

Cover Page

The EMS Sleep Health Study: A Randomized Controlled Trial

NCT04218279

Consent Form Date May 8, 2020



University of Pittsburgh

Department of Emergency Medicine
3600 Forbes Avenue
Iroquois Bldg., Suite 400A
Pittsburgh, PA 15261

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE: The EMS Sleep Health Study

PRINCIPAL INVESTIGATOR:

P. Daniel Patterson, PhD, NRP
University of Pittsburgh
School of Medicine
Department of Emergency Medicine
(412) 864-3830
pdp3@pitt.edu

SOURCE OF SUPPORT: The National Highway Traffic Safety Administration

Why is this research being done?

Poor sleep is a common problem in EMS. The purpose of this study is to evaluate the impact of sleep health education and training on indicators of EMS clinician sleep health and fatigue. We seek to enroll approximately 1,000 EMS clinicians affiliated with multiple EMS organizations that operate within the United States.

Who is being asked to take part in this research study?

Dr. Patterson and/or his associates are asking EMS clinician shift workers to participate in this research study: The EMS Sleep Health and Fatigue Education Study. This study is supported with funding from the National Highway Traffic Safety Administration to the National Association of State EMS Officials and the

University of Pittsburgh. This research study is led by Dr. Patterson and staff affiliated with the University of Pittsburgh Department of Emergency Medicine.

You and other EMS clinician shift workers are being recruited for this study to help researchers learn more about sleep health education tailored to EMS shift workers.

In order to participate, you **MUST** meet the criteria below:

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

You do not need to sign a consent form, but you will be asked to watch and listen to a video-based consent maintained on a study-designated website. Once you have watched the video-based consent, you will need to answer a question that documents whether or not you watched the consent video and agree to participate (ACCEPT), or if you DO NOT ACCEPT and do not want to participate.

What is involved?

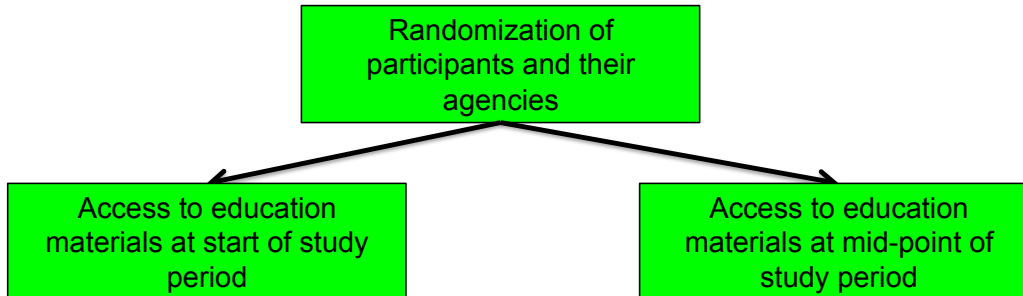
If you agree to participate, you will be asked to FIRST register for the study using a secure study-specific website developed by the University of Pittsburgh.

You will be asked to visit this study-specific website using the Internet to securely login and answer survey questions. The surveys include questions about your demographics, your sleep habits and fatigue, and shift work.

You will be asked to periodically use your mobile phone / cellular phone / or smartphone to answer brief questions about your sleep and fatigue during scheduled shifts and between shifts. You and others at your organization that agree to participate will be granted access to education and training materials that focus on sleep health and fatigue. Access will be provided with a secure link to a study specific website. We will ask that you watch these materials, which are designed to educate you on the importance of sleep health and the dangers of fatigue.

A participant's access to these materials will be either at the start or mid-point of the study period. We will use a randomization procedure to determine when you

are granted access to these materials; either at the start or mid-point of the study.



You may also be asked to be part of a subset of participants that periodically wear an Actigraph wristwatch for 7 consecutive days and complete a paper-based sleep diary. These Actigraph watches are used to objectively monitor sleep and wake cycles. If you wear an Actigraph watch, you may also be asked to complete computerized measures at different time points during the study that measure your reaction time. These reaction time measures are often used to objectively measure performance.

What are the possible risks, side effects, and discomforts of this research study?

Data Loss: The main risk from this study is the study team's loss of data collected that measure sleep, fatigue, and reaction time. This is a small risk (less than 1%, less than 1 out of 100 people), as all precautions will be taken to maintain data security and confidentiality, including assigning code numbers to all data for data transmission, analysis, and storage purposes.

Reviewing Study Materials:

You may find some of study materials to be tedious, stressful and/or boring. You may decide to discontinue participation at any point during the study.

Screen Time:

Prolonged time viewing a computer screen or other electronic device such as a smartphone may cause eyestrain. Most of the study materials will require your interaction with a computer or mobile smartphone or cellular phone device. You will be asked to view some of these materials on multiple days in a row (e.g., 7-days in a row), such as viewing and responding to text-messages. Other materials require less of your time. Eyestrain typically resolves within a few minutes by looking away from the computer.

Discomfort on Wrist from Actigraph:

Some participants will be asked to wear a wrist-worn Actigraph device, which may cause some discomfort or irritation at the site where applied. This device is commonly used to measure sleep and wake cycles and is a standard tool for research studies that aim to evaluate sleep and fatigue in shift workers. The device is most often worn on the left or right wrist. It can be removed during showers or baths, or other times when the wrist might be submerged in water for prolonged periods of time. However, the actigraph should be worn during time awake and during sleep. The device may cause some wrist irritation or discomfort. If you are asked to wear one of these devices and volunteer to do so, we will provide instructions on how to wear it and remove it for brief periods to avoid skin irritation. You may at any time choose to take off the device and discontinue participation in this aspect of the research study.

