Real-time intervention to reduce fatigue among Emergency Medical Services workers

Study Protocol Document

Short title: The Sleep and Teamwork in EMS Study
(SaFTiE)

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Background and specific aims

Problem:
More than half of Emergency Medical Services (EMS) workers report work-related mental and physical fatigue. Odds of injury among fatigued EMS workers are nearly double that of non-fatigued workers. There is a compelling need to reduce fatigue among EMS workers, yet few EMS organizations have a formal fatigue management program and many may not be cost-effective or evidence-based. This study addresses national goals of the National Occupational Research Agenda (NORA) and tests a novel approach to fatigue risk management that is easily scalable to large workforces and low-cost for employers of shift workers.

Significance:
This research study addresses fatigued EMS workers, for which there has been no standard for fatigue risk management. This proposal logically builds on our pilot trial, which demonstrated feasibility, high compliance, and a positive impact on indicators of sleep and fatigue. This proposal addresses national goals of the National Occupational Research Agenda (NORA) and tests a novel approach to fatigue risk management that is easily scalable to large workforces and low-cost for employers of shift workers.

Specific aims:
Aim 1: Determine the impact of the enhanced intervention on EMS worker fatigue and sleep health in a cluster-randomized trial.

Aim 2: Identify worker-level and EMS agency-level conditions linked to a reduction in worker fatigue.

Aim 3: Perform exploratory analyses to determine impact of the enhanced intervention on the incidence of work-related injury and workplace safety culture.

Hypothesis:
Our global hypothesis is that dissemination of tailored sleep health information combined with tailored alertness promoting strategies in real-time can improve intra-shift fatigue, sleep health, and ultimately workplace safety culture.

Overview of methods

We will use a parallel, two-arm cluster-randomized trial study design. The design is clustered because we will have multiple participants from the same organization (agency) participating. Thus, participants are clustered together.

Each participant will be asked to participate for 6 months using our mobile technology, the SaFTiE mobile app and text message platforms. These platforms deliver our study intervention materials via text and information shared on the mobile app.

Study site

The University of Pittsburgh main campus

The 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 personnel, expertise, computer equipment, and software needed to fulfill this study as designed. The Department of Health Information Management within the School of Health and Rehabilitation Sciences is also a partner in this project and has demonstrated, in numerous studies, to have the necessary personnel, expertise, and equipment needed to fulfill this study as designed.

Recruitment methods

Members of the study team will communicate with EMS agency directors and individual EMS clinicians using telephone and email communication and other methods as necessary (e.g., in-person communication).

Methods used:
-Directly approaching potential subjects (in-person)
-Email/Listserv/Electronic Mailing List
-Flyers/Posters or Brochures
-Radio/Television/Video announcements
-Telephone scripts
-Website/social media

Details:
We will use traditional paper-based research study flyers and standardized emails to connect with and recruit EMS agency directors to participate. We will also use a video-based version of our study flyer that can be hosted on our study website (www.saftie.pitt.edu) and circulated on social media.

We will communicate directly with EMS agency leaders and with individual EMS clinicians who may be interested in participating in this research study. Once an agency director or individual clinician reaches out to us, they will be screened.

We will ask agency administrators to set a date for opening enrollment. When that date arrives, the agency administration will distribute a paper-based study flyer (a standardized recruitment email) and help to distribute a video-based individual EMS clinician recruitment flyer (as a complement to the paper version) to their crew members via their internal email lists. We will also host the video flyers on our platforms for ease of viewing. We will ask the EMS agency administrators to post the paper-based study flyer in high traffic areas on the EMS organization and to circulate our video-based flyer.

If our communication is with an individual EMS clinician, they will be directed to the study website and asked to complete the screening form. If eligible, they will be assisted with signing up for the study and instructed to watch the video consent on our study website.

We have two recruitment videos. One that shows various aspects of the study and a second video that highlights various aspects of the mobile app.

Compensation / remuneration offered to participants

Our remuneration package for study participants will include $25 dollars to sign up/enroll, followed by $10 distributed for months 1 to 5, and then $25 at the end of the 6-month study distributed on the 6th month of participation. In total, a study participant who participates for the full 6 months may accumulate a total of $100 in remuneration.

