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TITLE: A Randomized, Double-Blind, Placebo-Controlled Trial of Doxazosin for Nightmares, Sleep Disturbance, and Non-Nightmare Clinical Symptoms in Post-Traumatic Stress

PRINCIPAL INVESTIGATOR: Anne Richards, MD, MPH

CONTRACTING ORGANIZATION: Northern California Institute for Research and Education Inc.
4150 Clement St 151NC
San Francisco CA 94121-1545

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Anne Richards, MD, MPH
Email: anne.richards@ucsf.edu

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Northern California Institute for Research and Education, Inc.
4150 Clement St 151NC
San Francisco, CA 94121-1545

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13. SUPPLEMENTARY NOTES

14. ABSTRACT
Posttraumatic Stress (PTS) is a condition that may develop after highly stressful life events and affects 8-10% of adults in the U.S. civilian population and up to 30% of soldiers exposed to combat. We are conducting a randomized, double-blind, placebo-controlled trial design to more definitively demonstrate doxazosin's clinical benefits for PTS nightmares, non-nightmare sleep disturbance, and overall PTS symptoms. To assess the effects of doxazosin on the main outcome of interest, PTS nightmares, eligibility will be based on the presence of PTS nightmares in the setting of full- or partial-syndromal PTS. We are using flexible dose design of doxazosin with a 4-week titration phase followed by a 4-week steady-dose phase. The primary scientific aims of our study are as follows: (1) To assess the effects of doxazosin, in comparison to placebo, on sleep disturbance and clinical symptoms of PTS through measures of nightmares, subjective sleep quality, and non-nightmare PTS symptoms, in adult men and women with chronic PTS; (2) To examine the effects of doxazosin on an objective measure of sleep/wake activity in adult men and women with chronic PTS; (3) To examine the effects of doxazosin, as compared to placebo, on depression symptoms, sexual health, and overall quality of life.

15. SUBJECT TERMS
Sleep disturbances, Nightmares, Post-Traumatic Stress, Doxazosin, Alpha-1 Antagonists

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1. INTRODUCTION:

We are currently performing a randomized, double-blind, placebo-controlled clinical trial to assess the effectiveness of doxazosin for the treatment of PTS nightmares, sleep disturbance, and non-nightmare PTS symptoms in adult male and female veterans with chronic PTS symptoms. The primary aims are to assess the effects of doxazosin, in comparison to placebo, on sleep disturbance and clinical symptoms. Eligibility is based on the presence of severe PTS nightmares in the setting of PTS. We will be using a flexible dose design of doxazosin with a 4-week titration phase followed by a 4-week steady-dose phase. Clinical outcome variables are based on prior studies of prazosin and doxazosin. The primary variables (Aim 1) will be: 1) PTS nightmare severity as measured by the CAPS interview; 2) subjective sleep quality as measured by the PSQI; and 3) total PTS score, minus distressing dreams item, as measured by the CAPS interview. For Aim 2, we will compare active medication and placebo groups on objective measures of sleep measured by at-home EEG at baseline and end-of-treatment as well as wrist actigraphy at baseline, mid-treatment, and end-of-treatment. Exploratory Aims will examine the effects of doxazosin, in comparison to placebo, on measures of depression, sexual health and overall quality of life.

2. KEYWORDS:

Sleep Disturbance
Nightmares
Post-Traumatic Stress
Doxazosin
Alpha-1 Antagonist

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The primary scientific aims of our study are as follows:

Primary Aim 1:
To assess the effects of doxazosin, in comparison to placebo, on sleep disturbance and clinical symptoms of PTS through measures of nightmares, subjective sleep quality, and non-nightmare PTS symptoms, in adult men and women with chronic PTS.

Primary Aim 2:
To examine the effects of doxazosin on an objective measure of sleep/wake activity in adult men and women with chronic PTS.

Primary Aim 3:
To examine the effects of doxazosin, as compared to placebo, on depression symptoms, sexual health, and overall quality of life.

We described our major tasks and target dates of achievement of these tasks as follows:

Major Task 1 (Months 1-6): Prepare Protocol and Perform Regulatory Procedures for Randomized Placebo Controlled Trial of Doxazosin: Completed
Study materials including protocol, consent form, and study documents have been created and submitted to the UCSF IRB. The study underwent full committee review and was granted final UCSF IRB approval. The study was submitted to SFVAMC regulatory personnel and granted approval by the VA Clinical Research Workgroup as well as the VA Research and Development Committee. The

study was submitted to HRPO and initial approval was received. A supplemental award was received by the study PI to add objective measures of sleep and sleep/wake activity. These changes were submitted to the UCSF IRB and approval was received. Final approval was received from HRPO and the study began recruitment.

