

PARTNERS HUMAN RESEARCH COMMITTEE PROTOCOL SUMMARY

Answer all questions accurately and completely in order to provide the PHRC with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.

PRINCIPAL/OVERALL INVESTIGATOR

Rebecca Robbins, PhD

PROTOCOL TITLE

Design and usability testing of a tailored intervention to increase awareness about sleep and sleep disorders among transportation workers

FUNDING

None

VERSION DATE

Tuesday September 28, 2021

SPECIFIC AIMS

Concisely state the objectives of the study and the hypothesis being tested.

The objective of this protocol is to conduct a focus group to identify beliefs, attitudes, and knowledge among employees in the transportation industry on shift schedules about sleep and sleep disorders, then pilot test a tailored intervention using classroom-based learning with follow-up behavior change text message reminders on the importance of sleep and sleep disorders treatment where appropriate.

BACKGROUND AND SIGNIFICANCE

Provide a brief paragraph summarizing prior experience important for understanding the proposed study and procedures.

Transportation shift workers (TSW, e.g., overnight, on-call, or rotating) have been identified as a high-risk group for health conditions (e.g., obesity, cardiovascular disease). Also, TSW are at risk for significant sleep barriers and a sleep disorder called obstructive sleep apnea (OSA). According to one study, approximately 36% of TSWs have OSA, a condition that exacerbates health risks and daytime sleepiness. A recent report from the American Academy of Sleep Medicine (AASM) showed that those with untreated OSA cost on average \$4,261 more than those without OSA. Also concerning, workers with OSA who are non-adherent to recommended OSA treatment (i.e., continuous positive airway pressure, CPAP) are at particularly high risk for motor vehicle accidents compared to those who are adherent.

This protocol outlines focus groups that will aim to identify knowledge, attitudes, and beliefs about OSA among TSW, followed by the design and deployment of a tailored intervention using classroom based learning with follow-up behavior change text message reminders on the importance of sleep and sleep disorders treatment where appropriate.

RESEARCH DESIGN AND METHODS

Briefly describe study design and anticipated enrollment, i.e., number of subjects to be enrolled by researchers study-wide and by Partners researchers. Provide a brief summary of the eligibility criteria (for example, age range, gender, medical condition). Include any local site restrictions, for example, "Enrollment at Partners will be limited to adults although the sponsor's protocol is open to both children and adults."

Briefly describe study procedures. Include any local site restrictions, for example, “Subjects enrolled at Partners will not participate in the pharmacokinetic portion of the study.” Describe study endpoints.

Overall Design: We will leverage a strong relationship with the U.S. Department of Transportation (DOT) that the principal investigator (Dr. Robbins) has developed over the past five years. Dr. Robbins will conduct interviews virtually via Zoom at U.S. Department of Transportation sites throughout New York State. Dr. Robbins will conduct focus groups and interviews to identify the OSA knowledge, attitudes, and beliefs among TSW. The results of this study will inform the development of a tailored intervention to address TSW and their specific barriers, which will be developed by Dr. Robbins (a skilled health communication researcher), deployed using classroom based learning with follow-up behavior change text message reminders on the importance of sleep and sleep disorders treatment where appropriate, and evaluated in a pilot study.

For studies involving treatment or diagnosis, provide information about standard of care at Partners (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

This protocol does not involve treatment or diagnosis. There are no alternative procedures, other than the subject exercising his or her right not to participate in the study. Participants will learn about sleep and sleep disorders, they will not receive personal diagnosis or treatment recommendations, but instead receive information on evidence-based sleep health tips and strategies and treatment for OSA.

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

Sound research design procedures are used in this study. There are no known risks or discomforts associated with completing the questionnaires or participating in this study.

As we described above, we will rigorously protect the confidentiality of the survey responses to the best of our ability. In the course of our prior safety research, we have used similar procedures and developed extensive experience with maintaining data security. However, there is a very small risk inherent in any type of data collection that the confidentiality may be compromised. In addition, in the context of the intervention portion of the study, it is possible that the messages may make individuals feel uncomfortable. Risks will be minimized by ensuring messages are general, informative, and designed according to published evidence and practice standards.

