ORIGINAL ARTICLE

The Effect of Real and Sham Acupuncture on Thermal Sensation and Thermal Pain Thresholds

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Objective: To compare the effect of real and sham acupuncture and a control intervention on thermal sensation and thermal pain thresholds.

Design: Single-blind, randomized controlled, repeated-measures trial.

Setting: Laboratory.

Participants: Eighteen acupuncture naive, healthy subjects with no history of upper-limb pathology or acupuncture contraindications.

Intervention: Subjects were randomly assigned (blind card allocation) to 1 of 6 possible orders of application of the interventions, which consisted of 25 minutes each of control, real, and sham acupuncture.

Main Outcome Measures: Thermal sensation and thermal pain thresholds measured with a thermal sensory analyzer before and after each intervention.

Results: There were increases in cold and hot pain and cold sensation thresholds with real acupuncture. The level of increase did not differ significantly from the changes that occurred with sham acupuncture and control interventions.

Conclusions: Although we observed a trend toward a decreased sensitivity to thermal pain and thermal sensation with real acupuncture, this trend did not differ significantly from the changes with control or sham interventions. Therefore, no support was provided for analgesic or placebo effects of acupuncture. The trend, combined with the relatively low power of the inferential tests applied does, however, suggest that further research is merited.

Key Words: Acupuncture; Placebo effect; Rehabilitation; Sensory thresholds.

ACUPUNCTURE'S POPULARITY IN the West has increased in the last 3 decades and is now practiced by many professionals, including physiotherapists, nurses, and general practitioners.[1,2] The parallel growth in public perception about the limitations of orthodox medicine and concerns about side effects has led to a substantial interest in and use of complementary and alternative medicines.[3-5] In the West, acupuncture is most commonly used to treat pain and musculoskeletal disorders.[2] There is a call for it to be more widely available within mainstream clinical practice; however, for acupuncture to be accepted, a demonstrable base of evidence is required.[2]

The efficacy of acupuncture can be investigated on the basis of 2 contradictory theoretical models: traditional Chinese medicine or the Western scientific model.[6] In traditional Chinese medicine, vital energy (qi) is believed to flow through the body in specific channels. Illness develops where this flow is blocked and acupuncture needles inserted in certain points are believed to restore this flow and balance the system.[3] Traditional Chinese medicine also embraces a holistic view of a person's health, in which all aspects of that person's life and how he/she interacts with his/her surroundings, are considered throughout treatment.[3,7] Advances in neurophysiology and pharmacology, along with the gate theory of pain now provide a possible alternative, more scientific, model for acupuncture that can explain its possible analgesic action through neurophysiologic processes attributable to both real and placebo effects.[6,8,9]

Investigation of both real and placebo effects can be based on the knowledge that pain is transmitted by thin myelinated, A delta and unmyelinated C nerve fibers to the dorsal horn in the spinal cord. Nociceptive information is then conveyed via the midbrain and thalamus to the cerebral cortex, where it is perceived.[10] Acupuncture is hypothesized to work at both segmental and nonsegmental levels. The postulated segmental effects arise at the spinal cord level; acupuncture is believed to stimulate the A beta nerve fibers, which in turn block the transmission of pain to higher centers—the gate theory of pain.[11] Nonsegmental effects, in general, occur at supraspinal levels.[12] Acupuncture is believed to stimulate A delta and C fibers in addition to A beta and these activate 3 centers: the spinal cord, the midbrain (periaqueductual gray and nucleus magnum raphe), and the hypothalamic pituitary complex. These centers release various endogenous pain modulators (eg, β-endorphins), and there are corresponding receptors distributed throughout the body.[5,13] Additionally, the stimulation of supraspinal structures brings about diffuse noxious inhibitory control, whereby a noxious stimulant (acupuncture) in 1 area of the body can reduce the perceived intensity of pain produced by a noxious stimulant (tissue damage) in another area of the body.[3,5,14]

It is also accepted that pain is a subjective, complex, multidimensional event that involves a sensory discriminative component and affective motivational and cognitive evaluative factors and can be influenced by a placebo effect.[15-17] Various explanatory mechanisms have been proposed: psychologic mechanisms may include both expectancy and motivational processes that can relieve pain even if no "real" treatment is applied.[10,15] Psychologic mechanisms can also mediate a physiologic effect, resulting in the release of some of the endogenous opioids referred to earlier.[15]

