The EMS Sleep Health Study:
A Randomized Controlled Trial

Study Protocol including Statistical Analysis Plan

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Table of Contents

Background and Specific Aims

Problem:
Greater than half of EMS personnel report poor sleep quality and fatigue. The odds of injury, medical error, and adverse events are higher among EMS personnel who report fatigue and poor sleep. There are few evidence-based interventions tailored to EMS workers that may improve sleep and reduce fatigue.

Significance:
A recent review of the published evidence shows that education and training tailored to the EMS personnel may reduce fatigue and improve safety on the roadways.

Specific Aims:
The purpose of the proposed study, is to measure the extent to which education and training in sleep health and fatigue will benefit EMS personnel and to explore the effects of a novel education intervention on EMS personnel. The study's two primary outcomes of interest include: [1] sleep quality as measured by the Pittsburgh Sleep Quality Index (PSQI); and [2] fatigue as measured by the Chalder Fatigue Questionnaire (CFQ).

Hypothesis:

Overview of Methods

We will use an experimental study design with a wait-list control group. We seek to enroll a maximum of 40 EMS agencies nationwide and approximately 10-to-50 individual EMS personnel from each agency. All agencies and individuals enrolled in this study will participate voluntarily over a six-month study period.

Study site:

University of Pittsburgh main campus

The University of Pittsburgh Department of Emergency Medicine has the necessary personnel and computer equipment, as well as software, to fulfill the study's aims. The Department of Psychiatry WPIC Office of Academic Computing is a partner in this project and has demonstrated, in numerous studies, to have the necessary personnel, expertise, computer equipment, and software needed to fulfill the study as designed.

Recruitment methods:

Members of the study team will use telephone and email communication to communicate with the EMS agency directors and individual EMS clinicians. Study team members will include the PI, co-investigators, and study coordinators / staff.

Methods for recruitment:

- Directly approaching potential subjects (in-person)
- Email/Listserv/Electronic Mailing List
- Flyers/Posters or Brochures
- Telephone scripts
- Website/Social Media

Details of recruitment methods:

We will use study flyers and standardized emails to first recruit EMS agency directors to participate in this study. Once an agency has agreed to participate, we will then ask the agency administrator to distribute a paper-based study flyer and standardized recruitment email to their EMS crew/staff via their email lists. We will also ask the administrators to post a paper-based version of the study flyer in high traffic areas of the EMS organization. Any representative of an EMS agency who comes across our study website (https://www.emssleephealth.pitt.edu) may wish to communicate with the study team about participation.

We also have video-based versions of study flyers. We will use the following methods to circulate these flyers:

[1] For the video-based version of the Agency Level Research Study Flyer, we will host the video version of the research study flyer on our study website. Agency directors who come into contact with our paper-based study flyer will be directed to view the video version on the study website, which we will keep password protected.

[2] For the video-based version of the Individual Level Research Study Flyer, we will ask the agency directors/administrators who have agreed to participate in our research study to circulate this video-based version on their internal email list-serve or internal computer system in a method similar to circulating the paper-based version.

Compensation / remuneration offered to participants

Our remuneration plan for study participants will include $5.00 (five dollars) to sign up/enroll, followed by $5.00 (five dollars) each month for the six-month study period. If a study participant completed the study as designed (6 months), he/she will receive a total of $35 total dollars.

Those who participate in this research study will have the opportunity to apply for 2.25 hours of continuing education credits offered by the Commission on Accreditation for Prehospital Continuing Education (CAPCE). The National Association of State EMS Officials (NAEMSO) will be the responsible for processing your individual application of continuing education. The information needed to apply for these continuing education credits will be available on the study website. Please see the attached letter from the NASEMSO regarding their role/responsibility in managing the continuing education credit processing.

Study design

Total number of subjects to be enrolled = 1500

Describe and explain the study design:
We will use an experimental study design with randomization at baseline and use of a wait-list control group. This design will ensure that all study participants receive the intervention, which may have significant benefits to EMS agencies and individual participants in terms of sleep quality and fatigue.

