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Review Article

Historical perspectives on using sham acupuncture in acupuncture clinical trials

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ARTICLE INFO

Article history:

Received 13 January 2021

Revised 5 March 2021

Accepted 23 March 2021

Available online 2 April 2021

Keywords:

Acupuncture

Sham interventions

History sham acupuncture

ABSTRACT

Background: Trials of acupuncture in the West began before textbooks about acupuncture were generally available. This placed trials at risk of possible faulty assumptions about the practice of acupuncture and adoption of problematic research assumptions and methods. Further, this lack of information has had an influence on the theories of developing a valid and reliable sham control treatment in clinical trials of acupuncture. This commentary explores these issues.

Methods: Literature review focussing on the time line of developments in the field, developments of sham interventions and use thereof and knowledge of physiological effects of needling.

Results: Early trials demonstrated a lack of knowledge about acupuncture. As the methodology of trials improved, new sham treatment methods were developed and adopted; however, the sham treatment methods were implemented without physiological studies exploring their potential physiological effects and without examining the broader practice of acupuncture internationally.

Conclusions: Mistaken assumptions about the practice of acupuncture reinforced by paucity of physiological investigations are factors that led to use of inappropriate sham interventions for acupuncture trials. These not only lead to confusing or misleading trial results, they, as far as we can see underestimate the effects of acupuncture leading to bias against acupuncture. There are significant problems with sham interventions and how they are applied in trials of acupuncture. Further research is needed to explore the effects of this both for future trials and for interpreting existing evidence.

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1. Introduction

Clinical trials of acupuncture began in Japan in the 1960s¹ with a big increase in the number of studies in the last twenty years.² When trials of acupuncture began outside Asia in the early 1970s, there were few publications about acupuncture available in English³ and little knowledge available about its practice.^{4, 5} Table 1 summarises general availability of clinical textbooks in the 1970s-1990s. Few detailed clinical texts were available before the mid-1980s, with little known about the international diversity of practice methods till the 1990s. Hence, many clinical trials may have been performed before a more detailed understanding had been

established of what constitutes the study and practice of acupuncture.

By the mid-1970s, varieties of the Chinese technique of inserted needling with sensory stimulation became a focus of study for clinical trial research published in English. Table 1 shows us that this focus developed before more detailed clinical textbooks were available. This lack of knowledge about acupuncture practice appears to have been problematic, as evidenced by the persistent lack of adequate treatments and often inappropriate treatments up through the 1990s with a paucity of literature citation to support treatment selection.⁶⁻¹⁰ To counter this, a way forward was the development and adoption of the STRICTA guidelines for reporting in clinical trials of acupuncture in the early 2000s.^{11, 12} During the period of the 1970s-1990s many different sham acupuncture methods were attempted^{13, 14} before much debate on the methodological requirements for such trials occurred and without a consensus

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Table 1
Timeline of influential acupuncture publications in English.

