

# Acupuncture Research - The first 10 years in Exeter

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## **Summary**

For 10 years, our unit has intensively researched the efficacy and safety of acupuncture. This is a brief summary of our work in this area. Specifically, it deals with the development of a sham needle, with various systematic reviews and prospective studies in the area of safety, and with our clinical trials and systematic reviews on efficacy. We also hope in the future that we will be able to contribute to the understanding of acupuncture as a therapeutic modality.

## **Keywords**

*Acupuncture, complementary medicine, research.*

## **Introduction**

The Laing Chair in Complementary Medicine was established in 1993. Its financial basis was an endowment from the Maurice Laing Foundation. This was meant to provide core funding for the first 10 years. Recently a second, major, generous endowment secured our medium-term future. The 'Clinical Research Unit' was founded in 1994, and the Department of Complementary Medicine in 1996. In 2002 we joined the 'Peninsula Medical School'. As the School does not have Departments, we are now officially 'Complementary Medicine' at the Peninsula Medical School, Universities of Exeter and Plymouth. Today the unit employs 13 researchers and four administrative staff with wide-ranging areas of expertise and professional backgrounds. Our tenth anniversary is a welcome occasion to review our work in relation to acupuncture research.

The aims of our unit were defined at an early stage and have essentially remained the same during the last 10 years. We aim: to conduct rigorous, inter-disciplinary and internationally collaborative research into the efficacy, safety and costs of complementary medicine (CM); to be neither promotional nor derogatory, but to struggle to be objective and to promote analytical thinking in this area. The overarching goal of all our research is to maximise the benefit and minimise the risk of CM for the patient. Our

primary allegiance has always been (and hopefully always will be) with the patient and with good science, not necessarily with interest groups such as CM providers or political/commercial lobbyists. The main research tools used are systematic reviews, meta-analyses, clinical trials, surveys and laboratory investigations.

## **Acupuncture Research at Exeter**

As we have published several hundred research papers in this field, it cannot be the aim to summarise the entire work in this short article (a full list of our publications is obtainable by emailing Julie Morgan at: [julie.ann.morgan@pms.ac.uk](mailto:julie.ann.morgan@pms.ac.uk)). Instead I will describe examples of projects which, in my view, are important.

## **Development of a Sham Needle**

Not having an acupuncture placebo that is physiologically inert and indistinguishable from genuine needling has impeded clinical research significantly. Following on from the innovative needle designed by Streitberger, the Park Sham Device (PSD) is an apparatus that has been developed with the intention of matching what an acupuncture-naïve subject expects to see and experience with needling.<sup>1</sup> The PSD appears indistinguishable from a real needle, but the needle tip is blunt and the shaft telescopes into the handle when downward pressure is applied. Thus

the skin is not penetrated. The handle of the needle is made of stainless steel wound into a regular tube shape, which gives consistent resistance to movement of the needle. In order to allow the sham needle to be retained in position at the acupoint for the same duration as a real needle, the Park tube was developed. This consists of an oversize guide tube with a plastic flange at one end. It adheres to the skin with double-sided tape. The standard guide tube provides a sliding fit within the Park tube.

Since its development and further revision, the credibility of the PSD was tested in a randomised controlled trial,<sup>2</sup> and an observational study.<sup>3</sup> In addition, its validity as a control for acupuncture trials was also shown in a further randomised controlled trial. Finally, a modification of the PSD was suggested as a control method for auricular acupuncture.<sup>4</sup>

#### ***Demonstration of Acupuncture's Safety***

We probably all intuitively feel that acupuncture is safe. Yet safety is far too important to be left to intuition or opinion, particularly as numerous cases of serious adverse effects have been documented in the medical literature.<sup>5-7</sup> It was therefore essential to try and evaluate this area in more depth.

As retrospective data<sup>5-7</sup> have obvious limitations, a systematic review was conducted of all prospective studies.<sup>8</sup> A search for prospective surveys of the safety of acupuncture was conducted using six computerised databases, enquiries to acupuncture organisations, and our own files. Nine surveys were located. Data on sample, size, types of patients, duration of study, types of acupuncture, definition of adverse events, method of evaluation, and findings were extracted. The most common adverse events were needle pain (1% to 45%) from treatments, tiredness (2% to 41%), and bleeding (0.03% to 38%). Feelings of faintness and syncope were uncommon, with an incidence of 0% to 0.3%. Feelings of relaxation were reported by 86% of patients. Pneumothorax occurred only twice in nearly a quarter of a million treatments.