The measurement of pain is therefore as complex as the phenomenon itself. One increasingly popular method is Quantitative Sensory Testing (QST), which is a psychophysical test that makes possible the quantitative assessment of temperature

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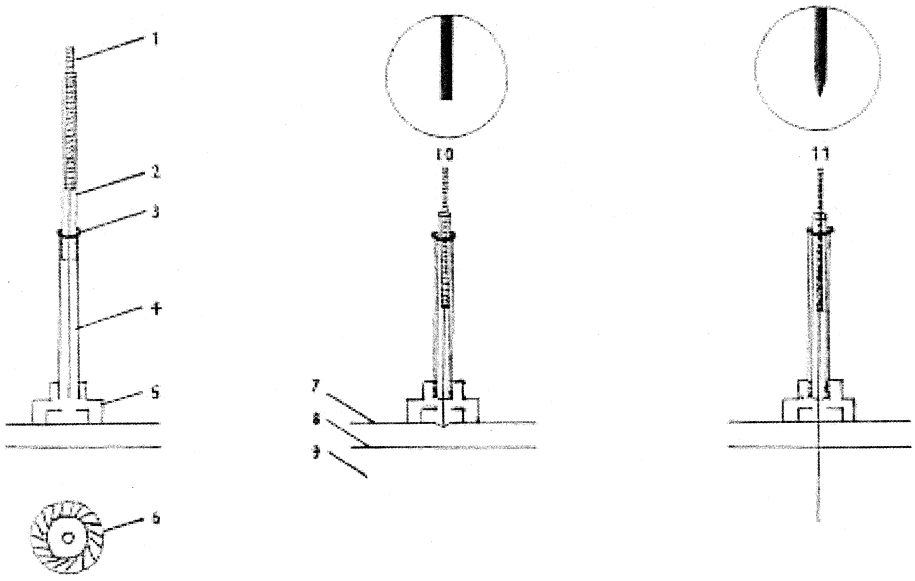

Fig 1. Park sham device with sham and real needle.[26] Legend: 1, needle handle; 2, guide tube; 3, guide O-ring; 4, Park tube; 5, flange; 6, double-sided tape; 7, skin; 8, dermis; 9, muscle; 10, dull tip of sham needle; 11, sharp tip of real needle.

sensation and pain perception.[18] It is known that the same nerve fiber types convey both thermal and pain-derived signals to the central nervous system.[18,19] Measuring the sensitivity of thermal sensation and thermal pain thresholds with QST therefore indicates the perceptions arising from the activity of the common pathway and provides insight into both the effectiveness and (possible) mode of action of any pain treatment.[18,19] QST, using the method of limits algorithm, is an accepted method with which to measure thermal sensation and thermal pain thresholds.[19,20] The literature on the effectiveness of acupuncture on both thermal sensation and thermal pain thresholds is conflicting.[17,21-23] These studies cannot be considered a definitive body of work, however, because of both a paucity of such studies and their differing and sometimes limited methodologies. A common vulnerability arises from the difficulty in providing a credible placebo for acupuncture. Various options that have been applied include acupuncture at nonacupuncture points and superficial needling.[22,23] Unfortunately, with both techniques an analgesic effect could occur via the diffuse noxious inhibitory control mechanism.[24] Ashton et al[25] applied a different placebo and compared subjects who received acupuncture with those who were given dissolved lactose, which they thought was aspirin. Although this is an imaginative solution, a placebo drug treatment is not a credible placebo for needling. The recent introduction of a novel placebo needle—the Park sham device[26]—may be a major development in acupuncture research in that patients can be conditioned to expect pain relief with the application of needles.[26,27] A test of the device has been reported in 1 study[28] on acupuncture naive subjects; it was found to be indistinguishable from a real needle, and was employed as the placebo in this study. The device gives the visual illusion that it penetrates the skin, but no penetration occurs because its shaft telescopes into the handle when downward pressure is applied (fig 1).

Our goal in this study was to address the lack of research into the analgesic and placebo effects of acupuncture by investigating the effect of real acupuncture, sham acupuncture, and a control intervention on thermal sensation and thermal pain thresholds. Cold sensation, warm sensation, cold pain, and hot pain thresholds, measured by QST, before and after these interventions were the outcome measures. The subjects' experience of sensation with the acupuncture interventions and their identification of the types of acupuncture were also explored to evaluate the effectiveness of the sham needles.