Published year	Category	Textbook / Details
1974	* C	<i>The Treatment of Disease by Acupuncture</i> , 3rd edition, by Felix Mann Introduction to acupuncture, dismissive of traditional acupuncture, but some clinical content, especially for medical doctors seeking a simplified approach
1975	* C	<i>An Outline of Chinese Acupuncture</i> by Academy of Traditional Chinese Medicine Introductory book on acupuncture for Doctors in China, translated to English – minimal clinical content
1978	* C	<i>Acupuncture The ancient art of healing</i> , 3rd edition, by Felix Mann Introductory book on acupuncture – minimal clinical content
1978	* C	<i>Current Acupuncture Therapy</i> by Jane Lee and CS. Cheung Introductory book on acupuncture – minimal clinical content
1978	* C	<i>Principle and Practice of Scientific Acupuncture</i> by Anton Jayasuriya and Felix Fernando Introductory book on acupuncture – somewhat more clinical content
1980	* C	<i>Essentials of Chinese Acupuncture</i> by Beijing, Shanghai, Nanjing Colleges of TCM More detailed book on acupuncture for doctors in China, translated to English – slightly more clinical content than the Outline of Acupuncture
1983	* C	<i>Acupuncture: a Comprehensive Text</i> by Shanghai College of TCM (translated by John O'Connor & Dan Bensky) First book on TCM in English – more clinical detail with some treatments
1983	* C	<i>The Web that has no Weaver</i> by Ted Kaptchuk Popular book detailing TCM, but not a clinical text – theory with diagnosis but no treatment details
1985	** C	<i>Fundamentals of Chinese Medicine</i> by Beijing, Nanjing, Shanghai Colleges of TCM (translated by Nigel Wiseman & Andy Ellis) First detailed clinical text on Chinese medicine, including some text on acupuncture First translation to apply a glossary based translation methodology Level of clinical detail and more detailed language difficult for many Western practitioners to absorb and use
1986	** C	<i>Foundations of Chinese Medicine</i> by Giovanni Maciocia More details of clinical content, but almost no use of a glossary and often very simplistic approach to descriptions allowing more readers to use the content – but at expense of clinical details
1987	** C	<i>Chinese Acupuncture and Moxibustion</i> by Xinnong Cheng English translation from Chinese text with more details of clinical practice and techniques than the previous Outline and Essentials texts
1988	* J	<i>Hara Diagnosis</i> by Kiiko Matsumoto, Stephen Birch Introduces Japanese acupuncture but minimal clinical content
1988	** C	<i>Fundamentals of Chinese Acupuncture</i> by Andrew Ellis et al. Glossary based translation and compilation with more details of clinical practice and techniques
1989	** M	<i>Acupuncture, Trigger Points and Musculoskeletal Pain</i> by Peter Baldry First detailed textbook for medical practitioners describing trigger point based system of acupuncture
1990	** J	<i>Introduction to Meridian Therapy</i> by Denmei Shudo First detailed clinical textbook of Japanese acupuncture detailing very shallow and light needling methods
1994	** C	<i>The Practice of Chinese Medicine</i> by Giovanni Maciocia More detailed clinical textbook of TCM practice
1995	** M	<i>Acupuncture Energetics: a Clinical Approach for Physicians</i> by Joseph Helms Detailed textbook on medical acupuncture clinical methods
1995	** J	<i>Chasing the Dragon's Tail</i> by Yoshio Manaka et al. Detailed clinical text describing Japanese acupuncture methods especially with shallow, light needling
1998	** J	<i>Japanese Acupuncture: a Clinical Guide</i> by Stephen Birch, Junko Ida Text detailing Japanese acupuncture treatment methods including non-inserted and shallow insertion acupuncture
1998	** M	<i>Medical Acupuncture a Western Scientific Approach</i> by Jacqueline Filshie and Adrian White Detailed textbook on medical acupuncture clinical methods
1999	** C, J, M	<i>Understanding Acupuncture</i> by Stephen Birch & Robert Felt First history clearly describing the variety of acupuncture methods of different countries. No clinical details

* , textbook introductory and basic with less clinical details;

** , textbook has more clinical details; C, Chinese based needling; J, Japanese based shallow needling; M, medical acupuncture (including shallow needling). This is a summary of influential publications in English that the authors (TA and SB) came across or contributed to during and after their initial studies in United Kingdom and in the United States, between 1979 and 1982, where there were almost no publications available in English that could be used as textbooks.

on their description and adoption. The large number of different sham acupuncture methods are problematic for a number of reasons, chief among them the inability to draw conclusions across the studies.¹⁴ The range of sham interventions also heralds a lack of agreement on what might constitute a valid sham intervention among researchers.

A few papers in the 1980s discussed sham methods and requirements, but with little consensus on how to proceed.^{15–20} After the establishment in 1992 of both the Office of Alternative Medicine (OAM) and the Society for Acupuncture Research (SAR), methodological discussions increased as critical analyses of methodological shortfalls and requirements emerged.^{10,21–26} This increased discussion of the quality and methodology of acupuncture trials led, in the US first to an FDA workshop on acupuncture in 1994, followed two years later by the reclassification of acupuncture so that is no longer considered experimental.²⁷ But

there was still little detailed debate about the methodological needs for sham acupuncture clinical trials.

