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Introduction

This report describes the progress on this project over first year on staff recruitment and training, IRB and other administration and subject recruitment to date. No data has been acquired to date.

Body

Key Research Accomplishments

Staff Recruitment and Training

Kristen Reinhardt was recruited as the research assistant/research coordinator for this project and began full time effort on the project as of March 9, 2009. She was trained in her duties which include IRB administration, subject recruitment, telephone screening, informed consent, subject scheduling, administration of questionnaires, acquisition of electrocardiographic recording techniques and urinary sample collection, and preliminary data management and analysis.

Jennifer Johnston, a Northeastern University clinical psychology graduate student and certified yoga instructor was recruited as the project leader and yoga instructor on this study. Her role includes preparing the yoga curriculum, instructing the yoga classes, managing IRB documentation and performing final data analysis

IRB Administration

An IRB protocol was drafted and reviewed by a representative of the USAMRMC Office of Research Protections (ORP) Human Research Protections Office (HRPO). The IRB protocol was submitted on 3/31/09 to the IRB of Brigham and Women's Hospital and was approved on 5/8/09. The protocol was then submitted to the USAMRMC Office of Research Protections (ORP) Human Research Protections Office (HRPO) on 5/11/09. Following a response to a request for clarifications and revisions from that office on 6/30/09, IRB approval from HRPO was received on 8/12/09.

Protocol Development

The yoga treatment protocol and manual has been completed in consultation with yoga instructors in the region with experience in instructing yoga to military veterans. The treatment protocol and manual were approved by the IRB on 8/14/09 and by the HRPO on 8/12/09.

Additional Administration

We have submitted an application to the Harvard Catalyst Center for Clinical Investigation for support of the proposed project, which will include partial support of assay costs and use of ambulatory outpatient clinical treatment space. Following a response to a receipt of a request for clarifications on this application, formal support of the study was confirmed in September, 2009.

Following IRB approval, an application was submitted for a Certificate of Confidentiality, which was formally approved on 10/9/09.

The study protocol was submitted to Clinical Trials.gov and was registered on that site as of 8/27/09.

Recruitment

Preliminary research was conducted to identify a list of potential organizations from which military veterans might be recruited and letters of support from those organizations were acquired. Advertising in public media was initiated for subject recruitment in early September, 2009.

As of September 24th we have received 38 inquiries from potential participants. We have conducted 36 telephone screens, which resulted in the enrollment of 7 participants to the study who have all signed informed consent.

Protocol Execution

As of 9/24/09, the 7 subjects have undergone partial or complete screening procedures and baseline outcome measures. Subjects have been applied to for appropriate scheduling times for the yoga intervention classes, which are tentatively scheduled to begin the first cohort of participants in mid-November.

Progress Relevant to Statement of Work

All tasks within the Statement of Work have been executed later than anticipated. This was largely due to the fact that although the grant was initiated on 9/25/09, substantial effort on the project, and disbursement of grant funds, did not begin until March of 2009. However, the project is now underway and recruitment and enrollment have been at acceptable levels.

Reportable Outcomes

None

Conclusions

Although the project is delayed relative to the grant start date, reasonable progress has been made on study startup and recruitment. There is no data to report at this time.

References

None

Appendices

None