Evaluation of a Work-Family and Sleep Leadership Intervention in the Oregon National Guard: A Behavioral Health Leadership Approach

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(1) Protocol Full Title
Evaluation of a Work-Family and Sleep Leadership Intervention in the Oregon National Guard: A Behavioral Health Leadership Approach

Short Title
Oregon Military Employee Sleep and Health (MESH) Study

Principal Investigator
Dr. Leslie Hammer (Oregon Institute of Occupational Health Sciences)

Brief Description
The current project is funded by the Department of Defense (PPQ # is 1008990; sponsor funding ID is PT150133; DoD contract # is W81XWH-16-1-0720). This study is a randomized controlled trial that will assess the effects of (1) the Family-Supportive Supervisor Behavior (FSSB) and Sleep Leadership training and (2) sleep/cognitive effectiveness feedback intervention on health and well-being among full-time employees in the Oregon National Guard, their supervisors, and their families. The interventions involving both health protection and health promotion are expected to contribute to improvements in employees' and their supervisors' sleep, risk behaviors, mental and physical health, and injury, as well as employees' and their spouse/partners' family experiences, health and well-being, and workplace outcomes.

(2) Objectives
The current study aims to improve health and well-being among full-time employees (including Military Technicians and Active Guard Reserves) in the Oregon National Guard (Army and Air Guard), their supervisors, and their families. The research team will adopt a comprehensive and integrative approach that is designed to have an impact on multiple risk behaviors and health outcomes. The primary goal of the proposed randomized controlled trial is to develop and test the effectiveness of (1) a Family-Supportive Supervisor Behavior (FSSB)/Sleep Leadership training intervention designed for supervisors (i.e., health protection at the supervisor level) and (2) an individual-level intervention for both supervisors and employees using actigraphic sleep tracking and cognitive effectiveness feedback (i.e., health promotion at the individual level).

Some of the expected intervention outcomes are reduction in risk behaviors, as well as improved physical and psychological health, and workplace outcomes among full-time employees within the context of the Oregon National Guard (Army and Air Guard), as well as their supervisors and their spouses/partners. Additionally, the current study adopts a waitlist-control experimental design for the FSSB/Sleep Leadership training, so the training will be made available to all location clusters in the control group that are interested; the wait-list control group will receive the individual-level actigraphic feedback intervention after the final data collection.

The primary hypotheses and research questions involve assessing the effects of the (1) Family-Supportive Supervisor Behavior (FSSB)/Sleep Leadership training and the (2) sleep/cognitive effectiveness feedback intervention on:

- Employees' and their supervisors' sleep (self-report and actigraphy measures), risk behaviors (e.g., drinking, smoking, and unsafe driving), mental and physical health (e.g., physical symptoms, functional impairment, PTSD symptoms, and depressive symptoms), and injury

- Employees' and their spouse/partners' global family processes (e.g., marital satisfaction), and spouse/partners' mental and physical health (e.g., physical symptoms, self-reported indicators of stress, functional impairment, and depressive symptoms)
- Employee, supervisor, and spouse/partner workplace outcomes (e.g., job satisfaction, organizational commitment, absenteeism, and occupational safety/injuries)

(3) Background

This study utilizes multiple interventional components to achieve the targeted outcomes. Specifically, the current study adopts an integrative approach to improving health and well-being among full-time employees in the Oregon National Guard, their supervisors, and their families, as well as their overall experiences at work. The integrative and systems-level approach involves both health protection and health promotion strategies, and it has been shown in the occupational health literature to be particularly effective at improving employee health and well-being. For *health protection*, the current study builds on, and extends, prior research in the civilian workforce with FSSB and Veteran-Supportive Supervisor Training (VSST). Elements of these two training programs will be integrated to develop an FSSB/Sleep Leadership training program for supervisors in the Oregon National Guard. The FSSB training was first developed by Dr. Hammer (PI in current protocol) and her colleague Dr. Ellen Kossek as part of their research with the Work, Family & Health Network (WFHN) study funded by the National Institute of Occupational Safety and Health (NIOSH). The research team has found significant intervention effects in previous FSSB training studies. FSSB training was also used as the basis for the development of the VSST intervention that is currently implemented in the Study of Employment Retention for Veterans (SERVe) project (PI: Dr. Leslie Hammer; IRB #0009369).

The research team will extend these previously-developed supervisor training interventions focused on increasing supervisor support for family and increasing civilian supervisor support for Service members to a military setting and specifically the National Guard and Reserves. The current training program also draws on the Behavioral Health Leadership concept, specifically Sleep Leadership, which aims to increase supervisor support for better sleep outcomes. In other words, sleep leadership refers to leader behaviors that are focused on improving and promoting good sleep patterns and environmental conditions for employees. By modifying this existing workplace training intervention and testing the specific effects within military units, we expect to see improved health and well-being among full-time Oregon National Guard employees and their families. This training intervention will eventually have the opportunity to be extended and widely implemented among our active duty military population, thus further informing evidence-based family-supportive policies across military settings, as well as improving health and well-being among Service members, their supervisors, and their families.

In addition to the supervisor FSSB/Sleep Leadership training, the current study includes an individual-level *health promotion* component which provides employees and their supervisors with sleep monitoring using actigraphy devices (Phillips Actiwatch 2) and in-person sleep/cognitive effectiveness feedback based on their daily sleep measurements (see Appendix A for a sample feedback report). The feedback will highlight and is expected to increase employees' and their supervisors' awareness of their daily activity and sleep/wake scoring, summary sleep data comparisons, cognitive effectiveness estimates derived from the sleep data, and recommended actions for improving sleep quality. The increased awareness of their sleep patterns and the actionable recommendations provided to improve their sleep are expected to encourage behavioral changes and ultimately result in more positive sleep, health,

and well-being outcomes. Because the research team has been successful with the supervisory training for FSSB in previous work, we anticipate that intervention effects on the targeted outcomes will be replicated in this study and even strengthened, given the integration of Sleep Leadership training elements and the addition of individual-level sleep/cognitive effectiveness feedback. Given that research on the effectiveness of actigraphic feedback is very limited, we seek to extend the literature by investigating how actigraphic feedback would change/improve subsequent outcomes related to sleep, health, and well-being among employees, their supervisors, and their spouses/partners.

