The Emergency Medical Services Sleep Health Study

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16. Abstract

While fatigue and poor sleep quality affect greater than half of emergency medical services (EMS) clinicians, there is no known standard for educating and training. The research team created the Fatigue Education Program for Emergency Medical Services, comprised of 10 brief education modules and based on recommendations from the American College of Occupational Environmental Medicine. The primary aim of this study was to determine if providing education and training to EMS personnel on the importance of sleep health and dangers of fatigue improves indicators of sleep quality and fatigue. The researchers used a pragmatic, cluster-randomized, wait-list control, 6-month study design. The primary outcome was the Pittsburgh sleep quality index-measured sleep quality at 3- and 6-month follow-ups. Intention-to-treat analyses revealed no differences between the intervention and comparison groups in mean sleep quality scores at 3- and 6-month follow-ups. Per protocol analyses showed that the greater the number of modules viewed, compared to no viewings, the greater the improvement in sleep quality and greater the reduction in fatigue. The largest improvement in sleep quality was observed among EMS clinicians who viewed eight to 10 education modules. Given these findings, the Fatigue Education Program for Emergency Medical Services may be a useful resource for EMS administrators who aim to fulfill the 2018 evidence-based guideline (EBG) recommendation of educating and training EMS workers on sleep and fatigue, which was one of the five EBGs developed and released in an earlier phase of this project.

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List of Acronyms

ACOEM	American College of Occupational Environmental Medicine
AEMT	advanced emergency medical technician
CAPCE	Commission on Accreditation for Prehospital Continuing Education
CCP-C	certified critical care paramedic
CFQ	Chalder fatigue questionnaire
CY	calendar year
EBG	evidence-based guideline
ED	emergency department
EMR	emergency medical responder
EMS	emergency medical services
EMS-SAQ	emergency medical services safety attitudes questionnaire
EMT	emergency medical technician
ESS	Epworth sleepiness scale
IAI	immediate access to intervention
ICU	intensive care unit
IRB	institutional review board
FP-C	flight paramedic - certified
LMS	learning management system
LTFU	lost to follow-up
NASEMSO	National Association of State EMS Officials
NEMSAC	National EMS Advisory Council
OFER	occupational fatigue, exhaustion, and recovery scale
OMB	Office of Management and Budget
PHRN	prehospital registered nurse
PSQI	Pittsburgh sleep quality index
SAS^	schedule attitudes survey[1]
SD	standard deviation
WHO	World Health Organization
WLC	wait-list control

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[1] Not to be confused with the SAS software, short for Statistical Analysis System, which is capitalized as a brand name.

Executive Summary

Fatigue and poor sleep quality affect greater than half of emergency medical services clinicians. The type of work performed and need to work in shifts disrupt the normal circadian pattern of wake during the day and sleeping at night. Previous research shows that targeted and tailored education and training on sleep health and fatigue can have a positive effect on sleep quality. Unfortunately, there is no known gold standard or existing program tailored to EMS first responders. In this study, the research team created a 10-module education program based on recommendations from the American College of Occupational Environmental Medicine Task Force on Fatigue Risk Management. The new program is referred to as the Fatigue Education Program for Emergency Medical Services and was created to provide EMS clinician shift workers with information on topics of sleep physiology, the hazards of fatigue, sleep disorders, the importance of diet and exercise, and other topics. The primary aim of this experimental research study was to determine whether providing education and training to EMS personnel on the importance of sleep health and dangers of fatigue improves indicators of sleep quality and fatigue. The research team used a pragmatic, cluster-randomized, wait-list control study design. The total duration of participation was 6 months. The primary outcome of interest was the Pittsburgh sleep quality index-measured sleep quality at 3- and 6-month follow-ups. From March to December 2020, the team enrolled 678 individual EMS clinicians from 36 EMS agencies. Intention-to-treat analyses revealed no differences between the intervention and comparison groups in mean sleep quality scores at 3- and 6-month follow-ups. However, per protocol analyses showed that the greater the number of modules viewed, compared to no module viewings, the greater the improvement in sleep quality and the greater the reduction in fatigue. The team observed the largest improvement in sleep quality among EMS clinicians that viewed 8 to 10 education modules. Given these findings, the Fatigue Education Program for Emergency Medical Services may be a useful resource for EMS administrators that aim to fulfill the 2018 evidence-based guideline recommendation of educating and training EMS workers on the importance of sleep health and fatigue mitigation, which was one of the five EBGs developed and released in an earlier phase of this project (the findings are less applicable to the remaining four EBGs).

Background

Emergency Medical Services

In the United States the EMS system is comprised of more than 20,000 EMS agencies and approximately 1 million EMS clinicians (National Association of State EMS Officials, 2020). These agencies and clinicians respond to unscheduled emergencies outside of the hospital setting 24 hours a day, 365 days a year. They are on the frontline of healthcare and public safety. Those who work in EMS provide time-sensitive medical care for the acutely ill and injured, stabilize patients, and quickly transport and transfer patients to hospital emergency departments. In addition, many aid the ill or infirmed with non-emergent transport between facilities. Ambulance transports to the nation's hospital EDs represent approximately 16% of annual ED volume (Cairns et al., 2021).

The types of EMS agencies that serve the public vary significantly across communities. Some are combined with fire services, which may require EMS clinicians to be certified in firefighting, technical rescue, and emergency medical care. Other EMS agencies are stand-alone operations and task their employees primarily with medical care responsibilities. Agencies staffed by a mix of paid and volunteer EMS clinicians or by an all-volunteer roster are more common in rural than urban areas.

Frontline EMS clinicians vary in terms of certification or licensure. An EMS clinician may be certified or licensed by their state of residence at the level of an emergency medical responder, an EMR; emergency medical technician, an EMT; advanced emergency medical technician, an AEMT; or a paramedic. Many people obtain nationally recognized certifications. An EMS agency that provides critical care services will often employ clinicians with flight-paramedic-certified, certified critical care paramedic, or prehospital registered nurse levels of training and certification.

Given that EMS care is provided 24 hours a day, EMS clinicians are deployed in shifts. Shift work refers to work scheduling arrangements outside of a traditional daylight work schedule of 9 a.m. to 5 p.m. (Sallinen & Kecklund, 2010). Shift work in EMS agencies includes night shifts and long duration shifts such as 12 hours, 24 hours, and, in some locations, shifts that are 48 hours or longer (Patterson, Runyon, et al., 2018). In addition, many EMS clinicians work back-to-back shifts, overtime hours, or at several EMS jobs (Patterson, Buysse, Weaver, Callaway, et al., 2015).

Fatigue in EMS

Large numbers of EMS personnel report poor sleep quality and mental and physical fatigue (Patterson, Buysse, Weaver, Doman, et al., 2015; Patterson et al., 2019; Patterson, Suffoletto, et al., 2010; Patterson et al., 2012; Patterson, Weaver, et al., 2015). More than half have reported poor sleep quality, and half have reported inadequate recovery between scheduled shifts (Patterson, Weaver, et al., 2015). Fatigue among EMS clinicians is associated with increased odds of injury, patient-related medical errors and adverse events, and workplace injury (Patterson et al., 2012).

The shift work scheduling required of EMS clinicians is one of several factors that contributes to high levels of work-related fatigue and poor sleep health (Patterson, Weaver, et al., 2015). Shift work disrupts the normal cycle of sleeping at night and the ability to maintain wakefulness

during daylight hours. The shift work arrangements used by EMS agencies include night shifts, long duration shifts, and shifts that rotate between daylight and nighttime hours (Patterson, Runyon, et al., 2018). This pattern of work inhibits many EMS personnel from obtaining adequate sleep (e.g., 7 to 8 hours per night), prevents EMS personnel from having a regular bedtime and wake time, and interferes with a person's ability to obtain sleep that is restful and satisfying (Drake et al., 2004; Shockey & Wheaton, 2017). Sleep that is regular, satisfying, efficient, and of adequate duration are all key components of sleep health and sleep quality (Buysse, 2014; Buysse et al., 1989). Interference with one or more of these components of sleep can lead to mental and physical fatigue. High levels of fatigue can, in turn, contribute to negative outcomes (Patterson et al., 2012).

The Fatigue in EMS Systems Project

Efforts to mitigate workplace fatigue in EMS have been limited. However, in 2013 the National EMS Advisory Council recommended that the National Highway Traffic Safety Administration examine the evidence germane to fatigue risk mitigation and disseminate that information to EMS leadership and administration (see www.ems.gov). In response, in 2015 NHTSA awarded a contract to NASEMSO, in partnership with the University of Pittsburgh and Institute for Behavior Resources, Inc., to complete a project targeting fatigue in EMS systems. In this project NHTSA focuses on the mitigation of fatigue for EMS systems, which enhances post-crash care by better ensuring that EMS professionals safely arrive on the scene of crashes and provide medical care that results in less treatment errors. This project has practical implications as, according to the National EMS Information System (NEMSIS) Technical Assistance Center (2022), some 12,000 EMS agencies responded to more than 1.4 million motor vehicle crashes in 2021. In addition, mitigating fatigue is particularly important for emergency vehicle drivers because fatigue associated with long shift hours negatively affects driving performance (Hsiao et al., 2018).

The project was divided into three phases. Phase 1 was designed to create EBGs focused on fatigue risk mitigation and tailored to the unique occupational demands and risks encountered by shift workers in the EMS setting. The results of Phase 1 included five EBGs for fatigue risk mitigation in the EMS setting, published in 2018 in a special issue of *Prehospital Emergency Care* (Patterson, Higgins, et al., 2018). Phase 2 was designed to experimentally test a minimum of one of the EBG recommendations that resulted from Phase 1. The EBG selected for testing was "*EMS personnel should receive education and training to mitigate fatigue and fatigue-related risks.*" Phase 3 focused on tailoring an existing biomathematical model to be applicable to EMS shift scheduling. Biomathematical models are frequently used in high-risk industries, such as aviation, to inform the timing, duration, rotation, and recovery periods of shift schedules (Dawson et al., 2011).

Study Aims and Hypothesis

This report presents Phase 2 findings. The primary aim of Phase 2 was to determine, in an experimental research study, if providing education and training to EMS personnel on the importance of sleep health and dangers of fatigue improves indicators of sleep quality and fatigue. Researchers hypothesized that education and training focused on sleep health and fatigue, delivered in an asynchronous manner and tailored to EMS shift workers, would lead to

improvements in sleep quality and a reduction in self-reported fatigue after the 3-month study interval.

Methods

The researchers used a pragmatic, cluster-randomized, wait-list control study design to evaluate the effect of a novel education and training program tailored to EMS clinician shift workers. Wait-list designs are widely used in sleep-related education-focused intervention studies (Murawski et al., 2018). The protocol for this study received approval from the University of Pittsburgh Institutional Review Board, was reviewed and approved by the Office of Management and Budget (Control Number: 2127-0742; ICR Reference Number: 201811-2127-003), and registered on ClinicalTrials.gov (NLM Identifier: NCT04218279). The study methods and findings from this trial are reported in accordance with the CONSORT 2010 statement, extended to cluster randomized trials (Campbell et al., 2012).

Experimental Trial Design

In this study randomization occurs at the agency level, with participants assigned to one of two groups: (1) the immediate access to intervention group, or (2) the wait-list control group. A statistical cluster was defined as an EMS agency. Participants in each cluster were assessed for eligibility, and, if screened as eligible, the people were asked to voluntarily enroll in the study.

Agencies randomized to the IAI group received immediate access to the intervention material via a secure, password-protected study-specific website. Agencies randomized to the WLC group crossed over at 3 months post-randomization and gained access to the intervention materials for a total of 3 months (6 months of total participation).

Recruitment of participants in EMS agencies began post-randomization of the agency. People were given 30 days to voluntarily consent and enroll. The University of Pittsburgh granted a waiver from obtaining written consent; however, all people who signed up for the study viewed a video-based consent procedure and documented their understanding of the study protocol and willingness to voluntarily participate by clicking "I ACCEPT." Participants then created a unique username and password login to access the study website. The total duration of this research study was 6 months and all interactions between the study team, agency clusters, and participants were intentionally not in-person, i.e., they occurred via telephone, email, a secure online website, and mobile phone text messaging. It is unknown whether this lack of face-to-face interaction affected the study.

Setting

The targeted population of interest were EMS agencies and their frontline EMS clinician shift worker employees in the United States.

Participant Eligibility

The criteria for EMS agency eligibility included: (1) provided 911 response or transport in the United States; (2) provided ground-based EMS services 24-hours-a-day (agencies limited to air-medical services only were not eligible); (3) employed 50 or more paid staff (small agencies and agencies that used all-volunteer staffing were not eligible); and (4) did not restrict use of personal mobile phones/smartphones during shift work. An EMS clinician was eligible to participate if: (1) the candidate was 18 or older; (2) worked as an EMS clinician (not solely an

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administrator); (3) worked a minimum of one shift per week; (4) worked and resided in the United States; (5) worked at an EMS agency that agreed to participate in this study; (6) had a cellular, mobile/smartphone that was capable of sending and receiving text messages; and (7) was willing to answer online surveys and respond to text message queries for seven days in a row every third week of the month for 24 weeks (6 months).

Recruitment

The researchers recruited EMS agencies with one-page, paper-based flyers sent to professional EMS organizations (i.e., NASEMSO, National Association of EMS Physicians, National EMS Management Association, and others) with a request that it be shared with members. The organizations shared the flyers with popular EMS trade journals and news outlets and requested information about the study be included in news updates and stories posted on their websites. The instructions contained in the flyers guided EMS agency administrators to contact the study team. All who expressed interest were screened for eligibility. Eligible EMS agencies that agreed to participate were randomized and given instructions that would help the study team recruit participants from those agencies. Enrollment began in February 2020. Enrollment for agency EMS clinicians closed 30 days after agency randomization. Enrollment was paused from March 2020 to June 2020 due to the COVID-19 pandemic. Enrollment of all new EMS agencies closed on December 15, 2020.

