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TITLE: Virtual Reality and Cellular Phones as a Complementary Intervention for Veterans with PTSD and Substance Use Disorders

PRINCIPAL INVESTIGATOR: Mark Z. Rosenthal, Ph.D.

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Durham, NC 27710**

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14. ABSTRACT The first year of this project has been fully devoted to hiring, training, and, most notably, integration of applications for regulatory approval across the Institutional Review Boards at Duke University Medical Center (DUMC), Durham Veteran's Affairs Medical Center (Durham VAMC), and the USAMRMC. We have worked carefully with regulatory affairs officers in each of these settings, in an iterative effort to integrate the necessary requirements of each of these boards. This process has been characterized both by predictable delays (e.g., DUMC and USAMRMC human subject IRB deliberation and iterative revisions to the protocol) and unexpected challenges (i.e., Durham VAMCIRB has not yet approved recruitment of subjects for the protocol). At present, the protocol has been approved by the DUMC and USAMRMC pending approval from the Durham VAMC, and a third IRB protocol is under review at the Durham VAMC. Accordingly, the project will be ready for immediate subject recruitment once approved by the Durham VAMC.						
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Annual Report

Project Title: Virtual Reality and Cellular Phones as a Complementary Intervention for Veterans with PTSD and Substance Use Disorders

Award No.: W81XWH-08-2-0209

Principal Investigator: Mark Z. Rosenthal, Ph.D.

I. Introduction

In the present project, we are testing a novel adjunctive intervention designed to complement exposure-based therapies for combat veterans with posttraumatic stress disorder (PTSD) and co-morbid substance use disorders (SUDs). The novel intervention uses virtual reality as a cue exposure platform to extinguish cravings to drug-related cues, and cellular phones as an extinction reminder platform to transfer learning effects from exposure/extinction in the clinic to adaptive responses in high-risk contexts for drug use in every day life. It is hypothesized that: (a) the complementary intervention will be acceptable and feasible and (b) compared to participants receiving exposure therapy alone, those receiving exposure therapy plus the complementary intervention will have better treatment outcomes at post-treatment and follow-up, as evidenced by lower PTSD symptoms, less substance use, and greater retention in treatment.

II. Body

Year 1 Tasks Outlined in the Statement of Work

These tasks below were identified in the Statement of Work as tasks to begin during year 1 (out of a planned four year project). The only task planned for completion in year 1 is "Regulatory Review."

Regulatory Review

Preparation for regulatory review began immediately upon receipt of funding in October 2008. Existing staff members in Dr. Rosenthal's program were identified to immediately assist with administrative preparation of materials while Dr. Rosenthal worked with Human Resources at Duke University Medical Center (DUMC) to recruit full-time staff members into the project team. Dr. Rosenthal and his staff worked with Dr. Jeffery Stephenson through the Department of Defense in order to prepare the appropriate paperwork for regulatory review by Institutional Review Boards at the DUMC, the Durham Veterans Affairs Medical Center (Durham VAMC), and the U.S. Army Medical Research and Materiel Command (USAMRMC). Dr. Rosenthal and his staff also worked with Dr. Jean Beckham's (Co-Investigator) administrative staff at the Durham VAMC in order to prepare regulatory materials, for recruitment only, through the Durham VAMC IRB. After assessing the needed forms and specific language requirements for each of these regulatory boards, Dr. Rosenthal and staff iteratively

integrated these IRB specific needs into a final study protocol. This study protocol was largely structured in line with the USAMRMC guidelines, in consultation with Dr. Stephenson. The process of iteratively refining all of the language to meet requirements of each IRB lasted approximately 6 months. In the interim, while the DUMC IRB was reviewing and modifying the protocol, and in line with Durham VAMC recommendations, Dr. Rosenthal submitted an IRB application for recruitment only at the Durham VAMC. The application to the Durham VAMC requested that flyers be posted in specific patient clinics, and that a pre-existing subject registry used for multiple other studies throughout the VA system be used to identify and recruit prospective subjects for the present project. The request to recruit subjects at the Durham VAMC was not approved, with the review committee deciding that a full-time VA staff member needs to be the PI on the IRB application, even for an application requesting recruitment only for a project at the adjacent DUMC. Accordingly, a new protocol was submitted with Dr. Beckham as the study PI, again requesting recruitment only for this project. After waiting for and eventually being reviewed, this second request was not approved. This time, the Durham VAMC IRB committee requested that a full study protocol be submitted to the VAMC, even though the only research activity for this project at the VA is recruitment. Upon consultation with the USAMRMC and further discussion between the Durham VA IRB, Dr. Beckham, and Dr. Rosenthal, it was decided that a full study protocol requesting recruitment only would be submitted. The protocol for this recruitment study is currently under review at the Durham VAMC. Despite these delays with the Durham VAMC IRB, the DUMC IRB has approved the study protocol, and the USAMRMC IRB has approved the protocol pending approval from the Durham VAMC.

