

Research in Acupuncture: problems to be addressed

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Basic and clinical research in acupuncture is fundamental both to explain the mechanisms of action and determine the effectiveness and limits of this ancient therapeutic method.

Problems to be addressed and proposed solutions.

- **Improve the quality of randomised controlled trials (RCTs)**
- **Translation of Western syndrome patterns into Chinese syndromes**
- **Improve the standard of the acupuncture used in trials**
- **Adopt more rigorous inclusion and exclusion criteria in systematic reviews**
- **Take extreme care when choosing the type of control**
- **Increase funding for acupuncture research**
- **Increase the number and quality of uncontrolled prospective studies**
- **Promote the growth of a research culture among acupuncturists**
- **Organise periodic public meetings**
- **Inclusion of an acupuncture expert in international clinical trial approval agencies**
- **Increase international collaborations**
- **Creation of an international body with the role of guaranteeing good practice in acupuncture research**

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INTRODUCTION

Basic and clinical research in acupuncture is fundamental both to explain the mechanisms of action and determine the effectiveness and limits of this ancient therapeutic method.

HISTORY OF RESEARCH IN ACUPUNCTURE

Clinical research in acupuncture developed in China starting from the 1960s, in the wake of the Chinese government's efforts in the 1950s to revive traditional medicine in order to guarantee a minimum level of health care to a population distributed over an extremely vast territory.

In that period, and for a number of years thereafter, an enormous number of uncontrolled, non-randomised studies were conducted on various pathologies; despite being carried out on numerically large population samples, they cannot be considered methodologically reliable or able to demonstrate effectiveness.

In the 1980s and 1990s, with the dissemination of knowledge in the fields of epidemiology and research methodology, the quality of research on acupuncture improved in China as well and an increasing number of controlled trials were published in scientific journals.

However, the papers published in Chinese journals in this period show basically two limits: poor methodological quality (e.g. lack of medium/long-term follow ups, lack of data regarding compliance and side effects) (Tang 1999) and a tendency only to report positive results. In a random selection of 252 acupuncture trials, Vickers et al. (1998) observed that all the studies conducted in China reported the therapy to be effective.

The Western world as well, albeit with some delay, began publishing an increasingly large number of randomised controlled clinical trials (RCTs) of better and better quality.

A strong acceleration occurred following the publication of the conclusions of the Consensus Conference on acupuncture organised by the U.S. National Institutes of Health (Bethesda, 3-5 November 1997). The conclusions, which were based on the evidence available in the literature up to that time, stated as follows: "...promising results have emerged, for example, showing efficacy of acupuncture in adult postoperative and chemotherapy nausea and vomiting and in postoperative dental pain. There are other situations, such as addiction, stroke rehabilitation, headache, menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome, and asthma, in which acupuncture may be useful as an adjunct treatment or an acceptable alternative or be included in a comprehensive management program. Further research is likely to uncover additional areas where acupuncture interventions will be useful".

RESULTS OF CLINICAL RESEARCH IN ACUPUNCTURE

Among the systematic reviews published on the effectiveness of acupuncture, those from the Cochrane Library highlight its effectiveness in the treatment of idiopathic headache (Melchart 2004), knee arthritis (Ezzo 2001), dysmenorrhoea (Proctor 2004) and lower back pain during pregnancy (Young 2004), in the inducement of labour (Smith 2004) and in the control of labour pain (Smith 2003), in the chemotherapy nausea and vomiting (Ezzo 2006), in the low back pain, (Furlan 2005), in the cervical pain (Trinh 2006); its uncertain effectiveness in the treatment of Bell's palsy (He 2004), chronic asthma (McCarney 2004) and tennis elbow (Green 2004) and ineffectiveness in the treatment of rheumatoid arthritis (Casimiro 2004), lower back pain (Van Tulder 2004) and patellofemoral pain syndrome (Crossley 2001), as well as for smoking cessation (White 2004).

As regards systematic non-Cochrane reviews published after 1997, acupuncture has been reported as being effective in postoperative nausea (Lee 1999) and dental pain (Ernst 1998); promising in the treatment of female infertility, (White 2003), fibromyalgia and myofascial trigger points (Holdcraft 2003) (Berman 1999) (Cummings 2001), subacromial pain (Johansson 2002) and insomnia (Sok 2003).

Other systematic reviews of RCTs have failed to reach conclusive findings with respect to chronic pain (Ezzo 2000), fibromyalgia (Sim 2002), lower back pain (Cherkin 2003), stroke rehabilitation (Park 2001) (Sze 2002), asthma (Martin 2002), obesity (Lacey 2003) and temporomandibular joint dysfunction (Ernst 1999).

A large number of individual randomised controlled clinical trials have also been published; among the most recent, worthy of mention in terms of quality and importance is a study published in the BMJ on the effectiveness of acupuncture in the treatment of chronic headache (Vickers et al 2004).

PROBLEMS TO BE ADDRESSED AND PROPOSED SOLUTIONS

Improve the quality of randomised controlled trials (RCTs)

Randomised controlled trials represent the gold standard of assessment methods: both the quality and results of systematic reviews depend on them.

