

**New Jersey Commission on Spinal Cord Research**

**Final Narrative Report**

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### **Original Aims of the Project**

The aim of the project was to determine the effectiveness of acupuncture in the treatment of shoulder pain in persons with chronic spinal cord injury (SCI). Shoulder pain is a common medical complication associated with upper limb overuse in persons with SCI, with a prevalence between 33% - 73%. A prior study found acupuncture to be effective in the treatment of shoulder pain in individuals with chronic SCI. Unfortunately, one of the limitations of the study was the lack of a separate, "placebo" control group. Acupuncture is moderately invasive, somewhat time consuming, and often administered by an enthusiastic and empathetic therapist. All of these factors have the potential to impact the treatment outcome, contributing to an expectation of clinical benefit or a "placebo-effect". Therefore, the aim of our project was to determine the effectiveness of acupuncture in the treatment of shoulder pain in individuals with chronic SCI by comparing it to a placebo control group (minimal acupuncture; light needling of non-acupuncture point) in a randomized, single-blind (participants), controlled trial.

Participants were randomly assigned to receive either traditional needle acupuncture or placebo acupuncture (i.e. "sham" or "minimal" acupuncture; light needling of non-acupuncture points). All participants received a total of 10 treatments over a 5-week period. The Wheelchair User's Shoulder Pain Index (WUSPI), a functional measure of shoulder pain intensity during activities of daily living, was used to monitor changes in shoulder pain during the treatment period in each group. Participants had to be acupuncture naïve, have chronic shoulder pain, be at least 1 year post-SCI, and use a manual wheelchair as their primary means of mobility. The original goal was to recruit 40 persons with chronic spinal cord injury/disease and shoulder pain.

### **Project Successes**

Twenty-six persons with SCI and chronic shoulder pain were enrolled in the study. Of the 26 persons entering the study, 17 completed the entire study. Nine individuals were withdrawn during the baseline period, prior to starting acupuncture or sham acupuncture treatment: 2 had complete resolution of their shoulder pain; 4 had medical complications associated with their SCI that forced them to drop out (e.g. severe back pain, syringomyelia, bowel obstruction, pressure ulcer); and 3 were lost to follow-up or unable to continue due to other commitments.

The 17 participants completing the study included 2 woman and 15 men with an average age of  $38.7 \pm 11.1$  years (mean  $\pm$  standard deviation) and consisted of six individuals with tetraplegia and 11 with paraplegia (average duration of SCI =  $11.3 \pm 9.0$  years). Five participants complained of unilateral shoulder pain and 12 complained of bilateral shoulder pain.

There was a significant reduction in shoulder pain intensity after treatment in both the acupuncture and sham acupuncture groups, with a 64% and 41% decrease in pain, respectively. The reduction in shoulder pain was maintained in both groups throughout the 5-week post-

treatment follow-up period. There was no significant difference between acupuncture and sham acupuncture in decreasing shoulder pain intensity. However, there was a medium effect size associated with the acupuncture treatment, suggesting that acupuncture may be superior to sham acupuncture in relieving shoulder pain in persons with SCI. The number of participants in our study (sample size) limited our ability to detect significant differences between the two groups, therefore, further research involving a larger number of participants is recommended.

The results from this study provide us with an estimate of the effectiveness of acupuncture. This information can be used in designing larger, multi-center, clinical trials investigating the effectiveness of acupuncture in persons with spinal cord injury and chronic shoulder pain.

## **Project challenges**

### Participant Recruitment

Participant recruitment for this study was a challenge, thus limiting our sample size. Our original target goal was to enroll 40 participants with SCI. This number was later adjusted to 30. Although shoulder pain is common in persons with SCI, many individuals were too busy to participate or did not have pain on a consistent basis or high enough intensity that would force them to seek medical treatment.

### Placebo Controls in Acupuncture

Clinical trials often include placebo control groups in order to help determine the efficacy of experimental treatments. The ideal placebo should have the same psychological impact as the experimental treatment and have no important physiologic activity. A good example is the “sugar pill” often used as a placebo control in experimental drug trials.

Historically, it has been difficult to develop an adequate placebo control for acupuncture trials. Placebo needles that do not penetrate the skin have been used and supposedly match what a person expects to see and experience with traditional acupuncture. Unfortunately, they mask the treatment site and may interfere with the acupuncturist’s ability to perform real acupuncture, resulting in a sub-optimal acupuncture treatment. Other trials have used “sham” acupuncture or insertion of acupuncture needles in “non-acupuncture” sites as a control. Depth of insertion and stimulation are the same as real acupuncture; only point location differs. However, it has been found that this form of sham acupuncture has an analgesic effect in 40 – 50% of patients. Studies have shown that penetration of the skin, whether or not they are classical acupuncture points, will often produce physiological effects.

In our study, we chose a form of sham acupuncture known as “minimal acupuncture”. Minimal acupuncture involves the insertion of needles away from classical acupoints, with the needles inserted to a depth of 1 – 2 mm and stimulated extremely lightly. We believed that this procedure would minimize the specific effects of the needling while maintaining its psychological impact. However, we observed a 41% reduction in shoulder pain intensity in our sham acupuncture control group, suggesting that there may be a physiologic response associated with even minimal needling of the skin.