(4) Study Design

This is an intervention study involving full-time employees at the Oregon National Guard (ORNG), their supervisors, and their spouses/partners. We are using an RCT approach to evaluate the intervention, specifically, a cluster-randomized (clustered by unit locations) pre-test post-test design. We will collect data from a minimum of 500 full-time employees, as well as their supervisors (about 200 supervisors). We will also recruit spouses and partners of those ORNG employees who are married/partnered to participate in this study. ORNG armories and facilities (field maintenance shops or headquarters), sometimes broken down to smaller units within those locations, will be randomly assigned to the intervention (training) and control groups. To accommodate multiple geographic locations and to build some flexibility into the timing of the training, we will have a phased roll out of the study. A phased roll-out can also maximize participant recruitment and retention in order to achieve the target sample size. Randomization of treatment groups will also occur through this grouping (i.e., cluster randomization).

The flow chart below illustrates the different project stages and the overall study design. The “N” numbers refer to the target sample sizes.

Baseline

Supervisors (“Sup”), employees (“Emp”), and employees’ spouses/partners in both training/intervention and control groups will first complete a survey (see Appendix B for survey measures to be completed by each group and see supporting document for the list of survey items that we will select from) during the baseline period. In the meantime (during baseline), supervisors and employees will also be asked to wear actigraphy watches for 3 weeks as part of our sleep data collection and preparation for in-person sleep feedback. We will be using the Phillips Actiwatch 2 actigraphy device - http://www.usa.philips.com/healthcare/product/HC1044809/actiwatch-2-activity-monitor.

When we distribute the watches to participants, we will verbally ask them to answer four questions regarding 1) their drill or annual training dates and locations in the next 3 weeks, 2) major events that may disrupt their sleep in the next 3 weeks, 3) other noteworthy factors that may affect their sleep in the next 3 weeks, and 4) any time where they might need to temporarily take off the actigraph watches for security and/or safety reasons. The full list of actigraph delivery questions can be found in the supporting document. Responses to these questions will be used for data quality control/management and for contextualizing actigraphic data.

Intervention

The intervention phase begins approximately one month after baseline. For **supervisors** in the training/intervention groups, the intervention will include a computer/web-based supervisor

training integrating concepts from Behavioral Health Leadership, Sleep Leadership Training, and the VSST/FSSB training mentioned above. Participation in this computer-based supervisor training is mandated by the Oregon National Guard leadership. Additionally, supervisors in the training/intervention group will be provided individual-level sleep/cognitive effectiveness feedback based on the actigraph data collected during baseline, and this feedback will be provided to the supervisors in person (see Appendix A for a sample feedback report).

For **employees** in the training/intervention groups, they will also receive an in-person sleep/cognitive effectiveness feedback report based on the actigraph data collected during baseline. During the intervention phase, spouses in the training/intervention groups and everyone in the control groups will not be recruited for any research activity and/or data collection.

4-month post-baseline
At 4-month post-baseline, employees, their supervisors, and their spouses/partners in both training/intervention and control groups will be asked to complete an online survey (see Appendix B for survey measures to be completed by each group and see supporting document for the list of survey items that we will select from).

9-month post-baseline
At 9-month post-baseline, we will repeat the procedure conducted during the baseline period - where supervisors, employees, and their spouses/partners in both training/intervention and control groups will be asked to complete an online survey (see Appendix B for survey measures to be completed by each group and see supporting document for the list of survey items that we will select from), and in the meantime, supervisors and employees will be asked to wear actigraphy watches for 3 weeks as part of our sleep outcome data collection.

When we collect the watches from participants after 3 weeks of actigraph wearing, we will verbally ask them to answer four questions regarding 1) their drill or annual training dates and locations in the past 3 weeks, 2) major events that disrupted their sleep in the past 3 weeks, 3) other noteworthy factors that affected their sleep in the past 3 weeks, and 4) any time where they had to temporarily take off the actigraph watches for security and/or safety reasons. The full list of actigraph delivery questions can be found in the supporting document. Responses to these questions will be used for data quality control/management and for contextualizing actigraphic data.

While participation in the computer-based FSSB/Sleep Leadership supervisor training is mandated by the Oregon National Guard leadership, participation in surveys and actigraph sleep/activity tracking is completely voluntary and is not mandated by the Oregon National Guard leadership.