Intervention

Recent systematic reviews of sleep health and fatigue programs show that there is no known gold standard or previously tested fatigue or sleep health education program tailored to EMS clinician shift workers (Barger et al., 2018; Murawski et al., 2018). For example, as described by Barger and colleagues, sleep health and fatigue programs can vary in terms of length of program, program delivery method (in-person or remote), and focus of the program (education, self-care, etc.). For this study, the researchers designed and produced the Fatigue Education Program for Emergency Medical Services. This program was comprised of 10 brief education modules formatted for hosting and distributing the material on a learning management system platform, a commonly used format for delivery and dissemination of EMS education and training.

The overall education program design and contents in each module were based on key principles for fatigue mitigation as outlined by the ACOEM's Task Force on Fatigue Risk Management (Lerman et al., 2012). The task force recommended that shift workers (in diverse occupational settings) be educated on the following:

(1) the hazards of working while fatigued;

(2) the impact of chronic fatigue;

(3) fatigue cannot be eliminated, yet it can be managed;

(4) adequate sleep is key to managing fatigue;

(5) basic sleep physiology;

(6) sleep hygiene/sleep health;

(7) sleep disorders;

(8) importance of diet, exercise, and stress management;

(9) fatigue recognition in oneself and coworkers;

(10) alertness strategies such as appropriate use of caffeine, rest or exercise breaks, and other strategies; and

(11) how to manage personal relationships for shift workers (Lerman et al., 2012).

The researchers tailored 10 education and training modules to be applicable to the EMS occupation. This was accomplished by first gathering scientific evidence from the published literature germane to the principles outlined by the ACOEM Task Force on Fatigue Risk Management. The evidence was then stratified into 10 specific module titles or topic areas that matched ACOEM recommendations:

(1) Hazards of Fatigue;

(2) Sleep Physiology;

(3) Sleep Health;

(4) Work-related Stress;

(5) Sleep Disorders;

(6) Fatigue Recognition;

(7) Adequate Sleep;

(8) Diet and Exercise;

(9) Alertness Strategies; and

(10) Managing Fatigue.

The researchers collated the published evidence into PowerPoint slides and arranged it into a narrative that would be of educational benefit and interest to frontline EMS clinicians. The research team performed in-depth interviews with EMS leaders, frontline EMS clinicians, and experts in sleep medicine. These recordings were edited and woven into the 10 education modules as complements to scientific evidence. Researchers then used a proprietary software program (Articulate360, New York, NY) to integrate the presentation slides, add voice-over narration and animation, and incorporate video interviews into a file format that could be hosted on an LMS platform. The research team aimed to keep the duration of each module brief, yet informative. The average duration of the 10 education modules was 13 minutes (minimum = 10 minutes, maximum = 16 minutes). During the study, access to the education modules was limited to those EMS agencies and people participating in this research study.

Procedures and Data Collection

Two online, mobile-enabled platforms collected the data. Platform 1 was a study-designated website managed by the University of Pittsburgh, where individual EMS clinician participants created unique logins, accessed cross-sectional surveys, and documented shift schedules during designated periods of text message assessments. Platform 2 was a text message system also managed by the University of Pittsburgh, which sends and receives standardized text message queries. The researchers used a communications platform service provider, Twilio, to expedite the text-based communication between Platform 2 and the study participants. The participants' shift schedules and a pre-defined interval of interaction informed the frequency of text message

queries. The pre-defined interval was set at 1 week of text message queries followed by 2 weeks with no queries. The intra-shift and inter-shift text messages adopted in this trial were informed by the protocols of two previous randomized trials (Patterson, Buysse, Weaver, Doman, et al., 2015; Patterson et al., 2014, 2017, 2019).

Participants used study website Platform 1 to document demographic information and respond to cross-sectional surveys immediately post-consent and enrollment, at 3 months and at 6 months. In addition to demographic information, participants used Platform 1 to complete the following questionnaires:

(1) the 21-item PSQI (Buysse et al., 1989);

(2) the 11-item Chalder fatigue questionnaire (Chalder et al., 1993);

(3) the 8-item Epworth sleepiness scale (Johns, 1991);

(4) the 30-item emergency medical services safety attitudes questionnaire (Patterson, Huang, Fairbanks, & Wang, 2010);

(5) five items from the schedule attitudes survey (Dunham & Pierce, 1986); and

(6) the 15-item occupational fatigue, exhaustion, and recovery scale (Winwood et al., 2005).

All surveys have been tested in diverse populations, shown to be reliable or valid, and have been used previously in studies that involved EMS clinician shift workers (Patterson, Buysse, Weaver, Callaway, et al., 2015; Patterson, Huang, Fairbanks, & Wang, 2010; Patterson et al., 2019; Patterson et al., 2012).

Participants were eligible for remuneration for participation in this research study, set at $5 dollars at enrollment and $5 dollars distributed each month of participation. In total, participants could earn up to $35 dollars for completing the study. All remuneration was distributed using a Visa card system operated by the University of Pittsburgh.

Outcomes

The primary outcome of interest was change in sleep quality at 3 months post-baseline as measured by the PSQI. The PSQI score ranges from 0 to 21 with lower scores indicating better sleep quality. Scores on the instrument greater than 5 are classified as poor sleep quality (Buysse et al., 1989). Previous research suggests that a 3-point decrease in the total PSQI score represents a clinically meaningful improvement in sleep quality (Buysse et al., 2011). Secondary outcomes of interest focused on changes in survey responses from baseline to 3 months and to 6 months for all survey measures, including the CFQ, ESS, EMS-SAQ, SAS^, and OFER. A clinically meaningful change in CFQ, a secondary outcome of interest, has not yet been defined.

Power Calculation (Sample Size)

This study was powered at 88% to detect a 0.4 standard deviation difference in mean PSQI score with 20 EMS agencies in each group (n=40 total clusters) and a minimum of 10 EMS clinicians per agency. With this level of enrollment, this study was powered at 90% to detect a 20% difference in self-reported fatigue as measured by the CFQ, assuming the WLC group had 50% reported prevalence of fatigue. Researchers conservatively assumed a 50% prevalence of fatigue for the WLC group as this results in the maximum variance for the test of proportions.

Preliminary data supported this power calculation (Patterson, Suffoletto, et al., 2010; Patterson et al., 2012; Patterson, Weaver, et al., 2015).

Randomization

Researchers randomized EMS agencies with a biased coin minimization procedure that accounted for the type and size of EMS agencies (Saghaei & Saghaei, 2011). This approach preserved allocation given that assignments were made adaptively as EMS agencies were enrolled with all research staff unaware of the probabilities of assignment, including those responsible for enrollment and intervention implementation.

Allocation Concealment Mechanism

The study team's senior statistician managed the treatment allocation until each EMS agency was determined eligible. When the administrators (e.g., chiefs, directors, or managers) of each EMS agency cluster were ready to implement the study protocol, the senior statistician sent the treatment allocation directly to the principal investigator and project coordinator via email, who then informed the EMS administrators of their status: either IAI or WLC group.

Implementation

The EMS agency clusters were separated according to strata based on agency type and size. Agency type was comprised of three strata: fire-based model, hospital-based/third-service model, and air-based/other type of EMS agency model. Agency size was divided into two strata: larger agencies with $\geq$300 employees versus smaller agencies with <300 employees.

Blinding

Researchers used an open-label study design. Blinding of participants and study team was not feasible, given the pragmatic nature of the study and implementation of the study protocol in the real-world setting. While blinding was not feasible, statisticians and data analysts were removed (not involved) in allocation or activities related to data collection of outcomes or secondary measures of interest.

Statistical Methods

The primary analysis followed intention to treat principles, which prescribes that all participants in a randomized trial that are included in the statistical analyses be examined according to the group to which they were originally assigned (Hernan & Hernandez-Diaz, 2012; Tripepi et al., 2020). The research team reported descriptive statistics without adjustment for agency-level clustering and used t-tests, tests of medians, chi-square tests, and Fisher's exact tests to examine differences in EMS agency (cluster) and participant characteristics by IAI and WLC group status. Hierarchical mixed effects models with random intercepts were used for hypothesis testing and to test the impact of the intervention on outcomes. With these models, the research team accounted for clustering at the agency level (nesting participants within their associated agencies), and the dependence between repeated measures at the participant level. The distribution of residuals was evaluated at each level of the models for linearity and heterogeneity. Formal tests and visual inspections indicated the models satisfied all necessary assumptions (e.g., normality, homoscedasticity, linearity). The research team checked for outliers and influential observations and sets of observations. In sub-group analyses, where appropriate, researchers

controlled for agency as a fixed effect in cases where it resulted in superior model fit. Comparisons conducted using agency-level fixed effects are noted in tables, figures, or in text where appropriate.

The research team defined "module views" as any amount of time watching an education module. Participants that viewed a module or modules in their entirety were considered "completed module viewing." Module viewing was stratified into 4 categories:

(1) No modules viewed;

(2) Low – with 1 to 3 modules viewed;

(3) Moderate – with 4 to 7 modules viewed; and

(4) High – with 8 to all 10 modules viewed.

The researchers performed per-protocol analyses to determine whether variation in exposure to the intervention materials was associated with a change in outcomes of interest (Hernan & Hernandez-Diaz, 2012; Tripepi et al., 2020). These analyses classified participants by their exposure to the education modules. The WLC group received access to the intervention at 3 months follow-up. Hierarchical mixed effects models were used to account for clustering at the agency level and the dependence between repeated measures at the participant level. The models characterize the relationship between exposure to the education module intervention and the outcomes of interest among those who engaged with the intervention and provided an outcome assessment after intervention exposure. The Bonferroni corrected p-value was reported when comparisons were implemented to test a hypothesis. All analyses were performed with the SAS statistical software version 9.4 (Cary, North Carolina).

Results

Of the 54 EMS agencies (clusters) screened, 48 were eligible and 36 were enrolled (Table 1, 2). The research team randomized 16 agencies to the IAI group and 20 to the WLC group. In total, 678 people completed the enrollment process (Table 3). Because of random assignment, four more agencies were assigned to the WLC group compared to the IAI group. Among IAI agencies, total individual enrollment was 316 compared to 362 for WLC agencies.

Table 1. CONSORT Flow Diagram

Enrollment	Assessed for eligibility (*n*=54 clusters)	
	Excluded (*n*=18 clusters)	
	- Not included because no response from agency leader after follow-up (*n*=11 clusters)	
	- Not included because agency has <50 paid employees (*n*=6 clusters)	
	- Chose not to participate (*n*=1 cluster)	
	Randomized (*n*=36 clusters)	
Allocation	Allocated to Intervention (IAI group) (*n*=16 clusters)	Allocated to waitlist control (WLC group) (*n*=20 clusters)
	n=316 people consented	*n*=362 people consented
	Mean (SD) cluster size = 20 (SD 16)	Mean (SD) cluster size = 18 (SD 13.3)
Follow-up (3 months)	IAI group	WLC group
	n=15 clusters	*n*=20 clusters
	n=211 people partially or fully completed the 3-month survey	*n*=225 people partially or fully completed the 3-month survey
	n=39 individual withdrawals	*n*=51 individual withdrawals
	n=12 people lost-to-follow-up (LTFU)	*n*=10 people lost-to-follow-up (LTFU)
	Mean (SD) withdrawals per cluster = 2.4 (SD 2.8)	Mean (SD) withdrawals per cluster = 1.6 (SD 3.0)
	Mean (SD) LTFU per cluster = 0.8 (SD 0.8)	Mean (SD) LTFU per cluster = 0.5 (SD 0.8)
Follow-up (6 months)	IAI group	WLC group
	n=15 clusters	*n*=20 clusters
	n=184 people partially or fully completed the 6-month survey	*n*=179 people partially or fully completed the 6-month survey
	From 3- to 6-month follow-up:	From 3- to 6-month follow-up:

	- *n*=22 individual withdrawals	- *n*=31 individual withdrawals
	- *n*=36 people LTFU	- *n*=51 people LTFU
	Mean (SD) withdrawals per cluster = 1.4 (SD 1.4)	Mean (SD) withdrawals per cluster = 1.6 (3.0)
	Mean (SD) LTFU per cluster = 2.3 (SD 1.8)	Mean (SD) LTFU per cluster = 2.6 (SD 2.8)
Analysis	IAI group Analyzed at 3 months: - *n*=15 clusters with a mean of 16.3 people (SD 13.6) per cluster Analyzed at 6 months: - *n*=15 clusters with a mean of 13.8 people (SD 11.3) per cluster Total clusters excluded (*n*=1) Reasons for exclusion: All participants in cluster withdrew or were LTFU	WLC group Analyzed at 3 months: - *n*=20 clusters with a mean of 14.8 people (SD 11.3) per cluster Analyzed at 6 months: - *n*=20 clusters with a mean of 11.0 people (SD 8.0) per cluster Total clusters excluded (*n*=0) Reasons for exclusion: None

Note: Some analyses and sample sizes reported in the document will involve IAI and WLC group sample sizes that differ slightly from the totals for 3-month and 6-month survey follow-up reported in this figure. These small differences are due to the fact that some participants did not complete the 3-month or 6-month follow-up, but were still considered active given responses to other study-related assessments (i.e., text message queries), and given that some participants partially (or fully) completed the baseline survey, 3-month survey, and/or 6-month survey.