METHODS

Design

This study was a single-blind randomized controlled repeated-measures (within-subject) trial. The independent variable was acupuncture (real, sham). The dependent variables were the thermal sensation and thermal pain thresholds.

Participants

A convenience sample of 18 healthy volunteers (12 women, 6 men; mean age ± standard deviation [SD], 29.1±9.2y) was recruited from among students at Queen Margaret University College, who responded to a general notice and word of mouth. All 18 subjects completed the study. Approval for the study was obtained from Queen Margaret University College Ethics Committee, and informed consent was obtained. Exclusion criteria were any upper-limb pathology in the last 5 years, previous acupuncture experience, or acupuncture contraindications (metal allergy, fear of needles, skin sensation problems, pregnancy, bleeding disorders, epilepsy, skin disorders, taking medication, taken alcohol in previous 24h).[29] Inclusion criteria were healthy, acupuncture naive, and no cognitive, mental, or communication impairment that would compromise the informed consent process.

Materials and Apparatus

We used the Park sham device[a] to deliver both the real and sham acupuncture.[26] A thermal sensory analyzer[b] delivered the thermal stimuli and recorded subjects' responses. The stimuli were delivered via a thermode held in position (against each subject's thenar eminence). Subjects were in a relaxed position with their forearm pronated to allow access to the acupuncture point. By using the method of limits algorithm, the stimuli were presented with increasing intensity and subjects were asked to indicate when they first perceived a specific sensation.[30] Subjects responded to the stimuli by pressing the response button and the computer recorded the temperature; table 1 presents the test parameters of the thermal sensory analyzer.

Table 1: Test Parameters of the Thermal Sensory Analyzer

Parameters	Values
Order of sensation presentation	CS, WS, CP, HP
Adaptation temperature (°C)	32
Rate of returning temperature (°C/s)	10
Temperature range (°C)	0–50
No. of stimuli for each sensation	3
Rate of temperature change (°C/s)	0.5
Interval between stimuli (s)	4–12 for CS and WS 4–6 for CP and HP

Abbreviations: CP, cold pain; CS, cold sensation; HP, hot pain; WS, warm sensation.

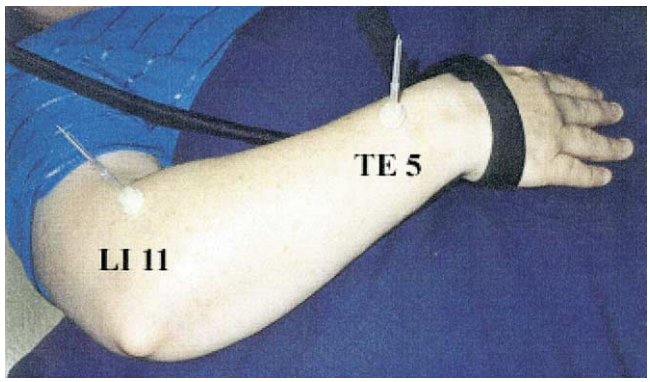

Fig 2. Location of acupuncture points.

Procedure

We did 2 pilot studies. First, a researcher completed the testing procedure twice so to be familiar with the protocol. Second, the intrarater reliability of assessment of the thresholds was measured. Five subjects were tested on 3 separate occasions (no more than 1wk apart). The results of the pilot work showed the reliability of the assessments to be "substantial" for the thermal sensations (cold, r=.68, warm, r=.77) and "almost perfect" for the pain thresholds (cold, r=.98, hot, r=.91).[31] Based on these findings, it was reasonable to hypothesize that any changes in the thresholds, in the main study protocol, could be attributed to the intervention.[31]

With 3 interventions, there were 6 possible orders in which they could be delivered. Subjects were randomly assigned, by blind card allocation, to receive one of the orders. For each intervention, subjects lay supine on a plinth, with the right arm exposed from the elbow downward. The elbow was flexed to 90° and supported on a pillow. Subjects could not see the computer screen, which displayed the stimuli delivered and their previous responses. The thermode was attached to the right hand, and the response button was held in the left hand. Subjects were given a practice cycle of the 4 stimuli at the start of each testing session. The following standardized instructions were given for each sensation.[19]

Cold sensation. "Press the button as soon as you feel a change in resting temperature."

Warm sensation. "Press the button as soon as you feel a change in resting temperature."

Cold pain. "Let the stimulus go past the first sensation of cold, until it starts to become uncomfortable, press the button as soon as it becomes painful."