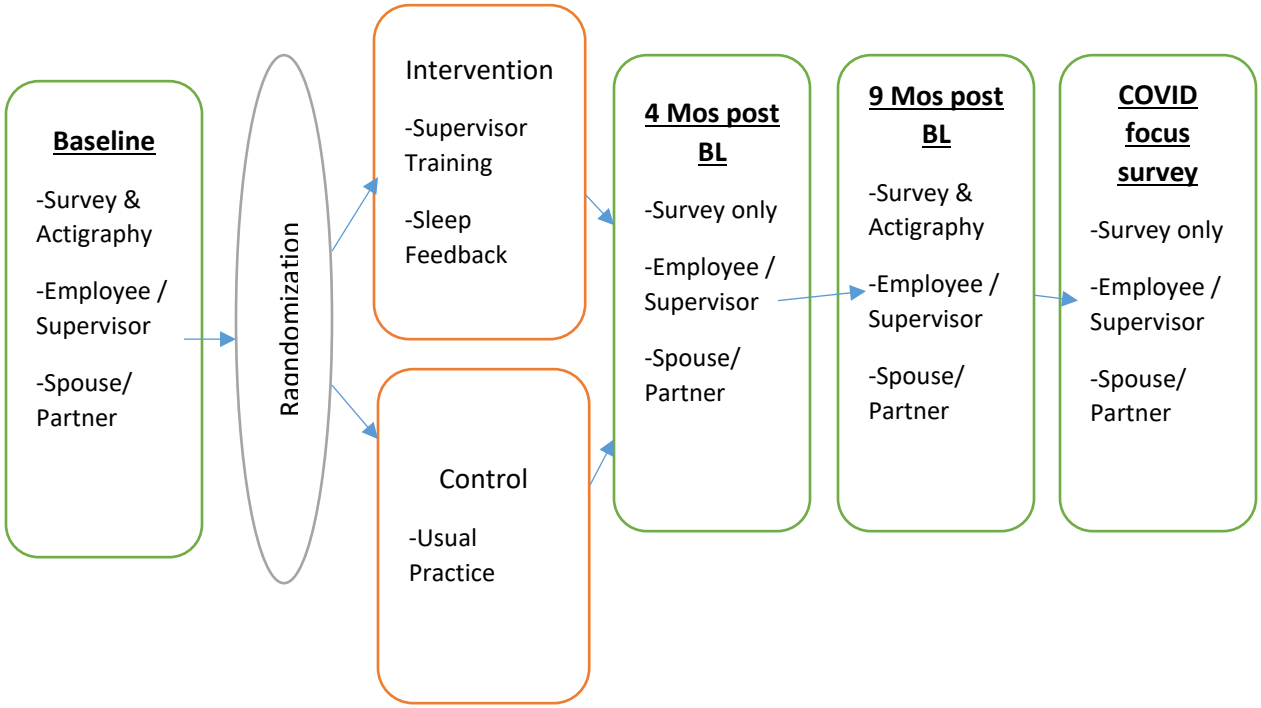
Waitlist-control intervention (No data collection involved)
Upon completion of data collection, supervisors in the control groups will receive the computer-based FSSB/Sleep Leadership training. Additionally, we will use the actigraph data collected from baseline and 9-month post-baseline to generate feedback reports (e.g., comparison estimates) for all participants in both intervention and control groups. These reports will only be used for feedback purposes, they are not part of the intervention.

The actigraph data collected from baseline and 9-month post-baseline will also be used for our internal data analyses (e.g., combined with survey responses for statistical analyses and hypothesis testing). Note that the current study is simply using the actigraphy devices to collect data related to participants' sleep and their daily activities. We are not testing the efficacy of the devices.

COVID-related Supplement: Survey data collection

Due to the extraordinary circumstances of the global novel coronavirus pandemic in 2020, we requested and received funding to collect an additional wave of survey data (no actigraphy) from all participants who responded at baseline, service members, supervisors and spouse/partners, using REDCap. We will remind participants that they previously provided consent when responding to the initial survey and reiterate that their participation here is voluntary. We will repeat the majority of the previous survey, with some exceptions, as well as the addition of several COVD-related items. The potential additional items have been added to Appendix B. Please note this list of items may be shortened but no additional items will be added at this time.
Overall, the process will be the same as with the 4-month data collection where the survey will be emailed to participants with no in-person contact. All surveys will be sent at one time in November 2020, regardless of when they completed their last survey; we will calculate that time lag and account for it in our analyses.

We will send the survey to the personal email that the participant previously provided with the instructions to complete OFF work time. To reduce the response burden on the participant, we will pipe in some information, including name, email, rank, work status, etc., and ask them if the information is still accurate and provide them an opportunity to update if needed. We will ask for electronic consent for this survey


Baseline
-Survey & Actigraphy
-Employee / Supervisor
-Spouse/ Partner
Randomization
Intervention
-Supervisor Training
-Sleep Feedback
Control
-Usual Practice
4 Mos post BL
-Survey only
-Employee / Supervisor
-Spouse/ Partner
9 Mos post BL
-Survey & Actigraphy
-Employee / Supervisor
-Spouse/ Partner
COVID focus survey
-Survey only
-Employee / Supervisor
-Spouse/ Partner

(5) Study Population

Number of Subjects

We anticipate recruiting approximately 500 full-time employees (Military Technicians and Active Guard Reserves) in the Oregon National Guard –Army and Air - and their supervisors to participate in the study. Given each supervisor oversees 5 or more employees, we anticipate recruiting at least 150 of the 180 first-level supervisors to participate in the study and take part in the FSSB/Sleep Leadership training intervention. We anticipate another 50 second-level supervisors to also participate in the study. Therefore, we expect to recruit a total of **500 employees** and **200 supervisors** into the study – they will be randomized by location cluster into the intervention and control conditions. Of the 500 full-time employees we will recruit, we expect that approximately 80% (400) of the employees will be married and/or cohabitating – based on our prior work with the SERVe study. All employee spouses/partners (anticipated number of **260 spouses/partners**) will also be invited to complete surveys that coincide with the employee surveys, pre- and post-intervention (i.e., baseline, 4-month and 9-month post-baseline). Personnel at the OHSU site will be responsible for all participant recruitment.

Inclusion & Exclusion Criteria

To be eligible for this study, a participant must be 18 years old, currently employed as a full-time Military Technician or Active Guard Reserve in the state of Oregon and working at least 32 hours per week. Already inherent with employment as a Military Technician and an Active Guard Reserve a participant must be at least 18 years old and work full-time. In the unlikely circumstance that a screen failure occurs (i.e., participants do not meet our inclusion criteria), their data will be retained for separate analysis to determine if findings are different from those who meet the inclusion criteria.

The Internet surveys will be developed and conducted via the REDCap program, which is monitored by the Oregon Clinical and Translational Research Institute (OCTRI) at OHSU - https://octri.ohsu.edu/redcap/. According to OCTRI, “REDCap is a secure, reliable, versatile and feature-rich web application for building and managing HIPAA compliant online surveys and databases.”