Table 2. Agency Demographics by Study Group

Variable	All agencies	IAI group	WLC group	P-value
Agency type				
Fire-based	12 (33.3%)	5 (31.3%)	7 (35.0%)	0.13[#]
Third-service	7 (19.4%)	1 (6.3%)	6 (30.0%)	
Air/ground combination	2 (5.6%)	0 (0.0%)	2 (10.0%)	
Hospital-based	7 (19.4%)	5 (31.3%)	2 (10.0%)	
Other[&]	8 (22.2%)	5 (31.3%)	3 (15.0%)	
Census region				
Mid-west	12 (33.3%)	7 (43.8%)	5 (25.0%)	0.38[#]
Northeast	5 (13.9%)	3 (18.8%)	2 (10.0%)	
South	12 (33.3%)	3 (18.8%)	9 (45.0%)	
West	7 (19.4%)	3 (18.8%)	4 (20.0%)	

Paid employees (full-time and part-time)				
51-99	10 (27.8%)	5 (31.3%)	5 (25.0%)	0.47[#]
100-199	11 (30.6%)	4 (25.0%)	7 (35.0%)	
200-299	2 (5.6%)	2 (12.5%)	0 (0.0%)	
300+	13 (36.1%)	5 (31.3%)	8 (40.0%)	
Paid employees (full-time and part-time)				
Smaller (<300)	23 (63.9%)	11 (68.8%)	12 (60.0%)	0.59^
Larger (≥300)	13 (36.1%)	5 (31.3%)	8 (40.0%)	
Total dispatch calendar year 2019				
<10,000	6 (16.7%)	3 (18.8%)	3 (15.0%)	
10,000-19,999	8 (22.2%)	3 (18.8%)	5 (25.0%)	0.83[#]
20,000-49,999	11 (30.6%)	4 (25.00%)	7 (35.0%)	
50,000+	11 (30.6%)	6 (37.5%)	5 (25.0%)	
Total transports CY 2019				
<10,000	9 (25.0%)	4 (25.0%)	5 (25.0%)	
10,000-19,999	12 (33.3%)	4 (25.0%)	8 (40.0%)	0.47[#]
20,000-49,999	7 (19.4%)	5 (31.3%)	2 (10.0%)	
50,000+	8 (22.2%)	3 (18.8%)	5 (25.0%)	
Formal fatigue program				
Yes	12 (33.3%)	6 (37.5%)	6 (30.0%)	0.63^
No	24 (66.7%)	10 (62.5%)	14 (70.0%)	
Total	**36 (100.0%)**	**16 (100.0%)**	**20 (100.0%)**	

Notes: [&]Other agency type includes non-profit and private agencies. ^The chi-square test was used for testing for group differences with categorical variables. [#]Fisher exact test was used in categorical variables with over 20% expected cell counts less than 5.

Table 3. Participant Baseline Demographics by Study Group

Variable	IAI	WLC	P-value
Sex			
Male	205 (67.9%)	255 (73.3%)	
Female	97 (32.1%)	92 (26.4%)	0.13[#]
Unknown	0 (0.0%)	1 (0.3%)	
Certification/license			
EMT-Basic	98 (32.5%)	112 (32.2%)	
Paramedic	187 (61.9%)	214 (61.5%)	0.85[#]
Nurse	5 (1.7%)	4 (1.1%)	
Other	12 (4.0%)	18 (5.2%)	
Where do most work as EMS clinician			
Air-medical-based EMS	7 (2.3%)	12 (3.4%)	
Hospital ED	17 (5.6%)	23 (6.6%)	
Ground-based EMS	241 (79.8%)	269 (77.3%)	0.74[^]
Hospital ICU	0 (0.0%)	1 (0.3%)	
Other	37 (12.3%)	43 (12.4%)	
Work several jobs			
Yes	90 (29.8%)	76 (21.8%)	**0.01**[^]
No	212 (70.2%)	272 (78.2%)	
Employment status			
Full-time	286 (94.7%)	338 (97.1%)	0.06[^]
Part-time	16 (5.3%)	10 (2.9%)	
Type of shift commonly worked			
24-hour	185 (61.5%)	231 (66.6%)	
12-hour	83 (27.6%)	79 (22.8%)	0.11[^]
8-hour	11 (3.7%)	4 (1.2%)	
Other	22 (7.3%)	33 (9.5%)	
Health			
Excellent	57 (18.9%)	92 (26.4%)	
Good	211 (69.9%)	223 (64.1%)	0.10[#]
Fair	33 (10.9%)	31 (8.9%)	
Poor	1 (0.3%)	2 (0.6%)	

Table 3 (cont.). Participant Baseline Demographics by Study Group

Variable	IAI	WLC	P-value
Race			
American Indian/Alaska Native	3 (1.0%)	7 (2.0%)	0.58#
Asian	0 (0.0%)	2 (0.6%)	
Black or African American	1 (0.3%)	4 (1.1%)	
White	284 (94.0%)	320 (92.0%)	
More than one race	8 (2.6%)	8 (2.3%)	
I prefer not to answer	6 (2.0%)	7 (2.0%)	
Ethnicity			
Hispanic or Latino	16 (5.3%)	18 (5.2%)	0.46^
Not Hispanic or Latino	274 (90.7%)	322 (92.5%)	
I prefer not to answer	12 (4.0%)	8 (2.3%)	
Young children at home			
Yes	155 (51.3%)	177 (50.9%)	0.45^
No	147 (48.7%)	171 (49.1%)	
Sleep disorders			
Yes	77 (20.5%)	76 (19.5%)	0.33^
None	240 (79.5%)	280 (80.5%)	
Proportion of participants with conditions			
Arthritis	0.07	0.06	0.22^
Depression	0.17	0.16	0.29^
Weight problems	0.22	0.20	0.28^
Diabetes	0.07	0.05	0.13^
High blood pressure	0.24	0.17	**0.01^**
Sleep apnea	0.14	0.12	0.25^
Migraine headaches	0.11	0.06	**0.02^**
Lung/breathing problems	0.06	0.05	0.22^
Heart problems	0.05	0.03	0.06^
Other	0.09	0.12	0.14^
None	0.41	0.47	0.05^
Participant demographic means (± SD)			
Height (in)	69 (3.7)	70 (3.7)	**0.00**
Weight (lbs)	208 (49.2)	201 (45.9)	0.06
Years of experience	15 (9.6)	13 (8.7)	**0.00**
Number of shifts worked last month	13 (6.7)	12 (4.7)	0.16
Alcoholic drinks (per week)	5 (6.4)	4 (4.9)	0.08
Cigarettes (per week)	2 (15.1)	3 (16.1)	0.41
Age (years)	39 (9.6)	37 (10.1)	**0.00**

Table 3 (cont.). Participant Baseline Demographics by Study Group

Variable	IAI	WLC	P-value
Baseline survey means (± SD)			
PSQI	8.8 (3.3)	9.0 (3.6)	0.26
Proportion with poor sleep	0.82	0.84	0.56
CFQ	6.6 (2.6)	6.6 (2.8)	0.37
Proportion with severe fatigue	0.88	0.84	0.09
ESS	8.7 (4.2)	8.0 (4.0)	**0.03**
SAS^	44.2 (26.5)	43.0 (22.5)	0.33
OFER - Chronic fatigue	35.8 (25.3)	36.3 (25.5)	0.42
OFER - Acute fatigue	60.4 (22.5)	60.1 (23.2)	0.39
OFER - Intershift recovery	47.8 (25.1)	48.9 (25.4)	0.29
EMS-SAQ - Teamwork climate	69.9 (20.9)	68.6 (22.3)	0.32
EMS-SAQ - Safety climate	72.2 (19.5)	73.3 (20.6)	0.14
EMS-SAQ - Stress recognition	56.4 (21.9)	59.5 (24.4)	**0.02**
EMS-SAQ - Perceptions of management	60.8 (24.8)	56.9 (23.6)	**0.01**
EMS-SAQ - Working conditions	65.2 (22.7)	64.0 (23.0)	0.32
EMS-SAQ - Job satisfaction	73.1 (22.7)	71.7 (23.2)	0.19
Subtotal	302 (100.0%)	348 (100.0%)	
Missing (non-response)	14	14	
Total	316	362	

Notes: ^The chi-square test was used for testing for group differences with categorical variables. #Fisher exact test was used in categorical variables with over 20% expected cell counts less than 5. The differences in continuous variables were tested using the Mann-Whitney U test. *p*-value <0.05 indicated in **bold**.

Baseline Data

Among the 36 agencies enrolled, the most common type of agency was fire-based (33%; Table 2). Most of the enrolled EMS agencies employed 51 to 199 employees (58%), reported 20,000 or more dispatches in calendar year 2019 (61%), and did not have formal fatigue risk management programs in 2019 (67%; Table 2). Following randomization, EMS agencies did not differ by agency type, census region, number of paid employees, total dispatches or transports in 2019, or by the presence or absence of a formal fatigue risk management program (*p*>0.05; Table 2).

Of the 678 EMS clinicians enrolled, 650 (96%) completed part or all the baseline survey. In total, 640 (94%) completed the entire baseline survey. The characteristics of participants in the IAI group and the WLC group did not differ by sex, certification/licensure, employment status, type of shift most commonly worked, health status, race, ethnicity, presence of young children at home, and other factors captured at baseline. However, they did differ in the proportion who hold several jobs (*p*=0.01). Statistical differences between groups at baseline were detected for select demographic characteristics (See Table 3). These included: participant height (1 inch difference), experience (2 years difference), age (2 years difference), and prevalence of high blood pressure and migraine headaches.

With respect to baseline measures of the primary and secondary outcomes, the mean score on the ESS at baseline was higher among participants in the IAI group than the WLC group (p=0.03). Participants also answered items from the EMS-SAQ, which is one of several survey instruments that measure organizational safety culture in healthcare organizations (Patterson, Huang, Fairbanks, & Wang, 2010). The 30-core items of the EMS-SAQ measure six domains of safety culture: safety climate, teamwork climate, job satisfaction, working conditions, stress recognition, and perceptions of management. Scores for each domain range from 0 to 100, with mean scores greater than or equal to 75 indicating a positive perception of the domain measured. The findings reported in Table 3, suggest that, on average, many personnel in both the IAI and WLC groups have a non-positive perception of organizational safety culture across domains as measured by the EMS-SAQ. At baseline, the mean score on the stress recognition domain of the EMS-SAQ was lower in the IAI group compared to the WLC group, and the mean score on the perceptions of management domain of the EMS-SAQ was higher in the IAI group than the WLC group (p<0.05; Table 3). These findings are similar to previous studies, which reveal wide variation in EMS-SAQ scores across EMS agencies (Patterson, Huang, Fairbanks, Simeone, et al., 2010).

Numbers Analyzed (Participation and Attrition)

Over the 6-month study period, 142 participants voluntarily withdrew, and 109 participants were classified as LTFU (Table 4). During the first 3 months of follow-up, 42 participants (13% of all IAI participants enrolled) voluntarily withdrew from the study versus 56 from the WLC group (16% of all WLC participants enrolled). During the first 3 months, among the IAI group, 13 participants were classified as LTFU (4% of all IAI participants enrolled) versus 10 participants in the WLC group (3% of all WLC participants enrolled). When considering the full 6-month study period, among the IAI group, 61 participants withdrew (19% of the total IAI group enrolled) versus 81 people in the WLC group (22% of the total WLC group enrolled). During the full 6-months study period, 48 participants in the IAI group were classified as LTFU (15% of all IAI participants enrolled) versus 61 participants in the WLC group (17% of all WLC participants enrolled).

The rate of attrition (withdrawals and LTFU combined) during the first 3 months of the study was similar between the IAI group (17%) and the WLC group (18%, p=0.37). The rate of attrition during the first 3 months was highest among fire-based (20%) and third-service agencies (20%), agencies located in the Southern United States (20%), agencies with over 300 employees (21%), among people reporting full-time employment (16%) and among people who commonly worked 24-hour shifts (17%; See Tables 4 and 5). When considering the full 6-month study period, the WLC and IAI groups showed statistically similar rates of attrition (WLC=39%; IAI=35%; p=0.20). Attrition over the entire 6-month study period was highest among air-ground combined agencies (42%), agencies located in the Southern United States (39%), agencies with over 300 employees (41%), people with EMT-Basic certification/license (42%), people reporting full-time employment (35%), and people who commonly worked 24-hour shifts (38%; See Tables 4 and 5).

In Table 4 below, withdrawal refers to a participant who (1) opted to cancel all text message notifications; (2) selected the option to withdraw from the study website (emssleephealth.pitt.edu); or (3) requested to be withdrawn from the study. LTFU refers to a participant who (1) did not complete the baseline or 3-month survey, did not respond to text

messages for over 1-month, and did not respond to any attempts to contact by email or phone; or (2) did not respond to text messages for over 2 months, and did not respond to any attempts to contact by email or phone. Attrition in the first 3 months refers to a participant withdrawing or classified as LTFU during the first 12 weeks post-enrollment. The 6-month period is defined as the participant's enrollment date to end of study (6 months post-enrollment). Percentages in parentheses are based on the total participants in a category (row) as the denominator and represent row percentages.