Hot pain. "Let the stimulus go past the first sensation of warmth, until it starts to become uncomfortable, press the button as soon as it becomes painful."

After the practice cycle, for all the interventions, the 2 acupuncture sites were cleaned with an alcohol wipe. Figure 2 shows the acupuncture points used, triple energizer (TE 5) and large intestine (LI 11).

Thermal sensation and thermal pain thresholds were recorded before the interventions. In the sham acupuncture intervention, 2 Park sham devices were used at the acupuncture points TE 5 and LI 11 for 25 minutes. In the real acupuncture intervention, the same procedure was followed except that real acupuncture needles were used in the Park sham device carrier. In the control intervention, subjects lay for 25 minutes with no input or stimulus given. Thermal sensation and thermal pain thresholds were measured again immediately after all interventions. Each subject underwent all 3 interventions within a 3-week period, receiving 1 a week, always on the same day and at the same time. After both sham and real acupuncture interventions, the subjects were asked to answer yes or no to the question: "Did you feel any sensation in your arm during the acupuncture?" Subjects were then given a list of possible sensations.[32] After the third intervention, they were asked to identify the different types of acupuncture. Figure 3 presents a CONSORT flow diagram illustrating the route taken by subjects entering the study.

Data Analysis

The thermal sensory software[a] automatically calculated a mean figure (in degrees Celsius) for the 3 measurements of each thermal threshold over each experimental cycle. All values were expressed as change from the adaptation temperature of 32°C. The 2 cold-based absolute thresholds were calculated as 32°– recorded value and the 2 warm/hot as recorded value – 32°. These "absolute" values of the threshold were used to calculate change in threshold after control, sham, or real acupuncture as threshold postintervention minus baseline. Thus, for all thresholds, positive values for change always repre-

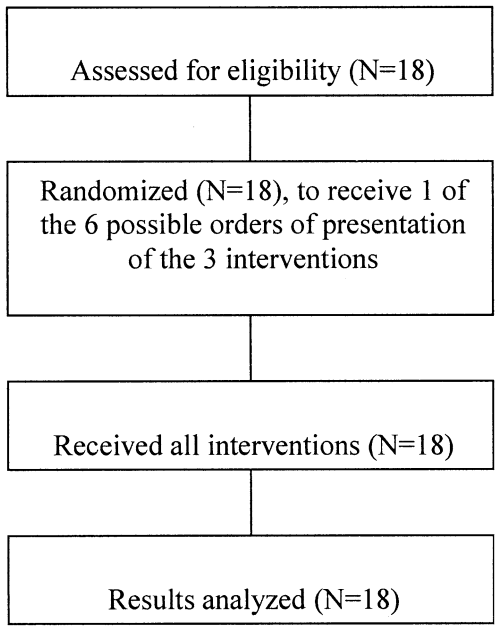

Fig 3. CONSORT flow diagram illustrating the route taken by subject's entering the study.

Table 2: Mean Thermal Sensation and Thermal Pain Thresholds Before (Base) and After (Post) Control, Sham, and Real Acupuncture Interventions

	Control		Sham		Real	
TT	Base	Post	Base	Post	Base	Post
CS	1.53±0.57	1.61±0.72	1.81±0.78	1.61±0.93	1.74±1.11	1.87±1.11
WS	2.29±1.75	1.63±0.98	2.27±1.94	1.55±0.92	1.91±1.33	1.69±1.17
CP	10.79±4.49	10.36±4.24	10.70±4.19	10.88±5.34	10.94±4.21	11.87±5.07
HP	10.19±3.54	10.19±3.44	10.59±3.16	9.68±5.18	11.02±2.88	11.87±3.02

NOTE. Values are mean degrees Celsius ±1 SD.
Abbreviation: TT, thermal threshold.

Table 3: Change in Thermal Sensation and Thermal Pain Thresholds After Control, Sham, or Real Acupuncture (post – baseline)

Thermal Threshold	Control	Sham	Real
Cold sensation	0.08±0.42	−0.21±0.64	0.12±0.69
Warm sensation	−0.66±1.45	−0.72±1.35	−0.21±0.99
Cold pain	−0.43±2.11	0.18±2.12	0.93±4.13
Hot pain	0.00±0.79	−0.88±3.57	0.85±1.83

NOTE. Values are mean degrees Celsius ±1 SD.