Major Task 2 (Months 1-5): Coordinate Study Staff for Clinical Trial: In Progress
The research coordinator became suddenly unavailable in the beginning of May 2019. A new research coordinator was hired to take over for the previous coordinator in June 2019 and is now fully trained. Additionally, a senior research assistant transitioned out of the lab in June 2020. We are currently in the interview process of hiring a new research assistant. One very experienced, full-time research assistant continues on the team. Additionally, we are in the process of training three new volunteer research assistants to assist in study recruitment efforts.

Major Task 3 (Months 6-42): Randomized Controlled Trial: In Progress
Implementation of the randomized controlled trial has continued, and study staff are actively recruiting and enrolling subjects in the clinical trial. Twelve subjects have completed all study procedures. In March 2020, recruitment and new enrollment suddenly halted as shelter-in-place orders were enacted in response to the COVID-19 pandemic. Under the direction of our Stress and Health Research Program, we ceased new enrollment. It is notable, however, that during the initial shelter-in-place circumstances we did successfully completed our two most recent completers via remote procedures. From March-May 2020 our team worked diligently to convert all study procedures to be performed remotely. During this time, we continued to recruit veterans via advertising and telephone pre-screening. In June 2020 we felt confident with our remote procedures plan to re-open enrollment. We are currently screening a veteran and aim to enroll our first fully remote participants in the coming quarter. We are able to restart despite strict clinical research limitations at the SFVAMC due to the pandemic.
The research study staff continue to pre-screen medical records of participants attending virtual clinics at the SFVAMC to identify potentially eligible participants for study recruitment. We are working with clinic leaders to tailor our recruitment efforts under remote circumstances by presenting via video conference to clinical staff at SFVAMC to educate staff about the study and referral procedures. We continue to aggressively recruit veterans in the Santa Rosa catchment area and have successfully completed our first Santa Rosa participant during year three. We have finalized our lab website in the effort to increase online recruitment, advertisement and outreach. Additionally, a system is in place with other members of our research program to refer participants to our study based on appropriate responses to intake screeners used throughout the SFVAMC.

Major Task 4 (Months 4-48): Data Analysis and Dissemination of Findings: Pending
The database created by the Data Core staff is functioning well and data are being entered into the study database as they are collected. Preliminary analyses regarding factors affecting recruitment and eligibility rates are being examined, so as to guide recruitment processes. The research team monitors data quality on an ongoing basis to ensure readiness for analysis upon completion of enrollment.

What was accomplished under these goals?

1) Major Activities: We have continued to actively recruit veterans through mailings, advertising and telephone pre-screening of interested participants. Twelve subjects have completed all study procedures, which is more than double our completion rate at the last annual reporting time. This is a direct result of our work over course of Year 3 to enhance flexibility in the implantation of the protocol and continued aggressive recruitment tactics deployed by study staff. We received IRB approval on several modifications to enhance study protocol and recruitment which are detailed in *section 5 Changes/Problems*. Unfortunately, our study was

not spared from the negative impacts of COVID-19. Enrollment of new participants was abruptly halted in March 2020 in response to Bay Area shelter-in-place orders and strict VA prohibition of clinical research involving any in-person visits. In addition, all staff transitioned to remote telework. It is notable that our team remotely completed our two most recent participants who were randomized and at mid-enrollment when this shift happened due to the pandemic. During the initial months of telework, our team worked diligently to solidify a plan for fully remote study procedures from start to finish and received the required IRB approvals. A plan for remote study procedures was already in-progress prior to shelter-in-place orders, however with dramatic turn of events in March 2020 it was brought to focus for completion. In June 2020 we felt confident in our preparations to begin screening recruits and re-opening enrollment for remote participation. At this time, we have successfully completed our first remote consent via video conferencing and are in the process of screening this recruit for eligibility. We aim to aggressively recruit and enroll remote participants in the upcoming quarter. Although enrollment numbers have been dramatically impacted over the last several months due to the pandemic, we are optimistic about our remote procedures process. We predict this will enhance recruitment and broaden our study reach to allow for enrollment of participants who would have been unable to participant in-person even outside of the pandemic circumstances. Additionally, we continue to develop new recruitment strategies. In the coming quarter we are initiating recruitment via posting advertisements on various internet platforms (i.e. Craigslist), developing our social media presence, obtaining a broader list of area veterans through the Defense Manpower Data Center (DMDC), and employing outreach to private practice clinics with a focus on trauma and veterans.

