

ACURATE: a Guide for Reporting Sham Controls in Trials Using Acupuncture

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This paper presents the Acupuncture Controls gUideline for Reporting humAn Trials and Experiments (ACURATE) checklist, an extension of The Consolidated Standards for Reporting of Trials (CONSORT), which is to be used with STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) when real and sham acupuncture needles are used in a study. This checklist focuses on a clear depiction of sham needling procedures to enhance replicability and enable a precise appraisal. We encourage researchers to use ACURATE in trials and reviews involving sham acupuncture to assist in the reporting of sham acupuncture procedures and related components.

Keywords: Acupuncture, Consort, Stricta, Reporting guidelines, Placebo

INTRODUCTION

Acupuncture is an invasive, non-pharmacological intervention. Treatment procedures using sham needles are identical to those of real acupuncture except for the blunt needle that is designed to not penetrate the skin [1-3]. Because sham needling involves minimal stimulation of the skin [4], it is possible that quantitative components such as the dose, duration, and treatment frequency, may influence the level of the overall effect induced by sham acupuncture. A reassessment of the components of the sham acupuncture procedure and related nonspecific effects would allow a further precise appraisal of the effectiveness of acupuncture [5,6].

In order to promote better reporting quality regarding sham acupuncture in clinical trials, a group of researchers developed a reporting guideline named Acupuncture Controls gUideline for Reporting humAn Trials and Experiments (ACURATE). As an extension of The Consolidated Standards for Reporting of Trials (CONSORT) [7,8], this guideline focuses on the reporting of the device as well as the treatment procedure of sham acupuncture, and is recommended for use with STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) when real and sham acupuncture needles are used in a study. The comprehensive reporting of

sham acupuncture interventions will improve replicability, and ultimately facilitate a thorough evaluation of potential factors that may influence the placebo effect of acupuncture.

THE ACURATE CHECKLIST

1. Scope of the ACURATE checklist

The purpose of the ACURATE checklist is to guide authors in describing the use and application of sham controls in clinical acupuncture trials in detail to allow the replicability and appropriate assessment of the effectiveness of acupuncture. The scope of the checklist applies to all types of study designs using sham acupuncture including clinical trials, case-control studies, and experiments using sham needles as their stimulation apparatus.

2. The ACURATE checklist description and guidance

The final checklist includes 22 items in 6 categories: (1) types of sham acupuncture, (2) details of sham acupuncture manipulation, (3) location of sham acupuncture, (4) treatment regimen, (5) practitioner, and (6) protocol and settings (Table 1). Descriptions and examples of the ACURATE items are detailed below.

Table 1. The ACURATE checklist

Category	Item	Description
1. Type of sham acupuncture	1a	Report the type of sham acupuncture.
	1b	Report whether the sham acupuncture is penetrating or non-penetrating.
	1c	Rationale for using the chosen sham acupuncture.
2. Details of sham acupuncture manipulation	2a	Report the number of sham acupuncture applied per subject per session.
	2b	Report the depth of sham acupuncture insertion (if there was no penetration, state this within the paper).
	2c	Report whether any response was observed during sham acupuncture manipulation (e.g. de qi or muscle twitch response).
	2d	Report if there was any stimulation using sham acupuncture.
	2e	Report if there was sham acupuncture retention.
	2f	Report details of other interventions administered in addition to sham acupuncture during one session.
3. Location of sham acupuncture	3a	Report the location of sham acupuncture (e.g. acupoint/non-acupoint or the exact location of the sites).
	3b	Explicitly state in the paper if the points are unilateral or bilateral.
	3c	Describe the reason for the chosen location of sham acupuncture.
4. Treatment regimen	4a	Report the number of treatment sessions.
	4b	Report whether the number of sessions were identical between real and sham acupuncture treatments.
	4c	Report the frequency and duration of treatment sessions.
	4d	Report the total trial period.
5. Practitioner	5a	Report whether the same practitioner is administering both real and control treatments (interventions).
	5b	Report whether there were conversations between practitioner and patient directly linked to the trial design, other than scripted instructions and preset information, prior to and during the treatment.
6. Protocol and settings	6a	Report the information regarding sham acupuncture provided to participants.
	6b	Report whether the information given to patients include the term to openly state that the control is inert (e.g. “fake”, “sham”, “dummy”, “placebo”, ...).
	6c	Describe how sham device was blinded from patients, and if done, how the blinding was assessed.
	6d	If done, report any modification in the sham acupuncture treatment procedure, and reason for the modification.
	6e	Report any difference in the treatment settings between real and sham acupuncture.