Because no single prospective study had a sufficient sample size, we organised a large prospective multicentre study of intensive event

monitoring.<sup>9</sup> Minor adverse events were reported every month, along with the total number of consultations. Minor or serious events were reported on separate forms when they occurred. A sample size of 30,000 consultations was necessary to identify with 95% confidence any adverse event with a frequency of 1 in 10,000 consultations. Estimates of incidences per 10,000 population were calculated with the acupuncturist (not the consultation) as the primary sampling unit. Data were collected from 78 acupuncturists. Sixty-one percent of the acupuncturists were doctors and 39% physiotherapists; 71% had practised for five years or more. In all, 31,822 consultations were included. Altogether, 43 'significant' events were reported, giving a rate of 14 per 10,000 (95% confidence interval 8/10,000 to 20/10,000). In addition, 48 apparently similar events were reported on the monthly forms, presumably due to different interpretations of 'significant'. Most adverse events had cleared within one week. None of these events was serious. A total of 2,135 minor events were reported, giving an incidence of 671 per 10,000 (42/10,000 to 1013/10,000) consultations. The most common events were bleeding and needling pain. Aggravation of symptoms occurred in 96 per 10,000 consultations.

Subsequently we also participated in a very similar German study.<sup>10</sup> Its main methodological differences were firstly that it was much larger, including nearly 100,000 patients, each of whom had an average of 7.8 treatments, and secondly that only doctor acupuncturists participated. In ~6900 patients (7%) adverse effects of acupuncture were documented. The most frequent problems were needling pain (3%), haematoma (3%) and bleeding (1%). Six serious adverse effects were noted including two cases of pneumothorax.

The overall conclusion of this work seems clear: acupuncture is a safe therapy, at least when it is administered by experienced and well-trained professionals. I believe that documenting this fact was immensely important. When I think back to the opposition we faced in getting this type of research off the ground, I cannot stop smiling. Rigorous research into safety issues is not, as some insisted years ago, to the detriment of the area of medical practice under scrutiny.

### *Systematic reviews of the effectiveness of acupuncture*

For a number of reasons (e.g. medical and statistical expertise as well as linguistic skills) our team is in a good position to conduct systematic reviews and meta-analyses of acupuncture. To date we have conducted (or collaborated on) the following such reviews:

- Ernst E. Acupressure for Nausea: A best evidence analysis. *Eur J Phys Med Rehab* 1996;6(1):28-9.
- Ernst E, White AR. Acupuncture as an adjuvant therapy in stroke rehabilitation? *Wien Med Wochenschr* 1996;146(21-22):556-8.
- Ernst E. Acupuncture/acupressure for weight reduction? A systematic review. *Wien Klin Wochenschr* 1997;109(2):60-2.
- Ernst E. Acupuncture as a symptomatic treatment of osteoarthritis. A systematic review. *Scand J Rheumatol* 1997;26(6):444-7.
- Ernst E, Pittler MH. The effectiveness of acupuncture in treating acute dental pain: a systematic review. *Br Dent J* 1998;184(9):443-7.
- Ernst E, White AR. Acupuncture for back pain: a meta-analysis of randomized controlled trials. *Arch Intern Med* 1998;158(20):2235-41.
- White AR, Ernst E. A systematic review of randomized controlled trials of acupuncture for neck pain. *Rheumatology* 1999;38(2):143-7.
- Ernst E, White AR. Acupuncture as a treatment for temporomandibular joint dysfunction: a systematic review of randomized trials. *Arch Otolaryngol Head Neck Surg* 1999;125(3):269-72.
- White AR, Rampes H, Ernst E. Acupuncture for smoking cessation. *Cochrane Database Syst Rev* 2002; (2):CD00009.
- Melchart D, Linde K, Fischer P, White A, Allais G, Vickers A, Berman B. Acupuncture for recurrent headaches: a systematic review of randomized controlled trials. *Cephalalgia* 1999;19(9):779-86.
- Park J, White AR, Ernst E. Efficacy of acupuncture as a treatment for tinnitus: a systematic review. *Arch Otolaryngol Head Neck Surg* 2000;126(4):489-92.
- Park J, Hopwood V, White AR, Ernst E. Effectiveness of acupuncture for stroke: a systematic review. *J Neurol* 2001;248(7):558-63.
- Cummings TM, White AR. Needling therapies in the management of myofascial trigger point pain: a systematic review. *Arch Phys Med Rehabil* 2001;82(7):986-92.
- Ernst E, White AR, Wider B. Akupunktur bei Rückenschmerzen. *Schmerz* 2002;16(2):129-39.
- Martin J, Donaldson AN, Villarreal R, Parmar MK, Ernst E, Higginson IJ. Efficacy of acupuncture in asthma: a systematic review and meta-analysis of published data from 11 randomised controlled trials. *Eur Respir J* 2002;20(4):846-52.

These articles have yielded mixed results. Many have been inconclusive, e.g. not producing

convincing evidence for the effectiveness of acupuncture in specific conditions. Nevertheless, I believe they constitute an important contribution to the research literature in this field. They have: raised important methodological issues; pointed to areas where clinical evidence is as yet insufficient; provided a more solid basis for future clinical trials.

The latter point is, in my view, particularly important. In an ideal world, we would have used every systematic review as a starting point for a clinical trial. Sadly, the UK research funding situation has, in many cases, prohibited this strategy. Occasionally we did, however, manage to obtain funding to initiate the trials we wanted to conduct.