2) Specific Objectives: Our specific objectives were consistent with our major activities. We aim to continue implementing the randomized controlled trail and increase enrollment numbers through various avenues including: aggressive advertising, telephone pre-screening, outreach at community-based outpatient clinics, pre-screening medical records of SFVAMC clinic attendees, presenting to SFVAMC clinical staff, and responding to relevant intake screeners.
3) Significant Results/Key Outcomes: No results to date.
4) Other Achievements: We have redesigned our approach to clinic recruiting due to telework and remote clinic procedures. This involves our study team presenting to clinical staff via video conferencing meetings and being available on short notice to screen potentially eligible clinic candidates via video conferencing.

What opportunities for training and professional development has the project provided?

Dr. Richards attended a professional development training on the computer programming language MATLAB to enhance her and the team's ability to perform sophisticated EEG analysis of the data collected with the Sleep Profiler ambulatory EEG device being used in the study.

Additionally, a research team representative attended the 2020 Virtual Congress hosted by the International Society for the Study of Trauma and Dissociation. Our research staff member attended several virtual workshops and discussions over the course of two days which centered on trauma and dissociation discussion. This allowed for the attendee to share relevant and up-to-date trauma research with our team.

How were the results disseminated to communities of interest?

Nothing to Report.

What do you plan to do during the next reporting period to accomplish the goals?

Our main priority is to continue aggressive recruitment and enrollment, both at the San Francisco VA and at our satellite clinic the Santa Rosa VA, using the resources described above. Our research team is fully trained, and we have worked out various kinks in the protocol implementation process, so that participants can now be run through the protocol smoothly and effectively. We plan to hire a new full-time research assistant in the coming months and complete the training of three new volunteer research assistants. Additionally, we plan to perfect our remote study procedures as we foresee Bay Area shelter-in-place orders and VA in-person research restrictions to continue.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report: pending completion of enrollment and data analysis

What was the impact on other disciplines?

Nothing to Report.

What was the impact on technology transfer?

Nothing to Report.

What was the impact on society beyond science and technology?

Nothing to Report.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

To enhance recruitment and eliminate factors that unnecessarily encumbered protocol implementation, multiple modifications have been submitted to the USCF IRB over the past year. All changes have been approved by the UCSF IRB and have been reported during relevant DoD quarterly reports. Recruitment of participants occurred at a slower rate than projected. We submitted several modifications to broaden eligibility criteria and enhance recruitment numbers, and these are now being implemented. The primary changes captured, and their justifications are as follows:

1) ECGs will be performed at eligibility only if clinically indicated (defined as history of cardiac disease, arrhythmia, or symptoms of potential cardiac origin such as chest pain).
    i) Justification: Doxazosin is widely prescribed in clinical practice for non-cardiovascular indications and an EKG is not normally performed in such situations, in that absence of a cardiac history or symptoms suggestive of cardiac disease. We have found that performing EKG's has resulted in excess burden for participants and research staff without significant impact on enrollment decisions. We have found that non-exclusionary findings on EKG have resulted in multiple steps to consult with cardiologists and primary providers with no added benefit. Our titration plan is slow and well-monitored with bi-weekly symptom assessments and weekly vital signs assessments, including orthostatics. Orthostatic BP and HR assessments already go beyond standard prescribing practice for this medication in non-cardiology clinics. To therefore avoid excess burden for staff and/or participants we plan to perform a baseline EKG only if clinically indicated, as defined by a history of cardiac disease, arrhythmia, or symptoms of potential cardiac origin such as chest pain. These rules were modeled on the VA Cooperative study of prazosin for PTSD and discussion with senior co-investigators Dr. Neylan and Karen Seal, as well as our medical monitors.