Vulnerable Populations

No individuals who are known to be members of a vulnerable population will be enrolled. We will not identify subjects on whether they are members of a vulnerable population. In other words, we will not collect any information about subjects’ status as part of any vulnerable populations, including prisoners, pregnant woman, children, neonates, and/or adults lacking capacity.

Setting

This is a multi-site study involving personnel/researchers at OHSU, Colorado State University (CSU), and Portland State University (PSU). OHSU will be the coordinating center for all research activities. OHSU personnel will be responsible for all stages of the research project, including recruitment at the Oregon National Guard facilities, consent processes, study procedures, interacting with study participants, data collection (primarily online surveys and actigraphs), data management, data analysis, and dissemination of findings. Surveys will be conducted online on REDCap, OFF work time. Personnel at CSU and PSU will assist with training development, making recommendations for survey measures, data analysis and dissemination of findings. Specifically, personnel at CSU (PI of sub-award: Dr. Tori Crain) will assist with reviewing the sleep leadership training materials, making suggestions for sleep-related survey measures, conducting actigraphy analyses, generating sleep feedback, analyzing data on intervention effects, and disseminating the study findings (e.g., peer-reviewed publications). Personnel at PSU (PI of sub-award: Dr. Cynthia Mohr) will assist with reviewing

supervisor training materials, making suggestions for family/spouse-related survey measures, assisting with dyadic-related statistical analyses, and disseminating study findings. IRB offices at CSU and PSU have ceded oversight to OHSU IRB. The ceding letters have been approved by OHSU on 1/23/2017 (reference ID: MOD00005655).

OHSU personnel will also be working closely with Major Matthew LoPresti, Ph.D. at Walter Reed Army Institute of Research (WRAIR). He will serve as a consultant on study design, sleep leadership training development, and actigraphic data collection and analysis. WRAIR will also provide an inventory (about 200) of actigraph watches (Actiwatch 2) and accessories for data collection (e.g., docking stations, licenses, watchbands), provide consultation and training on actigraph utilization, data collection, data management, data analysis and interpretation. Dr. LoPresti will only have access to de-identified data upon completion of data collection; they will not interact with any human subjects. A formal cooperative research and development agreement (CRADA) has been fully executed that covers the loaning of actigraphy watches from WRAIR to our research team and to include Dr. LoPresti's unpaid consultation and contract with de-identified data.

Kathleen Carlson, an assistant professor at OHSU and a core-investigator at the Portland VA Medical Center, is a co-investigator of the project. She will **not** use VA time or VA resources to work on this project.

Recruitment Methods

The Chief of Staff with the Oregon National Guard (ORNG), COL Stuart Mathew, will facilitate our introduction to work sites in locations around the state of Oregon, including the Portland area, the state capitol of Salem, and Klamath Falls, where a large Air National Guard base, Kingsley Field, is located. OHSU research staff will visit all locations to first meet with top leadership to explain the goals of the project, answer questions, and get buy-in. We will develop a customized timeline and recruitment process for the site location, which will involve research staff visiting in person to introduce the study and invite interested employees to sign up for the study via secured web link that will be distributed to them in the recruitment materials (see supporting documents). We will distribute one page flyers and FAQs at each of the worksites to advertise the study and to explain the scope and purpose of our research. We will also work with the ORNG HR department to advertise our study via internal email messages sent by the Chief of Staff and senior leadership for that unit. All recruitment materials will include information regarding what participation would entail, contact information for questions and further information, as well as how to sign up to participate. Please refer to supporting documents for all recruitment materials.

The recruitment materials above will be posted on-site approximately two months prior to baseline data collection. A small team of researchers will also visit the units in person during baseline period to do a final recruitment on site. Survey links will be emailed to participants' personal email addresses upon signing up. Participants will be asked to complete the surveys *off* work time in order to receive compensation (per federal regulations). Our team will ensure that supervisors of employees are not present during this recruitment so as to not influence participation. We will also provide the actigraphy watches to the participant during our visit at baseline, along with instructions for wear.

All spouses/partners who live with participating employees/supervisors will be invited to participate via the employee. Specifically, when a participant signs up, we will provide each employee/supervisor with information about the spouse/partner survey and ask if the employee/supervisor would either provide contact information for their spouse/partner or alert

the spouse/partner about the survey opportunity. We will also ask participating employees/supervisors to invite their spouses/partners to participate in this study after they complete the baseline survey and/or when we distribute the actigraphy watches in person. We will also post spouse-specific recruitment flyers, postcards and FAQs on-site during our visit to ORNG locations. After participating employees/supervisors complete the first survey, and after we receive the contact information (names and email addresses) of spouses/partners who express interest in participating in this study, we will send the spouses an email inviting them to sign up for the study and begin the first baseline survey. We will also have a phone number and email for spouses (and employees or supervisors) to reach out with any questions regarding the study.

Of the 500 employees we will recruit, we anticipate that approximately 80% (400) of the employees will be married, engaged, and/or cohabiting, based on our prior work. Similarly, we have previously obtained response rates of about 50-65% for spouses and therefore, we expect that approximately 65% of those spouse/partners will agree to participate in the study (i.e., 260). We anticipate an 80% response rate at the 4-month and 9-month follow up for spouses (*N*=208 and *N*=166, respectively).

We will use incentives to aid recruitment of supervisors, employees, and spouse/partners. While we anticipate training supervisors during company time, we have found in our past organizational research experience that providing participant payment helps to increase participation. Thus, we plan on providing supervisors and employees a $50 incentive for completing a survey and wearing the actigraph watch during baseline and during 9-month post-baseline, and a $25 incentive for completing a survey at 4-month post-baseline – thus they can earn up to $125 total ($50 baseline, $25 4-month post-baseline, and $50 9-month post-baseline). Employees' spouses/partners will be invited to complete three $25 surveys for baseline, 4-month post-baseline, and 9-month post-baseline, thus potentially earning up to $75 total. These monetary incentives will be provided in ClinCards, which are reloadable debit cards, and they will be given to the participants subsequent to the completion of each time point (baseline, 4-month post-baseline and 9-month post-baseline). We will also provide food and beverages during on-site recruitment.

