its inception in 2015. A descriptive analysis of these retrospective data will be conducted. This analysis is anticipated to provide a descriptive representation of those who have completed the training, potentially allowing NIOSH an opportunity to enhance training outreach.

Part 2 recruitment will include registered nurses (RNs) from across the United States to evaluate the effectiveness of the training on RN sleep and wellbeing. RNs recruited for the study should be working full-time night shift for the previous 6-months. RNs will be excluded from the study if they have worked less than 1 year, are pregnant or have a child less than 1 year of age, have been diagnosed with a sleep disorder, or have travelled/expect to travel across more than 1 time zone during the study or within 3 months of study initiation. Recruitment goal will be 50 RNs, based on prior training program studies using actigraphy, as well as to account for 15-20% attrition loss due to our longitudinal study design and other study withdrawal requests. To detect differences in sleep duration at two data collection points, power analyses calculations indicate a sample size of 35-40 RNs will provide 80% power with 1% significance level when between group correlation is 0.75.

B.2. Procedures for the Collection of Information

Part 1: This part 1 study will use CDC administrative data; therefore no data collection will be occurring. Data analysis will include central tendency and variation of survey variables. A test of equality for proportions will be conducted to compare characteristics (e.g. nursing specialty, worksite type) of the study population with the larger nursing workforce population from national survey data. A p-value of ≤0.05 will indicated statistical significance.

Part 2: The NIOSH study team will collect data and communicate with study participants. Potential study participants will meet with the study team via their preference of communication (e.g. videoconferencing, telephone, or email) to review the study protocol and discuss any questions or concerns. Baseline data collection procedures: Actigraphy watches will be distributed via registered mail to study participants. Training to use the watches will be conducted via videoconferencing. Participants will be asked to complete an online baseline survey via REDCap with questions regarding demographics, work characteristics which can contribute to fatigue (e.g., shift length, total work hours per week), sleep quality, daytime sleepiness, and wellbeing (Attachment B). Over a 7-day period, participants will wear the actigraphy watch and complete a daily sleep diary (Attachment C) via REDCap. Logged actigraphy data will be stored in the watch memory and can only be downloaded using specialized software. Study participants will be provided a unique study ID number

to be used in all survey material and with actigraphy watches. No personal identifying information will be included on the surveys or actigraphy data.

Online training: One-month after the baseline collection period, participants will complete the NIOSH online nurse training program. Following training completion, a study team member will contact participants to schedule the 1-month post-training data collection period. While scheduling, the study team will ask participants two questions related to intentions for changing behaviors which promote sleep health and two open-ended questions on training experience (Attachment B).

Post-training data collection (1-, 3-, and 6-months): At each data collection period, the study team will distribute actigraphy watches via registered mail and provide refresher training for actigraphy use via videoconferencing. Participants will be asked to follow the same sampling protocol they completed at baseline (7-day actigraphy and sleep/wake diary, online survey on sleep quality, daytime sleepiness, and wellbeing), as well as three open-ended questions (Attachment B) to describe strategies adopted to improve sleep, and facilitators and barriers to adoption.

Part 2 has two research questions guiding the study and requiring different statistical analysis:

Research question 1: Is sleep health and wellbeing significantly better at 1-, 3-, and 6-months post-training, compared to baseline?

Research question 1 analysis: Descriptive statistics (e.g. means, frequencies) will be reported for sleep health and wellbeing from each data collection period (baseline, 1-month, 3-months, and 6-months). Linear mixed modeling will be used to estimate the change in sleep health and wellbeing over time by calculating the mean differences in sleep health and wellbeing at 1-, 3-, and 6-months post-training (with baseline measures as a reference) and effect size estimates determined using 95% confidence interval. Statistical significance will be set at p=<0.05. We will control for the effects of potential a priori confounders such as demographic data (i.e., age, sex/gender identity, race, ethnicity, children, chronotype), workplace characteristics (i.e., tenure, hours of work/week, shift length, multiple jobs), and seasonality (to account for seasonal changes in daylight exposure and sleep patterns).

Research question 2a: What nurse characteristics (i.e., demographics, work characteristics) are predictors of behavioral intention?

Research question 2a analysis: Appropriate inferential parametric testing (i.e., t-test) will be used based on the level of the predictor variable data. Should the assumptions of parametric testing not be met, non-parametric testing (i.e., Mann-Whitney U test) will be used. Two-tailed analyses will be conducted with statistical significance set at p=<.05. Nurse characteristics (measured at baseline) will be analyzed with behavioral intention measured at immediate post-training.

Research question 2b: Is there a relationship between behavioral intention and sleep health (as a composite measure of sleep health)?

Research question 2b analysis: We will examine the correlation between behavioral intention immediately after completing online training with sleep health at 1-, 3-, and 6-months. Statistical significance will be determined by p=<.05 and Cohen's standard will be used to assess effect size.

Qualitative data analysis: Open-ended questions asked at post-training intervals will be analyzed for themes using content analysis.

B.3. Describe methods to maximize response rates and to deal with issues of non-response.