1) Type of sham acupuncture

Item 1a. Report the type of sham acupuncture

Specify the type of needle or device that the study used. If the authors invented their own device, it should be clearly stated as the readers are likely to be unfamiliar with the device. Avoid using general terms such as ‘sham acupuncture’ or ‘placebo acupuncture’ without elaboration.

Examples: “Streitberger needle”, “...placebo needles (half-cut, blunt-tip) were used”, “In sham-acupuncture, auditory and visual stimuli were provided with the Acupuntronic Kroman machine: 40 min of placebo stimulation by touching the patient’s skin with the needle without puncturing it”.

Item 1b. Report whether the sham acupuncture is penetrating or non-penetrating

Clearly state whether the sham needle used in the study is penetrating or non-penetrating. Although some specific sham needles, e.g., Streitberger, Park, and Takakura, are non-penetrating, other types of sham acupuncture should be identified based on their level of invasiveness.

Examples: “...received five non-penetrating acupuncture sessions...”, “...without needle insertion...”, “...shallow minimal acupuncture stimulation...”

Item 1c. Rationale for using the chosen sham acupuncture

The idea on which the sham acupuncture was selected in the study should be stated. Some of the possible rationales are similarities in visual and tactile stimulations compared to real

acupuncture, and difficulties in distinguishing sham needles from real needles.

Examples: "...indistinguishable from an actual acupuncture device...", "...to mimic real acupuncture", "...to cause a pricking sensation mimicking real acupuncture without actually puncturing the skin".

2) Details of sham acupuncture manipulation

Item 2a.

It is recommended that the total number of sham acupuncture needles applied to each patient per session is reported. Should any difference between the real and sham acupuncture groups arise in a two-arm study design, this should be identifiable through the reporting. If the trial was based on a pragmatic design and the number of sham needles applied to patients varied, the mean (or median) and range should be reported. Figures are recommended for elaborating on the location of non-acupoints.

Examples: "Sham acupuncture points included non-acupuncture points in the hands, legs, and lower back, and needle insertion at these points was shallow (see Figure)...", "6 small plastic rings were taped to the skin at sites away from any of the acupuncture meridians, 2 on the back, 2 on the lower legs, and 2 on the forearms (Figure)."

Item 2b.

If the needle was blunt-tip and not inserted into the skin, reporting of this item is recommended to simply state that there was no insertion or penetration. If, however, minimal or shallow needling was used for sham acupuncture, the depth of the needling should be specified, preferably providing the measurement in millimeters or cun, rather than simply stating the needling as "shallow," "minimal," or "superficial." The anatomical depth of the dermis or subcutaneous level can be used to express the depth of needling if the specific anatomical structure to which the needle was inserted can be identified. Reporting angles of insertion is recommended if applicable.

Examples: "...to a depth of 2 to 3 mm without manipulation...", "...sham group received five non-penetrating acupuncture sessions in which only the handle came into contact with the skin at the same points as the intervention group...", "a point located between K11 and the lateral margin of the foot (perpendicularly, 0.5-0.7 cm deep), and a point at the apex of the chin (oblique transverse-up insertion, 0.2-0.5 cm deep)..."

Item 2c.

If the study protocol includes the observation of specific responses to real acupuncture, reporting of this item should include whether such responses were observed or avoided

during the procedure of applying the sham needle. If such responses were collected from the patients regardless of eliciting a specific sensation, reporting of this item should include the type of collected responses.

Examples: "The acupuncturist did not manipulate the needles and no 'De-Qi' sensation was elicited in the sham electro-acupuncture group...", "In our study, de-qi was avoided in all 24 sessions of sham acupuncture treatment...", "No obtaining qi or muscle twitch...", "No specific sensation was sought by the treating practitioner in the performance of the needling, however, any sensations felt by the participant were recorded using the MASS instrument..."

Item 2d.

Stimulation or manipulation techniques of acupuncture needles include lifting, thrusting, or rotating the needle. If the study protocol includes a stimulation technique used in real acupuncture, reporting of this item should clearly state whether the same stimulation technique was applied to the sham acupuncture group. If there were no stimulation techniques applied to the sham acupuncture group, this must be clearly stated.

Examples: "The participants in this group received needling in the right side of the abdomen 1 cun lateral to CV-12, where there is no known acupuncture point, with manual stimulation similar to the acupuncture group...", "Procedures, electrode placements, and other treatment settings were the same as in the electroacupuncture group but with no skin penetration, electricity output, or needle manipulation for de qi...", "...flicking or rotation of needles was allowed...", "Needles were inserted unilaterally and without stimulation or manipulation..."