We will also mail directly to participants several popular EMS novelty items. These include coffee mugs, glove pouches, EMS shoulder patches, challenge coins, wallet sized reference index cards for special patient groups (e.g. burn patients), ball point pens, water bottles, keychains, and flashlights. We will mail these items monthly when a participant completes a monthly survey.

In addition, we will reimburse participants for smartphone data and text message use during participation. We will send active participants $50 at month 3 and $50 at month 6. We will issue this reimbursement for expenses on the University of Pittsburgh Vincent MasterCard.

Study design

Total number of subjects to be enrolled = 2500

Describe and explain the study design:
We will use a parallel, two-arm cluster-randomized trial study design. The design is clustered because we will have multiple participants from the same organization (agency) participating. Thus, participants are clustered together.

Each participant will be asked to participate for 6 months using our mobile technology, the SaFTiE mobile app and text message platforms. These platforms deliver our study intervention materials via text and information shared on the mobile app.

Primary and secondary outcomes:
Our PRIMARY OUTCOME of interest for Aim 1 is the proportion of workers that self-report fatigue as measured by the Chalder Fatigue Questionnaire (CFQ). The CFQ evaluates both physical and mental fatigue by eliciting a response of (Always, Sometimes, Rarely, Never) across 11 items. Item-level responses are recorded as (1, 1, 0, 0) with Always=1, Sometimes but not always=1, Rarely=0, Never=0. Scores are summed to reach a total score ranging from 0 to 11. Scores ≥4 indicate severe mental and physical fatigue.

Supporting citations for primary outcome:
Jackson C. The Chalder Fatigue Scale (CFQ 11). Occup Med (Lond). 2015 Jan;65(1):86. doi: 10.1093/occmed/kqu168. PubMed PMID: 25559796.

Cella M, Chalder T. Measuring fatigue in clinical and community settings. J Psychosom Res. 2010 Jul;69(1):17-22. doi: 10.1016/j.jpsychores.2009.10.007. Epub 2009 Dec 11. PubMed PMID: 20630259

Our SECONDARY OUTCOMES of interest include sleep quality as measured with the reliable Pittsburgh Sleep Quality Index (PSQI), and three additional measures of fatigue as measured by the Occupational Fatigue, Exhaustion, Recovery Scale (OFER).

Supporting citations for secondary outcomes:
Buysse DJ, Reynolds CFr, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatr Serv. 1989;28(2):193-213.

Winwood PC, Winefield AH, Dawson D, Lushington K. Development and validation of a scale to measure work-related fatigue and recovery: the Occupational Fatigue Exhaustion/Recovery Scale (OFER). J Occup Environ Med. 2005;47(6):594-606.

Timeline:
Duration of an individual subject's active participation: Six months.

Inclusion criteria for EMS agencies:
At the EMS Agency level, eligibility criteria for inclusion include: (1) the agency employs a minimum of 20 paid (full-time or part-time) EMS clinician shift workers; (2) employees work in shifts; (3) duties of EMS workers include standard tasks such as emergent or non-emergent patient care, driving/operating ambulances, and lifting/moving patients and EMS equipment; and (4) agency policies and procedures do not limit use of personal cell-phone or smartphone, with the exception of restrictions while driving and performing standard duties.

Exclusion criteria for EMS agencies:
At the EMS agency level, we are recruiting and enrolling EMS agencies that employ EMS clinicians who work primarily in ground-based EMS operations. We will exclude EMS agencies where the primary mission of that agency is to provide only one-type of EMS service, specifically only air-medical transport services. Air-Medical agencies that provide both air and ground-based services are eligible to participate. We will exclude agencies that do not allow their EMS clinician employees to use their personal cellular / smartphones during shift work.

Inclusion criteria for individual EMS personnel:
At the individual EMS clinician level, eligibility for participation will include answering YES to the following screening questions:

[1] Are you 18 years of age or older?

[2] Do you live in the United States (Hawaii & Alaska included)?

[3] Are you a licensed / certified EMS professional (e.g., EMT-Basic, Firefighter, Paramedic, Flight Nurse, or other type of prehospital clinician)?

