

Review article

Should systematic reviews assess the risk of bias from sham–placebo acupuncture control procedures?[☆]

Ian Appleyard^{a,*}, Thomas Lundeberg^b, Nicola Robinson^a

^a London South Bank University, Confucius Institute for TCM, London, UK

^b Foundation for Acupuncture and Alternative Biological Treatment Methods, Sabbatsbergs Hospital, Stockholm 113 82, Sweden

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Abstract

Introduction: Clinical guidelines depend on the analysis of randomised controlled trials in systematic reviews. How to interpret the results of acupuncture vs. sham–placebo procedures is a controversial aspect of the evidence base for acupuncture. Two inferences can be drawn from the acupuncture vs. sham–placebo randomised controlled trials. The first is whether acupuncture has a physiological basis. The second is whether there is any validity in traditional concepts of acupuncture practice. The degree to which sham acupuncture controls can physiologically be considered placebo controls has been challenged. However, whether these procedures should be considered ‘inert’ in terms of Chinese medicine theory has yet to be fully examined. This review aims to evaluate the extent to which sham–placebo procedures used in randomised controlled trials should be considered inert, with particular reference to traditional Chinese medicine theories. It also considers sham–placebo controls from a biomedical perspective.

Methods: Sham–placebo procedures were identified through reviews examining acupuncture controls.

Results: Four main types of sham–placebo control were identified. The procedures are heterogeneous and should not necessarily be considered as equivalent within systematic reviews.

Conclusion: These procedures cannot be considered as inert controls from either a Chinese medicine or biomedical perspective. There is a need to develop appropriate Acupuncture Control Assessment Guidelines to assess the risk of bias from sham–placebo controls when undertaking systematic reviews. The terminology used to describe control procedures needs to be developed and standardised.

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Introduction

At the heart of clinical guidelines and evidence-based medicine (EBM) are systematic reviews of randomised controlled trials (RCT). The conventional view is that systematic reviews of double-blind trials provide the most reliable evidence [1]. Consequently, there is a perceived need for acupuncture to be compared with a placebo control in order to for acupuncture

to be included in clinical guidelines [2]. The implementation of guidelines will be influenced by health service managers’ perceptions of the evidence base [3]. An ideal placebo control should be physiologically inactive yet psychologically credible [4]. Various procedures have been utilised as acupuncture placebo controls, however, the degree to which these should be considered physiologically inert has been questioned [5–9]. These procedures have been described as placebo acupuncture, sham acupuncture or minimal acupuncture. The usage of these terms has not been standardised [10]. Consequently, these descriptions are not used consistently to identify clearly delineated procedures; rather, they are used interchangeably to describe a number of different procedures. This lack of consistency may lead to misunderstanding of the currently available evidence.

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* Corresponding author at: London South Bank University, Faculty of Health and Social Care, 103 Borough Road, London, UK. Tel.: +44 020 7815 8014.

E-mail addresses: appleyai@lsbu.ac.uk (I. Appleyard), thomas.lundeberg@me.com (T. Lundeberg).

Acupuncture developed as part of Chinese medicine and is related to traditional Chinese philosophy. Consequently, the results of placebo–sham acupuncture RCTs have two implications. The first is the conventional proof of efficacy by demonstrating a specific effect. The second is the potential production of evidence that may validate traditional concepts such as acupuncture points.

This article reviews the main placebo–sham-minimal acupuncture methods and assesses to what extent they can be considered inert in terms of traditional Chinese medicine. It will also discuss whether the evidence suggests that acupuncture has a physiological basis. It proposes that guidelines be developed to evaluate acupuncture sham–placebo control methods. Procedures that are similar to real acupuncture may bias the results. It may not be appropriate to regard some procedures as sham or placebo controls within systematic reviews. This issue potentially may lead to acupuncture not being included within clinical guidelines, and/or hinder its acceptance amongst clinicians and managers, for conditions where in fact it is an effective referral option.