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

This proposal includes research involving human subjects (TSW). The PI has completed the Partners Health Care System's core human subject protection education requirements. All investigators are in compliance and will maintain compliance with NIH education and training requirements regarding human-subject research. Our organization has an accepted and currently valid general assurance on file with the Department of Health and Human Services (DHHS). The protocol will be reviewed by Brigham and Women's Hospital Committee for the Protection of Human Subjects from Research Risks according to the assurance provided to the DHHS, and will provide for continuing review as specified in the general assurance. This general assurance will apply equally to the study to be performed as described in this proposal. The investigators reserve the right to terminate the study at any time they feel it is necessary for the subject's welfare, or for research purposes. Subjects have the right to withdraw at any time.

FORESEEABLE RISKS AND DISCOMFORTS

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

a. Complications of surgical and non-surgical procedures

There are no procedures performed in this study.

b. Drug side effects and toxicities

There are no drugs used in this study.

c. Device complications/malfunctions

There are no devices in this study.

d. Psychosocial (non-medical risks)

The investigators will protect the confidentiality of all of the data collected during the course of this study to the best of their ability; however as with any type of research in which data are collected, there is a very small risk that confidentiality may be broken. If, during the study, we have reason to believe that a subject is at risk for harming themselves or others, we are required by law to take the necessary actions. This may include notifying the subject, their therapist(s) if applicable, or other individuals. If the Principal Investigator believes that it is necessary to disclose such information, the subject will be contacted and informed about the specific reasons for the disclosure. Such cases are extremely rare, but subjects are informed about this possibility in the research consent form. If information we collect is disclosed to another person who is not involved in this study, it is possible that the subject may suffer social harm such as workplace difficulties.

e. Radiation risks

There are no procedures that could introduce radiation risk that will be performed in this study.

EXPECTED BENEFITS

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, "It is hoped that the treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects." Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.

Potential benefits to participating individuals

The individual TSW will have the opportunity to learn about sleep and sleep disorders, specifically, OSA diagnosis and treatment, the vast majority of whom are undiagnosed according to Dr. Robbins' pilot data. This information could decrease their individual risk of motor vehicle crashes, and their long-term risk of cardiovascular disease, glucose intolerance, gastrointestinal disease, and other health problems. It could also improve their quality of life and job satisfaction. The DOT worksite manager or director will see who among their employees are involved in the study. However, this study does not report anything to either the state or employer regarding a suspected OSA risk among TSW in this study. The results of this study will further the knowledge of the impact of OSA and may provide a model program that can be applied nationwide to help other TSW employees suffering from untreated OSA.

Potential benefits to society

More globally, the knowledge generated by this study will illuminate the barriers to OSA among a high risk group, thereby offering utility to researchers and practitioners in behavioral interventions who may be interested in designing interventions to improve OSA awareness, evaluation and treatment rates among TSW.

EQUITABLE SELECTION OF SUBJECTS

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

This proposal includes research involving human subjects (TSW). All applicants will be considered without bias, regardless of race, ethnicity, or national origin.

Inclusion of Women. We expect the gender of study participants to reflect that of the nationwide TSW. While men outnumber women, there are women TSW who will be studied. (In 2011, women accounted for only 1.0% of all TSW recruited for another study conducted by Dr. Robbins.)

Inclusion of Minorities. We expect the minority representation in this study to reflect that of the TSW employee population nationwide. According to the Bureau of Labor Statistics

(2007), 41.8% of transportation workers are white, 15.2% are black, 34.8 % are Hispanic/Latino and 4.1% are in the Asian category.

Inclusion of Children. Children under the age of 18 will not be studied. The study population is limited to TSW employees and volunteers and therefore children will not meet the inclusion criteria.

When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and to have an interpreter present.

Individuals who do not speak English will not be excluded from participation. We will provide consent forms translated into Spanish for those who do not speak English (forthcoming, currently being translated by a Partners approved translation service).

For guidance, refer to the following Partners policy:

Obtaining and Documenting Informed Consent of Subjects who do not Speak English
<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Non-English-Speaking-Subjects.pdf>

RECRUITMENT PROCEDURES

Explain in detail the specific methodology that will be used to recruit subjects. Specifically address how, when, where and by whom subjects will be identified and approached about participation. Include any specific recruitment methods used to enhance recruitment of women and minorities.