2) Language changed in IRB study application to specify that orthostatic blood pressure changes will trigger consultation with a study physician or a medical monitor to determine whether dose reduction or study discontinuation should be considered.
   i) Justification: We noticed that prior language stated that orthostatic blood pressure changes will trigger consultation with the principal investigator and medical monitor to determine whether dose reduction or study discontinuation should be considered. We believe this initial statement was made in error and is overly cautious. Management of symptomatic and asymptomatic blood pressure changes are basic features of outpatient practice in psychiatry and internal medicine and in the context of these adverse effects a single physician is sufficient to determine the best course of action. While a dose change is indicated in the context of symptomatic changes, this is well-delineated in our protocol. The study provider will continue to consult with other study clinicians and/or medical monitors should any questions regarding appropriate clinical procedures or adverse events arise, as per clinical judgment and protocol.
3) Lowering exclusion criteria for standing systolic blood pressure from <110 mmHg to <100 mmHg at eligibility.
   i) Justification: Because we fear we will exclude many healthy, young participants with BP's on the low end of normal, we will lower the eligibility standing systolic blood pressure cutoff to 100 mmHg at minimum. We consulted with and received guidance and approval from the DSMB regarding this criteria revision. Again, baseline blood pressure assessments are not typically done in clinical practice and asymptomatic individuals with standing blood pressure on the low end of normal may be unfairly excluded as a result. Slow titration and close monitoring as previously described ensures the safety of our participants.
4) Altered exclusion language to specify that the standing systolic blood pressure reading used for eligibility determination will be taken at eligibility (Visit 0) instead of at baseline (Visit 1).
   i) Justification: We realized that our protocol for standing systolic blood pressure was too imprecise with respect to criteria for enrollment, and that we need to capture the standing systolic BP earlier <u>at eligibility and not at baseline</u> for purposes of inclusion criteria. We are therefore adding a standing systolic BP reading at eligibility prior to taking orthostatic vital signs measurements. Current language and protocol lacked clarity at which timepoint the BP measurement used for eligibility consideration would take place.
5) Phone screen can take place in person if preferred by prospective participant or study staff.
   i) Justification: If a participant is onsite at the VA and interested in completing screening procedures, it is beneficial for both the participant and the research team to be able to complete screening procedures in-person at the time of initial contact. Our current phone screen protocol does not specifically state that this can be accomplished in person if the participant and staff are available at the time a potential participant expresses interest in eligibility screening.
6) Research staff, in place of the study MD or NP, can complete the post-treatment phone call within one week of study termination to assess for any symptoms or concerns emerging in the context of study drug discontinuation. The participant will be placed in contact with a study NP or MD should any medical concerns emerge.
   i) Justification: This change is being implemented to increase feasibility for participants and research staff. As this is not a formal medical assessment, trained research staff can complete the function of the call and an MD or NP will be placed in contact with the participant to address any medical concerns if necessary. The post-treatment phone call is conducted for research purposes and has no clinical indication.
7) Change language to allow those who are pre-screened as high risk on the Berlin Sleep Questionnaire to have the option to complete written informed consent only and one night of at-home sleep apnea screening (using ApneaLink) before continuing with eligibility screening. Change language to allow those with an AHI of 15 or less based of ApneaLink data analysis to be eligible for the study regardless of OSA treatment status.

i) Justification: The majority of participants referred to the sleep clinic are lost to contact. This has been a large barrier to recruitment and we are losing otherwise eligible participants who could potentially benefit through the delays of going through a sleep clinic referral. Including those with an AHI score of 15 or less regardless of treatment status will in turn capture a more representative sample of the study's target population.