[4] Do you currently work in shifts (e.g., 8 hours, 12 hours, 16 hours, 24 hours, or other duration)?

[5] Do you work at least one shift per week as an EMS clinician?

[6] When you work shifts, does most of your work involve direct contact with patients and delivery of patient care?

[7] Do you currently own a cellular telephone or smartphone that can send and receive text messages AND operate mobile apps that can be downloaded from the Apple Appstore or GooglePlay?

[8] Are you willing to periodically answer online surveys, and send and receive text messages as part of a research study?

Exclusion criteria for individual EMS personnel:
At the individual EMS clinician/worker level, we will exclude individuals who primarily work administrative jobs/roles at the agency. We will exclude individuals who answer NO to any of the screening questions (see screening questions in #5 above).

EMS clinician workers are required to have certification / licensure to provide emergency medical services care. These individuals are 18 years or older. Thus no children or persons <18 years of age will be eligible or enrolled.

Power analysis:
Our power calculation was designed to determine the number of agencies and individual EMS clinician workers needed to detect an important impact on fatigue and sleep quality.

Given our experience, we feel it appropriate and necessary to have a moderate to low level of the anticipated number of individual enrollees per cluster (agency). With 60 total clusters (30 EMS agencies in the intervention group and 30 in the APC group) and an average of 10 individuals enrollees per cluster, we will have 83.7% power to detect:

[A] a 15% reduction in the point-prevalence of fatigue in the intervention assigned participants versus the APC assigned participants; and

[B] a clinically meaningful change of >3 points on the Pittsburgh Sleep Quality Index from randomization to 3 months and 6 months.

If we enroll a total of 100 EMS agencies (50 EMS agencies in the intervention group and 50 in the APC group) with an average of 5 individuals per cluster (agency), we will have 85.8% power to detect:

[A] a 15% reduction in the point-prevalence of fatigue in the intervention assigned participants versus the APC assigned participants; and

[B] a clinically meaningful change of >3 points on the Pittsburgh Sleep Quality Index from randomization to 3 months and 6 months.

A cluster is defined as an EMS agency with at least 2 individual participants enrolled. Locations (agencies) with 1 or no enrollments will not be considered as counting towards total cluster goal enrollment.

Statistical analyses:
The primary outcome for this agency-randomized trial is EMS worker fatigue related to shift work, measured by the CFQ at 3 and 6 months after randomization. To test the effect of the intervention on worker fatigue, we will use a generalized linear mixed model with logit link (due to the dichotomous nature of outcome: fatigued versus not-fatigued). We will use a random agency effect to account for the clustering of EMS workers within

agencies and a random worker effect to account for the correlation between repeated measures within worker. The main effects of time, intervention, and intervention*time interaction will be fit as fixed effects with primary focus on the contrast between the intervention and APC groups at 6 months post start of treatment period. The mixed model using both time points allows us to borrow information from the correlation between the time points for those workers with missing data on either time point. We will control for agency size since it will be a randomization stratification factor. We will use a similar approach to compare sleep quality, measured with the PSQI, between enrolled EMS workers at intervention agencies and enrolled workers at APC agencies. This analysis will use a linear mixed model (*assuming normality of these numeric outcomes*) controlling for baseline sleep quality and agency size. We will also report the intraclass correlation coefficients for fatigue and sleep quality to assess our assumptions for sample size analyses. Secondary analyses will adjust for EMS worker characteristics that are potentially imbalanced at baseline and have been shown to be associated with fatigue and sleep quality. Factors include, but are not limited to, years of experience, employment status, shifts per month, number of patients seen during shift, shift length, health status and number of medical conditions.

Research activities:
We will begin recruitment of EMS agencies by disseminating the Study Flyers (and the video-based study flyer) to various EMS agency contacts (e.g., the National Association of State EMS Officials email lists, the National EMS Management Association email lists, the National Association of EMS Physicians email lists, and with other organizations).

We will screen EMS agencies that respond to the study flyer for eligibility using a telephone-based (or via email) screening procedure.

