

# Researchers to Study Acupuncture for Fibromyalgia

Editorial Staff

According to the American College of Rheumatology, fibromyalgia is the second most common rheumatic disorder in the United States behind arthritis. While some organizations put the number of Americans suffering from fibromyalgia at three million, other sources believe the number is much higher - perhaps eight or nine million.<sup>1-3</sup> Patients diagnosed with fibromyalgia often suffer a wide range of debilitating symptoms, including fatigue, widespread musculoskeletal pain, stiffness and tenderness in the soft tissues, and sleep disorders. Some research has suggested a link between brain abnormalities and fibromyalgia, but a definitive cause has yet to be established.

Traditional treatments for fibromyalgia include stretching exercises, local applications of heat, and gentle massage, but the benefits of these therapies are usually of short duration. Similarly, small doses of antidepressants or nonsteroidal anti-inflammatory drugs may be helpful, but they are typically used only to help patients sleep and often carry unwanted side-effects.

Two randomized-controlled trials in Washington, D.C. and Washington state are attempting to see if a more radical form of care -- acupuncture -- can successfully treat people with fibromyalgia. The studies, sponsored by the National Center for Complementary and Alternative Medicine, are among the largest federally-funded acupuncture studies to be conducted in the U.S., and are hoped will find an effective treatment for a condition that is currently incurable.

In the Washington state study, researchers at Harborview Medical Center in Seattle will recruit 96 patients between the ages of 18-43 from a referral clinic and divide them into four groups. Three of the groups will be used as controls (one receiving acupuncture for an unrelated condition; one receiving needle insertion at non-meridian, non-point locations; and one receiving placebo acupuncture), with the fourth group receiving acupuncture twice a week for 12 weeks.

Just prior to (and during the course of) the study, researchers will track a variety of patient factors, including pain levels and overall pain threshold; the average number of tender points on the body; ability to function; quality of sleep; and level of fatigue. Patients will also be reassessed at one- and six-month intervals after treatment to see if acupuncture provides any long-term benefits.

In an outline describing their proposal, the researchers outlined several goals they hope to achieve from the study. In addition to establishing the effectiveness of acupuncture, they believe the experiment "will establish the most appropriate methods for choosing a control group should larger trials be conducted; suggest the optimum duration of treatment; and evaluate the utility of diverse allopathic and alternative outcome measures."

In the second study, scientists at Georgetown University are conducting a Phase III trial that could

incorporate as many as 3,000 test subjects between the ages of 18-65. As in the Washington state study, patients in the Georgetown trial will be randomized into one of four groups: 1) active site acupuncture, with stimulation; 2) active acupuncture, without stimulation; 3) sham site acupuncture, with stimulation; and 4) sham acupuncture, without stimulation.

The trial will last 13 weeks, with all subjects receiving treatment at an escalating frequency, beginning at once per week and ending at three times per week. The scientists theorize that this form of care, known as "forced titration," helps them detect any differences between subjects in responsiveness to acupuncture, as well as any factors that may predict a response to treatment (or lack thereof). Other goals of the study include collecting data on the mechanism, safety and cost-effectiveness of acupuncture, as well as determining how to achieve the best possible results from care.

### Eligibility Requirements

While the Washington state study is not yet open for patient recruitment, Georgetown researchers are currently recruiting patients for their trial. To be considered for the Georgetown study, patients must:

- meet the American College of Rheumatology's criteria for fibromyalgia;
- be a resident of the Washington, D.C. area;
- have continued, widespread pain for more than 50% of days;
- be willing to limit their consumption of any new medications or other forms of care related to the control of fibromyalgia symptoms during the course of the study; and
- be able to travel to the site of treatment up to three times per week, and to give informed consent to treatment.

### Contact Information

For more information on the Washington state fibromyalgia study, contact Dr. Debra S. Buchwald of the Harborview Medical Center at (206) 731-8218. To find out more about the Georgetown study, contact Jo Anne Stanback at (202) 784-0042.

### References

1. Questions and answers about fibromyalgia. Available from the National Institute of Arthritis and Musculoskeletal and Skin Diseases ([www.fhma.com/fibromyalgia.htm](http://www.fhma.com/fibromyalgia.htm)).
2. Fibromyalgia. Available online at [www.rheumatology.org/patients/factsheet/fibromya.html](http://www.rheumatology.org/patients/factsheet/fibromya.html).
3. *An Overview of the Fundamental Features of Fibromyalgia Syndrome*. Linden, VA: National Fibromyalgia Partnership, 1999.

NOVEMBER 2001