8) Addition of an alternate compensation plan in accordance with the proposed change of completing an at-home apnea screening earlier in the eligibility process.
   i) Justification: This alternative schedule has been created to ensure all participants completing eligibility are compensated the same up to that point. Apnea screening completed by the study team prior to further eligibility assessments is to the advantage of both the participant, from a clinical point of view, since it speeds up their evaluation for obstructive sleep apnea, and the study team.
9) Clarify the language to only exclude benzodiazepines taken for insomnia.
   i) Justification: Several otherwise potentially eligible participants have been excluded for taking benzodiazepines for anxiety that we believe could potentially benefit from study participation. We would like to clarify the language to only exclude benzodiazepines taken for insomnia.
10) Research clinicians may contact participant's primary provider (e.g. primary care physician and/or psychiatrist) upon signing of informed consent to obtain the provider recommendations regarding eligibility. For candidates with medical exclusion criteria, this may help clarify their eligibility prior to more extensive eligibility assessments.
   i) Justification: This is intended to help avoid eligibility assessments, that are often lengthy and intensive, by filtering out those who are not eligible for other medical/treatment reasons.
11) Recruits with a CAPS-IV recurrent distressing dream score of 4 or above will be eligible for enrollment with a CAPS-5 score of 18 or more. Recruits with a CAPS-IV recurrent distressing dream score of 3 or above will be eligible for enrollment with a CAPS-5 score of 20 or more.
   i) Justification: The primary study aim is to assess the effects of doxazosin, in comparison to placebo, on sleep disturbance through measures of nightmares and subjective sleep quality in adult men and women veterans with chronic PTS. From increasing experience, we have determined that our threshold of >20 on the CAPS is excessively high, especially for recruits with marked nightmare experience, and that the requested modification is appropriate in the context of our study aims. We believe that including participants with elevated nightmare symptoms, the primary target of the intervention, despite lower CAPS scores, will help us make more robust conclusions about the effectiveness of our intervention for our primary outcome.
12) Addition of the Timeline Followback (TLFB) to self-report measures.
   i) Justification: The addition of the timeline follow back is to assess recent substance use behavior. The TLFB is validated and involves asking participants to retrospectively estimate their daily substance use over the last month prior to the day of the study visit. This information will be valuable to capture for data analysis in order to characterize our sample and describe how frequently participants use various substances. Our long-term plan is to eventually incorporate this information into the Sleep Diary app.
13) At study investigator discretion, we may forgo some or all of the at-home sleep assessments.
   i) Justification: The at-home sleep assessments do not provide subjective nightmare data and therefore do not interfere with the primary study aim focused on collecting subjective sleep and nightmare data. This exception can be made on a case-by-case basis by the study investigator for someone that may not be a suitable candidate for at-home objective (EEG and/or actigraph) sleep assessments but still might benefit from study drug. Compensation will be adjusted accordingly to the study components the participant completes.
14) If a recruit with a cardiac history is determined eligible by all other eligibility procedures, we

will allow the participant to proceed with study enrollment if their cardiologist approves. If the cardiologist determines no contraindications to be present, then we will proceed with study enrollment. The study clinician and the recruit's cardiologist will work together to determine if an ECG is needed during eligibility procedures.

i) Justification: Several potential recruits have a history of varying cardiac diagnoses. If their cardiologist, who is familiar with their history, approves of their study involvement then we will proceed with enrollment as advised.

15) Removed part of inclusion criteria #3 that requires "partial syndromal PTS of at least 3 months duration" if current full syndromal PTS isn't met. Also altered that recruits with a CAPS-IV recurrent distressing dream score of 4 or above will be eligible for enrollment with a CAPS-5 score of 12 or more.

i) Justification: This modification is in response to a single subject exception that received approval on 1/27/2020. The primary study aim is to assess the effects of doxazosin, in comparison to placebo, on sleep disturbance through measures of nightmares and subjective sleep quality in adult men and women veterans with chronic PTS. From repeated experience, we have determined that our minimum threshold of ≥ 18 on the CAPS-5 is still excessively high, *especially* for recruits with marked nightmare experience, and that the requested modification is appropriate in the context of our study aims. It is possible for someone to meet full syndrome PTSD with a CAPS-5 of 12, which is how we determined this as the new threshold. We believe that including participants with elevated nightmare symptoms, the primary target of the intervention, despite lower CAPS scores, will help us make more robust conclusions about the effectiveness of our intervention for our primary outcome.

16) Added in a telehealth option to allow subjects to participate in study visits from their own homes. Participants will now have the option of attending all study visits from their residences using videoconferencing technology. Permission from the study physician is needed for remote participation.

i) Justification: This option mitigates participation barriers that many prior participants have experienced, including travel and time limitations. Study staff will communicate with remote participants via 2-way video streaming and will be able to call 911 in the case of an emergency. We predict the addition of this option will enhance recruitment.

17) Adjusted exclusion criteria #1 to the following: DSM-5 current serve alcohol or drug use disorder in the last 3 months. Moderate alcohol or drug use disorder in the last 3 months will be reviewed on a case-by-case basis.

i) Justification: Participants with moderate alcohol or drug use disorder in the last 3 months may be eligible to participant and will be reviewed on a case-by-case basis. Severe drug or alcohol use disorder in the last 3 months remains an exclusion criterion. This modification is crucial for reaching the representative population consistent with the research aims.

18) Modified the following components of the baseline medical screening: labs (venipucture), urine toxicology screen, and urine pregnancy testing for female subjects. These are all efforts to further accommodate remote study participation.

i) Justification:

1. Labs: if the subject has had labs drawn within the last year and their primary care physician is agreeable to their participation in the study, we will forgo requiring labs if the subject is unable to complete a lab draw on campus. This change is entirely consistent with standard clinical practice for the prescription of alpha blockers and does not pose a significant safety risk.
2. Urine toxicology screening: if the subject is unable to complete urine toxicology screening on campus, we will forgo the urine toxicology screening and rely on the clinical interview to assess for substance usage.
3. Urine Pregnancy testing: females of childbearing age may take an at-home

pregnancy test provided by the lab and confirm a negative result with the study team before proceeding if they are unable to take the test on campus

19) Updated eligibility assessment procedures to clarify vitals may be taken by study staff or by the research participant for those participating remotely.
    i) Justification: This is to accommodate for those participating remotely.

