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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.

17. Key Words
EMS, sleep, fatigue, sleep health, education, training

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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

[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

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						

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).

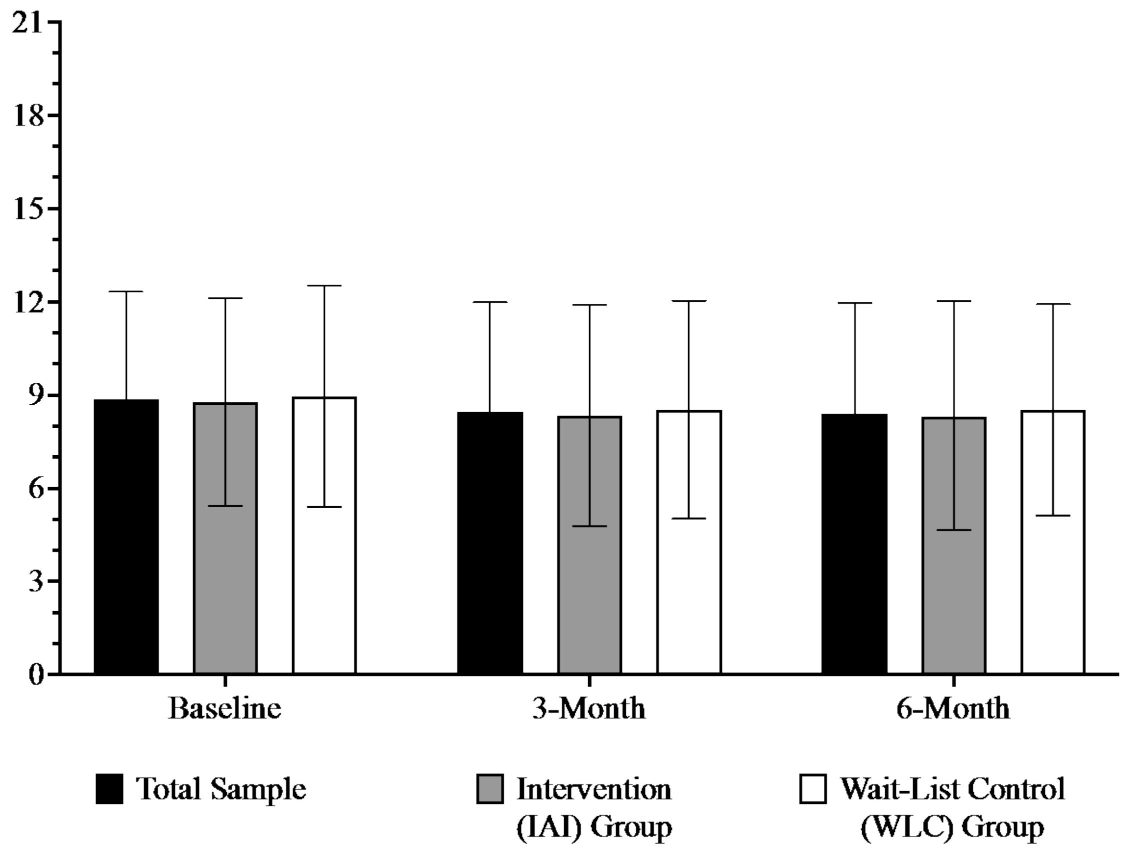

Figure 1. Mean PSQI Score at Baseline and Follow-Up

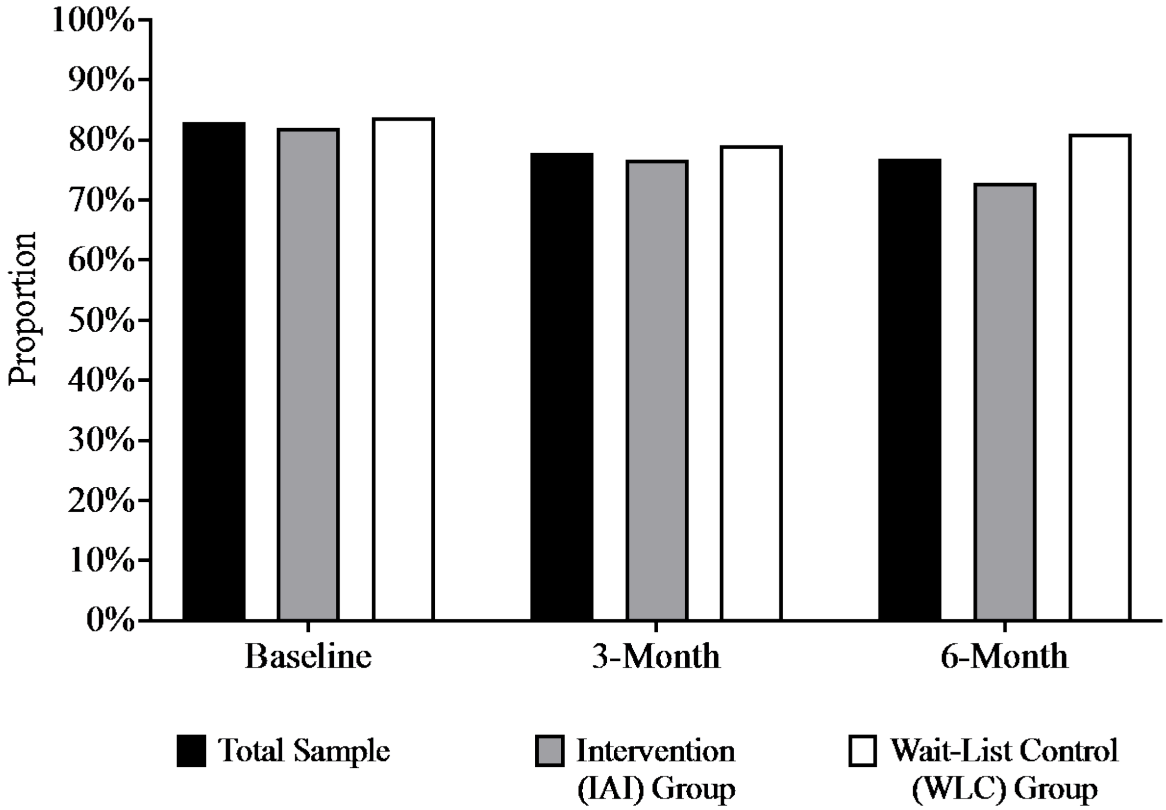

Figure 2. Proportion With Poor Sleep Quality at Baseline and Follow-Up

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.