Given that there may be an enhanced placebo effect associated with an invasive procedure like sham acupuncture, the degree of difference between results of patients receiving real and those receiving sham treatments may potentially be reduced. As a result, future randomized controlled trials to prove the efficacy of acupuncture may require more participants since the control is sham than studies that the control is a placebo pill.

#### Natural History of Shoulder Pain

Shoulder pain intensity levels decreased in some of our participants prior to even receiving any treatment. Shoulder pain can be caused by a number of factors and its intensity can vary substantially based on activity level, wheelchair set-up, and awareness of proper body mechanics during various activities of daily living. During the initial screening evaluation, we identified obvious factors in several individuals that could be contributing to their shoulder pain (e.g. improper wheelchair set-up, poor biomechanics, etc.). We felt ethically obligated to point these out. Once the appropriate changes were made, their pain symptoms resolved.

#### Medical Complications Related to SCI

Persons with SCI are prone to a variety of medical complications associated with their injury (e.g. urinary tract infections, pressure ulcers, bowel obstruction, syringomyelia, etc.). These complications can negatively impact their participation in research studies, especially those covering an extended period of time. Four individuals in our study had to withdraw from participation due to medical complications associated with their SCI. Unfortunately, participant dropout due to medical complications unrelated to the study intervention will be a challenge faced by all clinical trials involving persons with SCI.

### **Implications for future research and/or clinical treatment**

Due to lower limb paralysis, individuals with SCI must rely extensively on their upper limbs for their mobility and other activities of daily living. The daily performance of these activities places a great deal of stress on the shoulder joint leading to overuse, injury, and pain. Damage to the upper limb may be functionally and economically equivalent to a SCI of a higher neurological level so there is clearly a need for research into the prevention and treatment of this condition. Acupuncture has recently begun to gain popularity in the United States as a “new” promising approach for the treatment of pain. Indeed, one of the advantages of acupuncture is that the incidence of adverse effects is lower than many drugs or other accepted medical procedures (e.g. Ibuprofen, Vioxx, joint injections, etc.).

We observed a significant decrease in shoulder pain intensity with acupuncture, however, this change did not differ significantly from control or sham acupuncture. Indeed, there appears to be an analgesic or placebo effect associated with both acupuncture and sham acupuncture. The effect of the acupuncture was greater, suggesting that acupuncture may be superior to sham acupuncture in relieving shoulder pain in persons with SCI. There were no adverse effects associated with either the acupuncture or the sham acupuncture. Sample size limited the power to detect significant differences between the groups. Therefore, further research involving larger samples is recommended.

**Plans to continue this research, including applications submitted to other sources for ongoing support.**

The results from this study will be used as preliminary data to pursue a larger grant from the National Institutes of Health in February 2006. The grant will be either a multi-center, clinical trial comparing acupuncture and sham acupuncture in a larger population of persons with SCI and shoulder pain or a grant exploring issues surrounding acupuncture and sham acupuncture methodology and their effects on the pain centers in brain using advanced neuroimaging techniques.

**List of presentations and publications emerging from this research, including those in preparation.**Presentations:

Shoulder Pain in Individuals with Chronic Spinal Cord Injury. Spinal Cord Injury Grand Rounds, Kessler Institute for Rehabilitation, West Orange, NJ, October 2, 2002.

Acupuncture for the Treatment of Shoulder Pain in Chronic Spinal Cord Injury. Spinal Cord Injury Research Rounds, Bronx VA Medical Center, Bronx, NY. May 15, 2003.

Shoulder Pain in Spinal Cord Injury, Resident Lecture Series, Department of Physical Medicine and Rehabilitation, University of Medicine and Dentistry-New Jersey Medical School, West Orange, NJ, February 16, 2005

Management and Prevention of Shoulder Pain in Individuals Who Use Wheelchairs. New York Metro Abilities Expo, Edison, NJ, April 17, 2005

Instructional Course: Shoulder Management in Spinal Cord Injury. American Spinal Injury Association, 31<sup>st</sup> Annual Scientific Meeting, Dallas, TX, May 12, 2005.

Acupuncture in the Treatment of Shoulder Pain in Individuals with Spinal Cord Injury: a Placebo Controlled Study (poster). American Academy of Physical Medicine and Rehabilitation, 66<sup>th</sup> Annual Assembly, Philadelphia, PA, October 27-30, 2005.

Publications:

Dyson-Hudson TA, LaFountain M, Millis SR. Acupuncture in the treatment of shoulder pain in individuals with spinal cord injury: a placebo controlled study (Abstract). Arch Phys Med Rehabil 2005;86:e45.

Manuscripts in preparation:

Dyson-Hudson TA, LaFountain M, Kadar P. Acupuncture for Shoulder Pain in Persons with Chronic Spinal Cord Injury: A Randomized Controlled Trial.