If the initial communication comes from an individual EMS clinician NOT affiliated with an agency that reaches out to us, we will still allow this individual to participate in our study, yet we will not communicate with the agency director unless he/she wishes to communicate with us. In this situation, we may likely have multiple "clusters" with just one participant in it. The individual who decided to sign up for this study is participating as an individual and consenting to participate as an individual.

Next, we will execute / perform our randomization procedure which will determine if the agency (cluster) will be in the Intervention (Sleep/Fatigue) study group/arm or the Active Placebo Control (Teamwork) study group/arm. Once we know the agency's group assignment, we will ask EMS agency administrators to share study flyers (paper and video) with the employees. These study flyers will instruct the individuals within the EMS agency to visit the study designated website (www.saftie.pitt.edu) and follow steps for screening for eligibility. If the individual is eligible, he/she will be instructed to follow steps for enrollment.

All enrollment procedures for individual EMS clinician participants will take place on the

study designated website. First, persons who screened-in will be taken to the video consent webpage. Once there, the video consent will play and the individual will have a decision to make regarding participation. He/she will either click on one of two options: [1] I have watched the informed consent video and agree to participate (I ACCEPT) or [2] I DO NOT ACCEPT and do NOT want to participate in this research study.

Those who ACCEPT are then taken to a webpage where they type in the name of their EMS agency, their name, their cellular telephone number, and an email address. Our study tool will have a database of enrolled EMS agencies (clusters). When an individual types in the agency name, the information is verified in real-time and those who are affiliated with an agency in the system will be allowed to proceed. Those who type in an agency not verified will receive an error message and be directed to contact the study coordinator. The email and cellular telephone number are used to [1] get the individual registered in the automated texting platform developed by our research team; and [2] to email the individual a paper-based copy of the consent form and his/her temporary password for the study website. If an individual EMS clinician who is eligible, wants to participate, yet is unaffiliated with an agency in our database - our study coordinator will provide him/her with information that will allow them to move past this phase of the enrollment procedures. This information will be the name of their agency which will be obtained from the individual when he/she expressed interest in participation. We capture this information so that if additional individuals from the same agency want to enroll, they are then assigned to the same cluster (agency). This is important for purposes of analysis of clustered data.

Next, the individual will receive multiple welcome text messages that say: "Welcome to SaFTiE, the Sleep and Teamwork in EMS Study. You should receive an email with your password and instructions very soon."
"You can expect 3-11 questions at the start, end and every four hours of your registered shifts. You will get 8 questions each day off, as well."
"If you received this text message in error or ever want to end these messages, text "STOP". To get contact and study information text HELP at any time." "REMEMBER: DON'T TEXT WHILE DRIVING" "Download the SaFTiE app and use this as your CODE NUMBER: ####"

Next, the individual will check his/her email and obtain the temporary password and then visit the study website to sign-in (at www.saftie.pitt.edu). The participant will enter in a cellular phone number and temporary password. The participant will then follow a few steps to set a permanent (self-selected) password. The participant will then login again with the new password.

Next, the participant will use the CODE NUMBER sent via text message to download the SaFTiE app from the Apple Appstore or the GooglePlay store. The participant will enter in the CODE NUMBER - which allows for use of the SaFTiE app. No one can use the SaFTiE app without a valid code number. Each code number is created in real-time when a participant enrolls and is assigned a study ID# upon enrollment/consent.

When the SaFTiE mobile app is successfully downloaded, the participant will enter in a mailing address in the My Info section of the app - which is used for sending our remuneration. The participant will then be directed to the Surveys component of the SaFTiE mobile app to answer survey questions. After the survey questions are answered, the participant can view the other components of the app at any time. The app will send out reminders to fill out the Weekly Goals component on Saturday or Sunday of each week. The SaFTiE mobile app will also send out reminders to complete the monthly surveys to earn remuneration. The SaFTiE mobile app will also notify the participant when a new video story/interview has been posted / uploaded to the Stories component of the app. All participants will be asked to remain in the study using the app for a total of 6 months after downloading.