1.1. Purposes of control treatments

Placebo medications are used in controlled trials of a pharmacological substance in order to control for placebo effects and other non-specific effects of a therapy.²⁸ For the control treatment to be considered as a placebo treatment it must be indistinguishable from the test treatment and be physiologically inert.^{29, 30} Sham treatment is used as a control treatment in clinical trials of a technique or device in order to control for the same effects.²¹ The placebo pill or sham technique/device should avoid the known pathways of action of the tested therapy.³¹ Since acupuncture is a treatment method, it needs to be subjected to the same testing as other interventions: it must demonstrate effectiveness beyond

Sham acupuncture timeline

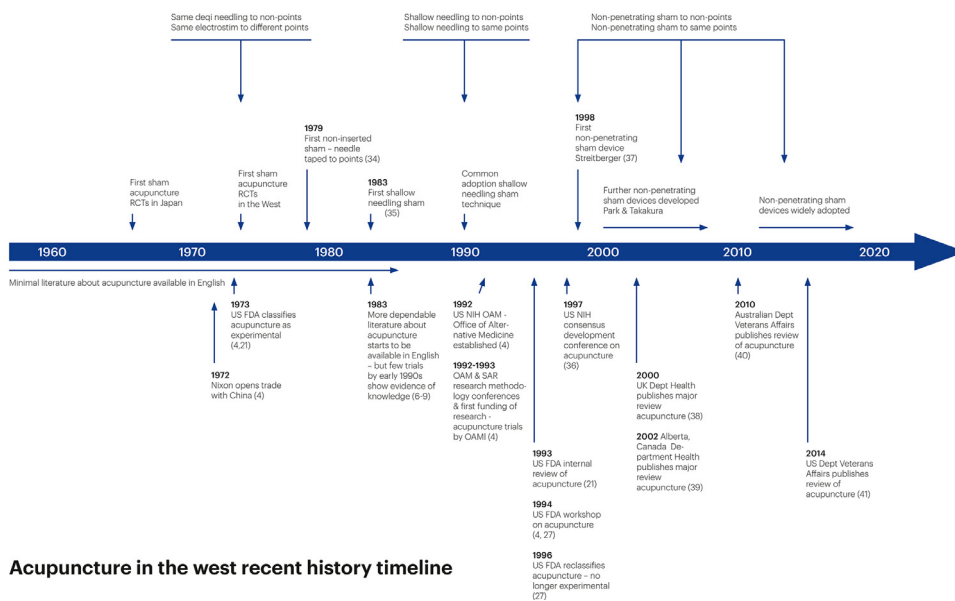


Fig. 1. Timeline for development acupuncture and sham acupuncture in English 1960–2020
Numbers in parentheses are to publications in the reference list.

placebo. Hence, it must be tested in clinical trials that compare it to an inert fake or ‘sham acupuncture.’ Inducing a need for a detailed understanding of how acupuncture works so that we can be confident that a selected sham treatment avoid the mechanisms by which acupuncture works.³² Leading on to several questions we are aiming to answer: Is there a gap between the appearance and use of sham acupuncture control techniques and the appearance of a developed corpus of clinical acupuncture literature in English? Is there evidence of problems that may have resulted from this gap?

2. Methods

We will examine English language textbooks on the history and practice of acupuncture, papers on clinical trials of acupuncture, research methods and sham control interventions along with physiological studies of acupuncture. Furthermore, we will map out the time line of developments in the field, developments of sham interventions and knowledge of physiological effects of needling. In this brief review, we did not adopt a systematic searching strategy because of the narrative nature of this study. We made a potential list of literature on acupuncture based on recall from our own experiences and discussed it with each other to confirm whether or not to include them. Having previously written a number of papers about research publications on acupuncture,^{6,10,13} we drew from those and related papers to expose details of the history and nature of trials and their methods.

