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14. ABSTRACT

One of the hallmark features of Posttraumatic Stress Disorder (PTSD) is a marked increased in physical arousal (i.e., increased heart rate, muscle tension, etc.) when recalling a trauma-related memory. In this manner, a treatment that decreased the hyper-arousal of a traumatic memory to less-impairing levels may do well in allowing an individual with PTSD to return to his or her daily life. However, there is an imbalance at the heart of combat PTSD-related research: in over three decades' worth of research on combat stress PTSD physiology, only 3% (66 out of 1,985 participants) of the Veterans studied were women. This paucity of research is in the face of the fact that PTSD is twice as likely to occur in women. Our research investigates a novel method of reducing the hyper-arousal associated with combat memories in Female Operation Iraqi Freedom and Operation Enduring Freedom Veterans with PTSD. Our study compares Female Veterans who take propranolol after a combat memory to both Female Veterans who take a non-active placebo pill after a combat memory and those who take propranolol after a non-combat memory (to make sure that propranolol doesn't have a general effect on physical reactions). All participants in our study are tested during the early follicular phase of the menstrual cycle, a time in which levels of estrogen are low. Data collection has begun and continues at this time. We are in the process of adding a second study site to complete the study.

15. SUBJECT TERMS
PTSD treatment, Women's Health, memory reconsolidation

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INTRODUCTION

In the current study, we will be investigating a method for blocking memory reconsolidation in three groups of female Veterans of either Operation Iraqi Freedom or Operation Enduring Freedom (OIF/OEF) with PTSD: 1) Individuals (n=20) who receive propranolol following recall of a traumatic memory (Propranolol-trauma); 2) Individuals (n=20) who receive a placebo following recall of a traumatic memory (Placebo-trauma), and; 3) Individuals (n=20) who receive propranolol following recall of an affective neutral memory (Propranolol-neutral). Memory recall will be psychophysiologically assessed by measuring facial corrugator electromyography (EMG), skin conductance, blood pressure and cardiovascular inter-beat interval responses immediately prior and four weeks following medication administration. We predict a significant drop in physiological reactivity to Veterans' trauma memories and PTSD intrusive symptoms in the Propranolol-trauma group.

BODY

The work accomplished in the last 12 months of the award focused on recruitment and patient intake. In this year, we screened 39 potential participants and enrolled 14. 20% of the 14 participants were excluded from completing session 2 of the protocol because of low resting heart rate and blood pressure. Our cardiophysiology exclusion criteria are in place to prevent the risk of a participant taking the study medication (a beta-blocker) and passing out. It appears that the OIF/OEF community engages in such a degree of regular and rigorous exercise that they tend to have a resting heart rate < 53 beats per minute, approximately 10 beats per minute lower than what we have found in a same-aged civilian community. This low heart rate, combined with a low blood pressure, places the Veteran at risk for taking propranolol. In discussion with our study consultant, there is no way to safely monitor our participants and amend our exclusion criteria.

Additional reasons for patient drop out included the exclusion criteria of testing positive for illicit substances at the time of the protocol and patient's not being able to schedule all four study sessions. Consistent with the Male OIF/OEF Veteran community that we have been in contact with, we could characterize our Female PTSD Veterans of consisting of two sub-populations, the first having a "full-schedule", including full-time employment, school work, or both, and; transient, recently re-located to Connecticut with little established living routine and employment opportunity. Both sub-populations find it difficult scheduling for the four clinical visits this study requires.

In the past summer, we contacted Mason, Inc., a Connecticut-based advertising firm with an expertise in recruitment for clinical trials. Using funds from Dr. Aikins' VA affiliation, a small campaign has been developed that would directly reach Female OIF/OEF Veterans in Connecticut. These materials have been approved by the VA Connecticut Human Subjects Safety committee and are under review at the Yale IRB and will be submitted to HRPO for review. This will allow us to reach an additional 800 Female Veterans.

We have also identified a collaborator who will establish a second study site. Dr. Shiva Ghaed is a clinician at Naval Medical Center San Diego and has expertise in treating Female Service Members with PTSD. She has a large patient flow in her practice and can assist us in completing patient recruitment.

KEY RESEARCH ACCOMPLISHMENTS

- In total, 79 female Veterans have been screened for the protocol. 15 were consented and enrolled. All 15 failed to complete the protocol.
- Of all the reasons for the 15 participants withdraw, we were surprised by the 20% that had to be excluded due to low resting heart rate and blood pressure. This finding is consistent with what we found with Male OIF/OEF Veterans enrolled into a similar protocol.
- New recruiting procedures will be implemented in Winter 2011 for a new pool of eligible participants.
- We have established a collaborative relationship with a scientist-practitioner who treats a large number of female Active Duty patients with PTSD.

REPORTABLE OUTCOMES

Female OIF/OEF-era Veterans with PTSD are extremely reluctant to engage in either clinical services or clinical trials. In the past year, we screened 39 Female Veterans and enrolled 14 into the clinical trial. Notably, none of the 14 participants completed the trial. Importantly, 20% of our sample was excluded from the trial because of a low resting heart rate and blood pressure. This is consistent with our experience with Male Veterans and presents an important limitation to the consideration of propranolol as a PTSD treatment. Further, illicit drug use and patient drop-out were the top two patient-factors for Female Veterans to not complete the trial. Our profile of participant engagement parallels that found with those Female Veterans who enroll in Psychiatric Services at the VA Connecticut Healthcare System. Using VA funds available to Dr. Aikins, a new recruitment advertising campaign has been designed for outreach into the OIF/OEF Female Veterans community in Connecticut. Further, Dr. Aikins has identified a collaborator who specializes in treating Active Duty Female Service Members at Naval Medical Center San Diego.

CONCLUSION

This research addresses important issues regarding the treatment of Female Veterans with PTSD. However, the ability to engage this community has proved to be much more difficult than originally anticipated. Engaging in a direct mailing campaign in Connecticut should increase our ability to recruit this population. Establishing a second study site at Naval Medical Center San Diego with a Clinical Scientist with a steady patient flow will also ensure study completion.

REFERENCES

N/A