To improve participant retention over the 7-month study period, email reminders will be generated via the REDCap, a CDC approved data collection and management system, for reminders of upcoming data collection periods. A NIOSH study team member will contact via each study participant via preferred method (e.g., phone, text) at the beginning and end of each 7-day data collection period to confirm delivery address and procedures for actigraphy watch delivery and return. Participants will be provided a non-coercive token (e.g., $25 grocery gift card) at the completion of each 7-day study follow-up period and return of actigraphy watch (sent back to study team via pre-paid postage). Additionally, after the end of the final data collection period, we will provide study participants a report of their individual results of self-reported sleep health and wellbeing

over the course of the study period, along with an additional $100 gift card as a non-coercive token of appreciation for completion of all 4 data collection periods. Personal data reports will be sent to the participant in preferred method indicated by participants at study onset (i.e., email, letter).

In the event of missing or corrupted actigraphy data, sleep diary data will be used. To reduce the potential for unanswered survey questions, we will: 1) pilot test the survey among a small group (< 9 individuals) of NIOSH and/or University of Cincinnati (study team affiliate) nurse researchers to ensure the questions are appropriate, understandable as intended, and applicable, and 2) provide a variety of answer options for each survey questions (e.g. “don’t know”, “prefer not to answer”).

In the case of non-adherence or lost to follow-up, we will only use the data up to the collection period in which it was gathered. For example, a participant who submits data for baseline and 1-month post training but is lost to follow-up at 3 and 6-month data collection, will be included in baseline and 1-month post training data analyses, if they permit their data to remain as part of the study. If a participant is lost to follow-up after baseline data collection, data inclusion would be restricted to descriptive analyses of participants.

Statistical guidance articles state bias is likely in analyses with more than 10% missingness and if more than 40% data are missing in important variables, then results should only be considered as

hypothesis generating. If patterns of >10% missingness with a specific participant are found, the data will be excluded, and a sensitivity analysis will be conducted. If we find >10% missingness among a specific question, we will test if this is random missingness or if there is a pattern. If the missingness is random, we will remove that question from analyses. If a systematic bias pattern is detected (missing is not random), we will have to consider how to manage the missing data, such as imputation with mean, median, or mode.

B.4. Describe any tests of procedures or methods to be undertaken.

We will pilot test the survey among a small group of 3-5 NIOSH and/or University of Cincinnati (study team affiliate) nurse researchers to ensure the questions are appropriate, understandable and applicable.

Survey questions are from reliable, validated instruments such as:

PROMIS Sleep Disturbance Scale [Yu L, Buysse DJ, Germain A, et al. Development of short forms from the PROMIS™ sleep disturbance and Sleep-Related Impairment item banks. *Behavioral Sleep Medicine.* 2011;10(1):6-24. doi:10.1080/15402002.2012.636266] is an 8-item survey with .90 reliability measures when compared to the Pittsburgh Sleep Quality Index.

PROMIS Sleep-Related Impairment Scale [Yu et al., 2011]is an 8-item survey with .90 reliability measures when compared to the Epworth Sleepiness Scale.

Well-being Index [Dyrbye LN, Johnson PO, Johnson LM, Satele DV, Shanafelt TD. Efficacy of the Well-Being Index to identify distress and well-Being in U.S. nurses. *Nurse Research*. Nov/Dec 2018;67(6):447-455. doi:10.1097/nnr.0000000000000313] is a 9-item scale has been compared to the Maslach Burnout Inventory and used among a broad group of healthcare professionals and other U.S. workers.

Behavioral intention questions were derived from questions used by the creator of the NIOSH Training for Nurses, Dr. Claire Caruso, in research associated with sleep and fatigue education training.

The Consensus Sleep Diary [Carney CE; Buysse DJ; Ancoli-Israel S; Edinger JD; Krystal AD; Lichstein KL; Morin CM. The consensus sleep diary: standardizing prospective sleep self-monitoring. *SLEEP* 2012;35(2):287-302] will be the sleep diary format used.

Demographic questions are from the Behavioral Risk Factor Surveillance System [Centers for Disease Control and Prevention (CDC). Behavioral Risk Factor Surveillance System Survey Questionnaire. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2018].

Workplace characteristic questions were drawn from the Quality of Worklife Questionnaire [National Institute for Occupational Safety and Health. Quality of Worklife Questionnaire. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2018].
https://www.cdc.gov/niosh/topics/stress/qwlquest.html] and the Agency

for Healthcare Research and Quality Surveys on Patient Safety Culture [SOPS Hospital Survey. Content last reviewed June 2021. Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/sops/surveys/hospital/index.html].

B.5. Individuals consulted on statistical aspects and individuals collecting and/or analyzing data.

NIOSH employees designed the questionnaire, performed pilot testing, and will be responsible for collection and analysis of all data. Key NIOSH contacts are listed below.

Project Officer:

Imelda S. Wong, PhD

Kwn0@cdc.gov; (513-533-6847)

Study team:

Beverly M. Hittle, PhD, RN

Nnx3@cdc.gov; (513-533-8355)

Claire C. Caruso, PhD, RN

Zhl1@cdc.gov; (513-533-8535)

Rebecca Guerin, PhD

Hlb3@cdc.gov; (513-533-8435)

Additional statistical consultation was obtained from Dr. Céline

Vetter, University of Colorado.

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