We will convenience sampling to recruit nationwide for EMS agencies. Moderately sized EMS organizations with (on average) between 50 + employees (EMS personnel) will be eligible to participate.

This approach will increase the likelihood of meeting enrollment goals by maximizing visibility of the study to as many EMS organizations as possible. Threats to external validity are limited due to the high degree of homogeneity of the EMS workforce (e.g., mostly male, middle aged, and mostly certified at the EMT-Basic level). All enrolled EMS organizations will be ground-based EMS operations; air-medical ONLY services will be excluded; however, dual air-medical/ground services may be eligible to participate. The sample will include dual fire-EMS operations as well. Participation from EMS organizations located in all U.S. Census regions will be achieved with nationwide recruitment. The study is powered to detect change in two outcomes of interest: [1] sleep quality as measured by the Pittsburgh Sleep Quality Index (PSQI); and [2] fatigue as measured by the Chalder Fatigue Questionnaire (CFQ). Maximum goal enrollment is set at n=40 EMS organizations.

Primary and secondary outcomes:
The study is powered to detect change in two outcomes of interest: [1] sleep quality as measured by the Pittsburgh Sleep Quality Index (PSQI); and [2] fatigue as measured by the Chalder Fatigue Questionnaire (CFQ).

Timeline:
Duration of an individual subject's active participation: Six months, plus up to one month that may be needed to process enrollment and close-out procedures for the EMS agency to which the individual participant is affiliated.

Inclusion criteria for EMS agencies:
The researchers will recruit EMS nationwide for EMS agencies to participate in this study. Moderately sized organizations with between 50 and 300 employees will be eligible to participate. While our primary target is agencies with between 50 and 300 employees, EMS agencies that employ less than 50 personnel or more than 300 will also be eligible to participate.

EMS operations that deploy EMS crews using ground-based ambulance services

will be eligible to participate. Dual ground-based and air-medical organizations will also be eligible, yet organizations that are exclusively air-medical are excluded. The study team will seek to achieve a sample of EMS agencies with goal enrollment based on these agencies being from all four major U.S. Census regions (Midwest, Northeast, South, and West), and inclusion of agencies that operate as dual fire and EMS systems.

Exclusion criteria for EMS agencies:
1: operate air-medical operations only
2: prohibit EMS personnel from using cellular/mobile, smartphones during shifts
3: prohibit EMS personnel from viewing study related materials (education materials) during shift work
4: agencies that do not operate within the United States

Inclusion criteria for individual EMS personnel:
1: 18 years of age or older
2: Currently working as an EMS clinician
3: Working a minimum of one shift a week
4: Working & residing in the United States
5: Working at one of the EMS organizations that agreed to participate in this study
6: Have a cellular, mobile, or smartphone that can send and receive text messages
7: Willing to answer online surveys and respond to text-message queries for seven days in a row every third week of the month for a total of 24 weeks/6 months

Exclusion criteria for individual EMS personnel:
1: Individuals <18 years of age
2: Not currently working as an EMS clinician
3: Does not work a minimum of one shift a week
4: Does not work and/reside in the United States
5: Does not work at one of the EMS organizations that agreed to participate in this study
6: Does not have a cellular, mobile, or smartphone that can send and receive text messages
7: Is not willing to answer online surveys and respond to text-message queries for seven days in a row every third week of the month for a total of 24 weeks/6 months.

Children will not be enrolled in this study. EMS organizations employ licensed/certified EMS clinicians. In order to be an EMS clinician licensed or certified by states within the United States, individuals must be 18 years of age or older.

Power analysis:
With a 40 total EMS agencies enrolled (20 intervention and 20 wait-list control), and with a minimum of 10 participants per agency completing the study, we have 88% power to detect 0.4 standard deviation difference in the mean PSQI. With this level of enrollment, we have 90% power to detect a 20% difference in self-reported fatigue as measured by the CFQ.

