AWARD NUMBER: W81XWH-17-1-0234

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.
San Francisco, CA

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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 94121-1563

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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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TABLE OF CONTENTS

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 experienced full-time research coordinator continues on the team. Two senior research assistants transitioned out of the lab in June 2020 and April 2021. We have hired a new full-time research assistant who will begin in July 2021. Two research assistants who are very familiar with study procedures have assisted the coordinator as needed during this transition time. Additionally, we are in the process of training two 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. Nineteen subjects have completed all study procedures, and one active subject is scheduled to complete in July 2021. 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. 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 and re-opened enrollment. We were able to remotely restart enrollment despite strict clinical research limitations at the SFVAMC due to the pandemic for the entirety of the study's year 4. Our capacity to be on site at the SFVA remains very restricted through this reporting period. Our study participants continue to operate primarily remote with the exception of some eligibility testing (labs and EKG). We are closely monitoring COVID-related guidelines for clinical research from the VA and UCSF.
We have successfully executed the remote completion of 7 new participants since the time of last year's annual report.

The research study staff continue to pre-screen medical records to identify potentially eligible participants for study recruitment. We continue to present to clinical staff at SFVAMC and beyond to educate referring clinicians about the study and referral procedures. We have increased our efforts to boost our presence on web-based platforms such as Reddit, Facebook and Craigslist. Additionally, our marketing campaign is underway with Trialfacts, the specialized patient recruitment service. We have also expanded our efforts to national recruitment and the inclusion of civilians, while enrolling veterans still remains our top priority.

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 emailing, advertising, and telephone pre-screening of interested participants. Nineteen subjects have completed all study procedures, which has increased from twelve reported at the last annual report time. This accomplishment is incredibly notable given the severe restrictions our study team has faced over the entire duration of study year 4 due to the COVID-19 pandemic. We received

IRB approval on several modifications to enhance study protocol and recruitment in light of COVID-19 challenges 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. 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. Over the past year, we have successfully executed 19 remote consent procedures via video conferencing. Additionally, we went on to enroll 8 participants, 7 of which have completed, and the 8th is currently scheduled to complete in July 2021. We aim to continue aggressively recruiting and enrolling remote participants in the upcoming year. Although enrollment numbers have been dramatically impacted over the last year due to the pandemic, we are confident in our remote procedures process and our ability to achieve desired recruitment numbers. Additionally, we continue to implement a variety of recruitment strategies. We have increased our social media presence and website accessibility for recruitment efforts. Study staff regularly post IRB-approved recruitment materials on platforms such as Reddit, Facebook and Craigslist and monitor for activity. We have also created a simple online survey to help us quickly determine who may be eligible for our study and are including that link in online postings. We are primarily targeting groups on these web-based platforms associated with veterans as well as those who identify as having experienced a trauma. We believe these platforms will serve us in not only recruiting veterans but also in expanding enrollment more aggressively to include civilians as well. Additionally, we have started to ambitiously recruit nationally in order to meet our recruitment goals. This includes reaching out to Mental Health points of contact listed at every VA location across the country. We have successfully connected with multiple VA providers via video meetings and email outside of VISN21 to present our study information. We plan to continue this networking strategy nationally to gain referrals. We are also considering expanding our Trialfacts contract nationally should we not see an impressive uptick in our current campaign's success during the initial three-month contract we have with them.

2) Specific Objectives: Our specific objectives were consistent with our major activities. We aim to continue implementing the randomized controlled trial and increase enrollment numbers through various avenues including: Trialfacts marketing campaign, aggressive advertising via various internet-based platforms (Reddit, Facebook, Craigslist), telephone pre-screening, outreach at community-based outpatient clinics nationally, pre-screening medical records of SFVAMC clinic attendees, presenting to VA clinical staff nationally, reaching out to broader list of Bay Area veterans through the Defense Manpower Data Center (DMDC), and responding to relevant intake screeners.
3) Significant Results/Key Outcomes: No results to date.
4) Other Achievements: We have successfully implemented our redesigned 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. This adjustment will also allow for enhanced ability to recruit nationally.