The central paradox of acupuncture research

The central difficulty in analysing the results of acupuncture clinical trials is ‘the paradoxical finding. . .that verum [real] acupuncture is not better than “sham” acupuncture but both are better than usual care’ [11]. The similarity between real and sham acupuncture outcomes has led some researchers to view the clinically relevant benefits as being due to expectation or placebo effects. In a review of peripheral joint osteoarthritis a statistically significant difference between real and sham acupuncture was observed. The difference was interpreted by Manheimer et al. as not being clinically significant and that much of it may be due to expectation or placebo effects [12].

Nevertheless, there is a growing body of evidence to suggest that real acupuncture is better than sham, which may provide clinical evidence that acupuncture has a physiological basis. A recent meta-analysis of data from nearly 18,000 patients demonstrated a statistically significant difference between real and sham acupuncture. “Patients who received acupuncture had less pain, with scores that were 0.23 (95% CI, 0.13–0.33), 0.16 (95% CI, 0.07–0.25) and 0.15 (95% CI, 0.07–0.24) SDs lower than sham controls for back and neck pain, osteoarthritis, and chronic headache, respectively” [13]. However, due to the relatively small effect size of real acupuncture compared to sham, controversy remains.

Methods

Preliminary reading on the current status of acupuncture research identified the development of a placebo control as one of the key challenges faced by the acupuncture research community [14–18]. Commentaries and papers questioning whether or not these controls should be considered as placebo have for the most part focussed on the potentially meaningful physiological responses that they may induce [5–9]. In a commentary on a recent White Paper, by the board of directors the Society of

Acupuncture Research, Alraek and Birch note that the description of superficial needling as a sham control derives from a lack of knowledge of the practice of acupuncture [19]. Consequently, we perceived the need to review these controls primarily from the perspective of Chinese medicine in addition to the biomedical perspective.

Reviews that examine the different types of sham–placebo control procedures were studied to identify the different types sham–placebo acupuncture controls previously used in clinical trials [4,9,10,16,20].

Results

The reviews described the same sham–placebo acupuncture controls [4,9,10,16,20]. They varied only in minor differences in terms of expression. For example Langevin et al. identify the ‘degree of insertion’ as one form of control, this refers to non-insertion and depths believed to be suboptimal [16]. Dincer and Linde use invasive and non-invasive controls as two categories. The category of invasive controls includes three forms of control superficial needling of ‘true’ acupuncture points, irrelevant acupuncture points and the use of non-acupuncture points [20].

The five reviews all identified the following four characteristics of sham–placebo acupuncture controls. These characteristics are used either individually or in combination [4,9,10,16,20].

- i. *Shallow needling*: the needles are not inserted as deeply as the perceived ‘real’ treatment
- ii. *Non-penetrating needles*: the best known is the Streitberger needle that performs like a theatre knife, the shaft recedes into the handle rather than penetrating the skin
- iii. *Non acupuncture point*: the needles are inserted at locations away from traditional acupuncture points
- iv. Needles are inserted at acupuncture points that are not traditionally indicated for a particular condition

Other types of controls were also identified, for example pseudo interventions such as switched-off lasers and TENS machines [4,20]. There are also attempts to control for other attributes associated with traditional acupuncture such dialogue with the practitioner and palpation. This review focuses on the use of needles as sham–placebo controls.

Shallow needling: the needles are not inserted as deeply as the perceived real treatment

The developments of sham acupuncture techniques have aimed to minimise the physiological effects [21]. By inserting the needles only to a shallow depth without any further stimulation to produce a sensation of tingling or aching (deqi) it is thought less likely to produce a physiological response. However, it is important to note that shallow needling is not a physiologically inert procedure [5,9].

Whilst shallow insertion cannot be considered a placebo in terms of biomedicine some commentators assert that in terms of traditional acupuncture it should be considered a placebo

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