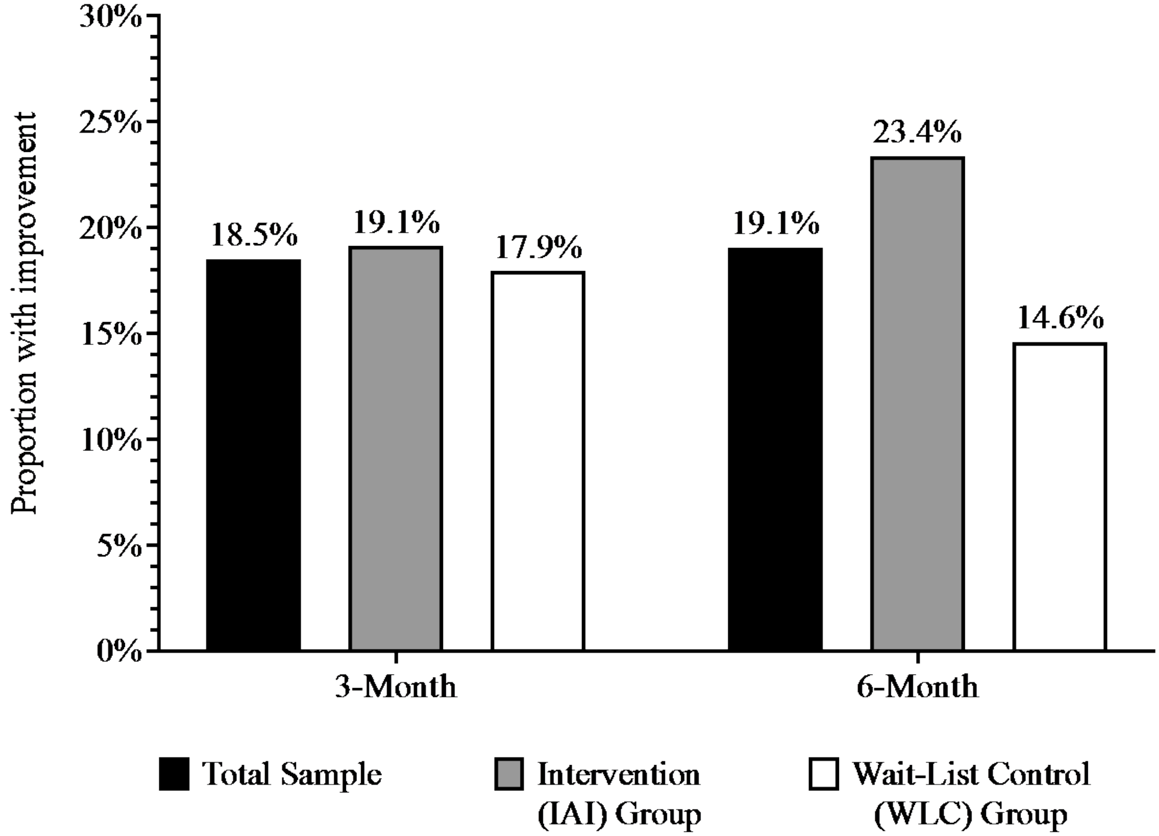

Figure 3. Clinically Meaningful Improvement in Sleep Quality Over Time by Study Group

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).

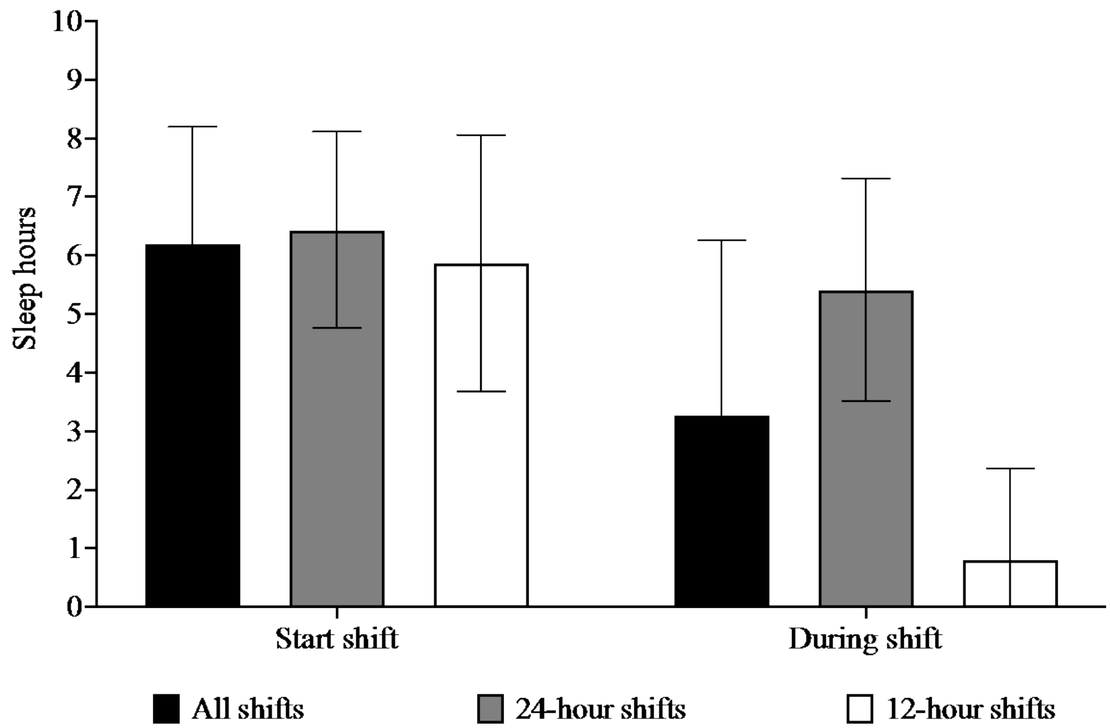

Figure 4. Sleep Hours Reported at Start and During Shift Work

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.