Participant Recruitment

As outlined above, the study protocol has not been approved for recruitment by the Durham VAMC, and is in the third iteration of review through the human subjects IRB at this institution. Over the past year, staff were hired and trained, and all infrastructure has been prepared for implementation of recruitment.

Diagnostic Evaluations

As outlined above, the study protocol has not been approved for recruitment by the Durham VAMC. Therefore, no diagnostic evaluations have been conducted. Over the past year, staff were hired and trained, and all project infrastructure for diagnostic evaluations has been prepared.

Symptom Severity Evaluations

As outlined above, the study protocol has not been approved for recruitment by the Durham VAMC. Therefore, no symptom severity evaluations have been conducted. Over the past year, staff were hired and trained, and all project infrastructure for symptom severity evaluations has been prepared.

Urine Testing

As outlined above, the study protocol has not been approved for recruitment by the Durham VAMC. Therefore, no urine tests have been conducted. Over the past year, staff were hired and trained, and all project infrastructure for urine tests has been prepared.

Treatment

As outlined above, the study protocol has not been approved for recruitment by the Durham VAMC. Therefore, no treatment has been conducted. Over the past year, staff were hired and trained, and all project infrastructure for treatment has been prepared. Study administrative staff and study therapists are prepared to begin treatment.

Data Management, Statistical Analyses, and Statistical Consultation

As outlined above, the study protocol has not been approved for recruitment by the Durham VAMC. Therefore, no data have been collected. Over the past year, staff were hired and trained, and all project infrastructure for data collection and management has been prepared. In addition, consultation has begun between the biostatistician, Dr. Strong, and Dr. Rosenthal, in anticipation of data collection.

Key Research Accomplishments

Research activities in year 1 have included:

- Hiring and training of all study staff
- Ongoing problem-assessment and problem-solving with consultants about project needs
- Infrastructure preparation at Dr. Rosenthal's clinic (e.g., updating virtual reality software and hardware, preparing cellular phone server software and hardware)
- Database preparation for all measures
- Initiation of recruitment partnerships at the Durham VAMC clinics
- Regulatory review and approval of all study materials across the respective IRBs at DUMC, the Durham VAMC, and the USAMRRC.

In addition, as outlined above, the primary barrier to implementation of this protocol has been difficulty obtaining regulatory approval across all three IRBs that are required to approve the protocol before recruitment and data collection can begin. A problem that we unexpectedly encountered is that all subjects will be recruited from the Durham VAMC, yet the Durham VAMC requires that a Durham VAMC staff member be the PI on all IRB protocols, and both Dr. Rosenthal and the study infrastructure/staff are at the DUMC. To solve this problem, and in consultation with the Durham VAMC IRB and through Dr. Beckham's (Co-I) program, we now have under review a full protocol to conduct a study at the Durham VAMC that will include only the previously planned and approved recruitment activities. We are ready to

begin recruitment, diagnostic evaluation, treatment, and all other data collection immediately upon final approval by the Durham VAMC for subject recruitment.

Reportable Outcomes

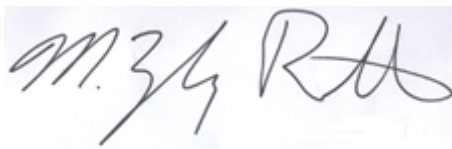
As detailed above, there are no reportable outcomes from year 1.

Conclusions

There are no study conclusions from year 1. We anticipate study conclusions to be generated at or near the end of data collection, during year 4.

References

None

A handwritten signature in black ink, appearing to read "M. Zachary Rosenthal". The signature is written in a cursive, flowing style.

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