

## RESEARCH ETHICS

## Acupuncture trials and informed consent

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*J Med Ethics* 2007;33:43–44. doi: 10.1136/jme.2006.016535

Participants are often not informed by investigators who conduct randomised, placebo-controlled acupuncture trials that they may receive a sham acupuncture intervention. Instead, they are told that one or more forms of acupuncture are being compared in the study. This deceptive disclosure practice lacks a compelling methodological rationale and violates the ethical requirement to obtain informed consent. Participants in placebo-controlled acupuncture trials should be provided an accurate disclosure regarding the use of sham acupuncture, consistent with the practice of placebo-controlled drug trials.

The randomised, placebo-controlled trial is widely regarded as the gold standard for assessing the efficacy of treatments. Complementary and alternative medicine treatments are being increasingly investigated according to such rigorous standards. In particular, acupuncture has been evaluated for a wide range of conditions in randomised, placebo-controlled trials.<sup>1</sup> A basic ethical requirement of this form of clinical research is valid informed consent, which includes informing prospective trial participants that they may be randomly assigned to a placebo control, designed to appear indistinguishable from the experimental treatment being evaluated.<sup>2</sup> To our knowledge, placebo-controlled drug trials almost invariably conform to this requirement. In the case of acupuncture trials, however, this standard of informed consent is often not observed.

**DISCLOSURE PRACTICES**

Lack of accurate disclosure to research participants about the use of sham acupuncture was evident in the case of four randomised controlled trials recently reported in leading medical journals. A trial conducted in Germany randomly assigned patients with migraine headaches to acupuncture, a sham acupuncture intervention or no treatment.<sup>3</sup> The article reporting results described the informed consent disclosure to participants

Patients were informed with respect to acupuncture and sham acupuncture in the study as follows: In this study, different types of acupuncture will be compared. One type is similar to the acupuncture treatment used in China. The other type does not follow these principles, but has also been associated with positive outcomes in clinical studies.

Two other German trials with a similar design, on patients with osteoarthritis of the knee<sup>4</sup> and

tension-type headaches,<sup>5</sup> compared acupuncture according to traditional Chinese medicine with minimal acupuncture defined as “superficial needling at non-acupuncture points”. Both articles stated that “minimal acupuncture served as a sham intervention”, and described the same disclosure to participants as in the trial of migraine headaches. Similarly, a recent trial on patients receiving acupuncture for the treatment of fibromyalgia in Seattle, Washington, compared acupuncture according to the practice of traditional Chinese medicine with three sham acupuncture interventions.<sup>6</sup> The report noted that “Potential participants were told that they had an equal chance of being assigned to 1 of 4 acupuncture interventions, none of which have been proven but 1 of which was believed to have the most potential to improve the symptoms of fibromyalgia”. Although participants in these four studies were not informed that they had a chance of receiving a sham acupuncture intervention, all the articles stated that participants provided written informed consent.<sup>3–6</sup>

This lack of adequate disclosure is not uncommon in the case of acupuncture trials. Linde and Dincer<sup>7</sup> examined published reports of 47 sham-controlled trials of acupuncture. Only 10 reports provided information on the disclosure to participants, and none of these mentioned that a placebo or sham intervention was used. Summarising the reported disclosures in these 10 trials, the authors noted, “Most trials seem to have suggested to patients that two different types of acupuncture were being compared.” Linde and Dincer also obtained patient information leaflets for 16 sham-controlled acupuncture trials published after 1989. Only seven of these clearly indicated that a sham or placebo acupuncture intervention was included in the trial.

Although extensive methodological discussions of placebo controls in acupuncture trials have been presented,<sup>8–10</sup> and many studies have been carried out to authenticate the validity of various sham acupuncture devices in use,<sup>11–15</sup> the rationale for this absence of accurate disclosure to participants is not clear. We speculate that this lack of transparency may come from the concern of acupuncture researchers that full disclosure may interfere with recruitment, discomfort with placebo interventions, belief that the sham controls are physiologically active or general inexperience with research and its ethical requirements. In any case, this practice poses serious ethical questions.