Item 2e.

The sham needle retention time should be reported clearly as a number. If the sham needle was applied without retention, this should be stated in the study. If the trial has a two-arm design comparing real and sham acupuncture, any differences in the retention time between the two groups should be stated.

Examples: "Participants in both groups reported to the clinic once a week; needle retention was 30 minutes...", "The needles were retained in position for 20 minutes..."

Item 2f.

In clinical trials where patients are enrolled, it is common to find other types of interventions, e.g., physiotherapy or moxibustion, conducted alongside acupuncture. In some studies, patients are allowed to continue with their standard therapy in addition to acupuncture. Reporting of this item should include the types of other interventions conducted

along with sham acupuncture within the study as well as the types of medical treatments allowed throughout the trial including rescue medication. If other treatments were down-regulated or stopped in the sham acupuncture group during the trial, this should be reported.

Examples: “In particular, no moxibustion or other additional complementary method was allowed...”, “...placebo laser (inactive laser device) with water pressure massage...”, “...patients were instructed and agreed not to take any regular medications for migraine treatment. In cases of severe pain, ibuprofen (300 mg per capsule with sustained release) was allowed as a rescue medication...”, “Both acupuncture groups were offered acupuncture as an add-on therapy to diclofenac...”

3) Location of sham acupuncture

Item 3a.

The location of the applied sham acupuncture should be depicted using standardized terminology. When acupoints are selected for the application of sham acupuncture, the names of the acupoints used should be stated in the study. In studies where non-acupoints are used, a description of the location using anatomical structures is recommended. To clearly depict the distance of the point used to the nearest anatomical structures or acupoints, measurements using millimeters or cun are recommended. Figures are also suggested to help readers understand the location and to enhance replicability.

Examples: “Sham acupuncture points included non-acupuncture points in the hands, legs, and lower back... (see Figure)...”, “The participants in this group received needling in the right side of the abdomen 1 cun lateral to CV-12...”, “The SHAM acupuncture group had the needles inserted 1 cm distally from the correct acupoints...”

Item 3b.

If the points used for sham acupuncture are unilateral, reporting of this item should include whether the side of the body used for the sham acupuncture treatment is identical to the part of the body for the real acupuncture treatment. If the points used for sham acupuncture are bilateral, reporting of this item should include whether these are identical to the corresponding points used for real acupuncture treatment.

Examples: “Needles were inserted unilaterally and without stimulation...”, “Sham treatment was administered over the kneecaps bilaterally and ST25 bilaterally...”, “In both groups, acupuncture needles (real or sham) were inserted, prior to the second impression taking, at point PC6, unilaterally, in the right arm with a perpendicular insertion angle...”

Item 3c.

Reporting the reasons for the location selected refers to the main goal that the study aimed to achieve by applying sham acupuncture on the specific point. The reason for the chosen location may include reduced therapeutic effect, sufficient distance from the meridians, or similarities to the acupoints used in the real acupuncture group. Depending on the researcher’s objective, the reason may rely on consensus among clinicians regarding the validity of the selected location.

Examples: “In this study, we applied non-penetrating sham acupuncture at heterosegmental non-acupuncture points, thereby avoiding segmental analgesia and minimizing any physiological effect in the sham acupuncture group.”, “These ear points were chosen for the sham auricular point acupressure (APA) treatment for two reasons. First, they not only were distinct from the zones of the ear (and the points therein) associated with lower back pain, but also corresponded to body regions in which the participant was pain-free. Second, they were equivalent in number to those points used in the real APA treatment group.”, “Sham EA was applied at points adjacent to the true acupuncture point, thought to be far enough away to be ‘off channel’ and to negate any antiemetic effect.”

4) Treatment regimen

Item 4a.

Using numbers is recommended when reporting this item. The frequency of the treatments throughout the trial should be reported. Deviations of treatment regimen within the trial, i.e., when the number of treatment sessions in a week changes over time, describing the treatment frequency using different ranges of treatment periods is suggested for clarification.

Examples: “The MwoA patients in the acupuncture groups received 20 treatments (30 min each) over a 4-week period: once per day for five weekdays followed by a two-day break...”, “...twice per week for 2 weeks, then once per week for 6 more weeks, for a total of 10 treatments during 8 weeks...”, “Each patient underwent two sessions per week for a total of 16 sessions. Each session lasted 25 minutes...”

Item 4b.