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

Dr. Richards attended the Sweet Dreams: Cognitive Behavioral Therapy for Trauma-Related Nightmares with Joanne Davis, PhD. This event focused on treatment of trauma-related nightmares.

Additionally, Dr. Richards and a postdoctoral research team member, Nikhilesh Natraj, PhD, were able to attend the virtual 2021 SLEEP Meeting. Dr. Richards and Dr. Natraj both presented at Sleep 2021.

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, national recruitment and enrollment using the resources described above. We have hired a new full-time research assistant and are in the process of hiring two volunteer research assistants. The study team has a plan in place to promptly train these new staff within the coming quarter and have them begin assisting in recruitment efforts immediately.

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

In response to several challenges introduced by the COVID-19 pandemic, several 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 as all study procedures were halted for a period of time under direction of the SFVA. We submitted several modifications to enhance study flexibility, and these are now being implemented. The primary changes captured, and their justifications are as follows:

1) Update exclusion criterion #11 (currently: current use of trazodone, sedative-hypnotics or benzodiazepines used for insomnia, atypical antipsychotics for the treatment of a primary psychotic disorder, alpha-1 antagonists, alpha-2-agonists, boceprevir, midodrine) to: *current use of a medication with alpha-1 blocking properties for insomnia, alpha-1 antagonists, alpha-2 antagonists, boceprevir; midodrine*. This will allow those who have severe sleep disturbances and nightmares taking sleep aids with non-alpha blocking properties in a stable fashion to be eligible.

a. Justification: This update will allow those who have severe sleep disturbances and nightmares while taking sleep aids with non-alpha blocking properties in a stable fashion to be eligible. This modification is in response to protocol enrollment exception reference # 277149. Additionally, criterion #2 is more explicit for excluding those with psychosis symptoms in the last five years. Antipsychotic medications can be sedating, therefore we initially wanted to exclude those taking these medications effecting their sleep. However, because our primary goal is to test the effectiveness of doxazosin on nightmares, we will not exclude participants for taking medications that may affect their sleep if they are still experiencing symptoms that satisfy the threshold for inclusion.

2) Update exclusion criterion #8 (currently: history of priapism) to history of priapism or refusal to hold off on as needed phosphodiesterase inhibitors
    a. Justification: This is to formally update our exclusion criterion with something we have already been screening for. Simultaneous use of doxazosin and a phosphodiesterase inhibitor may enhance the effects of adverse effects from both medications and is best avoided.
3) Update inclusion criterion #1 (currently: U.S. military veteran) to *U.S. military veteran or civilian*.
    a. Justification: We are expanding our potential participant population to now include civilians. This will enhance recruitment by expanding our potential participant population. Our goal remains to enhance our recruitment of veterans (which we are were effectively doing prior to COVID-19 related consequences) while also accelerating our overall recruitment through addition of civilian participants.
4) Update language to allow our study team to email study-related materials, information or questions as needed that contain no PHI or PII to participants (consents, links to video conferencing, surveys, Azure instructions). Participants can then return completed consents or study materials via mail, MyHealtheVet or encrypted email (Azure) depending on the preference of the participant and study team. Participants will be educated on the use of secure email communication via Azure.
    a. Justification: These changes are to accommodate and allow greater flexibility for remote consent and study procedures. These accommodations will decrease participant burden and increase likelihood of study participation. Participants will be able to opt out of email communication at any time. No PHI or PII will be sent via unencrypted email.
5) Update text message language to allow the study team to text participants or those at any part in the recruitment process (once initial contact is established) study-related questions or information that does not contain PHI or PII.
    a. Justification: This will allow for greater flexibility in communication with participants as some prefer corresponding via text message. Participants will be able to opt out of text message communication at any time.
6) Addition of the self-report surveys: Epidemic Pandemic Impacts Inventory (EPII) and COVID-related Distress Scale. The EPII and COVID-related Distress Scale will be administered at baseline and the final visit. The subjective response scale will be administered at V3.
    a. Justification: This is in response to the COVID-19 pandemic. These self-report surveys will allow our team to gather valuable information to understand how the pandemic is affecting our study participants.
7) Update recruitment identification methods to include the following language: Veterans testing positive for sleep apnea (with Apnea Hypopnea Index of at least 5) and recommended for PAP through the SFVAHCS Sleep Clinic will be informed about sleep research studies via phone call from study staff. They will be contacted if they check "yes" in response to a question in the questionnaire packet completed at time of sleep study to test for sleep apnea. This questionnaire packet is part of routine clinical care. The text of the specific question reads, "Do you consent to be contacted about sleep research?”