After the SaFTiE mobile app has been downloaded, each participant will be sent a variety of text message questions. Participants assigned to the intervention group will receive text-message queries for 7 consecutive days, followed by three weeks with no text-message queries. This pattern (one week on, three weeks off) is repeated for six months - and overlap with the timeline for use of the SaFTiE mobile app. The content of the text messages for those in the Intervention group is focused on fatigue and sleep. If a participant reports a high level of fatigue, sleepiness, or difficulty with concentration, he/she will immediately receive a fatigue-mitigation strategy message via text-message. These strategy messages will be pulled from a "bank" of messages based on the domains of the Sleep, Fatigue, and Alertness Behavior (SFAB) survey, which is administered to participants at baseline, at 3 months, and again at the 6 month follow up.

Participants in the active placebo group (Teamwork group) will also receive text-messages in the same format and timing as the intervention group (one week on, followed by three weeks off). The timing of text messages is like the Intervention group. The main difference between the two groups is the content of the text-messages. The content for the active placebo group is focused on teamwork. If a participant in the active placebo group reports a low level of teamwork when queried via text-message, the participant will immediately receive a teamwork promoting message pulled from a "bank" of messages that our computer platform will select from at random and automatically. These messages are NOT informed by any particular response to the SFAB survey. This is one key difference between the Intervention and Active Placebo groups.

All participants (in both groups) will be asked to answer survey questions via the SaFTiE mobile app once each month. Questions will be like those asked at baseline. Participants will be remunerated monthly for their participation.

At the end of calendar year 2021 and 2022 and 2023, we will send a letter to each agency contact (the agency Chief, Director, or Manager) and request a summary of their OSHA300 logs (agency-level injury data) be abstracted into a table.

We will mail a letter to all agency contacts in July/August 2023 notifying the contacts

that the study will be closed to NEW enrollments but remains active for data collection from all active participants until their end date has been reached.

Consent procedures

Waiver to document written / signed consent form approved.

All potential participants will view a video-based consent made available on the study designated website. We will use a video-based consent procedure whereby the potential participants watch a video version of the consent form and make a decision to [1] I have watched the informed consent video and agree to participate (I ACCEPT) or [2] I DO NOT ACCEPT and do NOT want to participate in this research study. We are requesting a waiver to document informed consent for all study subjects because it will be obtained via video-based methods. Our study is nationwide, which makes it extremely difficult to obtain written consent from all participants. We will still obtain consent from the subjects to participate via video, which does not increase risk. The study involves text messages, a mobile app, and continuing education videos. None of these normally require written informed consent.

Minimize coercion and undue influence:
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.

Ensure understanding:
Our consent video will provide a detailed description of the study. Potential participants will again 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.

Data safety monitoring

We will regularly report on progress with recruitment, enrollment, data collection, and any unexpected issues to the Department of Emergency Medicine's Data Safety Monitoring Committee (DSMC). The DSMC will meet at least once per month.

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 only 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 will be restricted to core members of the research team.

This research study is also covered by a Certificate of Confidentiality (CoC) from the Centers for Disease Control and Prevention (CDC). The researchers with this Certificate may not disclose or use information, documents, or data that may identify the participant in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless the participant has consented for this use. Information, documents, or data protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child above or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings); if the participant has consented to the disclosure, including for his/her medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Upon completion of this research study, we will de-identify all data, expunge all files that contain mailing addresses used for remuneration, and add a new randomly generated ID number to all records. All previously used ID numbers will be removed, therefore creating a new dataset with a new randomly generated ID assignment for each record. We will publish the study findings in aggregate in peer-reviewed medical journals. We will do everything possible to protect the participant's privacy.

Termination, withdrawal, or attrition

If a participant has not responded to study related text queries, or monthly surveys over multiple months, the study team will attempt to contact the participant to determine if he/she is still participating. The PI and co-investigators will meet to discuss these cases and make a group / consensus decision to classify the participant as withdrawn OR to continue attempts to reestablish communication over a specified period of time (e.g., up to a one month). If the team's attempts to contact the participant are unsuccessful, the team will monitor activity for one additional month, and if at that time there is no communication, 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. That email will [1] acknowledge the participant's withdrawal; [2] thank the participant for his/her time commitment to the study prior 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.