Any differences between the real and sham acupuncture treatment regimen groups should be reported if the study is a two-arm trial. If the trial design is pragmatic and the treatment regimen in the real acupuncture group is tailored by individual condition, the study should specify whether the same approach was taken for the sham acupuncture group.

Examples: “The acupuncture in both groups was administered with the same number of sessions, frequency, and treatment duration.”, “The SEA therapy protocol included the

same number and type of needle, duration, and frequency of sessions as for the EA treatment...”, “The guidelines for point prescription, treatment duration, manipulation, and treatment frequency were exactly the same as those for RA in all aspects.”

Item 4c.

Reporting of this item refers to the duration of the sham acupuncture session. If the design of a two-arm clinical trial includes the same duration as the real and sham acupuncture treatments, it must be stated.

Examples: “Needles were left in place for 20 minutes without stimulation...”, “Both the acupuncture and sham acupuncture treatments consisted of 12 sessions of 30 minutes’ duration administered over a period of 8 weeks (preferably 2 sessions a week for the first 4 weeks, followed by 1 session per week for the remaining 4 weeks).”, “...both true acupuncture and sham acupuncture consisted of twelve 30- to 45- minute sessions administered over a period of 6 weeks (2 per week) followed by 1 session per week for 6 weeks.”

Item 4d.

The total treatment period of the sham acupuncture group should be documented in numbers. If any variation is allowed in the trial protocol, it should be reported so readers understand the possible variance in the amount of stimulation among study participants.

Examples: “Women received two 25-min treatments a week for 4 weeks followed by one treatment a week for 8 weeks (total of 16 treatments over 12 weeks)...”, “...received 20 treatments (30 min each) over a 4-week period: once per day for five weekdays followed by a two-day break...”, “...twice per week for 2 weeks, then once per week for 6 more weeks, for a total of 10 treatments during 8 weeks.”

5) Practitioner

Item 5a.

In the context of non-specific effects induced by sham acupuncture, the individual approach to patients by practitioners, multiplied by the number of practitioners involved in the trial, could lead to a manifold effect. The absence of practitioner details is not an indication of the trial’s low quality; however, we recommend that studies clearly state the allocation of practitioners in patient groups. An explicit statement on whether the study includes only one practitioner or a number of practitioners, as well as whether they are administering real and sham needling should be provided.

Examples: “The same practitioner provided active and control acupressure interventions.”, “The placebo laser treatment was... conducted by the same blinded physiotherapist as in the DN group each session.”, “The procedure

was performed by the same experienced and licensed acupuncturist (with 6 years of experience) on all subjects.”, “All interventions were performed by one doctor of Korean Medicine with more than 15 years of experience.”

Item 5b.

Reporting of this item recommends an explicit statement on whether the communication was within the scope of preset and prepared information. If the protocol of the clinical trial states the instruction be provided from preset information, the practitioner’s adherence to this protocol should be clear. For studies with a pragmatic design that allows an interaction between practitioner and patient similar to that of an actual clinical setting, this should be clearly stated.

Examples: “There was also limited contact between the study participants and restricted conversation between the acupuncturist and participants during treatment.”, “In order to avoid any bias caused by the acupuncturist and the assessor (research assistant), the acupuncturist adhered to scripted speech during interactions with the participants...”

6) Protocol and settings

Item 6a.

Reporting of this item focuses on if and how the instruction regarding sham acupuncture is provided during the initial stage of the trial. Participants may be notified, during the enrollment or screening stage of a clinical trial, on the possibility of being randomized into a control group receiving sham acupuncture. In some studies, participants may be informed that they will be randomized to receive different “types” of acupuncture treatment; other studies may provide unanimous instructions to the real and sham acupuncture groups altogether. It is noteworthy that incomplete disclosure does not imply low quality of the trial; for some studies measuring the placebo effect, the information may have been omitted on purpose. However, this procedure should be described so readers understand the participant’s awareness of the intervention during the trial: an awareness of the possibility of it being sham or being a different type of acupuncture, or a belief that it is real.

Examples: “Before randomization, all participants were informed that they could be allocated to the needling acupuncture group (IG) or to a group where the needle will touch the surface (SG).”, “Subjects were informed that they had a 50% chance to be in the RA group and a 50% chance of being in the placebo group.”, “All patients were told that this was a study about the effectiveness of acupuncture analgesia for pain and they would receive traditional acupuncture.”, “Patients were informed in person and by an information sheet that they would be randomized to one of three arms: standard treatment, standard treatment plus sham

acupuncture or standard treatment plus true acupuncture.”
“All patients were provided with a patient information sheet which informed them that they were taking part in a randomized trial in which they could be treated with real acupuncture or an inactive treatment that looked like real acupuncture.”

