

Sham acupuncture devices – practical advice for researchers

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Abstract

Several validated sham acupuncture devices have recently become available. While some debate exists on whether such needles are the best placebo control for an RCT of acupuncture, practical advice based on research experience is missing from the literature. This paper shares our concrete experience using the most commonly used such sham needle (the ‘Streitberger needle’ and its paired verum needle) in a large RCT (n=135) which included a two-week run-in period. The placebo run-in gave us an opportunity to use the sham device on all participants, who were then re-randomised to receive genuine acupuncture or to continue treatment with the device. The blinding was successful both at the end of the run-in and at the conclusion of the trial despite the re-randomisation. We also report our experience with the sham needle in neuroimaging experiments where the magnetic machinery poses considerable challenges for acupuncture research.

Keywords

Sham acupuncture, sham needle, research protocols.

Introduction

The acceptance of acupuncture by the biomedical community requires evidence that the effect of acupuncture treatment is more than the accumulated non-specific effects associated with the entire ritual of needle insertion. This biomedical epistemological principle is embedded and given concrete form in the research apparatus of the placebo controlled RCT. In an ideal RCT, the genuine acupuncture should be compared to an apparently identical inert decoy procedure that is indistinguishable from the genuine acupuncture procedure. The development of credible, validated, reliable and usable placebo interventions has generated much excitement and debate. We recently completed a large RCT (n=135), with a two week placebo run-in, testing whether acupuncture treatment was efficacious for arm pain due to repetitive use, sometimes called repetitive strain injury (RSI).¹ The outcomes of this study will be reported elsewhere. Here we would like to report our experience with a validated acupuncture sham device – from here on called the *Streitberger* needle – and provide practical and concrete advice for its

efficient and effective use in future clinical trials. We also report on our experience on using the Streitberger needle in functional magnetic imaging experiments.

Methods

Adoption of the sham device

In the planning phase of our trial we considered some of the emerging sham controls published in the literature including empty guide tube,² toothpick or cocktail stick.^{3,4} During this time, a publication in a major medical journal reported that a new acupuncture sham device, the ‘Streitberger needle’ had been validated in a controlled trial.⁵ The device works like a retractable magic sword: the needle appears to be penetrating the skin, the patient sees and feels a sensation of needle penetration but the needle is actually retracted up the needle shaft. In the published validation study, volunteers were unable to distinguish the genuine acupuncture from sham acupuncture. Given the fact that this Streitberger needle was indistinguishable from a real needle and validated, we decided to adopt it as a control for our

RCT. After we began our study, we became aware of other acupuncture sham devices (such as the 'Park Sham Device'), with similar validation studies.^{6,7}

Some debate exists on whether such retractable acupuncture devices are the best control in acupuncture RCTs. Some people have wondered whether shallow needling at non-acupuncture points might be better; others have considered that perhaps these devices are not genuinely inert.⁸ There is also debate on whether needling at a genuine point can confound the 'inertness' of the control (by producing an acupressure effect) and therefore, the sham device should be used over non-points. As these broad issues are unlikely to be resolved quickly, in this article we will side-step these fundamental questions and simply report on our practical experience using the Streitberger needle in an RCT for RSI.

Results and discussion

Success of blinding

In our study, as in the first validation study and subsequent validation studies,^{9,10} and similar to the use of other acupuncture sham devices, the use of the Streitberger needle appeared to be an effective blinding tool. The two week placebo run-in conducted in our study was an attempt to identify and analytically eliminate high placebo responders. Therefore, all patients received the sham needle twice weekly for two weeks. After the run-in, participants were re-randomised to either verum or sham acupuncture for an additional four weeks of acupuncture twice weekly for a total of eight sessions. Unlike most run-ins we kept responders in the trial to see whether this method would provide an advantage for detecting the difference between genuine acupuncture and sham acupuncture. Patients in the verum (genuine) and sham arm received a 'manualised' semi-flexible treatment protocol,¹¹ using between six and 10 needles per session. At the end of the RCT, 71% of those on sham acupuncture thought they were receiving active treatment while 81% on genuine acupuncture thought they were receiving genuine treatment (P=0.20). We consider this outcome to demonstrate an exceptionally successful blinding procedure.^{12,13}