3. Development of sham acupuncture interventions

The first controlled trials of acupuncture were conducted in Japan in the 1960s and began in the West in the early 1970s,^{1,33} but these were published in Japanese and remain virtually unknown outside Japan. Fig. 1 sketches the development of the main sham acupuncture methods published in English, contextualizing them against the background of other important developments in acupuncture^{34–41}; see also Table 1. The first trials of acupuncture began exploring two claims: that the sensory stimulation needling technique of deqi is effective and that it is more effective if applied to specific loci. There was no clear idea how to do sham

acupuncture so early trialists designed their own approaches depending on what they thought to be important. Applying the same sensory stimulation techniques to loci not thought to be acupuncture points or not relevant to the symptom being treated in the trial⁴²; apply some other form of needle stimulation than TCM’s deqi sensory stimulation to the same acupuncture points³⁴ or to other loci.³⁵

By 1976, evidence began emerging that linked Chinese sensory stimulation needling with endorphins.^{1,4,5,43,44} This link was seen as very important as it increased the credibility of acupuncture.²¹ With acupuncture seen as a stimulation method to release endorphins this became the mechanism that acupuncture was thought to elicit, hence avoidance of this mechanism in the sham acupuncture treatment arm became more critical by the late 1970s. Efforts to avoid sensory stimulation with the needles led by the early 1980s to the regular adoption of the use of shallowly inserted needles with no manipulation – which became known as ‘minimal acupuncture.’³⁵ It was thought that this technique should suffice as a sham^{35,45} and even as a placebo treatment⁴⁵ control intervention for acupuncture trials, despite the fact that shallow sensationless needling was routinely used as a treatment method by many acupuncturists in Japan,^{1,4} Presumably this occurred because the research investigators involved were unaware of how Japanese acupuncture was practised. Additionally no physiological studies were conducted to test the hypothesis that shallow sensation-less needling is physiologically inert or to explore what physiological effects it might trigger and demonstrate that they are not relevant to the effectiveness of acupuncture. Hence the adoption of ‘minimal acupuncture’ as a sham control thought by some to be a placebo treatment was suppositional and not based on any evidence. In fact, a trial conducted in 1983 showing that shallow needling was effective appears to have been ignored by researchers,⁴⁶ but not by clinicians.⁴⁷ Reasons why emerging literature and evidence about shallow needling were ignored are not clear, but perhaps the absence of systematic debate allowed personal choices and preferences to dominate. The primary test of validity of these control interventions was to test and demonstrate the credibility of the sham intervention.^{48,49} We are not aware of pilot studies or physiological investigations⁵⁰ being conducted

to investigate whether this sham acupuncture technique is appropriate as a control treatment for acupuncture that can control for placebo effects.

Following use of 'minimal acupuncture' as a sham treatment for acupuncture, discussions began to emerge questioning whether this was a sufficient or appropriate sham control, with suggestions that non-penetrating sham would be better.^{25,26,50} Various non-penetrating sham techniques were starting to be used.⁵¹⁻⁵⁴ Then, in 1998, an innovative non-penetrating sham device was developed by Streitberger and colleagues,³⁷ which was thought to both control for placebo effects and finally address the limitations of other sham techniques, especially once it was found to be a credible treatment. Park and colleagues⁵⁵ and Takakura and colleagues⁵⁶ developed novel components to this sham-acupuncture technology. In all cases validation was performed through credibility testing and ensuring that the treatments could be blinded. Physiological studies were not performed to demonstrate that the techniques were inert, or to explore what physiological mechanisms are stimulated or to demonstrate that they are unimportant for treatment effectiveness. Nor were pilot studies conducted.

4. Discussion

We found that assumptions underlying the selection of sham interventions for trials of acupuncture were mostly based on the notion of using a control treatment with minimal or no sensory stimulation to control for the sensory stimulation of deqi. While a broader knowledge of the practice of acupuncture including non-sensory stimulation (non-deqi based) needling techniques was emerging (see Table 1 and Fig. 1) it appears not to have influenced the thinking of clinical trialists. Perhaps this is because this knowledge had not yet emerged in medical databases like Pubmed, and because trialists tended to test what they knew or had studied which was not based upon extensive surveys or reviews of the field. Additionally, we have seen that little or no physiological research was conducted to validate these sham interventions as being physiologically inert or whether physiological effects that result from not being inert have clinically relevant effects. Instead, validation focused only on establishing blinding and credibility of the interventions. This is insufficient given the multiple physiological pathways and their potential effects of any form of sensory stimulation from touch to frank pain.