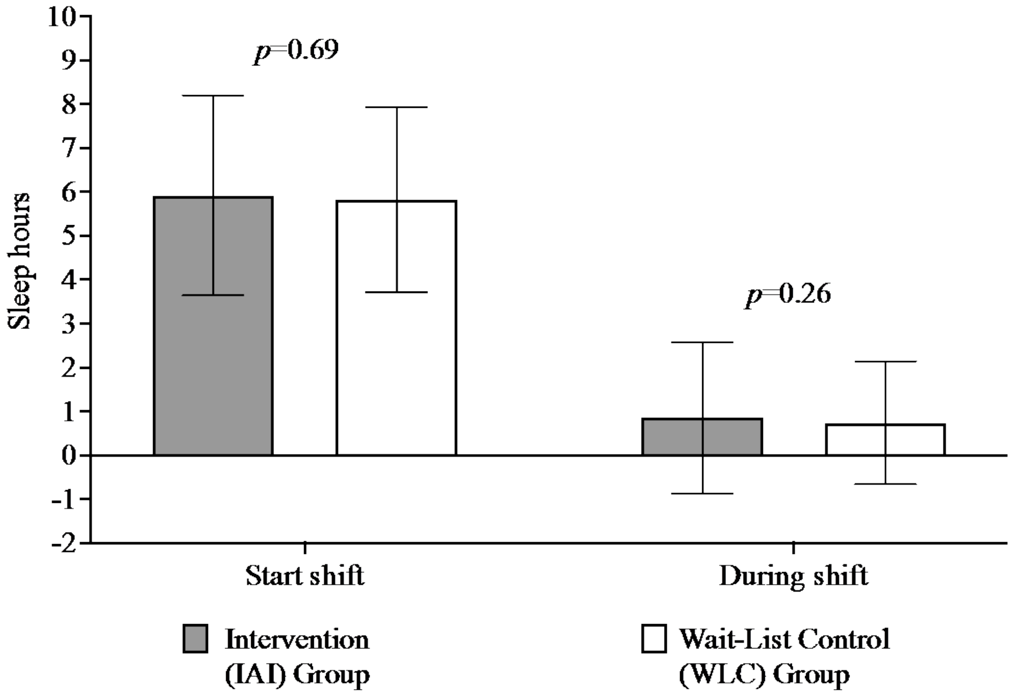

Figure 5. Mean and Corresponding Standard Deviation Sleep Hours Reported Pre-Shift and During Shift for 12-Hour Shifts