We will draw on established recruiting methods, which we successfully used during our prior study of TSW conducted by Dr. Robbins.

For the focus groups, we intend to contact approximately 5 to 20 DOT worksite managers in NYS. There are 80 DOT worksites across NYS. We will have preliminary telephone conversations with the training and education staff for DOT in NYS to determine the level of commitment from each department and to draw up procedural plans for conducting the protocol at specific sites. For the pilot study, we propose to similarly contact 5 to 20 DOT worksite managers in NYS to ascertain their interest and willingness to have their worksite be included in the pilot study. TSW at the DOT worksites that agree to take part in our study may be informed of the study via invitation emails, letters, flyers and informational brochures and an educational video which may be disseminated through departmental channels and may be sent directly to DOT worksites or individual TSW. Potential participants may also be asked to share the email with their colleagues to ensure wide dissemination of the invitation.

Provide details of remuneration, when applicable. Even when subjects may derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital,

parking fees or other inconveniences will result in additional out-of-pocket expenses related to study participation. Investigators may wish to consider providing reimbursement for such expenses when funding is available

Subjects will not receive payment for participation, per DOT guidelines, but will be eligible to complete the study during work hours.

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Recruitment-Of-Research-Subjects.pdf>

Guidelines for Advertisements for Recruiting Subjects

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Guidelines-for-Advertisements.pdf>

Remuneration for Research Subjects

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Remuneration-for-Research-Subjects.pdf>

CONSENT PROCEDURES

Explain in detail how, when, where, and by whom consent is obtained, and the timing of consent (i.e., how long subjects will be given to consider participation). For most studies involving more than minimal risk and all studies involving investigational drugs/devices, a licensed physician investigator must obtain informed consent. When subjects are to be enrolled from among the investigators' own patients, describe how the potential for coercion will be avoided.

Participants will be consented virtually due to the COVID-19 pandemic. Eligible participants will view on Zoom a virtual copy of the consent form via REDCap and provided sufficient time to review this document and ask Dr. Robbins or any other member of the study team accompanying her, any questions prior to agreeing to provide a digital e-signature on the REDCap platform. Participants will be allowed 12 hours before they will be asked to sign the consent form. Once the participants has sufficiently read the consent form and does not have any questions, the individual may provide their e-signature to indicate he/she understands the study and agrees to participate or he/she may check the square indicating "I do not wish to participate." Since this focus group portion of the study is considered minimal risk (survey), we believe this is a reasonable approach to the consenting process. Subjects participating online will not be limited in their time to review the consent form.

With regard to the pilot study, interested and willing participants will be asked to read and sign the consent form in person as the current COVID-19 policies permit in-person research procedures. Dr. Robbins will be available to answer questions subjects may have about the study, the consent form, and any study procedures.

According to our conversations with DOT personnel, non English-speaking participants include Spanish native speakers, but represent a low proportion of the employee population (<5%). Nevertheless, we will prepare translated consent forms and study documents to ensure

non-English speakers or individuals who are more comfortable speaking in Spanish, will be eligible for this study.

NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the PHRC website:

<https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb>

For guidance, refer to the following Partners policy:

Informed Consent of Research Subjects:

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Informed-Consent-of-Research-Subjects.pdf>

DATA AND SAFETY MONITORING

Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping rules for the study, when appropriate. Depending upon the risk, size and complexity of the study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

NOTE: Regardless of data and safety monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under his/her care.

Data that will be reviewed. A Data Safety Monitoring Board (DSMB) will be created for this study. The DSMB will review the following study-related aspects and make recommendations, as appropriate:

- Participant safety
- Initial approval of the protocol and consent forms and subsequent amendments
- Efficacy of the study intervention
- Benefit/risk ratio of procedures and participant burden
- Selection, recruitment, and retention of participants
- Adherence to protocol requirements
- Completeness, quality, and analysis of measurements
- Performance of individual centers and core labs
- Notification of and referral for abnormal findings

Planned frequency of review. Meetings are held twice a year, with additional meetings scheduled as needed. The NHLBI Program Office will be notified of scheduled meetings in advance should Program Officer and/or delegate wish to monitor the meeting.