We anticipate all these changes to help mitigate recruitment challenges encountered thus far, increase recruitment numbers and allow for a greater flexibility in scheduling participants to complete the trial.

Actual or anticipated problems or delays and actions or plans to resolve them

Enrollment has been dramatically impacted due to the COVID-19 pandemic. Due to shelter-in-place orders and strict limitations enacted by the SFVA regarding in-person research visits, no new participants were enrolled from March 2020 to present. Our response to the pandemic has been to hone our remote recruitment, enrollment, and study procedure processes. At this time, we are confident in our plan to shepherd participants from study start to finish in a remote manner and have re-opened enrollment. We are currently screening our first recruit since March 2020 for eligibility and aim to aggressively recruit and enroll remote participants in the upcoming quarter. Other challenges faced throughout the past year, primarily prior to the pandemic, have been addressed in multiple IRB-approved modifications. These changes, and their justifications have been noted above in the *Changes in Approach and Reasons for Change* section. We anticipate all these changes to greatly mitigate recruitment challenges encountered thus far, and to greatly increase recruitment numbers and allow for a greater flexibility in scheduling participants to complete the trial.

Changes that had a significant impact on expenditures

Nothing to Report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to Report.

Significant changes in use or care of vertebrate animals

Nothing to Report.

Significant changes in use of biohazards and/or select agents

Nothing to Report.

6. PRODUCTS:

- **Publications, conference papers, and presentations**

  Journal publications.

  Upon reviewing the 2018 Annual Report, we noted a journal publication that was mistakenly omitted. We have listed the publication below in this report.

Richards, A, Inslicht SS, Ruoff LM, Goldstein L, Metzler TJ, Chapman CM, Hubachek SQ, Neylan TC. An open-label pilot study of doxazosin extended release in PTSD: Results and recommendations for future research on doxazosin. FOCUS. 2018 Jan; 16:1, 67-73.
Status of publication: Published
Acknowledgment of federal support: Yes

Books or other non-periodical, one-time publications.

Nothing to Report.

Other publications, conference papers and presentations.

Nothing to Report.

- **Website(s) or other Internet site(s)**

  Nothing to Report.

- **Technologies or techniques**

  Nothing to Report.

- **Inventions, patent applications, and/or licenses**

  Nothing to Report.

- **Other Products**

  Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Anne Richards, MD, MPH
Project Role:	Principal Investigator
Researcher Identifier:	
Nearest Person Month Worked:	3
Contribution to Project:	Dr. Richards is the initiating investigator and has assumed the overall scientific and administrative responsibility for the project. She is taking the lead on study design, data quality control, data analysis, and preparation of results for dissemination.

Name:	Emily Staggs
Project Role:	Research Coordinator
Researcher Identifier:	N/A
Nearest Person Month Worked:	13
Contribution to Project:	Ms. Staggs is responsible for all

	coordination aspects of the study as well as managing study progress. This includes staff hiring, database and data collection materials creation, equipment purchasing, mobile sleep diary application development, regulatory correspondence, subject recruitment, and subject visit scheduling.

Name:	Katie Huang
Project Role:	Research Assistant
Researcher Identifier:	N/A
Nearest Person Month Worked:	23
Contribution to Project:	Ms. Huang was responsible for aiding in study activities including recruitment, outreach, telephone-screening, participant visits, scheduling, subject tracking, data entry, and other study tasks as needed. Ms. Huang is no longer with the study as of June 2020.

Name:	Aubrey Beck
Project Role:	Research Assistant
Researcher Identifier:	N/A
Nearest Person Month Worked:	16
Contribution to Project:	Ms. Beck is responsible for aiding in study activities including recruitment, outreach, telephone-screening, participant visits, scheduling, subject tracking, data entry, and other study tasks as needed. Ms. Beck is also responsible for facilitating study procedures conducted at the Santa Rosa VA.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report.

What other organizations were involved as partners?

Nothing to Report.

8. SPECIAL REPORTING REQUIREMENTS

Not applicable.

9. APPENDICES:

No appendices relevant to project status attached.