Many parameters contribute to determining the quality of RCTs in acupuncture and some of them are difficult to standardise. Frequently we may find that the papers published are excellent from a methodological point of view (recruitment, exclusion criteria, randomisation, etc.), but the acupuncture technique used does not meet minimum requirements of credibility and reliability. An example is the randomised, placebo-controlled cross-over study on the effect of acupuncture on patients affected with rheumatoid arthritis, published in *Rheumatology* (David et al. 1999). In this well-designed study, only acupoint LR 3 was used on all patients! No serious acupuncturist would venture such a treatment for this disorder.

Translation of Western syndrome patterns into Chinese syndromes

It is well known that good acupuncture treatment must be personalised and hence the choice must be based on individual and time-related criteria. The same pathological sign may be an expression of different Chinese syndromes, each of which calls for a different treatment. In the past some acupuncturists regularly used the concept of personalised treatment as an alibi for avoiding any type of experimental verification. In reality it is possible to find an honourable compromise between the principles of treatment standardisation and personalisation. For example, a tension headache can be associated with a limited number of Chinese syndromes; we can identify a minimum number of points with recognised efficacy and a broad range of action to be used in all patients, to which others may be added according to the Chinese syndromes identified.

Improve the standard of the acupuncture used in trials

In addition to addressing the problem of choosing points, mentioned previously, it is necessary to define other parameters which may influence the results of a study, e.g. number of sessions, needle stimulation technique and experience of the acupuncturist. Romoli et al. (1993) asked a large number of expert Italian acupuncturists to express an opinion about 30 possible items that might influence the result of an acupuncture treatment. It is interesting to note that in a recent trial demonstrating the effectiveness of acupuncture for the treatment of chronic headache, published in the BMJ (Vickers et al., 2004), several fundamental requirements were met: the acupuncturists had been practicing their profession for a median of 12 years, had attended at least 250 hours of postgraduate training courses and treated a median of 22 patients per week.

Adopt more rigorous inclusion and exclusion criteria in systematic reviews

It is debatable whether trials using forms of treatment other than traditional acupuncture (e.g. laser) should be included in the same review. This may occur because those who plan trials in the West are free to choose any type of treatment and call it “acupuncture” without fear of being challenged, since there exists no official parameter defined and validated by scientific bodies.

Take extreme care when choosing the type of control

To evaluate the effectiveness of acupuncture versus a placebo, it is necessary to choose control treatments that are really inactive. Several possible solutions have been proposed for this purpose.

Increase funding for acupuncture research

The lack of funding for studies in acupuncture is a structural problem. Private schools have funds sufficient only to maintain themselves; universities, barring a few rare exceptions, still show little interest; public agencies, which could procure funds, are not sensitive to this issue and still (wrongly) fail to see acupuncture as a therapy that could save a considerable amount of money. Needless to say, pharmaceutical companies make no financial contribution to studies concerning acupuncture, with the sole exception of some studies which (obviously) portray acupuncture in a negative light.

Increase the number and quality of uncontrolled prospective studies

Given the paucity of financial resources and the difficulty in completing RCTs of good quality, efforts should be focused on increasing pragmatic prospective studies, preferably of a collaborative nature (multi-centre) and with well-developed protocols, which may serve as a basis for randomised controlled clinical trials aimed at demonstrating the effectiveness and applicability of acupuncture as a therapy for certain pathological conditions.

Promote the growth of a research culture among acupuncturists

Plan seminars and/or lectures on research in acupuncture as a part of training programmes for acupuncturists.

Organise periodic public meetings

Organise periodic public meetings (based on the model of Consensus Conferences) in order to disseminate the available data concerning the efficacy of acupuncture in treating certain disorders.

Inclusion of an acupuncture expert in international clinical trial approval agencies

This figure could ensure beforehand that the acupuncture method used meets minimum acceptance criteria, irrespective of whether the results subsequently show to be favourable or unfavourable towards acupuncture.

Increase international collaborations

Especially with the medical community of China, a country that has successfully integrated Western models and acupuncture since the 1950s. In the past, many studies were published only in the Chinese language and have never been taken into consideration by Western scientific journals; the logical consequence is that a large quantity of data has never circulated in the West.

Creation of an international body with the role of guaranteeing good practice in acupuncture research

This organisation should stimulate a debate about what good acupuncture is and define the criteria to be observed in acupuncture RCTs, the standards to adopt in the description of studies, e.g. STRICTA (Standards for reporting interventions in controlled trials of acupuncture), inclusion / exclusion criteria and the criteria by which to assess studies in systematic reviews.

It should periodically organise a Consensus Conference, seeking the broadest possible participation of acupuncture schools and associations, in order to adopt and progressively adapt principles and guidelines concerning the issues raised.

It should create a mentality whereby both those who conduct trials and those who review them consistently refer to these documents.

This organisation should provide, where necessary, trial planning and assessment experts and act as arbitrator in the event of disputes.

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