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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.**

CONTRACTING ORGANIZATION: **Duke University
Durham, NC 27710**

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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 2 Tasks Outlined in the Statement of Work

These tasks below were identified in the Statement of Work as active tasks for year 2 (out of a planned four year project).

Regulatory Review

At the outset of Year 2, Dr. Rosenthal worked with his staff and the various IRB's to coordinate the approval of participant recruitment within the Durham Veteran's Affairs Medical Center. Upon consultation with the USAMRMC and several discussions between the Durham VAMC IRB, Dr. Beckham (Study Investigator within the VA), and Dr. Rosenthal, a full study protocol requesting recruitment only was submitted at the end of Year 1. The protocol for this recruitment study remained under review by the Durham VAMC until Quarter 2 of Year 2, when it was approved. Final regulatory approval was subsequently granted by the USAMRMC and Duke University Medical Center.

Participant Recruitment

Participant recruitment began in February, 2010. Recruitment methods have included posting flyers at the Durham VAMC and at selected treatment and community centers in

the Durham area, advertisements on the DUMC website and local free newspaper, and direct referrals from VA clinicians. At the time of this report, we have completed 85 screening phone calls, yielding 21 individuals eligible to be scheduled for a diagnostic assessment. The primary reasons for ineligibility were not having current substance use (inclusion criteria), having a trauma that was unrelated to military service (inclusion criteria), or being diagnosed with a psychotic disorder (exclusion criteria). The pace of recruitment so far is adequate for reaching the study's recruitment goals, and we will continue to improve recruitment methods to increase enrollment in the coming year. These improvements include refinement of advertisements to better target likely eligible individuals, increasing contacts with therapists who treat individuals who would likely be eligible for the study, and expanding recruitment to additional real-world and web-based locations that are relevant to veterans.

Diagnostic Evaluations

Of the 21 potential participants scheduled for diagnostic interviews, 15 completed the assessments, yielding 6 participants who were enrolled in the study. The primary reason for exclusion from the study was meeting criteria for a psychotic disorder.

Symptom Severity Evaluations

Symptom severity measures have been completed along with the diagnostic evaluations, described above.

Urine Testing

During this year, urine testing began with the 6 enrolled study participants. Urine testing is conducted 3 times a week, as stated in the study protocol.

Treatment

Over the past year, staff training on the prolonged exposure treatment was completed. Treatment was begun with the first 4 enrolled participants who presented for their first session of psychotherapy.

Data Management, Statistical Analyses, and Statistical Consultation

With the start of recruitment this year, data collection on the project has also begun. Screening data, diagnostic and symptom severity data, urine data, and weekly therapy-related assessments have all been collected for individuals who have had contact with the project. All data is entered into statistical software within a few days of being collected. No participant names are connected to unique ID numbers across all documentation, save for a single password protected electronic file used to maintain contact information, as described in the protocol. Statistical consultation has continued between the biostatistician, Dr. Strong, and Dr. Rosenthal, to facilitate effective and accurate data collection.

Key Research Accomplishments

Research activities in year 2 have included:

- The completion of the initial regulatory review process across the respective IRBs at DUMC, the Durham VAMC, and the USAMRMC
- Hiring and training of study staff and therapists
- Further infrastructure improvement at Dr. Rosenthal's clinic (e.g., updating virtual reality software and hardware, preparing cellular phone server software and hardware)
- The beginning of recruitment and assessment
- The beginning of active treatment for participants in the study
- The beginning of data collection and data entry
- Regulatory review and approval of all study materials across the respective IRBs at DUMC, the Durham VAMC, and the USAMRRC.

Reportable Outcomes

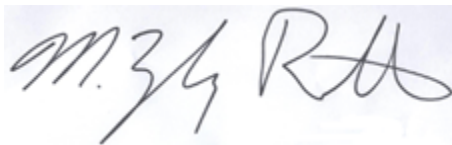
Because the study has just begun to collect data, there are no reportable outcomes from year 2.

Conclusions

There are no study conclusions from year 2. 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" or "M. Z. Rosenthal". The signature is written in a cursive, flowing style.

M. Zachary Rosenthal, Ph.D.
Assistant Professor
Duke University Medical Center