Survey data will be collected via the REDCap program through a secured web link and off work time so as not to interfere with work and take up valuable work time. In addition, this makes employees eligible for the offered incentives, as federal regulations prohibit monetary incentives for surveys during regular work hours. In addition, all electronic communications, including the recruitment materials, surveys and training will be 508 compliant (i.e., accessible to those with disabilities following Federal guidelines).

<u>Consent Process</u>

Prior to any data collection, employees, their spouses, and their supervisors will be provided with informed consent (see attached informed consent forms). The same informed consent forms address data collection during baseline, 4-month post-baseline, and 9-month post-baseline. At 4-month and 9-month post-baseline, we will provide participants with the same informed consent forms as baseline, and remind them about previous consent during baseline. We will also provide an option to save/print the consent forms at each time point. They will be told that their participation in data collection is voluntary and that all data will be kept confidential and not shared with their employer. We will ensure that employees' commanders or supervisors are not present (during recruitment) when they sign up for our study in order not to be seen as coercive.

For the follow up COVID-focused survey in November 2020, we will provide a revised consent form that is specific to this survey. Per currently guidelines, we will provide the text of the consent form, and ask them to provide their electronic signature by selecting the appropriate box and typing in their first and last name.

After they sign up for our study during recruitment, we will provide each participant a link to the online survey. A wavier of the HIPAA authorization signature requirement has been approved by the IRB. The informed consent will be at the very beginning of the online survey and participants will '*click'* agree. They also have the option to download and print the informed consent. We will also have printed copies during our on-site visits (during baseline period) for those who may want to complete the online baseline survey at a later point in time. In addition, we provide participants with the phone number to our office, as well as the number for OHSU's IRB, if they would like someone to read or go over the Informed Consent with them.

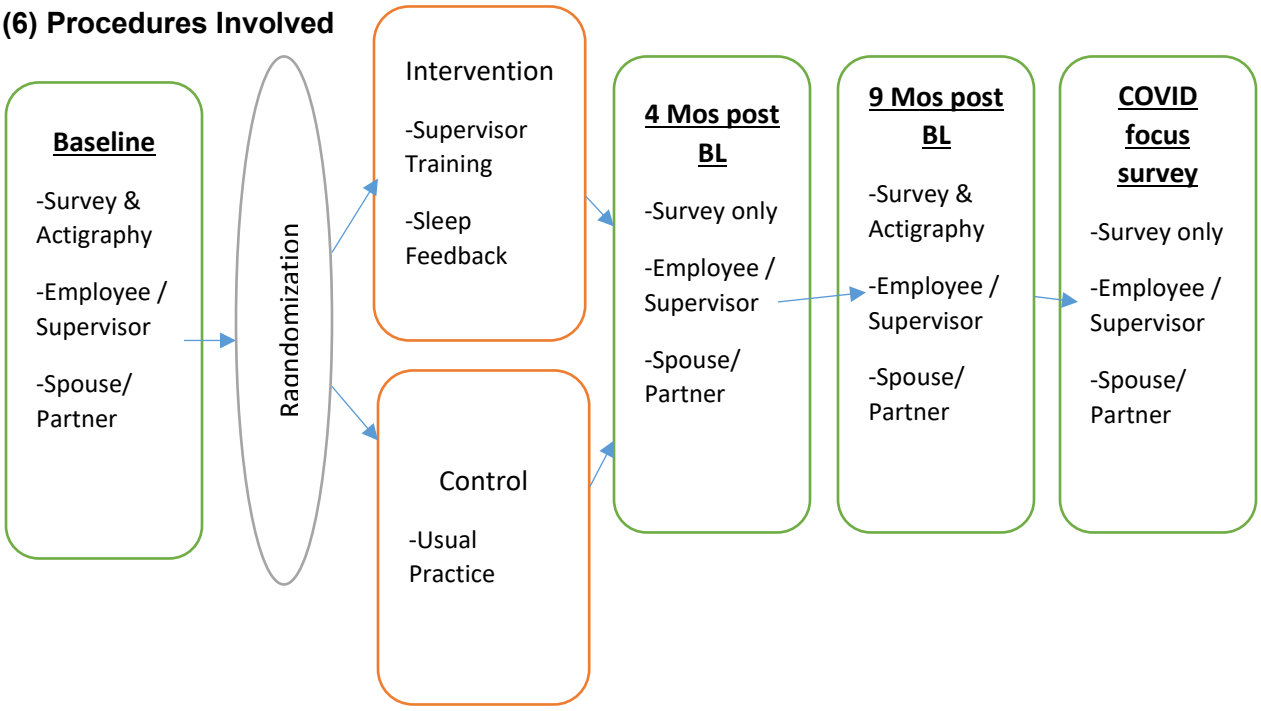
Employees, their supervisors, and their spouses/partners will be informed that we are interested in understanding the employee's experiences in the workplace and in the family as well as a number of sleep outcomes. As this is a waitlist-control experimental design, the same letters and consent forms will be used for both the intervention group and the control group. As such, those in the control group will eventually receive the intervention as well.

Employees and supervisors will receive the same consent form for their voluntary participation in completing the surveys and wearing the actigraphs, as their involvement in these two study components is the same. Specifically, employees and supervisors will complete the same surveys (with one exception that participants who identify as supervisors will answer several additional supervisor-specific questions) and wear the same actigraphs for 3 weeks at baseline and at 9-month post-baseline. Both employees and supervisors in the treatment condition will also receive the same sleep feedback reports during the intervention phase. We will not differentiate between employees and supervisors until after baseline data collection and when we randomize our experimental conditions.

