

Effectiveness of acupuncture in the treatment of chronic low back

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Greece Low back pain is a common musculoskeletal disorder defined as pain, muscle tension or stiffness in the lumbosacral area of the spine. It results in high health costs and incapacity to work causing a significant socio-economic burden. The optimal management of non-specific chronic low back pain has yet to be determined. Recently, acupuncture for chronic low back pain in addition to routine care is receiving increased recognition and acceptance by both patients and physicians. Clinicians treating patients with chronic low back pain with acupuncture may elicit an immediate sense of calmness with subsequent well-being benefits for their patients.

Apart from its analgesic effect acupuncture has been also shown to inexpensively improve functional outcome and quality of life and to be a safe and cost-effective treatment modality. In a meta-analysis of recently published clinical trials incorporating more than 10.000 patients with chronic pain, the analgesic efficacy of acupuncture compared to other treatment modalities was highly statistically significant ($P < 0.001$). Therefore, acupuncture should be a part of the armamentarium of every physician who treats patients with chronic low back pain.

Background-

Chronic back pain is a major public health problem and the primary reason patients seek acupuncture treatment. Therefore, an objective assessment of acupuncture efficacy is critical for making informed decisions about its appropriate role for patients with this common condition. This study addresses methodological shortcomings that have plagued previous studies evaluating acupuncture for chronic low back pain. Back pain is one of the most important health problems in developed countries. More than 50% of adults are bothered by back pain each year and 70% to 80% of adults are afflicted by it at some time in their lives. Back symptoms are the leading cause of visits to orthopedic surgeons and neurosurgeons and the second leading symptomatic reason for visits to all physicians. Back pain is the most costly ailment of working-age adults. An estimated \$25 billion are spent on personal medical care for back pain every year and compensation and lost productivity costs are much higher.

Back pain patients are often dissatisfied with conventional medical care, especially in comparison to care provided by non-MD's including CAM practitioners. Back pain is the leading primary reason for visits to licensed acupuncturists, representing about 1 in 7 visits, and acupuncturists consider it to be one of the conditions for which acupuncture is most effective.

Despite numerous published randomized trials evaluating acupuncture as a treatment for chronic low back pain, the efficacy and effectiveness of acupuncture for this common problem remains unclear. The 1997 NIH Consensus Development Panel on Acupuncture noted "many of these

studies provide equivocal results because of design, sample size, and other factors

Method & Design-

The acupuncture provided will be in accordance with the principles of Traditional Chinese Medicine (TCM) in terms of point selection and needling details. Although many styles of acupuncture are used in the U.S., we selected TCM because it appears to be the most commonly practiced [11,17] is the basis of the national certification exam for non-physician acupuncturists, and is the foundation of non-physician acupuncturist training in the states in which this trial is being conducted. The treatments will be provided by licensed acupuncturists, the group that provides the vast majority of acupuncture treatments in the United States.

In addition to the assigned treatments, all participants will receive a high-quality book about self-management of back pain and will retain access to the health care services to which they are entitled by their insurance coverage.

Participants will be followed for a one-year period following randomization and primary and secondary outcomes will be assessed by telephone interviewers masked to treatment assignment after 8, 26, and 52 weeks. The primary outcome will be dysfunction due to back pain and bothersomeness of back pain. Secondary outcomes will include general health status, satisfaction with back care, days of restricted activity, and use and costs of back-related health care for the year following randomization.

Bias will be minimized by a clinical protocol designed to offer maximum possible masking in a study of a physical procedure such as acupuncture. Although full double masking is not possible, this design permits masking of the assessor of outcomes and substantial masking of participants and the acupuncturist prescribing a treatment. Participants in the three "acupuncture" groups will know only that they will receive one of several methods of stimulating acupoints.

We will perform an intention-to-treat analysis of the data, i.e., the analysis will be by randomized assignment regardless of participation in treatment sessions. This trial was preceded by a pilot trial to assess the feasibility of a full-scale trial. The pilot study demonstrated the feasibility of carrying out a full-scale trial, provided estimates of recruitment rates, follow-up rates, and sample size requirements, and helped us optimize the clinical procedures.

Clinic sites

Acupuncture treatments will be performed in the Research Clinics at the two study sites. The Diagnosticians and Therapists will see participants in separate rooms. Therapists' rooms will resemble a typical acupuncture treatment room with a massage table for treatment and a table for acupuncture supplies. This table will be screened off from the massage table

to prevent participants from looking at the needles or non-insertive implements to be used in their treatment.

Study acupuncturists

Licensed acupuncturists will be recruited and trained as either Diagnosticians or Therapists and will function only in their assigned role throughout the study. All acupuncturists will be experienced TCM practitioners. We will require Diagnostician acupuncturists to have at least five years experience and Therapists to have at least three years experience with an emphasis on the treatment of musculoskeletal pain. All acupuncturists will need to agree to strictly adhere to the study protocol and to complete the rigorous training program developed in the pilot study. In addition, the Therapist acupuncturists will need to be comfortable administering all three treatments.

References-

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