**ETHICAL ANALYSIS**

Trial participants who are told that they will be randomly assigned to different forms of acupuncture are misinformed, when in reality they will receive either a traditional form of acupuncture or

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Received 27 February 2006  
Accepted 2 March 2006

a sham intervention designed to be indistinguishable from the real treatment being evaluated. Sham acupuncture is no more a form of acupuncture than a pill placebo is a form of medicine. Accordingly, failure to inform prospective participants that they have a chance of receiving a sham or placebo acupuncture intervention is deception that clearly deviates from the requirement of informed consent and thus violates the basic principle of respect for people.<sup>16</sup> An accurate description of the procedures included in a clinical trial is a basic element of informed consent.<sup>17, 18</sup>

Deception in clinical research is problematic and controversial but not necessarily unethical. An acknowledged requirement for the ethical use of deception, however, is that the departure from informed consent must be necessary to obtain valid scientific data.<sup>19</sup> This justification does not generally pertain to placebo-controlled clinical trials evaluating treatment efficacy, as an accurate disclosure about the use of placebo controls does not impair scientific validity. To be sure, sham-controlled acupuncture trials differ from placebo-controlled trials of pharmacological interventions, in that acupuncturists who deliver the real and sham interventions necessarily know which is being given.<sup>20</sup> In theory, this makes it more difficult to be assured that participants will be blinded to whether they receive the real or the sham intervention; however, it does not follow that adequate blinding to treatment is impossible in acupuncture trials, that provide accurate disclosure about the use of sham interventions.

Berman *et al*<sup>21</sup> conducted a sham-controlled trial on acupuncture for osteoarthritis of the knee that provided an accurate disclosure of the use of a placebo control. The informed consent disclosure to participants for this trial was included in the group of patient information leaflets surveyed by Linde and Dincer.<sup>7</sup> It stated, "You will be randomly assigned to either an acupuncture, placebo acupuncture, or self-help group. The second group will receive pretended acupuncture where the needles will be placed in nonacupuncture points." As part of the trial, the blinding to treatment was assessed by asking participants whether they believed they were receiving the real or the sham acupuncture. Most participants from both the acupuncture and sham groups believed that they received the real acupuncture, but higher proportions from the acupuncture group believed they received real acupuncture. This led the authors to conclude, "that the sham acupuncture procedure was a relatively credible blinding strategy".

The success of participant blinding may be diminished in sham acupuncture trials with accurate disclosure, as compared with trials that do not inform participants about the chance of receiving a sham intervention; however, no systematic data are available to evaluate this hypothesis. In clinical research trade-offs between methodological rigor and protection of research, participants are inevitable. We submit that accurate disclosure, consistent with informed consent, should take precedence over deceptive disclosure for the sake of maximising scientific validity, especially in the absence of rigorous data showing that accurate disclosure undermines satisfactory blinding of participants.

## ENDING THE DOUBLE STANDARD

Sham acupuncture trials show a double standard. Many depart from the standard practice of disclosing the use of placebo controls, characteristic of placebo-controlled drug trials. Moreover, the practice of disclosure among acupuncture trials is inconsistent, with some investigators accurately disclosing to participants that they may receive a sham intervention and others informing them that one or more acupuncture treatments are being evaluated in the trial. This inconsistency of informing that one or more treatments are being evaluated reduces the comparability of acupuncture trials, thus potentially impairing the validity of meta-analyses and systematic reviews.

The double standard for acupuncture trials should be obviated in favour of adhering to informed consent. Just as research on treatments used in complementary and alternative medicine should adhere to rigorous methodological standards, so it should abide by ethical standards for clinical research.<sup>22</sup> Research sponsors and ethical review boards should mandate accurate disclosure to trial participants about the use of sham acupuncture. Additionally, scientific journals should require that authors of research reports describing the results of sham acupuncture trials clearly indicate the form of disclosure to participants regarding trial interventions.<sup>23</sup>

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Funding: TJK is funded in part from grant 1 R01 AT001414-01 from the National Center for Complementary and Alternative Medicine.

Competing interests: None declared.

The opinions expressed are those of FGM and do not reflect the position or policy of the National Institutes of Health, the Public Health Service or the Department of Health and Human Services.

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