- For this DSMB all meetings will be conducted via teleconference.
- Review of interim data analyses will occur annually in the second of the two meetings of the DSMB scheduled each year.
- Ad hoc meetings may be scheduled as needed

Who will be responsible for review. The DSMB is an independent group advisory to study personnel and is required to provide recommendations about starting, continuing, and stopping the study. DSMB members and their expertise are listed in the DSMB Charter. Consistent with NHLBI policy, each DSMB is assigned an Executive Secretary (ES) to provide an unbiased study interface for the DSMB, and for preparing final recommendations and meeting report. Dr. Bosch will serve as the ES. The DSMB Chair is responsible for assuring the accuracy and timely transmission of the final recommendations and DSMB's report. *Ad hoc* members may be added to the DSMB to supplement expertise, as necessary for single or multiple meetings.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor safety reports and DSMB reports. Describe the plan for reporting adverse events to the sponsor and the Partners' IRB and, when applicable, for submitting sponsor safety reports and DSMB reports to the Partners' IRBs. When the investigator is also the sponsor of the IND/IDE, include the plan for reporting of adverse events to the FDA and, when applicable, to investigators at other sites.

NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Partners Human Research Committee guidelines for Adverse Event Reporting

If an adverse event occurs, the principle investigator and appropriate study staff will be notified so that the event may be reviewed. Any adverse event will be reported, as required, to the Partners IRB and the DSMB.

MONITORING AND QUALITY ASSURANCE

Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, specify who will review the accuracy and completeness of case report form entries, source documents, and informed consent.

NOTE: Regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in

accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

a. Independent monitoring of source data

Dr. Robbins will be responsible for collecting, monitoring and analyzing data. Standard procedures to ensure accurate, reliable data collection include well designed databases, data forms with clear instruction manuals, central training with hands-on practice, and on-going monitoring of all data collection.

b. Safety monitoring

A data safety monitoring board is not required for this study

c. Outcomes monitoring

There will be a substantial time lag (likely many months) between when the data is collected and when it is analyzed. Thus, it will not be possible for us to follow up on any information collected for a particular individual; in other words, our study cannot serve as a screening device to detect and prevent possible adverse health outcomes in the subjects. Subjects will be informed that this is the case, and if they have concerns about their physical or mental well-being, they should seek professional assistance.

d. Adverse event reporting guidelines

Any adverse events related to the protocol will be promptly reported to the IRB and the DSMB.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/DSMP-in-Human-Subjects-Research.pdf>

Reporting Unanticipated Problems (including Adverse Events)

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Reporting-Unanticipated-Problems-including-Adverse-Events.pdf>

PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed surveys/questionnaires; proper disposal of printed computer data; limited access to study data; use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.

NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

The information to be acquired by this study is highly sensitive Protected Health Information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). We therefore plan to take every precaution to protect privacy, ensure confidentiality and to establish a trusting, non-punitive environment. Confidentiality is critical to obtaining participation and therefore these data will be protected by the doctor-patient privilege. Some data will be collected electronically; other data will be collected on paper forms initially, and subsequently stored electronically (password protected) in a secure location. Through our prior research, we have developed extensive experience with maintaining this level of data security. Only study investigators and staff will have access to these data in identified form. Data from individual participants will be assigned numerical identification numbers, which will be used to link data records for each individual, and then the remainder of the analysis record will be de-identified. All identifiers will be maintained in locked filing cabinets at the Brigham and Women's Hospital. The name-code index will be maintained in a secure location, in an encrypted file on a password-protected stand-alone computer system that is not linked to the internet. We understand our responsibilities to protect the confidentiality of research and statistical information and have developed specific procedures to ensure that this information is only used or revealed in accordance with its intended research purposes. Because of the highly confidential nature of data on crashes and activities, we also intend to apply for a Certificate of Confidentiality for data protection from the National Institutes of Health.

SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS

Specimens or data collected by Partners investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects.

Specimens will not be sent to collaborators outside Partners.

Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

No identifiable data would be stored outside of Partners sites.

Subjects can withdraw from the study at any time by sending an email to the investigators stating their intention to do so.

RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS

When specimens or data collected by research collaborators outside Partners will be sent to Partners investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Partners investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB

approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.

Specimens/data will not be received from research collaborators outside Partners.