We assume that greater than 200 EMS agencies will express interest in this study. We assume that a large proportion (~65%) may express interest, yet will be unable or unwilling to participate for various reasons. We assume that among those EMS agencies that have agreed to enroll and participate, approximately 50% of the individuals at those agencies will agree to enroll and participate. With n=40 EMS agencies and an estimated ~n=50-to-100 individuals at those agencies willing to participate, we anticipate between 1,500 and 3,000 will agree to enroll. We will cap enrollment of EMS agencies to n=40 total agencies and seek to enroll a minimum of n=10 individuals per agency. With these numbers as our goals, we will achieve our goals for the power calculation outlined above.

Preliminary Data Source:
Patterson PD, Weaver MD, Hostler D. EMS Provider Wellness. In: Cone DC, Brice JH, Delbridge TR, Myers JB, editors. Emergency Medical Services: Clinical Practice and Systems Oversight. Second Edition. Chichester, West Sussex; Hoboken: John Wiley & Sons Inc., 2015 pp. 211-216. ISBN: 978-1-118-86530-9.

Statistical analysis plan
Intention to treat principles will be used for primary analyses. Descriptive statistics will be used without adjustment for agency-level clustering, and t-tests, tests of medians, chi-square tests, and Fisher's exact tests will be used to examine differences in EMS agency (cluster) and individual participant characteristics by IAI and WLC group status.

Hierarchical mixed effects models with random intercepts will be used for hypothesis testing and to test the impact of the intervention on outcomes. This approach will account for clustering at the agency level (nesting participants within agencies), and account for the dependence between repeated measures at the participant level.

Per-protocol analyses will be used to determine if variation in exposure to the intervention materials (education modules) is associated with a change in outcomes of interest. Hierarchical mixed effects models will be used to account for clustering at the agency level and the dependence between repeated measures at the participant level to characterize the relationship between exposure to the education module intervention and the outcomes of interest among participants who engage with the intervention and had an outcome assessment after intervention exposure. We will use Bonferonni corrected p-values when multiple comparisons are examined to test a study hypothesis. All

analyses will be performed with the SAS statistical software version 9.4 (Cary, North Carolina).

Research activities:
We will begin recruitment by disseminating the EMS Agency Flyer (paper-based version initially) to various EMS agency email listservs and distribution lists (e.g., ask the National Association of State EMS Officials to email their agency members).

Next, we will screen EMS agencies that respond to our study flyers to determine eligibility.

All EMS agencies will be randomized to either the intervention group or the wait-list control group. All agencies and individuals affiliated with the agencies randomized to the intervention group will have access to the study educational materials on the study website (https://www.emssleephealth.pitt.edu) once the individuals create their own account. All individuals randomized to the wait-list control group will receive access to the study educational materials - which are accessible on the study website.

Next, we will ask the EMS administrators to circulate a paper-based Research Study Flyer directly to the individual EMS clinicians using email and direct person-to-person distribution - AND -- to circulate a video-based version of the Research Study Flyer.

Next, we will instruct the individuals to visit our study designated website and follow the steps for screening (https://www.emssleephealth.pitt.edu). If after following the steps for screening the individual is eligible, he/she will then follow the instructions on the website for enrollment.

All enrollment procedures will take place on the study website (https://www.emssleephealth.pitt.edu). First, the individual EMS clinician will be taken to the video-based consent webpage. There he/she will play the consent video and then decide if he/she wants to follow through with enrollment. If he/she decides to enroll, then he/she will click on "(I ACCEPT) I have watched the informed consent video and agree to participate." OR - if he/she decides NOT to enroll, then he/she will click on the second option: "I DO NOT ACCEPT and do NOT want to participate in this research study."

For those who ACCEPT, they will then be taken to a new webpage on the study website that ask if they agree that all of the criteria for enrollment are TRUE. These criteria include all of the items asked on the screening page. This added step will provide final confirmation that the person signing up meets all criteria for enrollment.