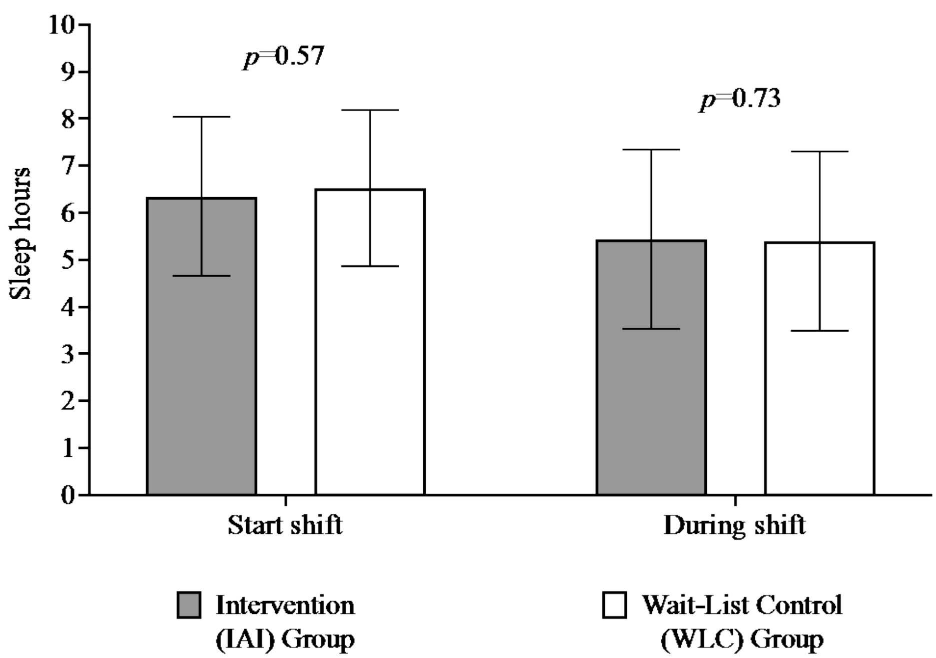

Figure 6. Mean and Corresponding Standard Deviation Sleep Hours Reported Pre-Shift and During Shift for 24-Hour Shifts

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).

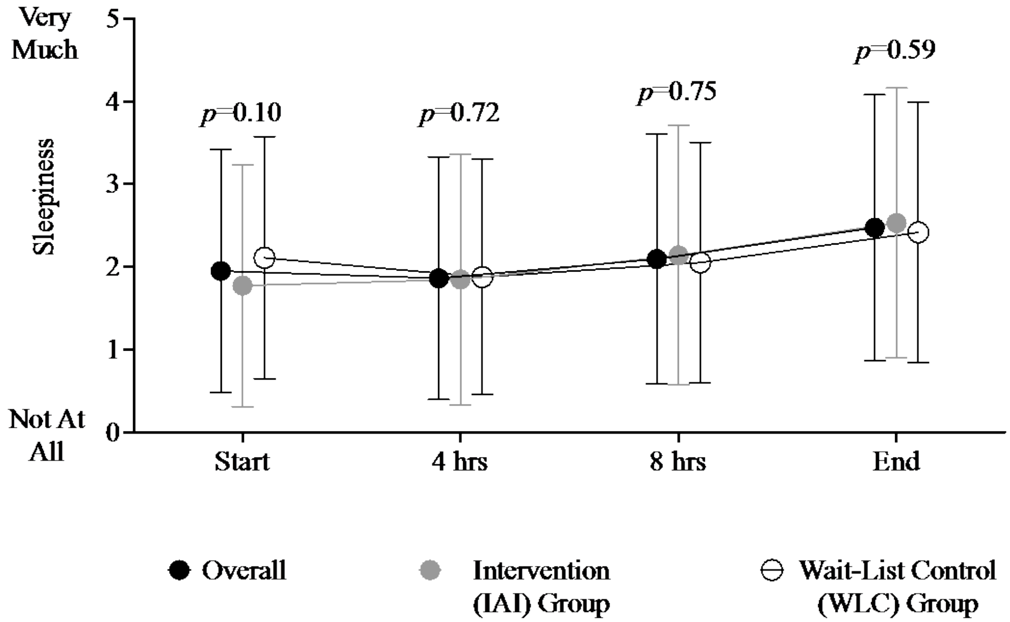

Figure 8A. Mean and Corresponding Standard Deviation of Self-Reported Sleepiness During 12-Hour Shifts by Study Group