Table 4. Withdrawals and Lost to Follow-Up by Agency Level Characteristics

Variable	Total	First 3 months			Full study period (6 months)		
		Withdraw + LTFU	LTFU	Withdraw	Withdraw + LTFU	LTFU	Withdraw
Intervention arm							
IAI Group	316 (100.0%)	55 (17.4%)	13 (4.1%)	42 (13.3%)	109 (34.5%)	48 (15.2%)	61 (19.3%)
WLC Group	362 (100.0%)	66 (18.2%)	10 (2.8%)	56 (15.5%)	142 (39.2%)	61 (16.9%)	81 (22.4%)
Agency type							
Fire-based	325 (100.0%)	65 (20.0%)	9 (2.8%)	56 (17.2%)	127 (39.1%)	46 (14.2%)	81 (24.9%)
Third-service*	123 (100.0%)	25 (20.3%)	5 (4.1%)	20 (16.3%)	48 (39.0%)	23 (18.7%)	25 (20.3%)
Air/ground combination	48 (100.0%)	7 (14.6%)	2 (4.2%)	5 (10.4%)	20 (41.7%)	9 (18.8%)	11 (22.9%)
Hospital-based	109 (100.0%)	17 (15.6%)	6 (5.5%)	11 (10.1%)	37 (33.9%)	18 (16.5%)	19 (17.4%)
Other	73 (100.0%)	7 (9.6%)	1 (1.4%)	6 (8.2%)	19 (26.0%)	13 (17.8%)	6 (8.2%)
Census Region							
Mid-West	194 (100.0%)	35 (18.0%)	11 (5.7%)	24 (12.4%)	71 (36.6%)	35 (18.0%)	36 (18.6%)
Northeast	116 (100.0%)	17 (14.7%)	4 (3.5%)	13 (11.2%)	38 (32.8%)	20 (17.2%)	18 (15.5%)
South	248 (100.0%)	49 (19.8%)	6 (2.4%)	43 (17.3%)	96 (38.7%)	39 (15.7%)	57 (23.0%)
West	120 (100.0%)	20 (16.7%)	2 (1.7%)	18 (15.0%)	46 (38.3%)	15 (12.5%)	31 (25.8%)

*Third-service involves an EMS agency that is neither police- nor fire-based (Gunderson, 2015).

Of the 36 EMS agencies enrolled in this study, 35 included at least one participant who completed the 3-month follow-up, and 35 EMS included at least one participant who completed the 6-month follow-up. Table 1 reports 15 clusters for the IAI group at 3 and 6 months due to the fact that people at one EMS agency were classified as active, given responses to text message queries, but did not complete the follow-up survey. For the primary comparison of interest (PSQI scores at baseline and at 3 months follow-up), data from 15 IAI assigned EMS agencies (210 participants) and 20 assigned WLC EMS agencies (225 participants) were available for analysis. For comparisons involving the 6-month follow-up period, data from 15 IAI assigned EMS

agencies (184 participants) and 20 assigned WLC EMS agencies (179 participants) were available for 6-month follow-up analyses.

Table 4 (cont.). Withdrawals and Lost to Follow-Up by Agency Level Characteristics

Variable	Total	First 3 months			Full study period (6 months)		
		Withdraw + LTFU	LTFU	Withdraw	Withdraw + LTFU	LTFU	Withdraw
	N	*N (%)*	*N (%)*	*N (%)*	*N (%)*	*N (%)*	*N (%)*
Total paid employees (full-time and part-time)							
Smaller (<300)	342 (100.0%)	51 (14.9%)	12 (3.5%)	39 (11.4%)	114 (33.3%)	57 (16.7%)	57 (16.7%)
Larger (≥300)	336 (100.0%)	70 (20.8%)	11 (3.3%)	59 (17.6%)	137 (40.7%)	52 (15.5%)	85 (25.3%)
Total dispatches CY 2019							
<10,000	71 (100.0%)	13 (18.3%)	6 (8.5%)	7 (9.9%)	29 (40.9%)	14 (19.7%)	15 (21.1%)
10,000-19,999	126 (100.0%)	20 (15.9%)	2 (1.6%)	18 (14.3%)	41 (32.5%)	18 (14.3%)	23 (18.3%)
20,000-50,000	221 (100.0%)	41 (18.6%)	5 (2.3%)	36 (16.3%)	92 (41.6%)	41 (18.6%)	51 (23.1%)
>50,000	260 (100.0%)	47 (18.1%)	10 (3.9%)	37 (14.2%)	89 (34.2%)	36 (13.9%)	53 (20.4%)
Total transports CY 2019							
<10,000	157 (100.0%)	31 (19.8%)	6 (3.8%)	25 (15.9%)	62 (39.5%)	27 (17.2%)	35 (22.3%)
10,000-19,000	220 (100.0%)	34 (15.5%)	4 (1.8%)	30 (13.6%)	81 (36.8%)	34 (15.5%)	47 (21.4%)
20,000-50,000	197 (100.0%)	37 (18.8%)	9 (4.6%)	28 (14.2%)	69 (35.0%)	32 (16.2%)	37 (18.8%)
>50,000	104 (100.0%)	19 (18.3%)	4 (3.9%)	15 (14.4%)	39 (37.5%)	16 (16.2%)	23 (22.1%)

Table 5. Withdrawals and Lost to Follow-Up by Individual Level Characteristics

		First 3 months			Full study period (6 months)		
Variable	**Total**	**Withdraw + LTFU**	**LTFU**	**Withdraw**	**Withdraw + LTFU**	**LTFU**	**Withdraw**
Intervention arm							
IAI group	316 (100.0%)	55 (17.4%)	13 (4.1%)	42 (13.3%)	109 (34.5%)	48 (15.2%)	61 (19.3%)
WLC group	362 (100.0%)	66 (18.2%)	10 (2.8%)	56 (15.5%)	142 (39.2%)	61 (16.9%)	81 (22.4%)
Age							
Average years	650 (SD)	36.8 (9.4)	34.5 (10.5)	37.2 (9.2)	36.4 (9.9)	34.8 (9.9)	37.6 (9.7)
Missing	28						
Sex							
Male	460 (100.0%)	75 (16.3%)	11 (2.4%)	64 (13.9%)	167 (36.3%)	73 (15.9%)	94 (20.4%)
Female	189 (100.0%)	23 (12.2%)	3 (1.6%)	20 (10.6%)	58 (30.7%)	24 (12.7%)	34 (18.0%)
Not specified	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	28						
Race							
White	605 (100.0%)	92 (15.2%)	13 (2.2%)	79 (13.1%)	208 (34.4%)	89 (14.7%)	119 (19.7%)
Black	5 (100.0%)	1 (20.0%)	0 (0.0%)	1 (20.0%)	2 (40.0%)	1 (20.0%)	1 (20.0%)
Asian	2 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (50.0%)	0 (0.0%)	1 (50.0%)
Mixed race	17 (100.0%)	2 (11.8%)	1 (5.9%)	1 (5.9%)	7 (41.2%)	4 (23.5%)	3 (17.7%)
American Indian/ Alaska Native	10 (100.0%)	2 (20.0%)	0 (0.0%)	2 (20.0%)	5 (50.0%)	3 (30.0%)	2 (20.0%)
Prefer not to say	13 (100.0%)	3 (23.1%)	0 (0.0%)	3 (23.1%)	4 (30.8%)	0 (0.0%)	4 (30.8%)
Missing	26						
Total	678						

Table 5 (cont.). Withdrawals and Lost to Follow-Up by Individual Level Characteristics

Variable	Total	First 3 months			Full study period (6 months)		
		Withdraw + LTFU	LTFU	Withdraw	Withdraw + LTFU	LTFU	Withdraw
Ethnicity							
Hispanic	35 (100.0%)	4 (11.4%)	1 (2.9%)	3 (5.7%)	12 (34.3%)	6 (17.1%)	6 (17.1%)
Non-Hispanic	596 (100.0%)	92 (15.4%)	13 (2.2%)	79 (13.3%)	209 (35.1%)	90 (15.1%)	119 (20.0%)
Prefer not to say	21 (100.0%)	4 (19.1%)	0 (0.0%)	4 (19.1%)	6 (28.6%)	1 (4.8%)	5 (23.8%)
Missing	26						
Certification/license							
Paramedic	401 (100.0%)	60 (15.0%)	7 (1.8%)	53 (13.2%)	126 (31.4%)	46 (11.5%)	80 (20.0%)
EMT-Basic	210 (100.0%)	33 (15.7%)	7 (1.8%)	26 (12.4%)	88 (41.9%)	48 (22.9%)	40 (19.1%)
Nurse	9 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (22.2%)	1 (11.1%)	1 (11.1%)
Other	30 (100.0%)	5 (16.7%)	0 (0.0%)	5 (16.7%)	9 (0.3%)	2 (6.7%)	7 (23.3%)
Missing	28						
Employment status							
Full-time	624 (100.0%)	97 (15.5%)	14 (2.2%)	83 (13.3%)	219 (35.1%)	93 (14.9%)	126 (20.2%)
Part-time	26 (100.0%)	1 (3.9%)	0 (0.0%)	1 (3.9%)	6 (23.1%)	4 (15.4%)	2 (7.7%)
Missing	28						
Types of shifts most commonly worked							
24-hour	416 (100.0%)	72 (17.3%)	10 (2.4%)	62 (14.9%)	156 (37.5%)	58 (13.9%)	98 (23.6%)
12-hour	162 (100.0%)	17 (10.5%)	2 (1.2%)	15 (9.3%)	53 (32.7%)	33 (20.4%)	20 (12.4%)
8-hour	15 (100.0%)	2 (13.3%)	0 (0.0%)	2 (13.3%)	4 (26.7%)	1 (6.7%)	3 (20.0%)
<8 hours	2 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other	55 (100.0%)	7 (12.7%)	2 (3.6%)	5 (9.1%)	12 (21.8%)	5 (9.1%)	7 (12.7%)
Missing	28						
Total	678						

Table 5 (cont.). Withdrawals and Lost to Follow-Up by Individual Level Characteristics

Variable	Total	First 3 months			Full study period (6 months)		
		Withdraw + LTFU	LTFU	Withdraw	Withdraw + LTFU	LTFU	Withdraw
Where do most work							
Ground-based EMS	510 (100.0%)	74 (13.1%)	13 (2.6%)	61 (12.0%)	175 (34.3%)	76 (14.9%)	99 (19.4%)
Air-medical	19 (100.0%)	1 (5.3%)	0 (0.0%)	1 (5.3%)	5 (26.3%)	3 (15.8%)	2 (10.5%)
Hospital ED	40 (100.0%)	8 (20.0%)	1 (7.1%)	7 (17.5%)	20 (50.0%)	11 (27.5%)	9 (22.5%)
Hospital ICU	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other	80 (100.0%)	15 (18.8%)	0 (0.0%)	15 (18.8%)	25 (31.3%)	7 (8.8%)	18 (22.5%)
Missing	28						
Health status							
Excellent	149 (100.0%)	25 (16.8%)	1 (0.7%)	24 (16.1%)	51 (34.2%)	16 (10.7%)	35 (23.5%)
Good	434 (100.0%)	59 (13.6%)	8 (1.8%)	51 (11.8%)	144 (33.2%)	67 (15.4%)	77 (17.7%)
Fair	64 (100.0%)	14 (21.9%)	5 (7.8%)	9 (14.1%)	28 (43.8%)	13 (20.3%)	15 (23.4%)
Poor	3 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)	1 (33.3%)	1 (33.3%)
Missing	28						
Several jobs							
Yes	166 (100.0%)	20 (12.1%)	3 (1.8%)	17 (10.2%)	51 (30.7%)	25 (15.1%)	26 (15.7%)
No	484 (100.0%)	78 (16.1%)	11 (2.3%)	67 (13.8%)	174 (36.0%)	72 (14.9%)	102 (21.1%)
Missing	28						
Young children at home							
Yes	333 (100.0%)	53 (15.9%)	7 (2.1%)	46 (12.5%)	115 (34.5%)	46 (13.8%)	69 (20.7%)
No	319 (100.0%)	47 (14.7%)	7 (2.1%)	40 (13.8%)	112 (35.1%)	51 (16.0%)	61 (19.1%)
Missing	26						
Total	678						

Primary Outcome (Intent-to-Treat Analyses)