sented an increase in the threshold and hence a decrease in sensitivity, and negative values always represented a decrease in threshold and hence an increase in sensitivity. Differences in the baseline values, which were observed before each intervention, were investigated with a separate repeated-measures analysis of variance (ANOVA) for each thermal threshold; for all thresholds, there were no statistically significant differences between baselines. Differences in the changes in threshold that occurred (from pre to postintervention) were therefore investigated with a separate repeated-measures ANOVA for each threshold. Normality of distribution was tested with the Shapiro-Wilk test; for thresholds in which distribution was not within acceptable limits of normality ($P<.05$), we used the nonparametric equivalent—the Friedman test. The statistical power of the inferential tests applied, as calculated by the SPSS, version 11.0,[c] software, is also reported. We used a sign test to assess the frequency of correctness of identification of type of acupuncture.

RESULTS

Mean thermal sensation and thermal pain thresholds are presented in table 2. There were no statistically significant differences ($P>.05$) between the baseline values of any of the 4 thermal thresholds recorded before application of each of the 3 interventions were applied. Inferential comparisons were therefore made of the levels of change calculated in degrees Celsius. The levels of change in thermal sensation and thermal pain thresholds are presented in table 3 as the mean of the changes calculated in degrees Celsius.

With the exception of warm sensation, all thresholds increased with the application of real acupuncture, representing a decrease in sensitivity. For the cold sensation threshold, there were increases under both control (.08°C) and real acupuncture (.12°C) and a decrease under sham (–.21°C). This suggests that real acupuncture increased threshold, to some degree, relative to sham, but only negligibly relative to control. In cold pain threshold, an increase also occurred with real acupuncture (.93°C). This contrasted with a smaller increase of .18°C with sham and a decrease with control (–.43°C), suggesting that real acupuncture increased threshold relative to both control and sham. For hot pain threshold, an increase of .85°C occurred with real acupuncture, whereas under the sham treatment, a –.88°C decrease occurred with no change under control. This again suggests that real acupuncture increased the threshold relative to both control and sham. Although this reveals an interesting trend to decreased sensitivity in 3 of the 4 thresholds, it must be noted that with real acupuncture the levels of change were small relative to the underlying variance in the data sets. The results of the inferential tests are presented in table 4.

Table 4 illustrates that none of the differences between the levels of change in threshold after each of the 3 interventions were statistically significant. However, in all thresholds the statistical power of the tests was low. Indeed, in all cases power was well below the widely accepted optimum level of .80.[33]

The results must be considered in the context that 12 of 18 subjects answered correctly when asked which type of acupuncture they had received. However, the answers may well have been correct guesses rather than identifications because this is not a statistically significant departure ($P=.238$) from the distribution expected had chance only been behind the decision. Four subjects did not report experiencing any sensations with the real acupuncture, and 8 experienced sensations with sham—interestingly, 2 subjects therefore experienced a

Table 4: Results of Inferential Tests of Change in Thermal Sensation and Thermal Pain Thresholds, After Control, Sham, or Real Acupuncture Interventions (post – baseline)

Thermal Threshold	Norm*	F (ANOVA)	Friedman χ^2	*df*	*P*	Signif†	Power‡
Cold sensation	Yes	1.971	NA	1.482	.168	No	.322
Warm sensation	No	NA	3.875	2	.144	No	.237
Cold pain	Yes	1.146	NA	2	.330	No	.235
Hot pain	No	NA	3.086	2	.214	No	.343

Abbreviations: NA, not applicable; Signif, significance.
*Data normally distributed and parametric test performed.
†Statistically significant at $P<.05$.
‡Power for repeated-measures ANOVA.

sensation with a type of acupuncture that they called sham. This further supports the argument that the subjects may indeed have been guessing.

DISCUSSION

Our results show no significant differences in the level of change in thermal sensation and thermal pain thresholds when the 3 interventions were applied. Hence, 2 inferences can be made: first, real acupuncture did not have any significantly greater analgesic effect (as represented by change in thermal sensation and thermal pain thresholds) in comparison with sham and control. Second, because there was no significant difference between sham and control, there was no evidence of a placebo effect with acupuncture.