For those who agree that all are TRUE, they will be taken to a webpage where they will type/enter in the name of their EMS Agency, their cellular/mobile phone number, and email address. Our study website is designed to cross-validate the agency name against a list that we maintain of EMS agencies that have agreed to participate. This verification takes place in real-time.

The individual's cellular/mobile phone number and email address will be used to

[1] get the individual EMS clinician registered with our automated text-messaging data collection system developed internally by the WPIC Office of Academic Computing;

[2] to email the individual a paper-based copy of the consent documentation; and

[3] to email the individual his/her temporary password to use when first logging into the study website where he/she will create a unique account and personalized password.

Next, the individual will receive four welcome text messages that say: "Welcome to the EMS Sleep Health Study" "You should receive an email with your password and instructions very soon." "REMEMBER: DON'T TEXT WHILE DRIVING." "If you received this message in error, please reply with one word: STOP."

Next, the participant will begin to answer the baseline survey located on the study website.

Once the baseline is complete, the participant will be instructed to visit the shift schedule calendar component of the study website and enter in his/her shift schedule starting on the first Sunday following enrollment and include any shifts during a 7 consecutive days. This action will inform the automated text-message system to send the participant unique text-message based queries daily over a 7 consecutive days. After those 7 consecutive days, he/she will not receive any text messages for two full weeks (minus a few reminder text messages). This process of one week with text message queries followed by two weeks with no text message queries will be repeated for the duration of the study (6 months).

As described above, all individuals affiliated with EMS agencies randomized at baseline to the intervention group will have access to the study materials following completion of the baseline survey -- available on the study website. All individuals affiliated with EMS agencies randomized to the wait-list control group will have access to the study intervention materials at 3 months.

Consent procedures

Waiver to document consent approved.

Potential participants will view the video-based consent materials that will be made available on the study designed website.

Potential participants will be allowed to rewind and watch the consent video multiple times if needed. They can also email or call the study team prior to selecting the ACCEPT or DO NOT ACCEPT options for consent.

Our consent video will provide a detailed description of the study. Potential participants will be allowed to rewind the video and watch multiple times. They can also communicate directly with the study team via email or telephone prior to deciding to ACCEPT or DO NOT ACCEPT consent.

We have also added the screening items to appear one more time after the individual watches the consent video. He/she must then CONFIRM that all of the screening items / eligibility criteria are TRUE. This added step will help to ensure the potential participant is aware of the study criteria.

Our study is nationwide, which makes it difficult to obtain written informed consent from all study participants. We will still obtain consent from the study subjects via a video-based procedure, which does not increase risk.

Data safety monitoring
Our study team will report on progress with recruitment, enrollment, data collection, and any unexpected issues to the Department of Emergency Medicine's Departmental Clinical Research Meeting (DCRM).

Protecting privacy
Only members of our research team are involved in this study protocol. No research findings will be provided to participant family members, insurance companies, employers, or any third party without the participant's authorization. All data that we collect for this research study will be assigned an ID number when received by our computerized data collection system. We will maintain a data file that contains the participant's name, mobile telephone number, and email address. This file will be located on a computer server and kept separate from the other data. This file will be password protected and access to this file will be restricted to core members of the research team. We will publish the study findings in aggregate in peer-reviewed medical journals.

Termination, withdrawal, or attrition
If a participant has not responded to study related text messages over multiple weeks, the study team will attempt to contact the participant to determine if he/she is still participating. If the attempts to contact the participant are unsuccessful, the participant may be classified as "withdrawn" or "lost to attrition," and his/her account on the study website will be suspended.

If a participant withdraws from the study, we will reach out to the participant with a standard email or telephone call. That email or telephone call will [1] acknowledge the participant's withdrawal; [2] thank the participant for his/her time commitment to the study period to withdrawing; and [3] extend an offer to the participant to contact the study team any time with questions. Our study does not have a category of partial withdrawal.