In the intention-to-treat analysis of 3-month follow-up data, which refers to examining participant data based on their initial randomization status, the mean scores on the PSQI measure of sleep quality did not differ by IAI or WLC group status (p=0.74, IAI n=210, WLC n=225). The mean scores examined at 6 months follow-up, based again on the intent-to-treat approach, did not differ by IAI and WLC group status (p=0.80; IAI n=184, WLC n=179, See Figure 1). In addition, the proportion of participants with a PSQI score greater than 5, which is referred to as a "poor sleep quality score," did not differ by IAI or WLC group status at 3 months follow-up (p=0.86), or at 6 months follow-up (p=0.14; See Figure 2).
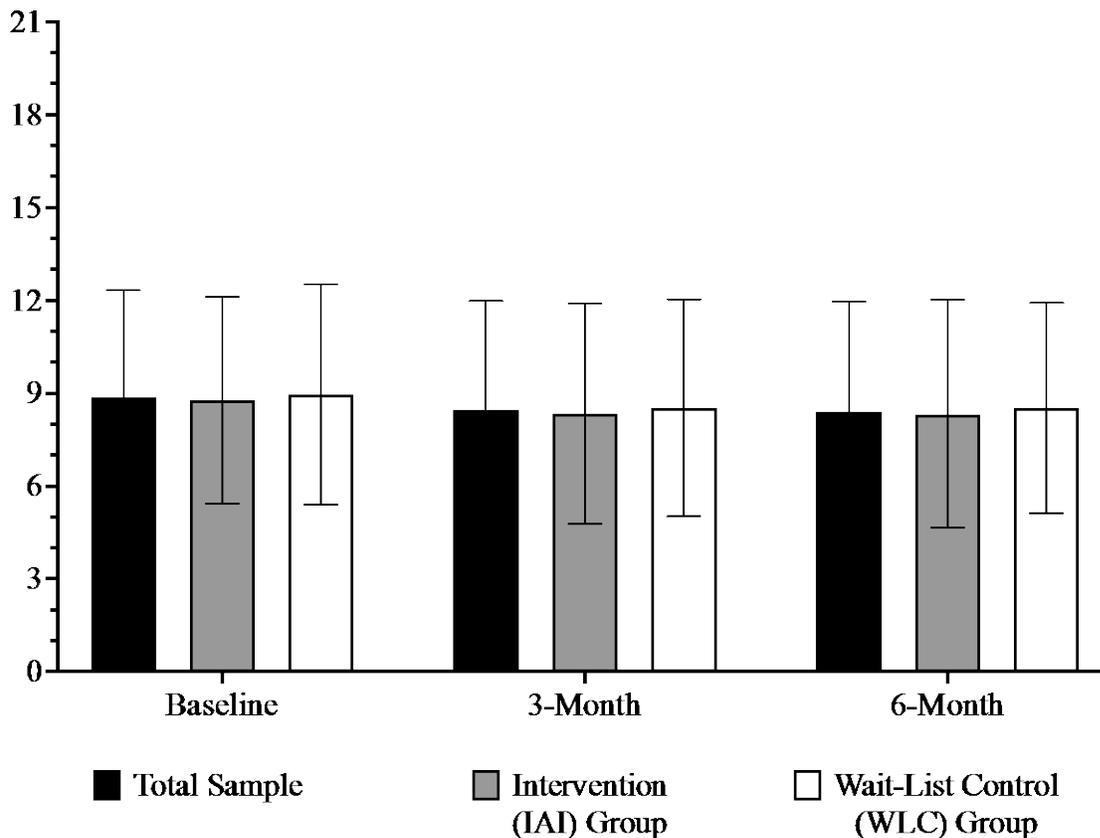
Figure 1. Mean PSQI Score at Baseline and Follow-Up
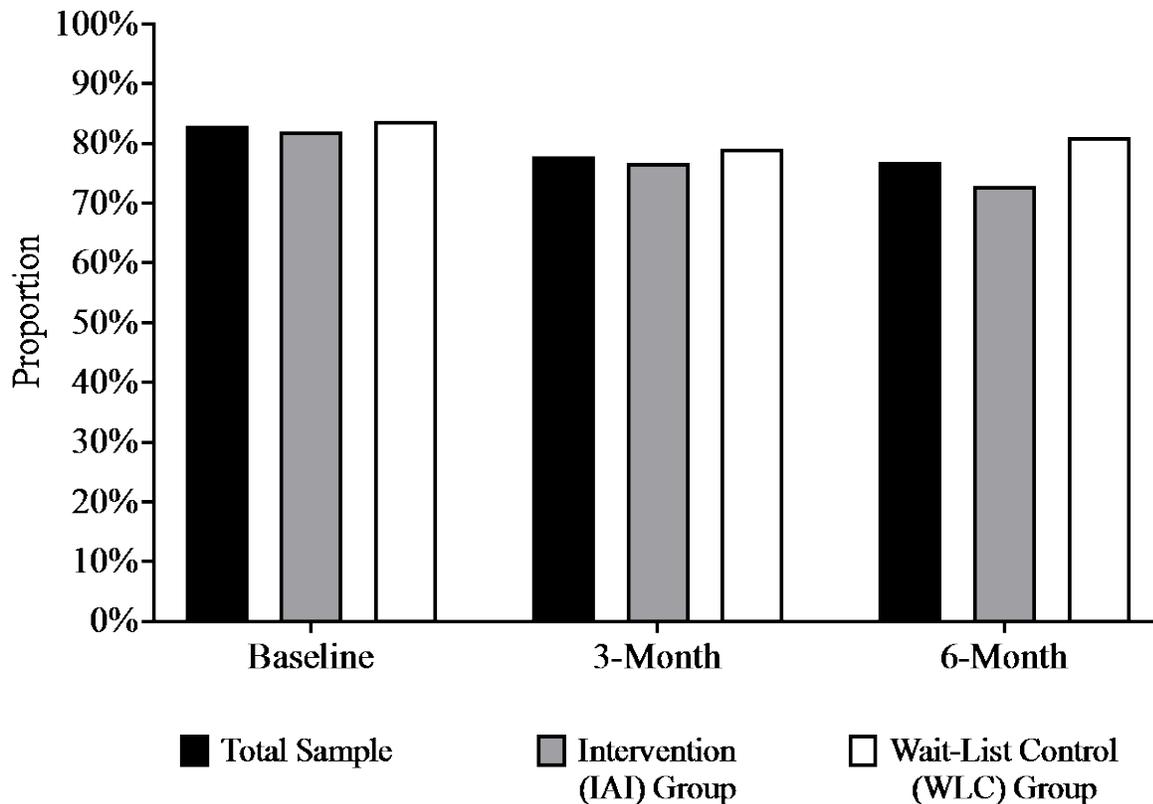
Figure 2. Proportion With Poor Sleep Quality at Baseline and Follow-Up

At 3-months follow-up, 19% (*n*=80) of all participants that completed the PSQI baseline and 3-month surveys (*n*=432) achieved a clinically meaningful improvement in the PSQI-measure of sleep quality (a decrease of 3 points on the PSQI; See Figure 3). At 3 months, the proportion that achieved this improvement did not differ by group status. Specifically, 19% of participants in the IAI group that completed the PSQI survey (*n*=40 out of *n*=209) achieved a clinically meaningful improvement in sleep quality (a decrease of 3 points on the PSQI), whereas the proportion in the WLC group was 18% (*n*=40 out of *n*=223; Figure 3; *p*=0.82). This analysis excluded three participants who did not complete the PSQI at baseline, which is needed to calculate improvement. At 6-months follow-up, and compared to baseline scores, 19% of study participants that completed the PSQI survey (*n*=69 out of *n*=362) achieved a clinically meaningful improvement in sleep quality. After adjusting for agency-level clustering, the proportion that achieved a clinically meaningful improvement in sleep quality did not differ by group status with 23% of participants in the IAI group (*n*=43 out of *n*=184) versus 15% in the WLC group (*n*=26 out of *n*=178) achieving a clinically meaningful improvement in sleep quality at the 0.10 level of statistical significance (Figure 3; *p*=0.07). This analysis excluded one participant who did not complete the baseline.
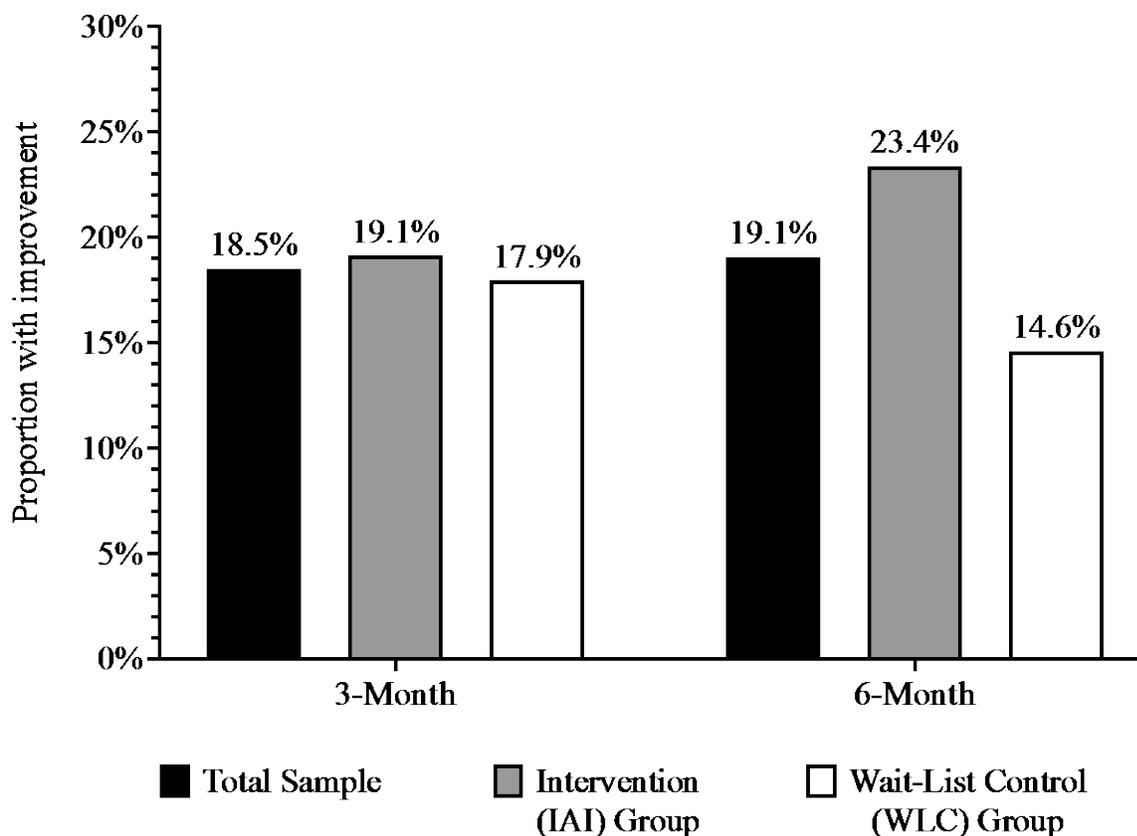
Figure 3. Clinically Meaningful Improvement in Sleep Quality Over Time by Study Group

Secondary Outcomes (Intent-to-Treat Analyses)

Secondary outcomes of interest included the CFQ, ESS, OFER, EMS-SAQ, and SAS^. In the intention-to-treat analyses that were adjusted for clustering and repeated measures, mean scores on the CFQ, SAS^, and OFER did not differ by IAI and WLC group status at baseline (See Table 3). However, differences by group status at baseline were detected for the ESS and select domains of the EMS-SAQ (See Table 3).

At 3-months follow-up, mean scores for the CFQ, ESS, OFER, EMS-SAQ, and SAS^ did not differ by IAI and WLC group status (Table 6; $p > 0.05$ for all comparisons). At 6-months follow-up, and compared to baseline scores, mean scores on these measures also did not differ by group status (Table 6; $p > 0.05$ for all comparisons).

Table 6. Secondary Outcomes by Study Group at 3 Months and 6 Months

Survey Instrument	3-month follow-up		6-month follow-up	
	IAI	WLC	IAI	WLC
	Mean (SD) or % (N)	Mean (SD) or % (N)	Mean (SD) or % (N)	Mean (SD) or % (N)
CFQ	6.6 (2.9)	6.5 (2.7)	6.3 (2.9)	6.3 (3.0)
% with severe fatigue (from CFQ)	84.8% (178)	85.3% (192)	82.1% (151)	78.8% (141)
Missing	0	1	0	0
ESS	8.8 (3.8)	8.5 (4.1)	8.9 (4.0)	8.3 (4.4)
Missing	0	3	0	0
OFER				
-Chronic fatigue	37.8 (26.1)	37.8 (28.8)	36.7 (25.6)	39.3 (27.5)
-Acute fatigue	57.6 (24.2)	57.8 (25.6)	57.8 (23.8)	56.6 (26.1)
-Intershift recovery	50.7 (26.1)	49.8 (26.6)	49.0 (26.7)	50.4 (26.7)
Missing	0	6	2	1
EMS-SAQ				
-Teamwork climate	67.7 (21.8)	66.3 (23.5)	67.2 (22.2)	65.4 (23.6)
-Safety climate	69.2 (19.5)	69.4 (22.9)	68.8 (19.6)	68.7 (21.3)
-Stress recognition	55.8 (25.4)	58.1 (24.7)	56.5 (26.4)	59.7 (24.2)
-Perceptions of mgmt.	58.5 (25.9)	52.1 (26.4)	58.1 (26.1)	50.7 (25.3)
-Working conditions	62.3 (22.6)	59.2 (25.8)	60.6 (25.5)	59.7 (24.6)
-Job satisfaction	68.2 (24.0)	67.2 (25.4)	69.6 (24.6)	65.1 (26.9)
Missing	0	6	1	1
SAS^	44.0 (28.4)	41.7 (25.1)	44.2 (27.7)	43.8 (25.6)
Missing	0	6	1	1
Total Participants	210	225	184	179

Notes: Tests for differences in secondary measures by group status (IAI vs. WLC) use linear mixed models (at 3 months and 6 months follow-up) with the secondary measure as the outcome, group status as the predictor, and a random intercept to adjust for clustering.

Additional secondary measures of interest included the texting platform, text message-assessed hours of sleep reported at the start of the shift (pre-shift) and reported at the end of shift, and self-reported measures of fatigue, sleepiness, and difficulty with concentration during shift work, as well as recovery between shifts. In total, the texting platform data collection system sent and received 636,927 text messages during the study period. Not all text messages required response from participants. The average agency-level compliance with text message questions, across all agencies, was 80% and ranged from a low of 62% to a high of 88%. In total, participants reported working 8,503 shifts during the study period and responded to text message queries during and in-between these shifts. Twelve-hour shifts (*n*=2,641 shifts) and 24-hour shifts

(*n*=4,426 shifts) were the most common duration shifts reported during the 6-month study period (83% of all shifts recorded).