a. Justification: This language is necessary for our study team to be able to receive participant referrals from a fellow research group (advised by Dr. Lizabeth Goldstein) operating out of the SFVAHCS Sleep Clinic. Her research staff will refer potentially eligible recruits to our study team by identifying those who indicated they consent to be contacted about sleep research.

8) Update recruitment language to allow our study to be shared via social media postings. The owner/admin may be the original poster or a general Richards Lab handle on social media will be created to post when appropriate. This option will benefit us to utilize the social media platforms of Veteran organizations, universities, community centers, etc. Only IRB-approved language will be posted. We will not be corresponding with recruits via social media but only sharing IRB-approved recruitment language.
    a. Justification: We are trying to reach a younger demographic which we believe will enhance recruitment.
9) Update study information to allow us to recruit by mailing to a large list of Veterans obtained from the DoD via a DMDC request. This mailing process will be identical to our already-approved mailing process. We will mail out an IRB-approved invitation letter, brochure, and response postcard (a self-addressed stamped envelope will be included for the subject to return the response postcard) to large numbers of Veterans who meet broad criteria, based on diagnostic codes in Veteran health records, and who live within 75 miles of the SFVA medical center. We will contact patients after they have had the opportunity to mail in the postcard (after two weeks) or have initiated contact with us themselves.
    a. Justification: This will allow us to reach Veterans who may not yet be registered with the VA but may qualify and be interested in study participation. We believe this will enhance recruitment.
10) To continue recruitment while study staff are working from home, we would like to email recruitment information to recruits in lieu of sending letters. Sending and receiving physical mail from the San Francisco VA poses several logistical challenges as the study is currently working in a remote capacity. We would follow identical procedures as when we mail letters, but the contact would be via email with an opt out option, and a follow-up call in two weeks if the recruit has not opted out of follow up contact.
    a. Justification: This will reduce physical mailing burden for both study participants and study staff.
11) Update the consent document to include the Stress and Health Research Program anti-racism language.
    a. Justification: We are updating our consent language to include our Stress and Health Research Program's anti-racism language. The goal of this language is to set a precedent with the participant that we strive for an environment of mutual respect for both the study participant and study staff.
12) Include the option for participants to obtain eligibility labs from an external laboratory source, Quest Diagnostics. Quest Diagnostics will not receive participants' identifying information. Study staff will call ahead when a participant is scheduled to obtain labs at Quest to provide a "John Doe" name to label the sample. The study team will then be able to match the sample from Quest to the correct participant with the name given and date and time of the sample. This will ensure the participants' private identifying information is protected.
    a. Justification: Given the current limitations due to COVID-19, our research study's ability to obtain eligibility labs at the SFVA is severely restricted. Adding an external laboratory source will allow for greater flexibility for study participants in obtaining eligibility labs. Our proposed method of providing Quest with a "John Doe" name will ensure the participants' identifying information remains private and is protected.
13) Update recruitment and enrollment language to include the ability to expand nationally. We are seeking approval to recruit veterans nationally utilizing our remote study procedures which are already in place. Dr. Richards is authorized to prescribe across state lines to participants as

long as they are enrolled in the VA Health Care System and creating a medical record at the SFVA is already part of our approved procedures for enrolling a participant. We plan to utilize our external laboratory source for eligibility labs when necessary and carry out the rest of the study procedures remotely. Of note, doxazosin is not a controlled substance and is able to be shipped across state lines by our VA research pharmacist.

   a. Justification: Expanding recruitment and enrollment nationally will greatly enhance our ability to reach our enrollment goals. Through the COVID-19 pandemic, we have proven our ability to carry out remote study procedures and feel it is a natural progression to expand our applicant pool nationally using this strategy.