### *Clinical Trials*

A randomised clinical trial was designed as a pilot to test procedures in preparation for a multi-centre trial investigating the effect of acupuncture as a treatment for tension headache.<sup>11</sup> Ten patients suffering from episodic, tension-type headache were recruited. Patients were randomised to receive either brief needling to tender areas or selected traditional points (Group A), or pressure from a cocktail stick supported within a guide tube to defined, non-tender and non-acupuncture areas (Group B). The patients' view of treatment sites was obstructed so that no indication could be gained as to which form of treatment was being given. Throughout the period of the trial, duration, frequency and intensity of headaches were recorded, from which the mean weekly headache index was calculated. There was no difference between the changes in weekly headache index in the two groups. However, Group A experienced a larger number of headache-free weeks than Group B.

The follow-up of this pilot was a multicentre, randomised clinical trial, which tested the hypothesis that acupuncture is more efficacious than sham control procedure in the prevention of episodic tension-type headache.<sup>12</sup> Fifty subjects were randomised to receive a course of treatment with either brief acupuncture or a sham procedure. Subjects were followed up for three months. Changes in headache were assessed by daily diary, the primary outcome measure being the number of days with headache. No significant differences

were found between the changes in the two groups for any measure at any time point.

The objective of another study was to compare acupuncture with sham (placebo) acupuncture for treatment of nausea of pregnancy.<sup>13</sup> In a subject-blinded, randomised, controlled trial, 55 women between six and ten weeks' gestation were given genuine, traditional-style acupuncture or sham treatment with a cocktail stick on three or four occasions over three weeks. The main outcome measure was nausea score, as determined by subject report on a visual analogue scale in a daily diary. Nausea scores decreased from a median of 85.5 (interquartile range 71.25–89.75) to 47.5 (interquartile range 29.25–69.5) in the acupuncture group and from 87.0 (interquartile range 73.0–93.0) to 48.0 (interquartile range 14.0–80.0) in the sham treatment group. There was strong evidence of a time effect but no evidence of a group effect or a group-time interaction.

We also performed a randomised, sham-controlled, patient and evaluator-blinded trial of acupuncture for smoking cessation with two parallel treatment arms.<sup>14</sup> Seventy-six adult smokers received either 100Hz electroacupuncture with needles inserted into the appropriate point in each ear or a sham control procedure over the mastoid bone. Interventions were given on days one, three, and seven of smoking cessation. Nicotine withdrawal symptoms were measured by visual analogue scale recorded in a daily diary for 14 days; smoking cessation was quantified by CO measurements. There was no significant difference between the mean reduction of withdrawal symptoms of the two groups from day one to day 14. Fifteen participants (39%) who received electroacupuncture and 16 participants (42%) who received a sham procedure were abstinent on day 14.

Minimal acupuncture is easily incorporated into primary care consultations, but there is no convincing evidence for its effectiveness. In a cohort study, minimal acupuncture was given to 32 patients with acute neck pain.<sup>15</sup> Neck pain scores, measured by the Northwick Park Neck Pain questionnaire, fell from an average of 12.1 ( $\pm 5.4$ ) before treatment to 4.8 ( $\pm 5.6$ ) at three months ( $p < 0.001$ ). Three months after acupuncture treatment, 76% of patients reported

themselves 'much better'. Out of 18 patients who had had pain lasting less than two weeks, 16 required only one treatment. These results suggest that minimal acupuncture may be an effective treatment for neck pain and further definitive studies are recommended.

From these brief descriptions of our acupuncture studies, it is fairly obvious that their results are disappointing overall. It is noteworthy that the trial with the weakest design (uncontrolled cohort study) was the only one that generated a positive result.<sup>15</sup> I would argue, however, that results of clinical trials can be valuable, regardless of direction of outcome.

### Conferences

During the last 10 years we have (co-) organised many occasional conferences where acupuncture was a main topic. In addition, we have created an annual scientific conference on CM which has always had dedicated sessions on acupuncture. For our tenth anniversary we have decided to take this conference to the Royal College of Physicians in London on 21/22 November 2003, to cope with the larger number of delegates (~400) we expect to attend. ([www.ex.ac.uk/FACT/sympo](http://www.ex.ac.uk/FACT/sympo)). More information can be obtained from Barbara Wider ([B.Wider@exeter.ac.uk](mailto:B.Wider@exeter.ac.uk)).

### Discussion

There is no question that our ten years' of research has significantly contributed to CM in general and to acupuncture in particular. We are proud that a recent, independent and systematic review of centres of excellence in CM research has identified our unit as the most productive of all CM research units worldwide.<sup>16</sup> Our results in acupuncture research have been mixed but, in my view, have nevertheless increased our understanding of the issues involved. I hope that in future our research efforts will continue and will be as successful as they have been in the past.

### Acknowledgements

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