The computer-based FSSB/Sleep Leadership training is mandated by ORNG leadership. Even though it is mandatory, we will be collecting consent from supervisors for the intervention/training data (including quiz data and behavioral self-tracking data), in particular, so we may use data from the supervisor computer-based training and link directly with survey responses of employees and their supervisors. There is a separate consent form for supervisors who are participating in this computer-based FSSB/Sleep Leadership training because not all supervisors who participate in this computer-based training are also participating in the survey and actigraphy portions of the study.

Supervisors will receive the full consent and authorization form before being asked to provide consent to have their online training data used for research. To clarify, supervisors will complete the FSSB/sleep leadership training as part of their workplace training initiatives, but will have the voluntary option of allowing us to use their de-identified data in the evaluation of the training.

(6) Procedures Involved



The current cluster-randomized study design involves baseline and two separate post-baseline measurements to test the effectiveness of the supervisor FSSB/Sleep Leadership training and sleep/cognitive feedback on a sample of full-time Oregon National Guard employees and supervisors. Supervisors of employees in the intervention/treatment condition will receive the supervisor FSSB/Sleep Leadership training at 1-month post-baseline. All supervisors, in both treatment and control conditions, will be invited to participate in the baseline and follow-up surveys (4-month and 9-month post-baseline) assessing their knowledge of FSSB and sleep leadership concepts, as well as assessing outcomes related to our study hypotheses. Additionally, employees and all their spouses/partners will be invited to participate in the survey study at baseline and both post-baseline follow-ups.

The supervisor FSSB and Sleep Leadership training intervention is a computer/web-based training of supervisors – integrating concepts from Behavioral Health Leadership, Sleep Leadership, and the VSST/FSSB training described above. Sample screenshots of the supervisor training are presented in Appendix C. The training will be delivered to supervisors through a 1- to 2-hour, online, self-paced training consisting of multiple modules to be completed over the course of a pre-determined 2-week period of time. The training will occur approximately 1-month post-baseline data collection, which will include survey interviews and health assessments. Following completion of the computer/web-based training, supervisors will be instructed on how to implement a behavioral self-monitoring exercise using web-based behavior-tracking that will continue for 2 weeks and will enhance transfer of training into actual behaviors at work. The activity concludes with delivery of summary feedback and reflection on the training transfer experience.

We will use a waitlist-control design where we will eventually make the FSSB and sleep leadership training available to all location clusters in the control group that are interested. Upon

completion of data collection, we will also distribute sleep/cognitive effectiveness feedback reports to participants in both intervention and control groups. To accommodate multiple geographic locations, a limited number of actigraphy devices and to build some flexibility into the timing of the training, we will have a phased roll out of the study to last approximately 3 years.

We plan on taking a cluster, or group, randomization approach, or more specifically, a sequential cluster random assignment within Blocks (see Table below) to assign participants to treatment and control conditions. Based on the list of locations and units, we will identify approximately 24 clusters for the study, half to be randomized to the intervention group and half to control. Randomization will occur once units have been identified and before data collection. The research team recruiting and collecting data will be kept blind of the randomization results.

Further clustering of facilities into groups of facilities is a second level of clustering. There are several reasons for this extra step. First, clustering facilities that are geographically close will help to minimize research-related travel expenses to the facilities because travel to several facilities in the same study intervention arm can be accomplished in one trip. Second, clustering facilities that are geographically close will help to minimize contamination across study intervention arms as geographically close facilities will tend to be assigned to the same intervention condition; furthermore, this may also serve to boost intervention effects as supervisors in intervention locations that are geographically close may talk with one another and share ideas and experiences. Third, creating clusters of facilities will help to balance better the number of employees across the study intervention conditions, an important issue given the variability in employees in facilities across the state.

Based on our recruitment projections (500 employees, 200 supervisors), the table below breaks down the randomization numbers. Within each of 3 Blocks, there will be 8 total clusters, randomized into 4 treatment and 4 control. The cluster of 4 represents the second layer described in the paragraph above. Based on a preliminary roll out plan, we anticipate that Block 2 will be slightly larger than Blocks 1 and 3.

Randomization Design Plan

	Intervention	Control
Block 1 (begins Year 1)	4 clusters of units • ~ 75 employees across units (non-supervisor) • ~ 30 supervisors	4 clusters of units • ~ 75 employees across units (non-supervisor) • ~ 30 supervisors
Block 2 (begins Year 2)	4 clusters of locations • ~ 100 employees across units (non-supervisor) • ~ 40 supervisors	4 clusters of locations • ~ 100 employees across units (non-supervisor) • ~ 40 supervisors
Block 3 (begins Year 3)	4 clusters of locations • ~ 75 employees across units (non-supervisor) • ~ 30 supervisors	4 clusters of locations • ~ 75 employees units (non-supervisor) • ~ 30 supervisors

In addition to the supervisor FSSB/Sleep Leadership training, we will be providing a sleep-related feedback intervention for employees and supervisors in the intervention group using actigraphy. Actigraphy represents a reliable and valid objective measure of sleep not used for the diagnosis of sleep disorders. Actigraphs, specifically Actiwatch 2 watches, are wristwatch-

like devices that contain an accelerometer, continuously measuring movement as a proxy for waking activity. During baseline period, all supervisors and their employees in both intervention and control groups will be asked to wear the actigraphy devices continuously for 3 weeks, with instructions for care by research staff, but only those in the intervention group will receive individual-level feedback during the intervention stage. Those in the control group will not receive feedback at this time.

Approximately 1 month post-baseline (during intervention stage), data from the actigraphy bands will be downloaded, processed by our research staff and individual, in-person feedback will be given to participants in the intervention group (see Appendix A for sample feedback report). The feedback is designed to highlight (1) sleep data from the previous 3 weeks highlighting daily activity and sleep/wake scoring; (2) summary sleep data comparisons with data from the general population, including average time of sleep onset, sleep duration, time of onset variability, and longest sleep period (scores differing from the norm were indicated with an asterisk); (3) cognitive effectiveness estimates charted from the 3 weeks derived from the sleep data and using a color-coded system of green, amber, and red; and (4) recommended actions for improving sleep.