Item 6b.

A specific term used to disclose sham acupuncture information is reported in this item. The level of disclosure can vary from not at all to completely open. Some studies might describe the intervention in a way that explains real and sham acupuncture to avoid an impression of being inactive. The purpose of this item is to endorse reporting of the type of disclosure employed in the trial, rather than endorsing a specific type of disclosure, as this specific detail is at the discretion of the researchers and related to their study objectives. Reporting the exact term or phrase to describe the sham acupuncture is recommended.

Examples: “All patients were provided with a patient information sheet, which informed them that they were taking part in a randomized trial in which they could be treated with real acupuncture or an inactive treatment that looked like real acupuncture.”, “The nature of the sham needle was not stated; however, the word ‘sham’ was used.”, “The participants were informed that they would receive one of the two acupuncture treatments; one followed the style of traditional Chinese medicine, and the other one did not, but it was also effective according to previous studies.”

Item 6c.

Reporting how blinding was carried out in the sham acupuncture procedure would help readers understand whether the procedure was applied as intended. Many studies use simple statements to describe blinding in the trial; however, this item suggests using a blinding index such as the Bang Index to identify the level of successful blinding, especially in studies describing their trial as single- or double-blind.

Examples: “The success of blinding was examined after the sixth treatment; in all three groups the majority of participants reported that they did not know which acupuncture group they were in (82.8% for acupuncture, 89.8% for minimal acupuncture, and 83.3% for non-invasive sham acupuncture), suggesting that subject blinding was successful.”, “...blinding property, was measured with a blinding index (BI), calculated as the difference in the estimated probabilities of correct vs incorrect guesses (> 0 [null] indicate a more correct guess).”, “Blinding indices, 0.47 (95% CI, 0.33 to 0.61) and -0.31 (95% CI, -0.49 to -0.13) in the acupuncture and sham groups, ... Following the logic of Bang et al., instead of declaring it a failure in blinding, these results indicate high ‘response bias.’”

Item 6d.

Reporting this item includes modification of the sham acupuncture treatment protocol created with the intention to provide additional cues, other than the information regarding the sham acupuncture presented directly to patients. Such cues usually aim to blur the discrepancy between the real and sham needle. If done, such cues will likely influence the patient’s expectation, which may subsequently have an impact on the non-specific effect of acupuncture.

Examples: “The patients in both groups were told that they may or may not feel an electrical current sensation.”, “To further emphasize the imaginary power of this sham procedure, visual and acoustic signals accompanied the red light emission.”, “To maintain blinding, the interventionist script noted that the needles may not be felt.”

Item 6e.

For studies with identical settings between the real and sham acupuncture procedures, a clear statement is recommended. For studies that involve different settings for sham acupuncture, an elaborate description of the differences is suggested.

Examples: “To strengthen the credibility of the imaginary power of this sham procedure, visual and acoustic signals accompany the red light emission.”, “The same visual setting, manipulations, stimulation procedures, time, and questionnaires as in the real acupuncture group were used in order to have the same psychological impact, but the sham needle just moved inside the foam pad providing the same visual appearance as that in the real acupuncture groups.”, “Procedures, electrode placements, and other treatment settings were the same.”

CONCLUSIONS

This paper presents the ACURATE checklist, an extension of the CONSORT, to be used with the STRICTA when real and sham acupuncture needles are used in a clinical study. This checklist focuses on a clear depiction of the sham needling procedures to endorse a transparent description of its components in future studies and to enable a precise assessment of the effects. Doing so will allow a deeper understanding of the level of stimulation from sham needling and the effects of context from its treatment regimen.

This guideline is not intended for *ad hoc* modifications. Researchers are invited to provide feedback and comments on the ACURATE, as this guideline will be updated based on the feedback.

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AUTHORS' CONTRIBUTIONS

YSL: Methodology, Investigation, Formal analysis, Writing – original draft. SYK: Investigation, Writing – original draft. HL: Methodology, Writing – review & editing. YC: Conceptualization, Writing – review & editing. MSL: Supervision, Writing – review & editing.

ETHICAL STATEMENT

This study was approved by the ethical review committee at Gachon University, Republic of Korea (Approval No. 1044396-202008-HR-159-01).

DATA AVAILABILITY

The data associated with this study can be made available upon reasonable request to the corresponding author.

CONFLICT OF INTEREST

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