Meaningful comparison of our results with those of previous acupuncture research is problematic. Only Lundeberg et al[23] used computerized QST and, in accord with our present results, reported no significant differences between real and placebo acupuncture—placebo being defined as superficial needling. Man and Baragar[22] also found no analgesic or placebo effect of acupuncture on thermal sensations; unfortunately, they did not report how thermal sensation was measured and placebo was defined as acupuncture on nonacupuncture points. By using a similar placebo model to Man and Baragar,[22] Berlin et al[21] reported contrasting results. Berlin found a significant difference between real and placebo acupuncture, with real acupuncture delaying the onset of the pain terminating response to a heat source. In an extremely small and select sample of 4, "scientists," Day et al[17] reported no significant acupuncture effect on their subjects' ability to discern between different intensities of heat from a calibrated heat dolorimeter. Our results counter those of Ashton et al,[25] who reported a significant difference between acupuncture and a placebo drug treatment in terms of pain tolerance using the cold pressor test; they concluded that acupuncture increased cold pain "threshold."

The low power of the inferential tests we applied is worthy of note. The power of all the tests was below .343, which is well below the minimum .80 recommended.[33] It is possible that a type II error may have occurred, and the trend seen here may reach significance if repeated in a future study with a larger sample. It is equally possible, however, that the low power resulted from a small effect size. Although it is true that we saw a trend to reduction of sensitivity to both thermal sensation and thermal pain thresholds with real acupuncture, this trend was small relative to the underlying variance of the data sets. Consequently, it could be argued that an analgesic effect of real acupuncture cannot be definitively ruled out on the basis of these results and further study is recommended.

Twelve of the 18 subjects correctly identified the type of acupuncture they were receiving; because this is not a significant ($P=.238$) departure from the distribution expected with random choice, it appears these may in fact have been correct guesses rather than genuine identifications. Because this decision was made after subjects had experienced all 3 interventions, there may also have been a question of recall accuracy. This interpretation is further supported by the fact that 8 subjects experienced a sensation with a form of acupuncture they later reported to be sham; therefore, we recommend that future research fully explore this issue. The production of valid placebo acupuncture in research is notoriously difficult. Our finding may suggest that the Park sham device is not a foolproof solution to this problem. The efficacy of the Park sham device is based on only 1 previous study that included hospital patients who had suffered "strokes."[28] Any resulting neurologic deficits in these subjects may well have included sensory changes that may in turn have affected the results. Further work is required to fully establish claims that the Park sham device is a credible acupuncture placebo.

Four of our subjects did not experience any sensation with the real acupuncture, which some may argue indicates that the acupuncture was not applied correctly. The question of the need for subjects to experience a sensation (commonly termed, di-qi—a numbness or toothache type ache/pain at the point) for acupuncture to be effective is debated among both clinical acupuncturists and acupuncture researchers and the question has not been settled.[5] In light of this debate, all inferential analysis was repeated on only the 14 subjects who perceived a sensation with real acupuncture; all tests remained nonsignificant. This suggests that experience of sensation was not an influencing factor on our results.

The external validity of the present study may have been limited by the mode of delivery of the stimuli, via the thermode, and its application site, the thenar eminence. The method of limits algorithm also has limitations because verbal instructions must always be considered to be open to some degree to subjective interpretation. As pain has many components, a wider range of outcome measures than we applied here may also be required to evaluate fully therapies aimed at pain modulation. This view is supported by the Sensory Decision Theory, which acknowledges that pain has a psychologic component and takes into account measurement of both sensory and attitudinal components.[34] Another methodologic issue with this study may be that the operator collecting the outcome measures was not blinded to the type of acupuncture delivered. Unfortunately, financial constraints ruled out our use of this model and we recommend that future research involve 2 operators: one to deliver the intervention and one to collect outcomes.

CONCLUSIONS

We found no statistically significant differences between real and sham acupuncture and a control intervention on thermal sensation and thermal pain thresholds in this cohort. Consequently, no support was provided for the analgesic and placebo effects of acupuncture. A trend to a reduction in sensitivity to all thresholds was observed with real acupuncture, but the changes were small relative to the underlying variance. The low power of the inferential tests applied could have resulted from either a type II error or a small effect size. Further study is recommended. Pain is a multidimensional experience involving different processes. In future studies of the efficacy of acupuncture, it may be appropriate to assess not only thermal sensation and thermal pain thresholds but also the wider spectrum of pain perception and experience, evaluation of coping strategies, attitude, and functional abilities.

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Suppliers

a. Park Sham Device; Jongbae Park, 23 East Grove Road, Exeter EX2 4LX UK.
b. TSA 2001 NeuroSensory Analyzer; Medoc Advanced Medical Systems Ltd, 45 Ha'oren St, PO Box 423, Ramat Yishai, 30095 Israel.
c. SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.