

# Scientists Design New Placebo Acupuncture Needle

STUDY FINDS DEVICE IS OF "HIGH CREDIBILITY"

Editorial Staff

A long-standing point of contention to the validity of randomized, controlled acupuncture trials has been the inability of investigators to create and implement a true placebo, or "sham," acupuncture needle. The crux of this contention has been that patients know whether they are receiving acupuncture because they can see or feel a needle being inserted, which gives rise to the placebo effect and can skew the results of an otherwise sound study. A secondary point to this argument is that needles cause an effect on subjects whether being inserted at specific acupuncture points or not, and that this effect, though unintentional, may produce subjective data, lessening a study's credibility.

Over the years, scientists have tried various methods for mimicking the sensation of an acupuncture needle, including the sharp end of a pencil; a practitioner's fingernail; a needle guide tube - even the end of a cocktail swizzle stick - all without producing the desired effect. Researchers in Germany may have finally solved this problem with an experimental placebo needle used as part of a headache study, the results of which have been published in *Forschende Komplementärmedizin und Klassische Naturheilkunde (Research in Complementary and Classical Natural Medicine)*.<sup>1</sup>

Sixty-eight patients with a history of tension-type headache were chosen for the study. Half were assigned to an acupuncture group; the other half to a placebo group. Before being assigned, each patient was notified that they would receive one of two acupuncture treatments, and that it was not known which type was more effective. At the first treatment, patients were told that they might feel a pricking sensation from the needle, and that the *de qi* sensation could occur after the needle was inserted. Patients in the placebo group were further told that the needles would only be inserted gently and superficially, which would require the use of a small cube to keep them in place.

The placebo needle used in the study consisted of a real acupuncture needle (#16, 30 x 0.3 millimeters), with the tip removed and a new tip rounded off with a diamond polisher so as to touch, but not puncture, the skin. A cube-shaped block of sterilized foam was used as a holding device for the needle, with a ring of adhesive tape affixed to bottom of the foam to hold it in place on the skin. By inserting the needle through the foam, the view of the volunteers would be blocked such that they would not know whether the needle had actually penetrated the skin. In addition, once the needle touched the skin, it was gently twisted by the practitioner to enhance the illusion of treatment.

Patients in both groups received two treatments per week for five weeks, and received acupuncture bilaterally at the same points (GB20, LI4, LR3 and TW5). In the placebo group, needles were inserted, manipulated and left in place for 30 minutes, using a total of eight placebo needles per session. In the true acupuncture group, slightly different needles were used (#8, 0.3 x 0.3 millimeters or #2, 0.2 x 0.15 mm) and were also left in place for 30 minutes after insertion.

To determine the credibility of the placebo needles, the investigators subjected the volunteers to a three-part questionnaire. The first section asked patients about their interest in and knowledge of acupuncture; the second section focused on the patients' acceptance of acupuncture as a treatment for headache; and the third section measured the credibility and expectations of the patients toward the actual treatment. To test credibility, the patients filled in the third part of the questionnaire after the first treatment. After four or five treatments, patients were then asked to state whether they felt the needle being inserted and whether they had felt the *de qi* sensation.

### Researchers Find "No Significant Differences" between Treatments

Sixty-four patients answered the questionnaire. After tabulating the results, the scientists found "no significant differences" between the groups' responses in any section. In the interest section, the difference between the true and placebo acupuncture groups was two-hundredths of a point; in the general acceptance section, the difference was seven-hundredths of a point; and in the credibility section, the difference was less than half a point.

The placebo needle fared nearly as well when patients were asked about needle insertion and *de qi* sensation. Every patient in the true acupuncture group said they felt the needle being inserted; 28 patients in the placebo group said they also reported a feeling of needle insertion. The fact that the experimental needle design was able to fool more than 87% of the patients in the placebo group into thinking they had been needled shows that it was quite effective in achieving its intended goal as a placebo. Although the experimental design did not work as well as a true acupuncture needle, the researchers felt this was due to the placebo needles being pressed down differently than real needles. They added that "this problem can be overcome by adequate training with the placebo needle."

In addition, only 34% of those in the placebo group reported feeling the *de qi* sensation compared to more than 80% of those receiving true acupuncture. Furthermore, although the placebo needles never punctured the skin, they retained the illusion that they were inserted for the duration of treatment. The scientists reported that there were no instances of "spontaneous removal," or a needle falling out from its location, during the study.

The fact that more than a third of patients treated with the placebo needle experienced *de qi* did raise some concerns among the scientists, who said that the results of their experiment "call into question the main claim of placebo needles that they only are eliciting a placebo response." To avoid producing the *de qi* response, they proposed that future studies use non-acupoints for placebo needling.

### Needle Shows Great Potential for Use in Future Studies

Unlike most acupuncture studies, which are performed to measure the effects of treatment for a particular condition, the aim of the German study was to judge the credibility of a placebo needle that could be used in later studies. The scientists stopped short of calling their design a complete success, but believe their results show that the experimental needle "is of high credibility" and provides acceptance by patients "similar to that of real acupuncture."

While the outcome of the German study has yet to be confirmed independently, the experimental needle holds tremendous promise for the future of acupuncture and Oriental medicine. If the needle design fares as well in future tests, it could revolutionize the way acupuncture trials are conducted in the U.S. and elsewhere. As the scientists noted in their conclusion, "preparing the needle is easy and does not require any special technical appliance," meaning that it can be used quickly and without much training. In addition, the researchers noted that "compared with other

placebo needles, it is certainly the most economical" product available, which would reduce the costs of future studies. Finally, and perhaps most importantly, it could pave the way for the next generation of researchers to produce what the medical and insurance industries have claimed the Oriental medicine profession would never be able to deliver -- randomized, large scale, placebo-controlled clinical investigations that provide convincing evidence of the safety and effectiveness of acupuncture.

### *Reference*

1. Fink M, Gutenbrunner C, Rollnik J, et al. Credibility of a newly designed placebo needle for clinical trials in acupuncture research. *Forschende Komplementärmedizin und Klassische Naturheilkunde* 2001;8(6):368-72. Available online at [www.karger.com/journals/fkm](http://www.karger.com/journals/fkm).

APRIL 2002