The mean hours of sleep pre-shift for all shifts were 6.2 hours (*SD* 2.0) over the 6-month study period (Figure 4). The mean hours of pre-shift sleep over the entire 6-month study period were 5.9 hours (*SD* 2.1) for 12-hour shifts and 6.4 hours (*SD* 1.6) for 24-hour shifts (Figure 4). The mean hours of sleep reported during shift work, for all reported shifts, was 3.2 hours (*SD* 3.0; Figure 4). The mean hours of sleep obtained during shifts (intra-shift) over the entire study period was 0.8 hours (*SD* 1.6) for 12-hour shifts and 5.5 hours (*SD* 1.9) for 24-hour shifts (See Figure 4).
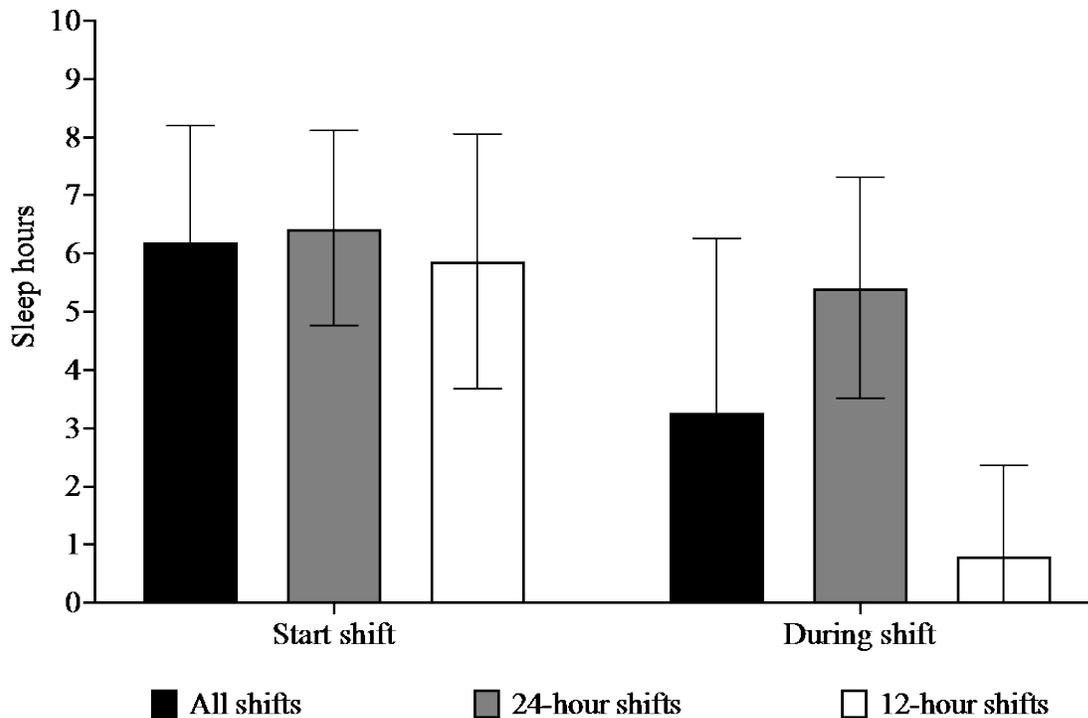
Figure 4. Sleep Hours Reported at Start and During Shift Work

In the intention-to-treat analyses, the mean hours of self-reported sleep pre-12-hour shifts among participants in the IAI group was 5.8 hours (*SD* 2.1; Figure 5). The mean hours of sleep reported pre-12-hour shifts among participants in the WLC group was 5.9 hours (*SD* 2.3) and did not differ from that reported by the IAI group (*p*=0.69; Figure 5). Among participants in the IAI group, the mean hours of sleep reported pre-24-hour shifts was 6.4 hours (*SD* 1.7), and it did not differ from mean hours of sleep reported by participants in the WLC group, which was 6.5 hours (*SD* 1.7; *p*=0.57; See Figure 6). Comparisons between groups are isolated to the first 3 months of the study and statistical tests were adjusted for clustering and repeated measures.
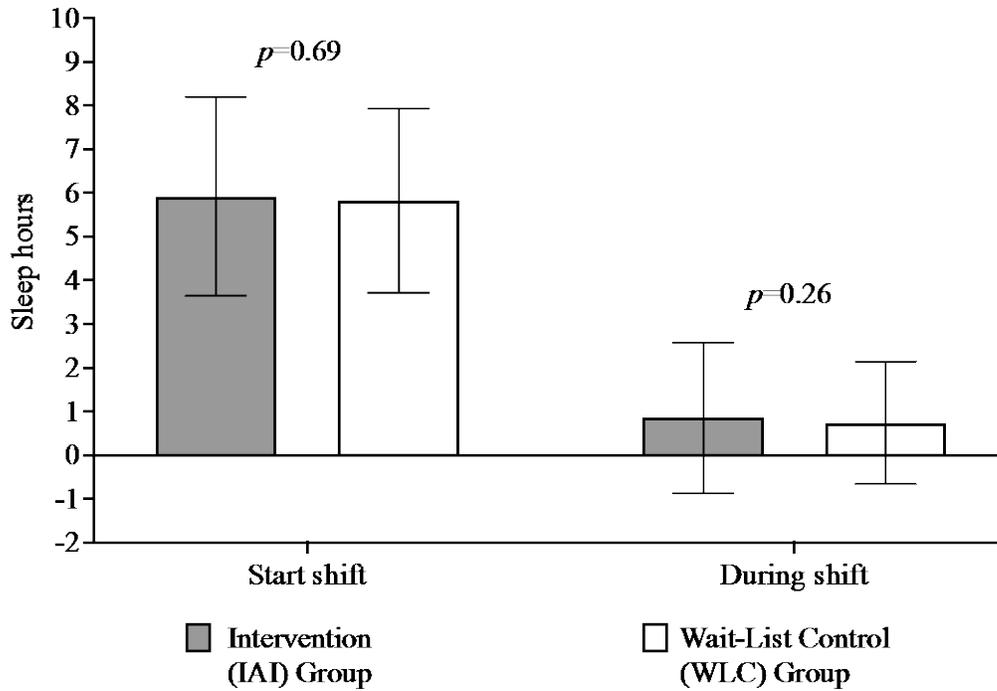
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Figure 5. Mean and Corresponding Standard Deviation Sleep Hours Reported Pre-Shift and During Shift for 12-Hour Shifts
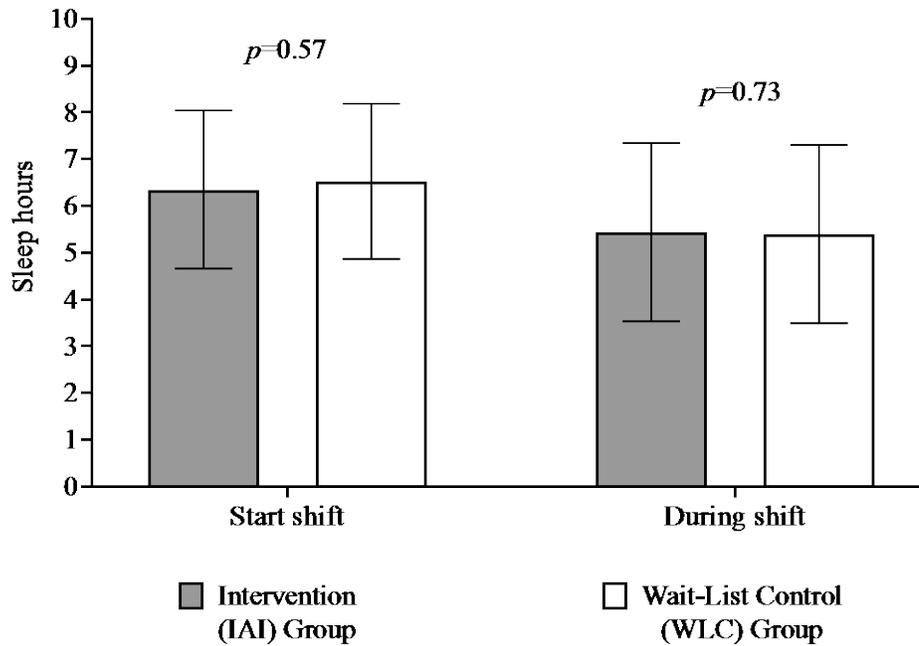

Figure 6. Mean and Corresponding Standard Deviation Sleep Hours Reported Pre-Shift and During Shift for 24-Hour Shifts

In the intention-to-treat analyses, among participants in the IAI group, the mean hours of self-reported sleep obtained during 12-hour shifts was 0.7 hours (*SD* 1.4; Figure 5). The mean was not different from that reported by participants in the WLC group, which was 0.9 hours (*SD* 1.7; *p*=0.26; Figure 5). The mean hours of self-reported sleep obtained during 24-hour shifts among participants in the IAI group was 5.4 hours (*SD* 1.9). The IAI mean was not different from that reported by participants in the WLC group, which was 5.4 hours (*SD* 1.9; *p*=0.73; Figure 6). Intention-to-treat comparisons were isolated to the first 3 months of the study, before the wait-list control was offered the intervention. Statistical tests accounted for agency-level clustering and repeated measures.

Figures 7, 8, 9, and 10 show the mean values associated with text message reported fatigue, sleepiness, difficulty with concentration during scheduled 12-hour and 24-hour shifts, and for the mean values associated with self-reported recovery between scheduled shifts registered after the IAI group viewed education modules and prior to the WLC participant access to the modules. Participants in the IAI group that worked 24-hour shifts reported a higher level of fatigue at the end of their shifts than did participants in the WLC group (*p*<0.05; Figure 7B). As shown in Figure 8B, IAI participants that worked 24-hour shifts reported a level of sleepiness at time points during their shift that was higher than the level reported by participants in the WLC group (*p*<0.05; Figure 8B).
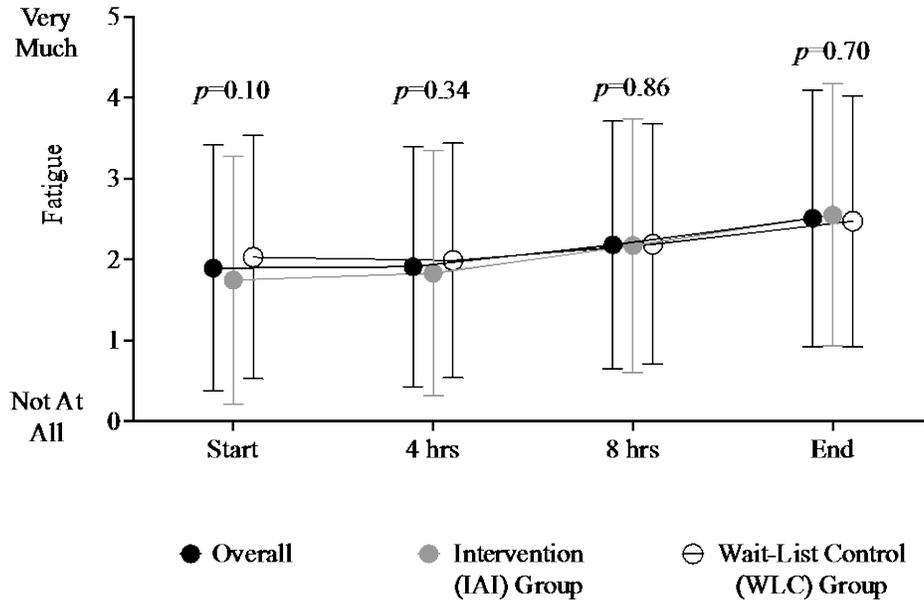
Figure 7A. Mean and Corresponding Standard Deviation of Self-Reported Fatigue During 12-Hour Shifts by Study Group
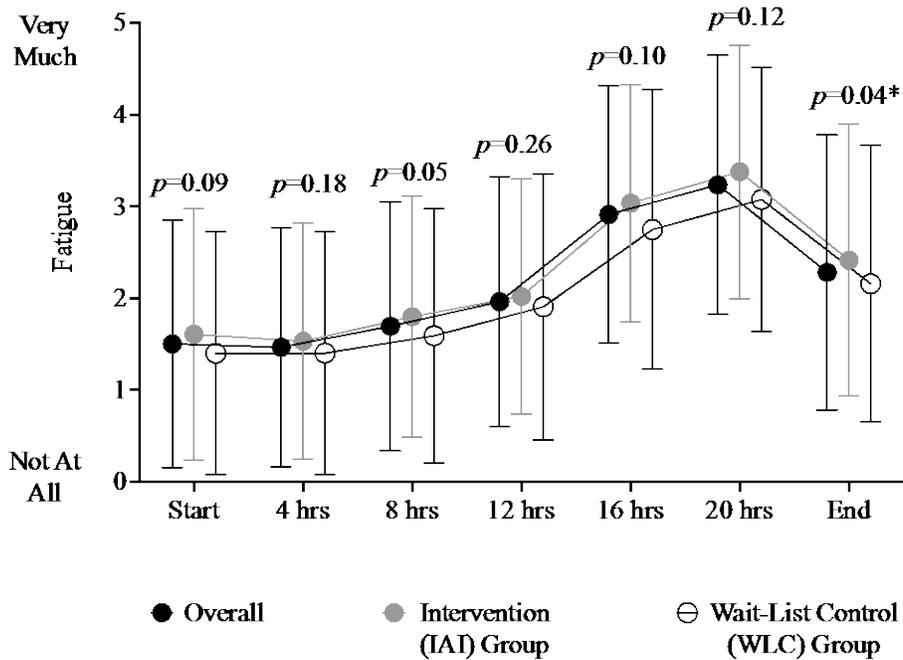