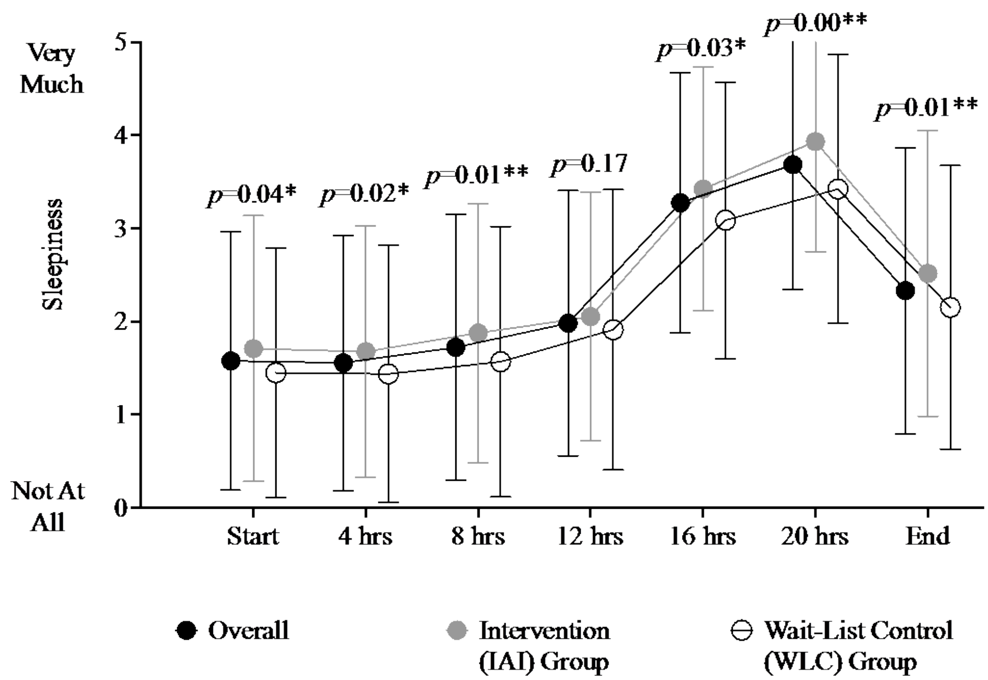

Figure 8B. Mean and Corresponding Standard Deviation of Self-Reported Sleepiness During 24-Hour Shifts by Study Group

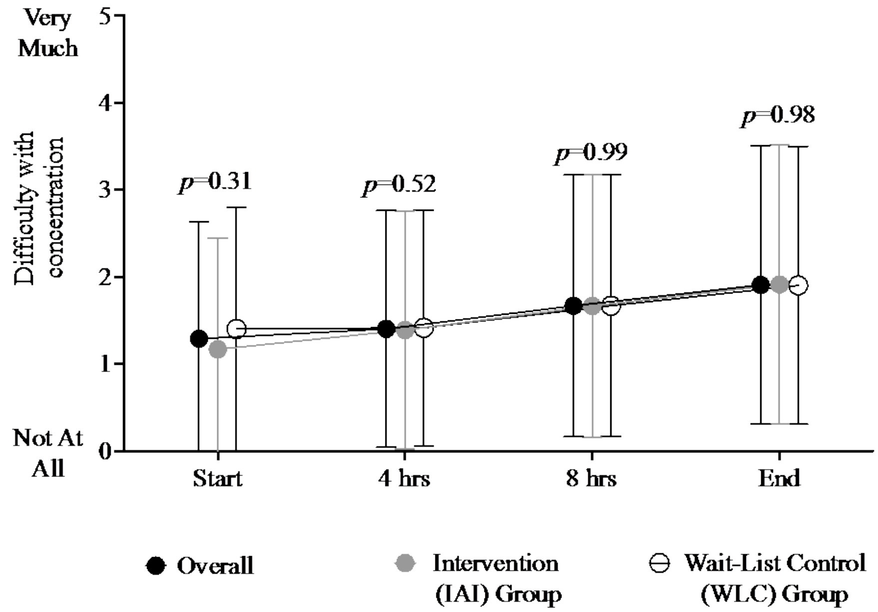

Figure 9A. Mean and Corresponding Standard Deviation of Self-Reported Difficulty With Concentration During 12-Hour Shifts by Study Group

