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Auricular Therapy for Treatment of Musculoskeletal Pain in the Setting of Military Personnel: A Randomized Trial

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14. ABSTRACT
The research project has been submitted for a NCE to October 31, 2017. This is due to several delays including transition of the protocol site and change of PIs due to deployment and retirement. Since these changes initiated in August 2015, the protocol has been able to recruit 12 additional subjects. At this point the protocol has received IRB approval and initiated enrollment.

15. SUBJECT TERMS
Auricular Therapy; Musculoskeletal Pain

16. SECURITY CLASSIFICATION OF:

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INTRODUCTION:

Musculoskeletal injuries resulting in pain are one of the most common reasons for disability and missed duty among military personnel. Preliminary research has show auricular therapy as a potential adjunctive treatment in this setting. This study will be a randomized trial of 150 subjects examining whether the addition of a specific auricular therapy protocol to standard care will have a beneficial impact on the pain and functionality of subjects who sustain an acute or sub-acute musculoskeletal injury. Specifically, the research study will attempt to determine whether auricular therapy provides a) more rapid and significant pain relief than usual care; b) more rapid and significant relief of co-morbidities related to pain (sleep disruption, mood changes, etc) than usual care; c) more rapid and significant return of functional ability than usual care; and d) more rapid and significant reduction in need for other therapies including pain medication?

BODY:

This research project was initially planned for in theater, but due to difficulty finalizing a clinical site in theater with investigators trained in the protocol (auricular therapy), was moved to the Naval Medical Center San Diego. Subsequently, the initial Balboa Navy PI and several investigators had to be replaced due to deployment and retirement. At this point, an updated group of investigators, safety officers and research support staff have been identified and transition to enrollment at MCRD under the direction of PI Dr. Mark Tucker. After orientation at MCRD with staff, enrollment was recommenced on August 14, 2015 with 12 subjects enrolled to date. Carol Anne Drastal RN and research assistant Giselle Valdivieso have been active on site at MCRD to enable enrollment. Additionally Carol Anne Drastal RN is in discussion with secondary sites including Camp Pendleton to provide additional enrollment opportunities.

KEY RESEARCH ACCOMPLISHMENTS:

Since the last annual report:

- HRPO renewed approval memorandum granted on July 17, 2015
- Protocol renewal by Navy IRB
- Dr. Tucker became newest site PI 7-2015
- Change in the main recruitment site to MCRD
- Tour and protocol planning with Dr. Tucker at MCRD August 11, 2015
- Enrollment initiation at MCRD August 14, 2015 with 12 subjects enrolled to date
• Efforts for additional recruitment from Camp Pendleton Acupuncture Clinic and NMCSD Physical Therapy are underway

REPORTABLE OUTCOMES:

• No reportable outcomes have resulted from this research as of this time.

CONCLUSION:

The protocol will continue with focus on increasing enrollment and sites for enrollment in the coming quarter.

REFERENCES:


APPENDICES / SUPPORTING DATA:

SF-425 and NCE have been separately submitted