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• Research Article

The effects of Park sham needles: a pilot study

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ABSTRACT

BACKGROUND: When performing clinical trials involving acupuncture, it can be difficult to choose a placebo control.

OBJECTIVE: To validate the Park sham needle for use as a double-blind control intervention.

DESIGN, SETTING, PARTICIPANTS AND INTERVENTIONS: Two different methods were employed. First, a researcher blinded to needle type administered the Park sham or a real needle, chosen at random, on the arms of 16 healthy volunteers. The researcher and the volunteers independently recorded which needle type they thought had been applied at each acupuncture point. Second, 19 patients with shoulder impingement syndrome were randomly assigned to receive acupuncture applied with the real needle or the Park sham needle, once a week for 6 weeks alongside a course of physiotherapy. At the end of the 6 sessions the patients recorded which needle type they thought was being used. The results were analyzed with a Fisher's exact test. This study was carried out in the Outpatient Department of Physiotherapy in Charing Cross Hospital, London, UK, on healthy volunteers and patients with shoulder impingement pain. The age range was 23 to 54 and 22 to 74 years respectively.

RESULTS: Of the healthy volunteers, there was no difference (P=0.23) between the number of needles that were correctly (n=43) or incorrectly identified (n=53). All patients thought that they had received the real needles. The researcher correctly identified all needles that were applied.

CONCLUSION: The researcher delivering the acupuncture recognized the needle type. However, both healthy and patient volunteers were blind to the needle type. This demonstrates that the Park sham needle is an effective single-blind control. It should be noted that the number of patients recruited was small and the study was underpowered to detect an effect of treatment.

Keywords: acupuncture; placebos; shoulder impingement syndrome; validation studies as topic; pilot projects

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1 Introduction

Double-blinded, randomised controlled trials (RCTs) are considered as the "gold standard" of evidence-based medicine. In acupuncture studies, the use of RCTs can be very challenging due to the difficulty of providing a robust, double-blinded placebo control. The problem with many of the current acupuncture control methodologies is that of blinding: the patients are aware of whether or not they are receiving acupuncture, and the researchers are aware of whether the patients are receiving the active intervention or placebo.

In recent years, placebo acupuncture needles have been developed to help provide a suitable placebo control. All

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the placebo acupuncture needles are designed with the principle of a placebo needle that slides within the needle handle, providing the appearance of the needle shortening and penetrating the skin. The Park sham needle, the Streitberger placebo needle, and the Takakura and Yajima placebo needle have all undergone validation studies to evaluate their effectiveness as an acupuncture control[1–6]. However, some problems with each of these studies leave open the question of the needles' validity as tools for a double-blind control. For example, in 2002[1] a validation study using the Park sham needle on patients with acute stroke concluded that the needle delivered through its device was effective at blinding all 58 patients and could be used as a valid control for acupuncture studies. However, one possible limitation was the study population. The stroke patients were likely to have altered skin sensations that may have impacted the results. Other problems with these validation studies included using only healthy populations, the delivering of the acupuncture in non-clinical settings or they did not use the Park sham needle[2–4]. White *et al*[5]and Kleinhenz *et al*[6] both performed RCTs using patient (*i.e.*, non-healthy) populations, but in both these studies they used the Streitberger needle and not the Park sham needle[5,6].

Although there are problems with some of these studies, they do seem to demonstrate that placebo needles may be successful at blinding the subject to the needle type. However, it remains unclear whether the needles can be used as a double-blind intervention. All three placebo needles are based on the same design principle, and no one particular placebo needle has been validated to clearly demonstrate its effectiveness at providing a robust double-blind control, so we chose to validate the Park sham needle delivered through the Park sham device. The device has a double-tubed system which is attached to a plastic base and then attached to the subject's skin using double sided sticky tape (Figure 1). The inner tube is placed in its extended (highest) position and lowered into the outer tube as a needle is lowered. The Park sham device is able to house either the Park sham needle or a real acupuncture needle. The Park sham needle has the appearance of a real needle; it is packaged in the same way as an acupuncture needle and is made of stainless steel, measuring 0.25 mm × 50 mm. When a downward pressure is placed on to the handle of the Park sham needle, the needle slides into the handle, giving the appearance of the needle sliding into the skin. The Park sham device is required to prevent the Park sham needle falling off the skin, but also to prevent the subject seeing which form of needle is being used, *i.e.*, the Park sham needle or a real acupuncture needle.

The aim of this study was to assess whether the Park sham needle and device can be used effectively as a double-blind placebo control, in order to prepare for a clinical trial on the effectiveness of acupuncture in a population of patients suffering with shoulder impingement syndrome (SIS). To provide a robust validation of the Park sham needle and the device, three objectives were tested using two different methods. The three objectives were: can an experienced acupuncturist feel the difference in a Park sham needle as compared to a real acupuncture needle? Can a healthy person receiving acupuncture tell if the Park sham or real needle is being applied? Finally, can a patient who has a SIS tell if the Park sham needle or real needle is being applied? Two different methods were employed to fulfil these objectives: a test of the effectiveness of the placebo needles in healthy volunteers and a test of the use of placebo needles in patients ensuring a match to the method of application when conducting an RCT.

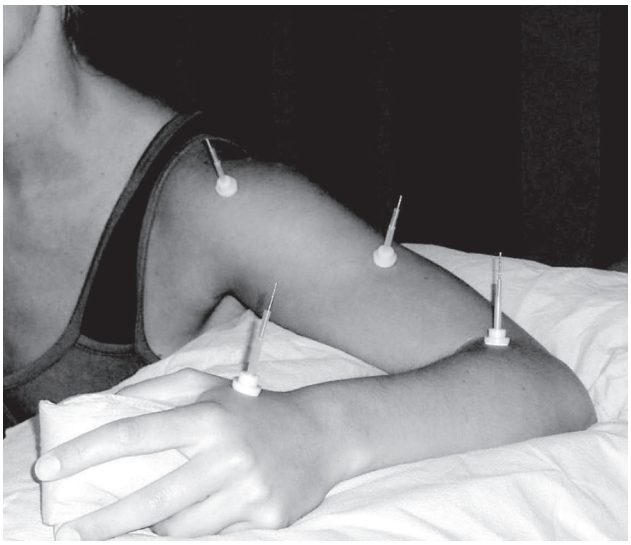

Figure 1 The Park sham device attached to the skin
The device has an inner and outer tube which is attached to a plastic base. The base is attached to the subject's skin using double sided sticky tape. The inner tube is placed in its extended (highest) position and lowers into the outer tube as a needle is lowered. The Park sham device is able to house either the Park sham needle or a real needle. When a downward pressure is placed on to the handle of the Park sham needle, the needle slides into the handle giving the appearance of the needle sliding into the skin as the needle shortens.

2 Methods

The study was approved by the North West London Research Ethics Committee 1.

2.1 Study population

One researcher (first author) who is a senior physiotherapist and has 4 years of acupuncture experience applied the Park sham or real needle through the Park sham device. The Park sham needle and device was purchase from AcuPrime (http://www.acuprime.com/). Sixteen healthy volunteers who had no neck or shoulder pathologies and 19 people with SIS were recruited. The healthy volunteers were staff members recruited from a national health service hospital. The patients were recruited sequentially from the physiotherapy department of the same hospital. SIS was diagnosed using a combination of a common pattern