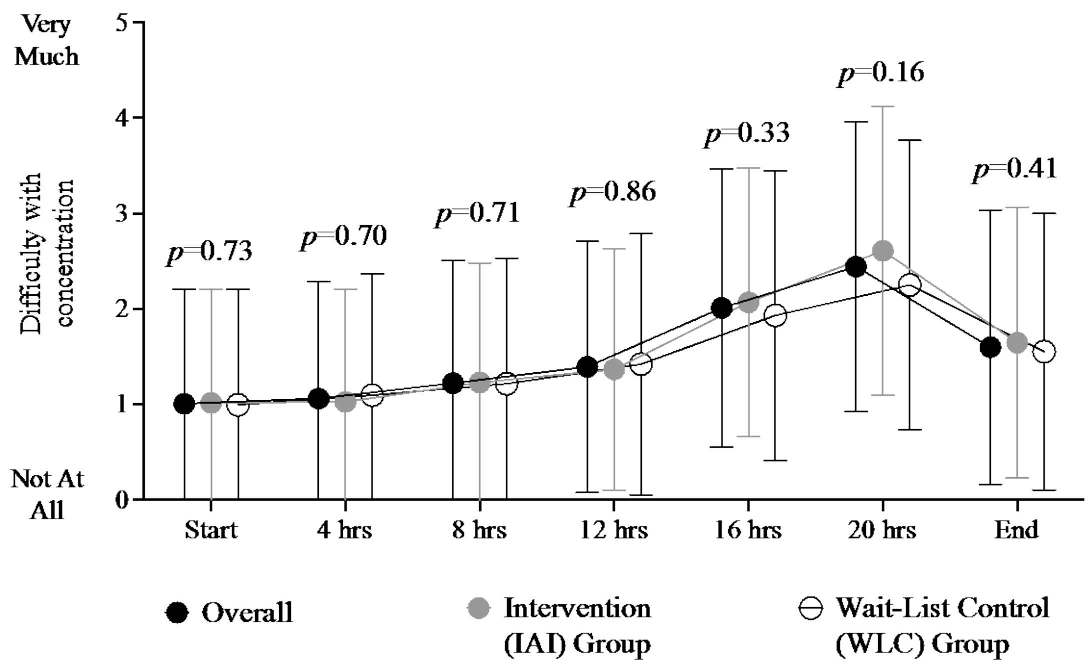

Figure 9B. Mean and Corresponding Standard Deviation of Self-Reported Difficulty With Concentration During 24-Hour Shifts by Study Group

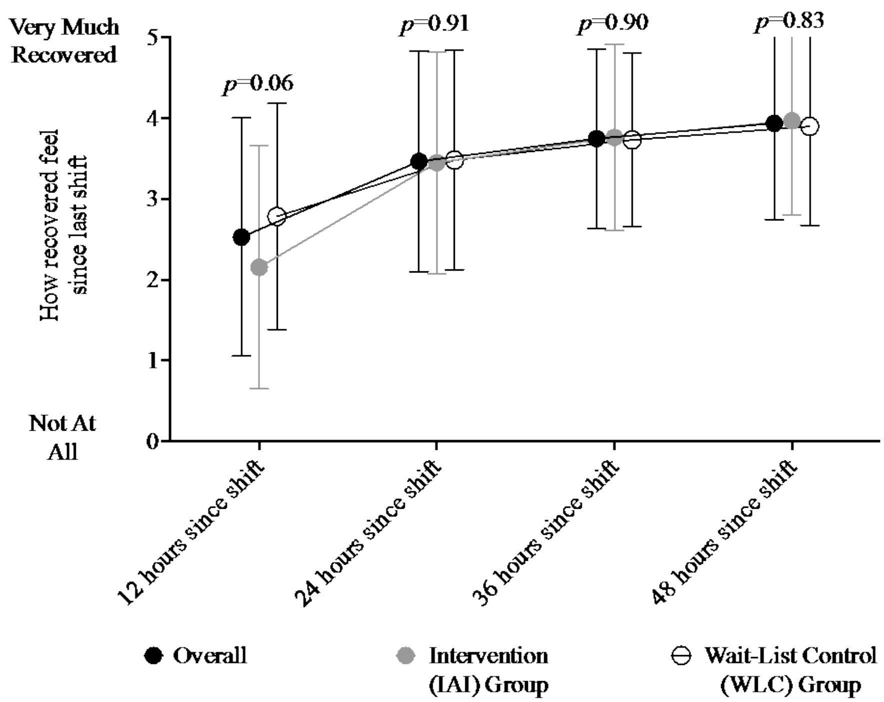

Figure 10A. Mean and Corresponding Standard Deviation of Self-Reported Inter-Shift Recovery After 12-Hour Shifts Stratified by Study Group

