Background: Streitberger and Park sham needles have been developed and used as non-penetrating sham acupuncture needles that can be blinded in randomized controlled clinical trials assessing the efficacy of acupuncture. Ideal sham acupuncture should not be distinguishable from an actual acupuncture treatment provided to the experimental group to ensure patient blinding; additionally, it should not have any physiological or biological effect. Providing evidence for such sophisticated sham acupuncture devices is critical, as control settings in clinical studies are based on research verifying their validity.

Methods: Three core electronic databases – PubMed, EMBASE, and the Cochrane Central Register of Controlled Trials – will be used to search for validity verification studies of sham acupuncture devices. Clinical studies that verify the validity of non-penetrating sham acupuncture devices will be included in the review.

Results: The study design, participant information, experimental and control groups, study population's experience with acupuncture, outcome variables, and results of studies that verify the validity of sham acupuncture devices will be systematically reviewed.

Conclusion: This systematic review of validity verification studies of sham acupuncture devices is expected to help the development of more sophisticated sham acupuncture, as well as the design of studies verifying its validity in the future.

Keywords: acupuncture, protocol, review, sham acupuncture, validation

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Introduction

Acupuncture, defined as the insertion of needles into the human body for therapeutic purposes, is one of the most commonly used treatments worldwide [1]. However, in evidence-based medicine, the effectiveness of a specific intervention can only be verified by randomized controlled trials (RCTs) [2].

For successful RCTs, it is important to establish a control group that can be blinded without specific effects [3]. While blinding is relatively easy in pharmaceutical clinical trials where a placebo can have the same appearance as the treatment drug but no effect, setting up a control group that can be blinded in non-pharmaceutical clinical trials with intervention, such as acupuncture, is more complicated [4].

For example, the penetrating sham acupuncture needling of a non-acupoint that is not in line with the traditional meridians or a traditional acupoint unrelated to the intended therapeutic purpose of the experiment may cause physiological activation effects; this renders such approaches inappropriate for placebo-controlled treatment [5]. Therefore, in addition to sham needles appearing like real acupuncture needles, the resultant physiological effects on the human body should be minimal, which would enable effective blinding of participants during clinical trials [6].

Non-penetrating sham acupuncture devices have been developed to overcome such limitations, and Streitberger and Kleinhenz [7] as well as Park et al [8] sham needles have been commercialized as blindeable sham products for randomized controlled clinical trials to evaluate the efficacy of acupuncture needles.

Non-penetrating sham acupuncture needles have dull points to prevent the needle from penetrating the skin directly; they also enable blinding such that subjects cannot distinguish between real and sham needles. To set up ideal sham groups in the future, sham and real needles should be identical or induce the same psychological effects (while their physiological effects on the body are minimized), and both subjects and practitioners can remain blinded throughout long-term clinical trials [9,10].

There is thus a need to continue research on the
development and validation of sham acupuncture that meets the ideal criteria. Clinically friendly sham devices are needed to establish a scientific basis for the effectiveness of acupuncture treatment. This study aimed to provide a protocol for systematic review of clinical studies verifying the validity of sham acupuncture to provide evidence for establishing control groups, which is essential for clinical studies evaluating the efficacy of acupuncture needles.

**Methods**

1. **Databases and search terms**

Three electronic databases, PubMed, EMBASE, and the Cochrane Central Register of Controlled Trials, will be searched for relevant literature published from the launch of each database till July 2022. The search terms used will be “(acupuncture or needle) AND (sham or placebo) AND (validation or validity or validating or validate or credible or credibility).” Author searches for Streitberger K, Park J, and Takakura N will also be conducted for additional studies.

2. **Inclusion criteria**

Two reviewers will conduct the literature selection independently. The inclusion criteria are: 1) original articles, 2) clinical trials, and 3) validity verification studies that used a sham acupuncture control group. In the primary inclusion and exclusion process, literature judged to be irrelevant to the topic of the current study will be excluded based on their titles and abstracts. In the secondary stage, literature suitable for the present study will be included by reviewing the full text of articles whose suitability for inclusion was not apparent from the abstract. In case of disagreement, the reviewers will discuss and resolve it through a consensus process.

3. **Data extraction**

The two reviewers will independently extract the following data from the selected studies, according to a predetermined extraction format: 1) study design, 2) acupuncturists and participants, 3) experimental and control groups and treatment, 4) participants’ experience with acupuncture, and 5) results. The study design of the clinical trials will be classified as either RCT or crossover. Information about acupuncturists and participants will comprise details regarding the subject of validity verification, such as the number of subjects acupuncturists treated, number of participants, and participant’s health status/specific diseases. Regarding the experimental and control groups and treatment information, details related to the real and sham acupuncture groups will be collected. Reported outcome variables and study results will be investigated. The outcome variables will include study blinding, sense of penetration, degree of pain, deqi sensation, and related quantifiable measures.

4. **Data analysis**

The outcome variables of the selected validity verification studies will be analyzed using descriptive statistics (i.e., mean, standard deviation, and frequency analyses).

**Discussion**

In clinical studies on the effectiveness of acupuncture, it is crucial to establish a reliable control group that can exclude the placebo effect [11]. Previous meta-analyses of clinical studies on acupuncture for chronic pain, such as neck and back pain, demonstrated that actual acupuncture treatment has clinically significant effects on pain compared to sham acupuncture, indicating that high-quality clinical evidence can be obtained by applying placebo-type sham acupuncture [12,13]. However, the patient’s experiences and expectations and complex treatment situations may make it difficult to accurately measure the specific effects of acupuncture [14]. Nevertheless, success in blinding patients by applying sham acupuncture and attempting to measure the specific effects of acupuncture is vital to secure reliable study results [15]. Therefore, the difference in the degree of pain and deqi sensation due to actual needle penetration can be measured as an important outcome variable compared to the non-invasive sham needle control group [16].

In order to establish a high level of scientific validity for acupuncture, its efficacy must be demonstrated to be superior to a placebo control in a double-blind RCT design. Sham acupuncture is, therefore, accepted as an appropriate control in clinical trials of specific effects of acupuncture, and maintaining blinding in the trial process is an important means of minimizing bias in the study results.

This systematic literature review will provide extensive and comprehensive information regarding participants, experimental and control groups, and outcome variables extracted from the available clinical studies verifying the validity of sham acupuncture to date. It will thus summarize the latest research trends related to the development and validation of sham acupuncture methods.

In addition, this systematic literature review of clinical studies verifying the validity of sham acupuncture will provide important clues for establishing sham acupuncture control groups, which are essential for RCTs evaluating the effectiveness of acupuncture. Overall, the information provided in this review will provide a basis for better design approaches for sham acupuncture validity verification.
studies in the context of the need for new and more sophisticated sham devices, as well as verification studies that meet the ideal criteria.

Authors Contributions

Conceptualization, planning data acquisition and analysis, formal investigation, and writing – review and editing: SML. The author has read and approved the final manuscript for submission.

Conflicts of Interest

The author has no conflicts of interest to declare.

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Ethical Statement

The review will not require ethical approval, because it does not involve human participants or unpublished primary data. The findings of this systematic review will be disseminated by the publication of the manuscript in a peer-reviewed journal.

Data Availability

All relevant data are included in this manuscript.

References