What is lost in the acupuncture trial when using a sham intervention?

Controversy still surrounds the evaluation of acupuncture's effectiveness as a therapeutic intervention in the era of evidence-based medicine, and this is exemplified by published clinical research on acupuncture for menopausal hot flushes among climacteric women. Ee *et al*[1] conducted a randomised control trial (RCT) in patients experiencing hot flushes who were mainly acupuncture-naïve Caucasian women in Australia. Patients were randomised to receive 10 treatment sessions of either verum acupuncture, which involved needle insertion at six classical acupuncture points, or sham acupuncture, which involved stimulation at six non-acupuncture sham points with sham devices, over the course of 8 weeks. It was demonstrated that both interventions improved the hot flush score (the primary outcome of this study) by approximately 40% relative to baseline, and that the improvement continued up to 6 months following the end of treatment in both groups with no statistically significant difference between the two arms. Soon after the study was published, Reuters released an article entitled 'Acupuncture needling doesn't ease menopausal hot flashes' (http://www.reuters.com/article/us-health-menopause-acupuncture-idUSKCN0UX2I6) and the BMJ issued a news article entitled 'Real acupuncture for hot flushes is no better than sham, study finds'.[2] However, this rather superficial interpretation of the results demands further scrutiny.

In order to understand the clinical implications of this type of acupuncture research, it is important to consider the influence of different control interventions. According to a recent Cochrane review, hot flush severity was not significantly impacted by acupuncture or hormone therapy, although hot flush frequency was significantly decreased by hormone therapy.[3] However, when compared with no treatment, acupuncture significantly decreased both the frequency (standard mean difference (SMD) −0.5, 95% CI −0.69 to −0.31) and intensity (SMD −0.54, 95% CI −0.73 to −0.35) of hot flushes.[3] In addition, acupuncture exhibited effects equivalent to venlafaxine, which is one of the standard non-hormonal drug treatments for women with hot flushes in whom oestrogen is contraindicated.[4] Judging from the results of these studies, acupuncture appears to be an effective treatment for menopausal hot flushes, with an effect similar to that observed 'within-group' in the study by Ee *et al*.[1]

Several issues regarding the intervention termed 'real' acupuncture in the study by Ee *et al*[1] are worthy of further discussion. In order to achieve blinding of participants, the authors used a 'base unit', which is a necessary component of the sham needle selected by the authors that facilitates its retention on the skin, in both groups.[5] The base unit consists of a Park tube and flange, which has double-sided tape for attachment to the skin and a guide tube, which in turn slides into the Park tube. The total height of the unit is approximately 6 cm when the guide tube is free of the Park tube and 4 cm when it is inserted (figure 1). This presents a potential issue when attempting to deliver 'real' acupuncture using this unit; a 4 cm 'real' acupuncture needle body with approximately 2 cm of needle handle can theoretically be inserted into the skin approximately 0 to 2 cm, but the actual depth of insertion may not exceed 1 to 2 cm because the handle

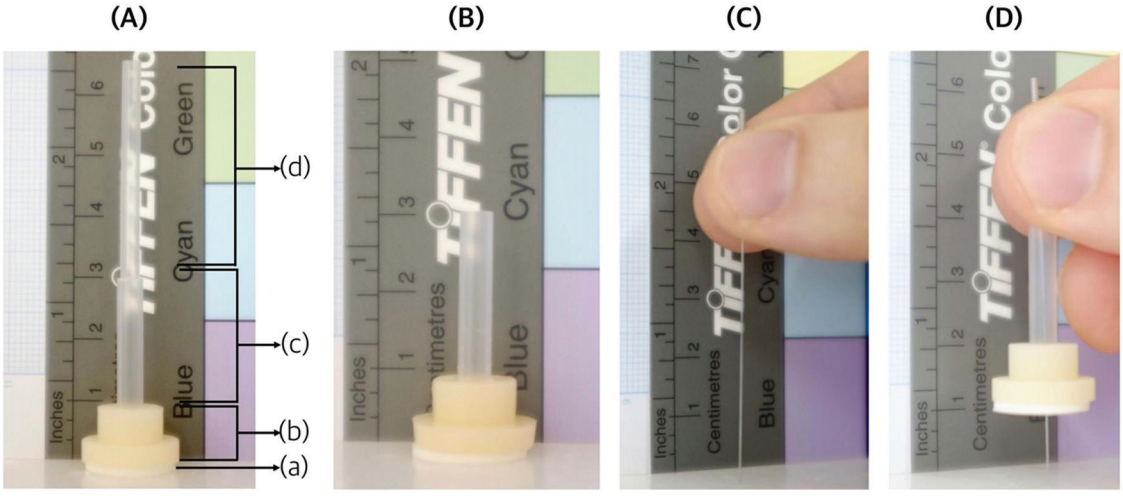

Figure 1 (A) Sham acupuncture base unit consisting of double-sided tape (a), flange (b), Park tube (c) and guide tube (d) with guide tube fully extended from Park tube. (B) Base unit with guide tube removed. (C) 4 cm verum acupuncture needle (without base unit), which can easily be inserted to a depth of up to 4 cm. (D) 4 cm verum acupuncture needle together with base unit, demonstrating restriction of needle insertion resulting in a shallower insertion relative to (C).

of the acupuncture needle must rise upward over the Park tube in order to elicit the *de qi* sensation through a twirling needle manipulation. In standard clinical practice, the physician can hold the 2 cm handle of an acupuncture needle fully and insert, pull and rotate the needle to induce *de qi* at 0 to 4 cm of depth. In this sense, acupuncture with a sham base unit renders the type of needle stimulation fundamentally different from that which can be achieved without it; arguably only shallow insertion and weak stimulation are possible, making it doubtful that this type of treatment constitutes a 'proper' intervention reflecting actual 'real' acupuncture in clinical practice, even though it mimics verum acupuncture by penetrating the skin.

Furthermore, in our own experience of conducting clinical trials using this base unit, we have encountered situations whereby needles were inserted only into the double-sided tape below the flange, and not into the skin, because the tape frequently covers the opening of the flange base. In addition, when practising acupuncture, physicians generally identify prospective points of insertion (ie, classical acupuncture points, tender points or myofascial trigger points) with the fingertips before needling, and the flange of the unit may interfere with this process. From personal experience, given that use of the base unit affects point localisation, needling and the manner of stimulation, it is difficult to mimic usual (appropriate) acupuncture practice. If 'real' acupuncture in the trial consequently fails to replicate clinical practice of acupuncture, then the results of the study are unlikely to reflect the true effects of acupuncture as it is delivered in the real world setting. Other factors in the study by Ee *et al* that bring the appropriateness of their acupuncture intervention into doubt include the selection of acupuncture points, the frequency of treatment, and the experience and educational status of the acupuncture practitioners. All of these factors must be considered before drawing any conclusions on the effect of 'real' acupuncture in this trial.

CONCLUSION

Using sham acupuncture in an attempt to blind participants and thereby assess the specific effect of acupuncture can produce another limitation for clinical acupuncture trials by potentially attenuating the effects of 'real' acupuncture. Further discussion regarding study design and control interventions for acupuncture research is necessary.

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Notes