As we explored the sham interventions, we additionally uncovered another significant problem for the non-penetrating sham devices. The Streitberger and Takakura groups made several methodological mistakes in their development and testing of their sham devices. Given that sham acupuncture studies have varied the sites of needling and the techniques of needling there are three basic types of sham acupuncture, each of which investigates different questions.⁵⁷ One of the three sham models applies the sham technique to the same acupoints as the test treatment while holding placebo equal between the two groups, this is a comparison of only the two techniques of treatment not a test of acupuncture's effectiveness (one of the other two sham models).⁵⁷ These trials showed that the sham technique was as effective as the real technique. By their own efforts, the researchers that developed the sham devices have themselves demonstrated that the devices should *not* be used in clinical trials of acupuncture as a control treatment. The 2009 trial of So and colleagues investigating acupuncture to improve effectiveness of IVF procedures also used a non-penetrating sham device applied to the same points as the real treatment.⁶³ This trial found the non-penetrating sham needling to be significantly *more* effective than the 'real' needling,⁶² which was viewed as demonstrating that acupuncture

is not effective to assist IVF procedures rather than that milder sensory stimulation of the treatment points is more effective than heavier sensory stimulation of the treatment points for increasing IVF's effectiveness.⁶² Putting aside the trialists' poor understanding of trial methodology, this trial is important because when we look to the probable mechanisms by which acupuncture might work to assist IVF procedures, it is likely due to the increased relaxation that acupuncture can produce.⁶³ The milder stimulation of the non-penetrating device will stimulate structures and pathways at or just below the skin, which are probably more relaxing than the pathways triggered by deeper needling that is more stimulating.⁶⁴ In this last example, we see probable physiological explanations for why the non-penetrating sham devices are not appropriate. From the above, serious questions emerge about the use of sham acupuncture with the findings from these studies. The non-inertness of sham acupuncture has been known for more than three decades,^{19,57,65-67} with no meaningful efforts to counter this or account for this in study design and interpretation of results except for the use of the no longer used non-comparative¹⁶ 'mock TENS' control.²⁶ The use of non-inert sham introduces bias against acupuncture with risk of underestimating its' effectiveness.^{57,66} Given the depth of problems we have exposed above with how sham studies have been conceived and conducted, it is important to examine these problems in more depth.

4.1. Conclusions

Since acupuncture related techniques and knowledge expanded in the 1970s in the western world, clinical trials have been conducted with a number of different types of sham acupuncture procedure, none of which can be accepted as proper sham controls in the sense of indistinguishability *and* physiological inertness. Current debates around the clinical evidence of acupuncture for various conditions appear to be derived from misunderstandings regarding the heterogeneous nature of acupuncture practice in different regional environments and the inappropriate selection of sham control techniques without clear consideration of research questions. We hope that this brief overview on the history of sham acupuncture techniques will be helpful for future researchers to understand the current problems about acupuncture studies. We suggest further analysis of the different sham procedures used in clinical trials of acupuncture is in order to better understand what purposes they can serve and what research questions they can answer. This will help to standardize how such trials are analysed and interpreted in systematic reviews, meta-analyses and to make the evidence base for acupuncture clearer.

Declaration of Competing Interest

The authors declare no conflict of interests.

Acknowledgement

Assistance provided by Merete Lindén Dahle with the design of Fig. 1, was greatly appreciated.

Author contribution

Conceptualization: SB, TA, MSL, and THK. Methodology: SB, TA, MSL, and THK. Resources: SB and TA. Writing – Original Draft: SB, TA, MSL, and THK. Writing – Review & Editing: SB, TA, MSL, and THK. Visualization: TA.

Funding

No specific funding was received for this study.

Ethical statement

Not applicable.

Data availability

The data used for this study are included in this manuscript.

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