Figure 7B. Mean and Corresponding Standard Deviation of Self-Reported Fatigue During 24-Hour Shifts by Study Group
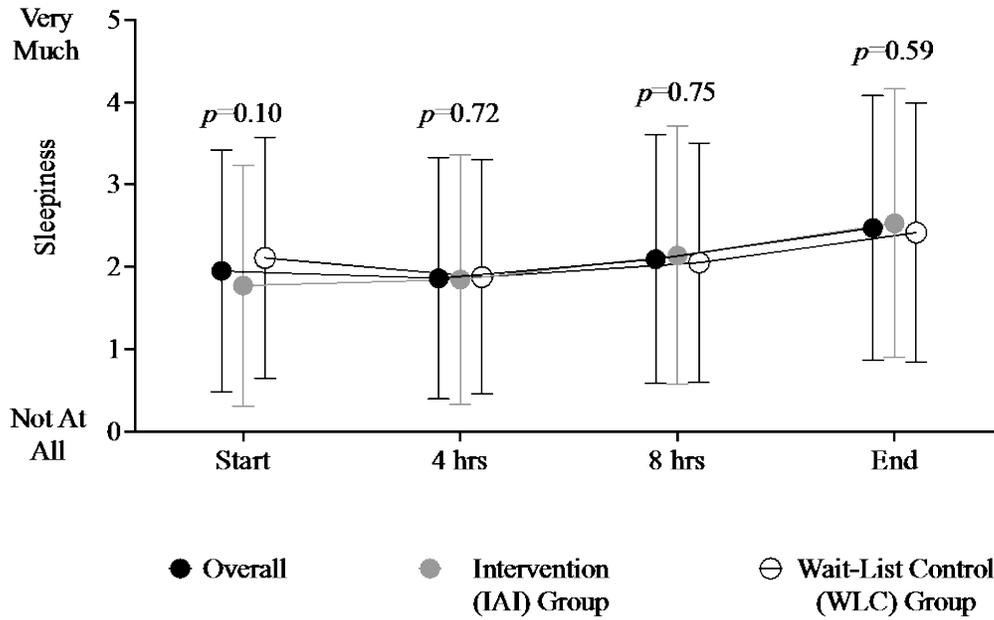
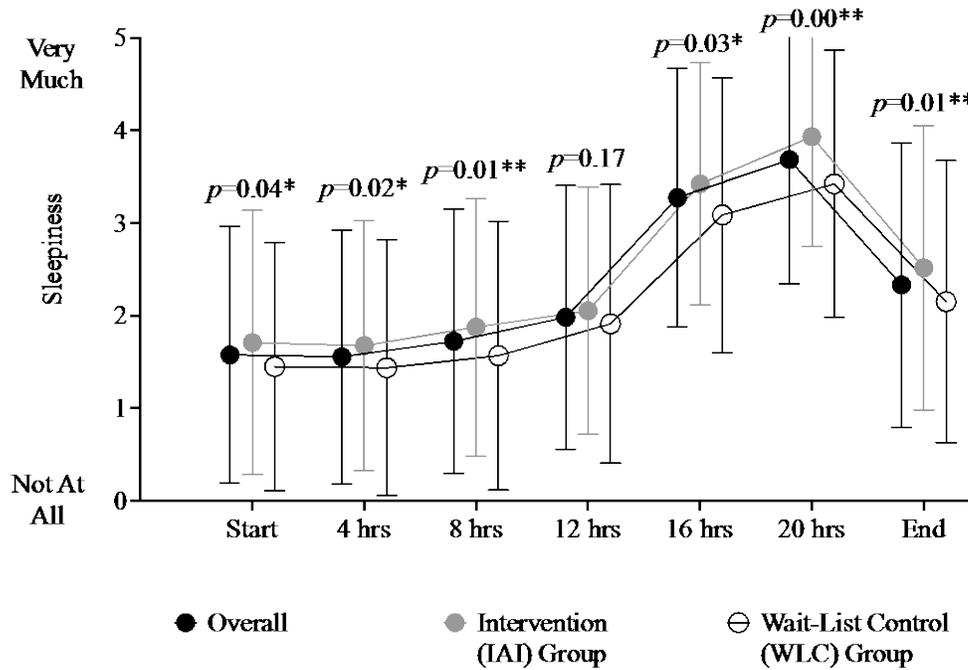*Figure 8A. Mean and Corresponding Standard Deviation of Self-Reported Sleepiness During 12-Hour Shifts by Study Group*

Figure 8B. Mean and Corresponding Standard Deviation of Self-Reported Sleepiness During 24-Hour Shifts by Study Group
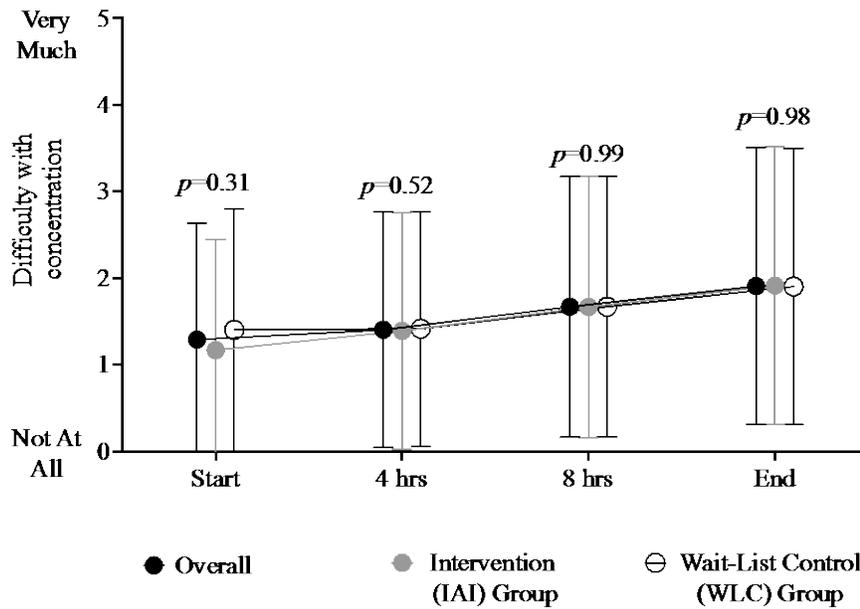
Figure 9A. Mean and Corresponding Standard Deviation of Self-Reported Difficulty With Concentration During 12-Hour Shifts by Study Group
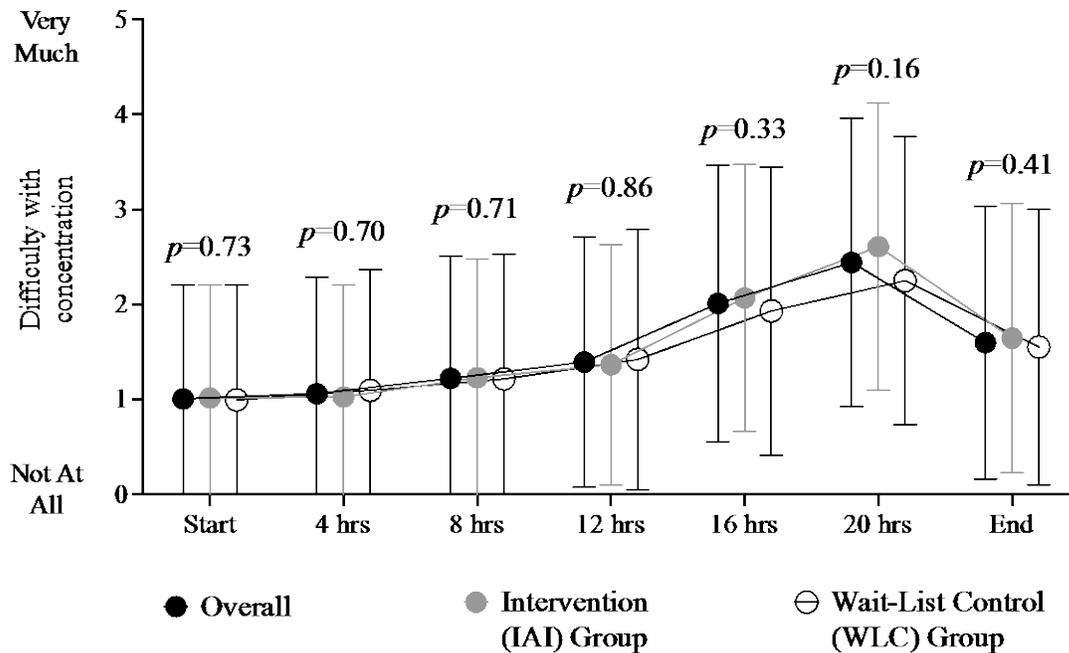

Figure 9B. Mean and Corresponding Standard Deviation of Self-Reported Difficulty With Concentration During 24-Hour Shifts by Study Group
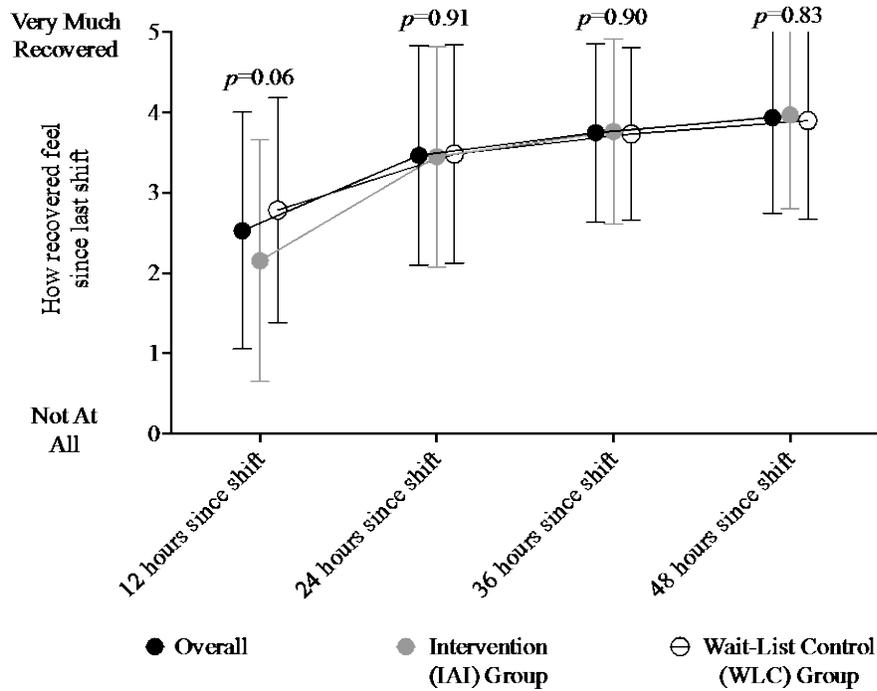
Figure 10A. Mean and Corresponding Standard Deviation of Self-Reported Inter-Shift Recovery After 12-Hour Shifts Stratified by Study Group
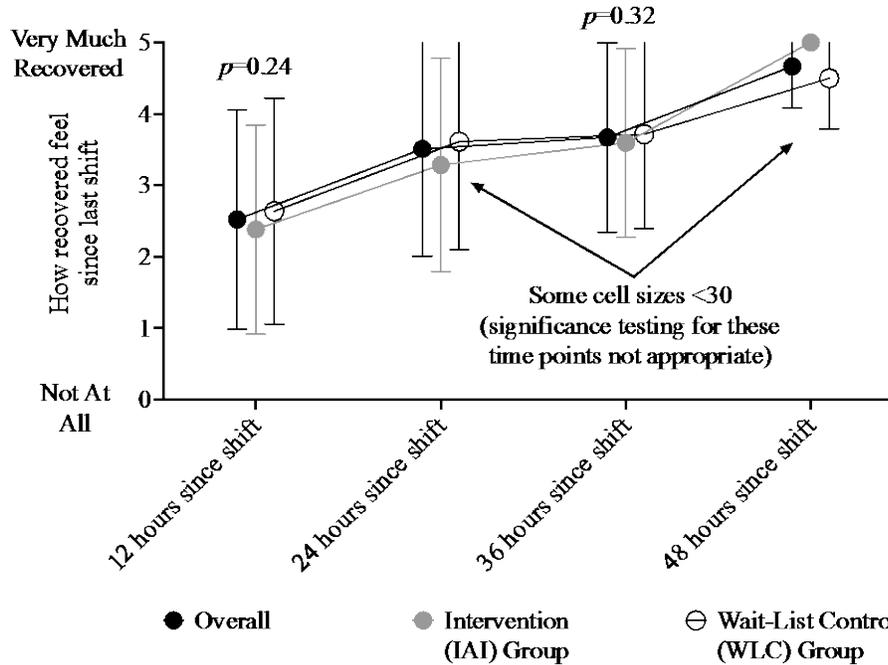

Figure 10B. Mean and Corresponding Standard Deviation of Self-Reported Inter-Shift Recovery After 24-Hour Shifts Stratified by Study Group

Per Protocol Analyses

Per protocol analyses refers to an analytical approach where study participants are identified based on their adherence to the study protocol and whether or not they received some or all of the intervention (Tripepi et al., 2020). Per protocol analyses are complementary to intent-to-treat analyses and provide a more comprehensive assessment of intervention impact.

Among the 316 EMS clinicians enrolled in the IAI group, 43% (*n*=136) viewed one or more of the education modules. In total, 37 participants in the WLC group viewed one or more education modules immediately prior to completing the 3-month survey assessment. The 3-month and 6-month follow-up data from these people were added to the IAI group in per-protocol analyses to assess the impact of module viewing on follow-up measures. Among these 37, 16% (6) showed a clinically meaningful improvement in sleep quality ($\geq$ 3 point decrease in PSQI) at 3 months compared to baseline; 49% (18) experienced a worsening in their PSQI score; 16% (6) showed an improvement (reduction), yet not a clinically meaningful improvement in PSQI; and the remaining 19% (7) showed no change from baseline to 3 months. Among the 362 EMS clinicians enrolled in the WLC group, 24% (*n*=87) viewed one or more of the education modules after gaining access to the modules at 3 months follow-up.

Among the 136 IAI participants who viewed the modules, 47% viewed 1 to 3 modules (Low), 5% viewed 4 to 7 modules (Moderate), and 48% viewed 8 to 10 modules (High). Among module viewers in the IAI group, 30% in the Low module-viewing category completed viewing the entirety of the modules accessed compared to 43% in Moderate category, and 46% for High viewing category.

Among the 87 WLC participants who viewed the education modules, 54% were classified as Low module viewers with 1 to 3 modules viewed, 10% were classified as Moderate module viewers with 4 to 7 modules viewed, and 36% were classified as High module viewers with 8 to 10 modules viewed. Among the Low, Moderate, and High module viewers in the WLC group, the proportion of viewers who completed viewing the entire module or modules varied by category. Among the Low module-viewing category, 30% completed viewing the entirety of the modules accessed compared to 33% in the Moderate viewing category, and 68% in the High module-viewing category.

