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TITLE: Using Propranolol to Block Memory Reconsolidation in Female Veterans with PTSD

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

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. During the first year of the 3 year project, institutional review approvals were obtained from Yale University School of Medicine, VA Connecticut Healthcare System, West Haven Campus, and U.S. Army Medical Research and Materiel Command Office of Research Protection Human Research Protection Office. Patient recruitment is underway.

15. SUBJECT TERMS
Psychological Health Treatment, Female Service Members

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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: In the first year of this three-year award, we successfully met our first task objective by finalizing the study design in consultation with grant mentors and obtaining Institutional Review Board approvals from the Yale University School of Medicine, VA Connecticut Healthcare System, West Haven Campus, and U.S. Army Medical Research and Materiel Command Office of Research Protection Human Research Protection Office. We were able to successfully train and implement study procedures with staff. Furthermore, as we received preliminary feedback from the OIF/OEF community that weeknights and weekends may be more available for time to participate in research, we successfully revised our Statement of Work to include a third study site, the Clinical Research Unit of the Connecticut Mental Healthcare Center.

We were also successful in completing Task 2, which was to initiate subject recruitment. The VA Connecticut Healthcare System OIF/OEF patient care coordinators agreed to promote our study by sending a study announcement to all female OIF/OEF veterans registered in the VA Connecticut Healthcare System. The current count of this registration is @640 female OIF/OEF veterans. An additional research team has indicated the rate of Military Sexual Trauma in this cohort to be @33%, which suggests a potentially large recruitment pool for our study.

By the end of Year 1, we began Task 3, which was to enter participants into the study protocol. We received numerous phone inquiries about the protocol and scheduled several intake appointments. At the end of Year 1, we had 1 participant sign the informed consent and then dropped out of the study before session 1 could begin.

We noted two significant deviations from our original Statement of Work for Year 1. 1) Task 1 was estimated to be completed in 6 months when in fact it was completed in approximately 9 months. 2) Task 3 was estimated to include data collection from 12 participants. We note significant delays in receiving institutional review board approval from the VA Connecticut Healthcare System that accounted for the lost time. Further, getting approval for the recruitment letter was not finalized until the end of Year 1.

An important observation regarding the clinical presentations of female OIF/OEF veteran potential participants was mentioned at the interim report at the 2009 Military Health Research Forum, Kansas City, MO: a high degree of suspicion regarding confidentiality of research records from the VA and the military. The chief concern of potential participants was that either the VA or the military would learn of the participant's involvement in the Yale School of Medicine research protocol. Despite our best efforts to assure individuals of the confidentiality of the Yale research records, we believe this played a strong role in the female veterans' decisions to opt out of the

research. We hope that recruitment via the VA Connecticut Healthcare System female veteran cohort will eliminate this concern, as these veterans are already registered within the VA system (our initial recruitment efforts came from the community).

One possible consideration with regard to recruitment would be to revise the inclusion criteria to allow civilian females with PTSD of a similar age range to the veterans. Both veteran and civilian populations report a history of poly trauma, including sexual assault and abuse. In this manner, incorporating both samples into the study may also improve the applicability of the findings while maintaining the original Statement of Work Timeline. We will continue to evaluate this in the beginning of Year 2 while we receive responses from our recruitment letter.

KEY RESEARCH ACCOMPLISHMENTS:

- All institutional review board approvals obtained
- Staff trained on protocol
- Statement of Work revised to include additional research site (Clinical Research Unit of the Connecticut Mental Healthcare Center) for after-hours participant data collection (evenings, weekends).
- Recruitment initiated.

REPORTABLE OUTCOMES: Interim presentation at the 2009 Military Health Research Forum, Kansas City, MO.

CONCLUSION: The potential implication of this research, when completed, would be an evaluation of propranolol as a single-dose treatment for combat-related Posttraumatic Stress Disorder in female veterans.

REFERENCES: n/a

APPENDICES: n/a

SUPPORTING DATA: n/a