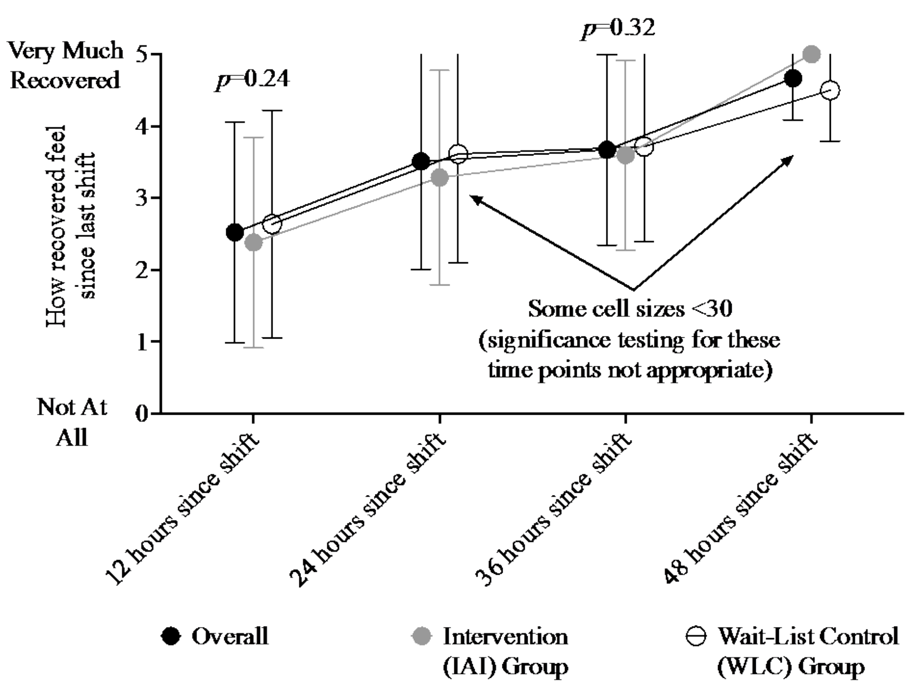

Figure 10B. Mean and Corresponding Standard Deviation of Self-Reported Inter-Shift Recovery After 24-Hour Shifts Stratified by Study Group

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 (≥ 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 to7 modules (Moderate), and 48% viewed 8 to10 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).

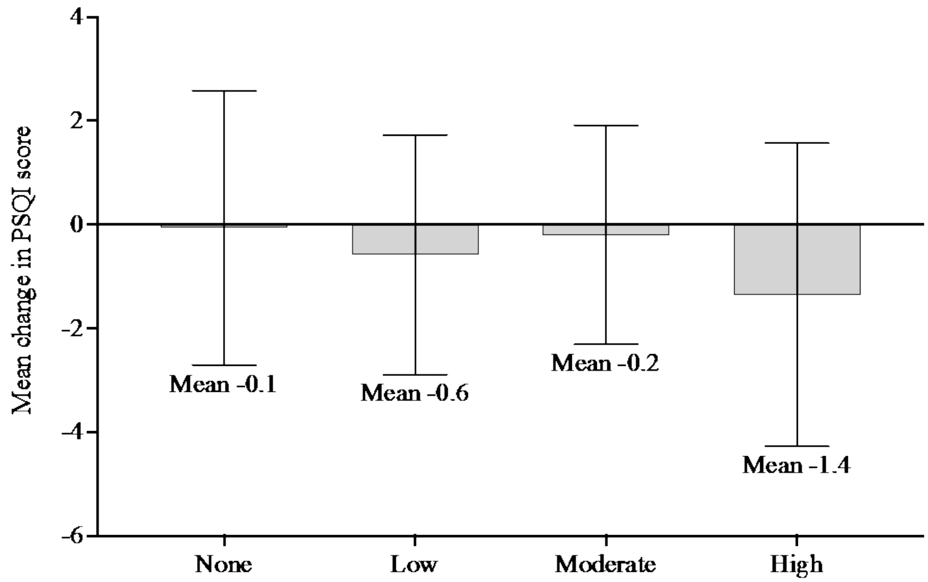

Figure 11. Change in Mean PSQI Score by Module Viewing Category at 3 Months Follow-Up

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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