DEVELOPMENT AND VALIDATION OF A SHAM ACUPUNCTURE NEEDLE

A Capstone Project

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by

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ABSTRACT

Background: The popularity of acupuncture as an adjunct therapy in the treatment of several illnesses made it imperative to conduct scientific studies of its efficacy in clinical trials. The creation of a control group in acupuncture research studies has been challenging due to the subjective nature of acupuncture, and the positive results of acupuncture treatment are often dismissed as a placebo effect. The development of sham needles and sham acupuncture protocols have been tested and successfully marketed. These sham needles are costly, making it necessary to design a similar sham needle that is cost-effective and easy to be duplicated by researchers when grants are not available.

Purpose: This study developed and validated a cost-effective sham needle device used in the pilot study "A Randomized Placebo-Controlled Pilot Study on the Potential Effects of Acupuncture for Radiation Cystitis and Prostatitis" at the Naval Medical Center San Diego (NMCSD).

Methods: Single blinded random study using 40 subjects with previous acupuncture experience. Subjects were divided in two groups of 20 participants, Group A and Group B. Group A, the control group, received insertion on LI-4 with real acupuncture needle, and Group B received insertion on LI-4 with the costeffective sham needle device. After retention of needle for 1 minute, subjects in both groups filled out a qualitative survey of the sensation they experienced.

Results: Eighty percent of the sham group felt that they were needled, compared to 90% of the verum group. The sham group reported half as much intensity on the needle sensation as the verum group.

Conclusion: The cost-effective sham needle tested in this study proved to be a viable low-cost alternative to current sham needles on the market.

Key Words: Acupuncture, sham needle, placebo.