14) Update recruitment language to include the use of the specialized patient recruitment service, Trialfacts. Participants will be recruited nationally utilizing Trialfacts' marketing strategy.
   a. Justification: We believe expanding recruitment nationally will greatly enhance study enrollment by expanding our pool of potential participants. Only IRB approved language will be used for Trialfacts' marketing campaign. We have not received Trialfacts recruitment/marketing materials for our study at this point, but we will submit them to the IRB upon receiving.
15) Update the protocol to amend reasoning for forgoing an ECG if the participant's *PCP, or cardiologist if the participant has one*, determines an ECG is not necessary and approves of their study enrollment.
   a. Justification: We have found that our requirement of a participant's cardiologist determining if an ECG is necessary is unreasonably restrictive, as many participants are not followed by a cardiologist. We are requesting to enroll a participant with the okay of their PCP. When there is no cardiologist, a PCP is reasonable for weighing in on safety.

These changes were necessary to facilitate the ability of the study to continue under conditions implemented due to the COVID-19 pandemic. We anticipate all these changes to not only help mitigate challenges encountered thus far due to COVID, but to also allow for continued flexibility and enhanced study success beyond the pandemic.

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

Recruitment and enrollment has been dramatically impacted due to the COVID-19 pandemic over the past year. Shelter-in-place orders and strict limitations on research enacted by the SFVA starting in March 2020 have continued through this reporting period.

Despite these challenges, we continue to implement our fully remote study recruitment and enrollment procedures. Since the time of the last annual report we have successfully completed seven new participants for a total of 19 completers (12 completers at last report). Additionally, we have active participant scheduled to complete in July 2021.

In April 2021 our full-time research assistant transitioned out of her role to pursue graduate school. As a result, we temporarily shifted staff from other projects to assist in recruitment and study procedures.

We have hired a new full-time research assistant who is starting in July 2021 and we are also in the process of hiring two new volunteers to assist with recruitment efforts. A gap in available volunteers on the team to assist in recruitment efforts prior to the hiring of these two recent volunteers resulted in a decrease of completed phone screens. The team is prioritizing the rapid and successful training of these three new staff in the coming month. This new additional manpower to the team will drastically increase our ability to boost recruitment and enrollment efforts.

Our capacity to be on site at the SFVA remains very restricted through this reporting period. Our study participants continue to operate primarily remote with the exception of some eligibility testing (labs and EKG). We are closely monitoring COVID-related guidelines for clinical research from the VA and UCSF.

We continue to utilize our external laboratory contract with Quest Diagnostics as the majority of

recruits feel more comfortable traveling outside of their homes to a lab site located nearby versus traveling to the SFVA or an associated CBOC.

Additionally, we have just kicked off our campaign with Trialfacts, the specialized patient recruitment service. We are in close contact with the Trialfacts team to continue to optimize their advertisement strategy for our study. The study team is optimistic that Trialfacts will boost recruitment success.

Lastly, the original grant for this study was scheduled to end on 6/14/2021, however, we were granted a NCE through 6/14/2022.

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

Nothing to Report.

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)**

  www.richardslab.ucsf.edu

- **Technologies or techniques**

  Nothing to Report.

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

  Nothing to Report.

- **Other Products**

  Mobile Sleep Diary Application, available in the Apple App Store and Google Play store.

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:	12
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:	Aubrey Beck
Project Role:	Research Assistant
Researcher Identifier:	N/A
Nearest Person Month Worked:	8
Contribution to Project:	Ms. Beck 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. Beck was also responsible for facilitating study procedures conducted at the Santa Rosa VA. My Beck is no longer with the study as of April 2021.

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.