We will use online, electronic surveys (i.e., RedCap) for all employees, supervisors, and spouses/partners at baseline and at 4-months and about 9-months post-baseline, following supervisor FSSB/Sleep Leadership training and in-person sleep/cognitive effectiveness feedback for the treatment group. We will also conduct a COVID-related survey in November 2020 to assess the effects of the pandemic. Surveys will be completed OFF of work time. In addition, we will collect objective sleep data with actigraphy devices at baseline and 9-month post-baseline as an objective health indicator from employees and their supervisors. We will be using the same actigraphy devices, and all participants will be wearing the watches for 3 weeks at baseline and 9-month post-baseline. Supervisors in the treatment condition will also be briefly surveyed at the time of training using a survey program within the computer-based training module. All supervisors – regardless of study conditions – will be invited to participate in the baseline & follow-up surveys assessing their knowledge of FSSB and sleep leadership concepts & assessing outcomes related to our hypotheses. All spouses/partners who live with the employees will also be invited to participate in the survey study at baseline, 4- and 9-month post-baseline. Spouse/partners will not participate in any of the actigraphy data collection.

Upon completion of data collection, we will use the actigraph data collected from baseline and 9-month post-baseline to generate feedback reports (e.g., comparison estimates) for all participants in both intervention and control groups. These reports will only be used for feedback purposes, they are not part of the intervention. The actigraph data collected from baseline and 9-month post-baseline will also be used for our internal data analyses (e.g., combined with survey responses for statistical analyses and hypothesis testing). Note that the current study is simply using the actigraphy devices to collect data related to participants' sleep and their daily activities. We are not testing the efficacy of the devices.

(7) Data and Specimens

Handling of Data and Specimens

Confidentiality of participants' responses will be maintained. Results will only be reported in aggregate form. Data from the online surveys and actigraphic assessments will be kept on our secure server at OHSU and only designated persons from our research team will have access. The REDCap program monitored by the Oregon Clinical & Translational Research Institute (OCTRI) at OHSU will be used for all survey data collection. It is designed to handle data collected from human subjects, while systematically accounting for related confidentiality issues.

It is also HIPAA compliant. Further, the data are protected behind a firewall and is accessible only by authorized research staff with a login and password combination, thus ensuring the confidentiality of all survey responses, email addresses, and personal information.

Steps to be taken to protect the safety and confidentiality of all participants include the use of study code numbers for identification, data linkage of employee surveys, spouse/partner, and supervisor data. Participant unique identification numbers will be used to match survey responses between employees, their supervisors, and their spouses/partners. After merging the responses, the final datasets used for data analysis will be completely de-identified. Additional steps taken will include, reporting of aggregate data, and destroying all identifiers within three years after completion of the study. Participant code number lists and participant contact information will be kept in separate locked file cabinets. We plan to store the de-identified data (data from the online surveys and actigraphic assessments) indefinitely after the end of the study on our secure server at OHSU and on Box; only designated persons from our research team will have access.

Researchers collecting data for the proposed study will follow all guidelines and protocols as authorized by the OHSU Research Integrity Department/Institutional Review Board. Personally identifying information such as name and phone number will be used strictly for recruitment, and scheduling. All contact information will be securely stored in a separate locked file cabinet in a locked office by research staff and will be destroyed within three years of study completion.

Sharing of Results with Subjects

Individual-level sleep/cognitive effectiveness feedback will be distributed in person to those in the intervention group as part of the intervention design. Individualized reports containing actigraphic measurements and summary estimates relevant to participants' own sleep habits, sleep quality, sleep quantity, etc. will be shared with participants during the sleep/cognitive effectiveness feedback intervention period (around 1-month post baseline; during intervention phase). Aggregated results without any identifying information will also be shared via email to all participants. Their email addresses and other identifying information will be kept separate from the individual-level data.

Upon completion of data collection, we will use the actigraph data collected from baseline and 9-month post-baseline to generate feedback reports (e.g., comparison estimates) for all participants in both intervention and control groups. These reports will only be used for feedback purposes, they are not part of the intervention.

(8) Data Analysis

Descriptive and Psychometric Analyses:

As we are exclusively using established and validated measurement instruments, we do not anticipate psychometric problems. However, we will perform the standard set of psychometric analyses on each of these measurement instruments to verify their performance with the current sample. Analyses will include descriptive item and scale statistics and verification of scale reliabilities and factor structures. Assessment of scale reliabilities (e.g., Cronbach's alpha) and factor structures will use established confirmatory factor analysis methods. In the event that we find poorly performing measurement instruments, we will explore whether better psychometric performance can be obtained by deleting some of the scale items, as long as doing so is theoretically defensible.

Power Analysis:

This section documents the power analyses we conducted for the planned analyses for hypothesis testing. We focus on power for the analyses involving employee-level outcomes. To estimate power for Service member-level outcomes, we based our effect size estimate for the intervention's effect on physical health from the data reported in Hammer et al. (2011), i.e., d = .33 (ICC = .03) after controlling for baseline physical health and a workplace intervention's effect on sleep problems (d = .30; ICC = .01) from (Adler, Gunia, Bliese, Kim & LoPresti, working paper). We assumed 24 randomized clusters. Throughout, we set alpha = .05 to define statistical significance. Power analyses for the employee-level outcomes were conducted using Optimal Design (Version 2.01) software package (Raudenbush, Spybrook, Congdon, Liu, and Martinez, 2011). With these assumptions, the estimated power for the effect of the intervention on physical health would be .95 and on sleep problems would be .83 with 500 enrolled employees at baseline. Assuming an attrition rate of 20% (see Missing Data discussion below) resulting in a total sample size of 400 employees across the 24 randomized clusters, the estimated power for the effect of the intervention on physical health would be .86 and on sleep quality would be .80. Thus, we have demonstrated adequate power to test our hypotheses for employees.