On average, participants who viewed the education modules reached their module viewing status (Low, Moderate, or High) within 46 days (*SD* 44.0) after first accessing the education modules. In per-protocol analyses, comparing education module viewing independent of treatment assignment, change in the mean PSQI sleep quality score was associated with module viewing status at 3-months follow-up (*p*=0.02; Figure 11). Compared to participants who viewed no modules, participants in the High module-viewing category experienced the greatest improvement in PSQI-measured sleep quality (overall *p*=0.00, Bonferonni-corrected *p*=0.01; Figure 11).
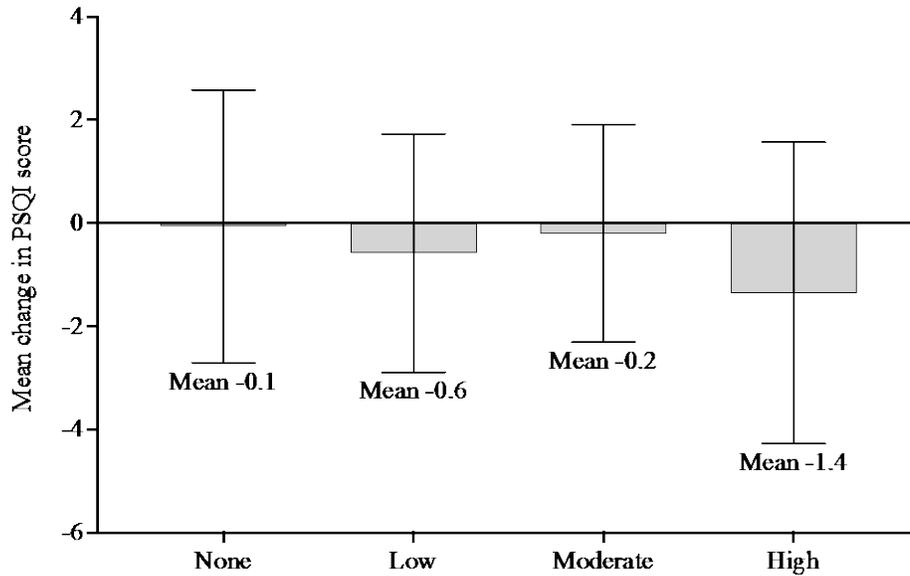
Figure 11. Change in Mean PSQI Score by Module Viewing Category at 3 Months Follow-Up

At 6 months follow-up, compared to baseline, module viewing was not associated with change in PSQI-measured mean sleep quality score (p=0.17). There was no association between number of modules viewed and change in mean sleep quality at 6 months (p=0.59).

In per-protocol analyses, change in the secondary measure CFQ, when treated as a continuous variable, was associated with the number of modules viewed at 3 months follow-up (p=0.04). Specifically, the CFQ-measure of physical and mental fatigue decreased by 0.074 points for every one additional module viewed. Because there is no standard for how best to treat the outcome and exposure variables, the research team examined the relationship between module viewing and CFQ-measured fatigue in continuous and categorical form. When looking at the overall association between CFQ and module viewing as a categorical variable (categorized as None, Low, Moderate, and High module viewing), at 3 months, the association was non-significant at the 0.05 level. In additional analyses, the high module-viewing group had a greater improvement (a reduction in fatigue) in CFQ-measured mental and physical fatigue compared to the "None" module viewing group; however, this comparison was not statistically significant at the 0.05 level (unadjusted p=0.05, Bonferonni-corrected p=0.15). No other secondary measures were associated with either module viewing status or number of modules viewed (at 3 months and 6 months follow-up).

Text message-based self-reported sleep hours obtained pre-shift and the hours of sleep reported during 12-hour and 24-hour shifts did not differ by module viewing status (p>0.05 for all time points). In per-protocol analyses, self-reported text message responses for perceived fatigue, sleepiness, and difficulty with concentration measured at the start, during, and end of 12-hour and 24-hour shifts did not differ by module viewing status (p>0.05 for all time points). Perceived recovery after shift work did not differ by module viewing status (None, Low, Moderate, or High module viewing status) when measured via text message at 12 hours, 24 hours, 36 hours, and 48 hours following 12-hour and 24-hour shifts (p>0.05 for all time points).

Discussion

A high percentage of frontline EMS clinician shift workers experience fatigue and poor sleep, yet there are few sleep health education and training programs based on the evidence and tailored to first responders. The aim of this two-arm, experimental research study was to assess the impact of a novel education and training program on reliable and valid indicators of sleep and fatigue among EMS clinician shift workers. At 3-months follow-up, intention-to-treat analyses showed no differences in mean sleep quality or fatigue scores between the intervention and comparison groups, which questions the effectiveness of the intervention. Per-protocol analyses showed that the greater the number of education modules viewed by the 3-month follow-up, the greater the improvement in sleep quality and the greater the reduction in fatigue ($p<0.05$). However, the effect for the greater number of education modules viewed was not statistically significant at 6-months follow-up, suggesting that further investigation regarding the sustainability of the effect may be warranted. In addition, it is unclear whether the statistically significant difference of -1.4 in the PSQI score is a clinically meaningful difference in terms of improving sleep quality.

A meta-analysis of experimental or quasi-experimental studies shows that education and training of shift workers contributes to improvements in sleep quality (Barger et al., 2018). It is notable that none of the studies examined in this meta-analysis involved EMS clinician shift workers as study subjects. Therefore, this study is among the first to test an education and training program tailored to EMS clinician shift workers and focused on sleep quality and fatigue. The education program tested in this study involved mostly asynchronous interaction between study participants and the intervention materials. Text message-based interactions were automated and person-to-person level interactions were limited to email, some text messaging, and telephone communication when needed. To that end, a direct comparison of this study's findings to the findings from previous research in other domains is difficult, based on differences in the study population and type and method of delivery of the intervention.

Several factors may help to explain the findings. On March 11, 2020, the World Health Organization declared infections caused by COVID-19 a global pandemic. In response, many governments implemented lockdown and stay-at-home orders that contributed to fundamental changes in how societies behaved and slept during 2020 and during the winter months of 2021. A research study compared self-reported sleep during COVID-19 lockdown periods to pre-lockdown and showed that 60% of subjects reported not reaching 7 hours of sleep per night pre-lockdown versus only 37% during the COVID-19-related lockdown (Leone et al., 2020). This pattern of behavior, related to COVID-19 may, in part, explain why nearly 18% of participants in the comparison group (the WLC group) reported a clinically meaningful improvement in sleep quality from baseline to 3 months. The first 3 months of the study was a period when participants in the WLC group did not have exposure to the intervention; however, for many communities and EMS agencies in this study, it was a period that overlapped with lockdowns, shutdowns, and stay-at-home orders related to the COVID-19 pandemic. Widespread changes in sleep patterns during this time may have had an impact on the study.

Another finding of interest is the decrease in the proportion of WLC participants that achieved an improvement in sleep quality at 3 months to 6 months follow-up. At 3 months, 18% of WLC participants experienced a clinically meaningful improvement in sleep quality. At 6-months follow-up, which followed approximately 3 months of exposure to the intervention, the percentage of WLC participants with a clinically meaningful improvement in sleep quality was

15%. It is unknown why there was a decrease in clinically meaningful improvement in sleep quality after exposure to the intervention. One possible explanation could be that the effects of the intervention were experienced by participants soon after exposure (after the 3-month assessment, but before the 6-month assessment) and that they may have dissipated with time. If accurate, repeated exposure to the intervention, over regular intervals, may have a longer lasting impact on sleep quality and other indicators of sleep health.

The study also used text-message assessments sent at regular, short intervals to assess the impact of the intervention on diverse indicators of sleep and fatigue. The text messages were delivered to participants using a platform similar to one used in previous research (Patterson, Buysse, Weaver, Doman, et al., 2015; Patterson et al., 2014, 2017, 2019). Findings from two text message questions (one about fatigue and one about sleepiness) obtained from participants that worked 24-hour shifts shows that participants in the intervention group (the IAI group) reported that fatigue and sleepiness varied by time within 24-hour shifts. While these findings may be surprising, they are not new. Previous research has observed a similar pattern with 24-hour shifts where EMS clinicians in an intervention group received information about mitigating fatigue, yet reported a higher level of fatigue than people in a comparison group who received no information about fatigue mitigation (Patterson et al., 2019). One potential explanation for these findings is that people in the intervention group had an increased level of awareness regarding the dangers of fatigue, and, as a result, were more likely to report fatigue and sleepiness.

Attrition, loss to follow-up, and poor adherence to protocol are common problems in experimental studies, including studies that involve interventions that seek to change behavior like sleep habits (Dodd et al., 2012; Murawski et al., 2018). In fact, nearly all trials experience some level of attrition and protocol non-adherence at the cluster level and at the level of people within clusters (Dodd et al., 2012). Our study was impacted by attrition and poor adherence to protocol. Approximately 18% of participants in each group were lost to attrition at 3 months. At 6 months, attrition affected nearly 40% in each of the study groups. This pattern of attrition is comparable to previous intervention studies that aim to change human behavior (Linke et al., 2011; Murawski et al., 2018; Querstret et al., 2017). There also is reason to believe that the COVID-19 pandemic played a role in attrition and non-compliance. Incorporating use of adaptive study designs may help to attenuate these issues given that they are unavoidable.

Excessive daytime sleepiness is often associated with poor sleep and fatigue. Subjects with worse daytime sleepiness at baseline may be more responsive to the education intervention than would people with less daytime sleepiness. While there were differences in ESS-measured daytime sleepiness at baseline that might be perceived as a potential contributing factor in our findings, further analyses of these data reveal no differences between the IAI and WLC groups in the change in daytime sleepiness at 3 months and 6 months follow-up relative to baseline. Many EMS professionals work several jobs (80% in some locations), overtime hours, long duration shifts, and rotating shift schedules (Frakes & Kelly, 2007; Patterson, Runyon, et al., 2018; Patterson, Suffoletto, et al., 2010). Despite the education materials in this study having been tailored to EMS workers, select patterns of work may have made it difficult for many to implement and maintain many of the recommendations for improving sleep health presented in the intervention.

Generalizability

The demographic characteristics of EMS agencies and individual participants in this study are like the characteristics of organizations and individual EMS clinicians who engaged with previous observational and experimental research studies. Findings from this research study are likely generalizable to a large proportion of EMS agencies and clinicians in the United States.

Limitations

This study has many limitations. First, recruitment, enrollment, and attrition were likely impacted by the COVID-19 pandemic. Recruitment began February 2020, yet due to the pandemic, recruitment was halted from March to June 2020. During this time, there were no new agency enrollments. The inability to recruit and enroll during this time may have impacted the research team's ability to reach goal enrollment of 40 total EMS agencies (clusters). About two-thirds of all withdrawals (66%) and 44% of all participants classified as LTFU occurred between the months of August 1 and December 30, 2020. This period coincided with an increase in COVID-19 infections.

Second, the study protocol was open-label, and blinding of investigators and participants was not feasible. The lack of blinding, which is often associated with wait-list control study designs, may have impacted behavior and responses to survey and text message queries. Previous research and commentary from experts in the design of randomized trials suggest that many participants were aware of their status post-randomization and may have altered their responses or behavior due to dissatisfaction in group assignment (Adamson et al., 2008; McCambridge et al., 2014; Silverman & Altman, 1996).

Third, sleep duration and sleep patterns of many adults changed during the COVID-19 pandemic (Bann et al., 2021; Leone et al., 2020; Salfi et al., 2021), and there is reason to believe that this played a role in the impact of the intervention.

Another limitation associated with this study was poor adherence to protocol. Low adherence to protocol is often reported in intervention studies (Dodd et al., 2012), yet the reasons for low adherence can differ between studies. Despite having access to the intervention, not all participants accessed the intervention material, and not all who accessed the materials fully engaged with all the materials. The participants who viewed some or all of the materials may have been more motivated or possessed a higher level of interest in the study than those who did not view most of the materials, which may explain the difference in sleep quality for participants in the High module-viewing category as compared to participants who did not view any modules. Another potential explanation for low adherence is the level of remuneration offered for participation: $5.00 for enrollment and $5.00 monthly for a total of $35.00. It is unclear if greater remuneration or a different method or type of remuneration would have led to greater adherence to protocol. Low adherence in this study is a limitation, yet the findings from the intention-to-treat and per-protocol analyses address questions about the effectiveness of the intervention depending on the level of adherence.

Finally, the intervention developed for this study involved 10 modules and over two hours of content that had not been used in previous studies. Since the modules were developed specifically for this study, the study cannot answer whether modules with different content, length, or production value may affect the results. In addition, access to all of the modules was given at the same time to participants, making it difficult to know whether there were order

effects as participants could choose the order in which they viewed the modules. Further testing and development of the training modules could improve delivery and potentially effectiveness.

Conclusions

The research team detected no differences in the mean sleep quality score at 3 and 6 months in the intent-to-treat analysis. Among EMS clinicians who viewed the education modules, the greater the number of modules viewed, the greater the improvement in sleep quality and greater the reduction in fatigue at 3 months. The largest improvement in sleep quality was observed among EMS clinicians that viewed 8 to 10 education modules (out of the 10 available education modules). Given these findings, the Fatigue Education Program for Emergency Medical Services is a promising resource for EMS administrators looking to educate and train EMS workers on sleep and fatigue as recommended in the 2018 EBGs (Patterson, Higgins, et al., 2018). However, additional evaluation using more refined second-generation training modules tested outside of the COVID-19 environment may provide a clearer picture of overall effectiveness.

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