The Streitberger needle

The sham acupuncture device devised by Streitberger is comprised of two pieces, a copper

needle handle and a stainless steel shaft with a blunt tip. When the blunt tip is pressed against the skin, the patient feels a slight prick and the shaft of the needle moves up into the handle, thereby appearing to shorten and thus be penetrating the skin. The needle is held in place by a small plastic ring which is covered with sterile tape or a band-aid. It is actually this tape and ring which holds the needle upright. Participants who are treated with real acupuncture needles also have the same tape and ring apparatus at each acupuncture point. The following is step-by-step advice on using the Streitberger needle, currently manufactured by Asiamed Inc. This advice is a summary of our experience with the needle. We expect that our suggestions will be helpful for using any acupuncture sham device in future RCTs.

Step by step advice on successful use of sham needle devices

Set up the treatment room before the treatment

Whenever possible, keep all sham needles and other supplies out of the direct view of the patient, such as on a trolley (cart) or table behind the patient's head. The less the patient sees, the fewer questions will be raised about the sham needling device. It is not only advisable to have the equipment table out of the patient's direct sight when they are on the treatment table, but also removed from where they might sit to get ready for treatment (remove shoes etc). This prevents participants from being tempted to pick up supplies or to ask unnecessary questions about the devices or needles.

Materials needed

Although the Streitberger device comes standard with sterile plasters or band-aids to cover the rings, we found them difficult to use; they did not always adhere to the skin and it was hard to view insertion of the needle through them. We opted to use ¼ inch wide *Steri-strips* (manufactured by 3M). We found *Steri-strip* adhesives to be stronger, less irritating to sensitive skin, latex free and appropriate for both sham and active needling. Some researchers have used latex free paper tape, such as 3M *Micropore* or surgical type *Transpore* tape, but neither of these tapes is sterile when packaged. Since the *Steri-strips* are sterile, Clean Needle Technique (CNT), a US national standard in clean clinical acupuncture practice, is adhered to. In addition, acupuncturists

found it easier to view the points when inserting active needles through the *Steri-strips*.

Set up all materials before the patient arrives. This will expedite the needle placement and will assist in maintaining blinding. It may be helpful to open needle packages before the patient enters by peeling the backing paper half way down the packaging, as Streitberger placebo needles occasionally separate and fall apart when removed from the bubble packs. Open the *Steri-strips* and peel back the tape to insert rings underneath, being careful not to compromise the sterile entry point of the needle. All of this preparation will cut down on interaction with and questions by a curious participant.

Inserting 'the needle'

Swab all the points with alcohol before needling to comply with CNT guidelines, and also to remove excess oil from the patient's skin, and allow for better adhesion of the tape. Allow the point time to dry. Apply the *Steri-strips* with rings to increase adherence to the skin. If the protocol calls for palpation, 'mark' the point by sticking the ring and *Steri-strip* as you palpate. This serves not only to isolate the exact location of where you want to place the needle, but also to give another 'reason' for using the strip and ring apparatus if the participant inquires about it. Some patients have seen pictures of acupuncture and will ask about the rings. One useful response is 'We want to zero in on the exact point.' When 'inserting' the needles, handle only one at a time, since the shaft and body separate and can fall apart easily. Overlap your inserting fingers slightly on the shaft of the needle, to prevent it from collapsing in on itself during insertion into the strip and ring. We found it useful for the acupuncturists to stand with their dominant insertion hand closest to the patient's head, so that only the back of the hand was most often visible to the patient during insertion, to cut down on the participant's view of the insertion process. For example, if the acupuncturist is right handed, inserting the majority of the points from the patient's left side effectively shielded the participant from a full view of the insertion, and masked any technical difficulties they had with the needles (such as a stuck or overly loose shaft). Once securely in place, acupuncturists can reveal the functioning needle and the appearance of its insertion.