Missing Data and the Application of Intent-to-Treat:

Missing data intermittently during the study and/or dropouts are inevitable and an issue faced by all longitudinal studies. There is no consensus, however, on the optimal analytical strategy to analyze missing data. Using the standard missing data taxonomy (Rubin, 1987), we will follow the recommendations made by Nich and Carroll (1997, 2002) and conduct intent-to-treat analyses using three strategies. In the first strategy we will extend the multiple imputation method of Little and Yau (1996) to allow for non-monotone missing values, which could occur intermittently during the study period. Monotone missing patterns require subsequent variables to be missing once a variable is missing. We will impute unobserved outcomes based on study condition, observed subject-level covariates at baseline and observed follow-ups. Inferences will be made on imputed datasets using Rubin's method (Barnes, Lindborg, & Seaman, 2006; Rubin, 1996). Our second analytical strategy will consider selection models and pattern-mixture models (Michiels, Molenberghs, Bijnens, Vangeneugden, & Thijs, 2002) based on different factorization of the joint distribution of the response variables and the missing patterns. As different strategies require different assumptions for the estimated treatment effects to be unbiased and some assumptions are not testable, comparisons of these strategies serve mainly as sensitivity analyses of their influence on the estimated key parameters of each Aim. A third strategy will consider the use of Full Information Maximum Likelihood methods in the analysis of incomplete data as implemented in several software programs (e.g., Mplus; Muthen & Muthen, 2007). As mentioned in the prior section, this study is adequately powered for an attrition rate of 20%.

Analysis of Research Questions/Hypotheses:

The data for this study are generated from a cluster randomized experimental design with all participating supervisors and their employees within a facility cluster randomly assigned to either an intervention or usual practice control condition. Standard general linear and generalized linear mixed model approaches for cluster randomized designs (i.e., hierarchical linear models, multilevel models; Murray, 1998; Murray, Varnell, and Blitstein, 2004) will be used for data analysis for our research questions/hypotheses to account for the nesting structure in the data. As these models are now widely used and understood and are available in numerous statistical software packages, our discussion here on the specifics of these analyses will be brief. In each case, link functions for these models will be determined by the scaling of each outcome variable. Furthermore, in each analysis we will use the outcome variable at baseline as a predictor in the model to adjust for unexpected imbalance from randomization and

to increase the statistical power for and precision of parameter estimates. Cluster differences will be modeled as random effects. Finally, the recruitment wave (i.e., block), rank, gender, unit type, marital status, and mental health symptoms will be used as predictors in the statistical models. Of interest in these models is the direction, magnitude, and statistical significance of the parameter corresponding to the indicator of intervention group, which appears at the organization level of the multilevel analysis. For example, Physical Health scores at 4-months will be regressed on an indicator of intervention condition and Physical Health scores at the pre-intervention assessment, minimally specifying a random effect for the intercepts across organizations. As needed, depending on attrition and missing data, this basic generalized linear mixed model will be extended in the analysis of the specific aims as mentioned in a prior section (e.g., multiple imputation for missing predictor variable values, FIML estimation for missing outcome variable values).

(9) Privacy, Confidentiality and Data Security

Confidentiality of participants' responses will be maintained. Results will only be reported/published in aggregate form. Data from the online surveys and actigraphic assessments will be kept on our secure server at OHSU and on Box; only designated persons from our research team will have access. REDCap is designed to handle data collected from human subjects, while systematically accounting for related confidentiality issues. The data are protected behind a firewall and is accessible only by authorized research staff with a login and password combination. REDCap also meets the privacy standards set forth by the Health Insurance Portability and Accountability Act (HIPAA), ensuring the confidentiality of all survey responses, email addresses, and personal information.

Steps to be taken to protect the safety and confidentiality of all participants include the use of study code numbers for identification, data linkage of employee surveys, spouse/partner, and supervisor data. Only OHSU personnel in this project, specifically Krista Brockwood, Phoenix Rainbird and Jason Malach-Fuller, will have access to the code key. Additional steps taken will include, reporting of aggregate data, and destroying all identifiers within three years after completion of the study. Participant code number lists and participant contact information will be kept in separate locked file cabinets.

Researchers collecting data for the proposed study will follow all guidelines and protocols as authorized by the OHSU Research Integrity Department/Institutional Review Board. Personally identifying information such as name and phone number will be used strictly for recruitment, and scheduling. All contact information will be securely stored in a separate locked file cabinet in a locked office by research staff and will be destroyed within three years of study completion.

(10) Risks and Benefits

Risks to Subjects

Efforts will be made to minimize risks associated with this study. Minimal potential risks for participation include breaches of confidentiality associated with data collected for research purposes and minimal psychological distress associated with the psychological distress survey measures and sleep feedback. Additional potential, but not expected, risk is that a supervisor may be upset about being contacted to participate in a study or may not like the supervisor training. Supervisors can discuss these issues at any time with research staff.

Risk management and emergency response:

To mitigate potential distress related to the psychological well-being survey items, participants will be made aware that participation is completely voluntary and that they are welcome to withdraw involvement at any moment without consequence. The data is protected behind a

firewall and is accessible only by authorized research staff with a login and password combination. Further, surveys are securely protected under the REDCap survey program, which meets the privacy standards set forth by the Health Insurance Portability and Accountability Act (HIPAA), ensuring the confidentiality of all survey responses, email addresses, and personal information. Additionally, a list of resources to assist with psychological and physical distress, family resources, at both the state and national level will be provided on our study website.

Potential Benefits to Subjects

We expect positive results for all study participants, including reduced stress and increased social support. Employees of these supervisors are also expected to benefit from this training because the supervisors are expected to be more supportive of their employees. Longer term, these effects are expected to create a more supportive work environment for study participants, which has positive effects on safety, health, well-being, family, and organizational outcomes among participating employees, supervisors, and spouses/partners. We also expect that providing study participants (from both intervention & control groups) with individual/personalized sleep feedback will reduce sleep problems and improve sleep awareness.