Discomfort of finger from PVT testing:

Some participants will be asked to complete a reaction time test at the start and end of scheduled shifts with an iPad/mobile device. The psychomotor vigilance test (PVT) is a standard test that evaluates a person's reaction time. The test is administered on a mobile device. The participant taps the screen of the mobile device repeatedly over a period of 3 to 5 minutes. This tapping action may cause some discomfort to the finger. This discomfort typically resolves within a few minutes after completing the test. If you are asked to participate in this aspect of the study, you may decide at any time to not participate or to stop participation during the test.

Additional Cost:

If your cellular / mobile phone or smartphone provider charges you for individual text-messages, you may experience charges on your bill that result from participation in this study.

What does the study team have access to?

The Principal Investigator, Co-Investigators and study personnel will be able to view all study materials and how you as a participant have interacted with these materials. The study team will also have access to the data collected with the wrist actigraph and PVT reaction time test when it is being collected. Once the study has completed data collection, all of the data collected will be de-identified and examined in aggregate.

Potential Benefits:

You may experience benefits in the form of increased awareness of the dangers of fatigue and benefits of good sleep health. You may benefit from this study by learning more about how to improve your sleep health and lessen your fatigue. However, benefits are not guaranteed. This study will help researchers and employers learn more about the impacts of shift work on health and safety, and may lead to improvements in the general health, sleep health, and safety of EMS clinicians.

Remuneration/Compensation:

Those who qualify for the study and choose to participate will receive remuneration worth approximately \$35 U.S. dollars. Participants will receive remuneration in the form of a gift card totaling approximately \$35 in value. A \$5 Visa or MC gift card will be distributed at the beginning, when you enroll, every month you complete the study, and at the end of the study (month 6). All gift cards will be distributed via U.S. Mail directly to participants.

Those who participate in this research study will have the opportunity to apply for 2.25 hours of continuing education credits offered by the Commission on Accreditation for Prehospital Continuing Education (CAPCE). The National Association of State EMS Officials (NAEMSO) will be the responsible for processing your individual application of continuing education. The information you need to apply for these continuing education credits will be available on the study website.

What if I decide to NOT take part in this research study?

Your participation in this study is completely voluntary. You should feel no pressure to participate. If you decide not to participate in the research study, you will not in any way harm your relationship with Dr. Patterson, his associates, or with the University of Pittsburgh. You are free to stop participating in the study at any time. This too, will not harm your relations with Dr. Patterson, his associates, or with the University of Pittsburgh.

Your withdrawal from this study will not negatively affect your job in any way. Your research data may be retained and analyzed for the purposes of this study.

To withdraw from this study,

- 1: Please email or call the study team and inform them of your decision to withdraw; OR
- 2: You can use the “withdraw from study” option on the study’s website.

Confidentiality:

The records of this study will be kept confidential. In any publication, we will not include any information that will make it possible to identify you or your

participation in the study. Your de-identified research data and the documents that you signed for this study may, however, be reviewed and/or photocopied by the University of Pittsburgh, or other persons/agencies as required by law or allowed by federal regulation. To that extent, confidentiality is not absolute.

- Since you are being compensated for your participation in this study, your name, address, and social security number will be released to the University of Pittsburgh Accounting Office. If the total reimbursement for your participation in research is greater than \$600 in a year, this will be reported to the Internal Revenue Service (IRS) as income.
- Your Personally Identifiable Information (PII) will be kept secure and separate from your research study data. Your identity will not be linked to your research study data.
- There is a strong defense against breach of confidentiality. For example, we will de-identify your data and use a Participant ID to track your research study data. We will keep your data secure on password protected computer servers, in locked filing cabinets, located in locked offices on the University of Pittsburgh campus. We will also request each participant that does not already have a passcode on his/her phone create one prior to starting the study. We will also ask each participant to delete the text message conversations from their phone on a regular basis.

Authorization:

- If you wish to take part in this research study, you will be asked to consent to this study at the end of this video.
- You will then be required to confirm your understanding of the consent by selecting the “ACCEPT” button on the study website before you can continue.
- This allows the study sponsor and investigators to collect, process, and pass along any relevant information collected from you during the study to other study team members.
- Note that the file containing your name, telephone number, and email will be kept separate from the research study data. No Personally Identifiable Information (PII) will be shared. There is a strong defense against breach of confidentiality.
- Also, of special note, your data will never be shared with your supervisor or employer, and therefore not used for disciplinary action.
- As previously stated, your Personally Identifiable Information (PII) will be kept in a secure file separate from your research study data.
- The research study team will use your PII for purposes of maintaining contact and communication with you during the study.
- Your PII will not be shared with anyone not on the research study team.
- We will store your research study data on secure computer servers maintained by the University of Pittsburgh and the University of Pittsburgh

Medical Center. It is the policy of the University of Pittsburgh to maintain all research records for at least 7 years following final reporting or publication of a project.

- These databases may be audited or accessed by the following:
 - [a] the study investigator and research staff of Dr. Daniel Patterson;
 - [b] the study sponsor and/or its associated companies (i.e., the National Highway Traffic Safety Administration in collaboration with the National Association of State EMS Officials); and
 - [c] regulatory or other governmental authorities of the United States, other persons authorized by the study sponsor, the University of Pittsburgh, and other persons or agencies as required or allowed by federal regulations; and
 - [d] UPMC hospitals or other affiliated healthcare providers.
- A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Final Notice:

You have been informed that your name, sleep health, and other relevant personal data will be collected and processed for the purpose of characterizing the impact of sleep health and fatigue education and training on key indicators of sleep and fatigue among EMS clinicians.