Stimulating the needle

Each study will have its own protocol for standardising the needle stimulation. When using Streitberger needles, it is important to push the needle shaft into the handle to make the needle appear as if it has reached a desired depth, and to give *some* stimulation. However, we do not advise pushing the handle into the shaft making it appear deeper than an active needle, or give more or less stimulation than you would to an active needle. In a run-in trial, this is especially important as participants can notice the difference in apparent depth and stimulation when they are given both sham and active needles during the course of study.

Removing the needle

When removing the Streitberger needle, shield the fact that it has been shortened into itself by grasping the area where the shaft meets the handle between the thumb and index finger, so the participant cannot recognise the change in its size. Again, having the back of the removing hand face the participant's head will aid blinding. We recommend placing all needles in a nearby sharps container immediately to conceal the fact that they are indeed shorter when they are removed. Remove the strips and rings after all needles are disposed of. If you remove the tape, ring and needle at the same time, the placebo needle shaft and handle may separate and blinding will be compromised. Having long handled, sterile cotton swabs available for immediately swabbing blood after active needling may also cut down on patient perception of treatment group. After removing the ring, use a sterile cotton swab to wipe and apply pressure on the point for two seconds. This should be done whether or not the point is bleeding, and these procedures will serve to further blind the subject. Keep in mind that the more carefully participants observe practitioners handling each needle (real or placebo), the more they will perceive the needles as sharp and real.

Damaged devices

In our experience, approximately one needle in 50 was defective, due to either a loose handle or a shaft that was completely missing. Needle handles may be tightened by gently twisting the copper coils around the shaft, but obviously this should not be done in front of the participant.

Practitioner perspectives

In general, most practitioners did not believe blinding was compromised by technical problems with administering the placebo treatments. Obviously, our protocol tried to avoid potential problems. For example, if our protocol called for using points on the tip of the fingers or toes there would be a problem with getting needles to stand in place.¹⁴ Practitioners reported they were able to shield any problems with the needles from the patient. Practitioners also reported that the patients never seemed to consider that the needle never penetrated the skin. Details on practitioner opinions and feelings about using sham devices will be reported elsewhere.

Using the Streitberger needle in neuroimaging experiments

Recently, functional magnetic resonance imaging (fMRI) has been used to investigate brain mechanisms of acupuncture needle stimulation.¹⁵⁻¹⁹ Additionally, the use of sham acupuncture has helped advance both acupuncture and placebo research.²⁰ While crucial to experimentation, use of the Streitberger needle proves a challenge when used in an MRI scanner. Methodological precautions should be taken to ensure that the metallic acupuncture needles are not absorbed into the magnet. Firstly, it is important that the acupuncturist hold the joint of the needle handle and the shaft tightly, to counteract the force from the magnetic field before the needle is inserted. Secondly, insertion at a slight angle, with the tip of the needle directed toward the subject's head (also the direction toward which the needle is absorbed into the magnetic field) is recommended because this will cause the magnetic force to pull the needle toward the skin rather than toward the scanner. Some researchers have suggested tying a thread to the needle and connecting it to the patient's skin, as a further precaution to keep the needle from flying into the machine or the patient (P White, personal communication). No further blinding is necessary because the patient's view of the procedures is obstructed while lying in the scanner.

Conclusion

The Streitberger sham acupuncture device is an effective masking device for blinding in RCTs of acupuncture. Care must be taken to prevent giving patients clues as to whether they are receiving active

or placebo treatment in terms of preparing treatment, handling needles, needle stimulation, needle removal and needle disposal. Potential adverse events such as skin irritation from the adhesives holding covering the rings should be anticipated. The challenges of using a sham needle in a neuroimaging machine can be overcome.

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Ted Kaptchuk works as a consultant for Kan Herbal Co, Scotts Valley, CA.

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