



Guideline

ACURATE: A Guide for Reporting Sham Controls in Trials Using Acupuncture ☆



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ABSTRACT

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) and to be used along with STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) when both real and sham acupuncture needles are used in the 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 reporting of sham acupuncture procedures and the related components.

Keywords: acupuncture, CONSORT, STRICTA, reporting guidelines, placebo

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Introduction

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

and is recommended to be used along with STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) when both real and sham acupuncture needles are used in the study. A comprehensive reporting of sham acupuncture intervention would improve replicability, and ultimately facilitate a thorough evaluation of potential factors which may influence the placebo effect of acupuncture.

The ACURATE checklist

1. Scope of ACURATE checklist

The purpose of the ACURATE checklist is to guide authors to describe the use and application of sham controls in clinical acupuncture trials in detail to allow 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). Description and examples of ACURATE items are detailed below.

2.1. 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 Acupunctronic 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. While some specific sham needles, e.g., the Streitberger, the Park, the Takakura, are known to be non-penetrating, other types of sham acupuncture should be identified on their level of

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.

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 based on which the sham acupuncture was selected in the study should be stated in the study. Some of the possible rationale are similarities in visual and tactile stimulations compared to real acupuncture, and difficulties in distinguishing sham 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”.

2.2. Details of sham acupuncture manipulation

Item 2a. Report the number of sham acupuncture applied per subject per session

It's recommended that the total number of sham acupuncture needles applied per patient per session is reported. Should any difference between 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 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. Report the depth of sham acupuncture insertion (if there was no penetration, state this within the paper)

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 using measurement of millimeters or cun, rather than simply stating the needling as “shallow,” “minimal,” or “superficial.” Anatomical depth of 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 KII 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. Report whether any response was observed during sham acupuncture manipulation (e.g. de qi or muscle twitch response)

If the study protocol includes 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 sham needle. If such responses were collected from the patients regardless of eliciting 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. Report if there was any stimulation using sham acupuncture

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

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. Report if there was sham acupuncture retention

Sham needle retention time should be reported clearly in numbers. If sham needle was applied without retention, this should be stated in the study. If the trial is a two-arm design comparing real and sham acupuncture, any differences in the retention time of two groups should be elaborated.

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

Item 2f. Report details of other interventions administered in addition to sham acupuncture during one session

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”

2.3. Location of sham acupuncture

Item 3a. Report the location of sham acupuncture (e.g. acupoint/non-acupoint or the exact location of the sites)

The location of where sham acupuncture was applied should be depicted using standardized terminology. When acupoints are selected to apply sham acupuncture, names of the acupoints used should be explicit in the study. In studies where non-acupoints are used, 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, measurement using millimeters or cun is recommended. Figures are also suggested to help 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. Explicitly state in the paper if the points are unilateral or bilateral

If the points used for sham acupuncture is unilateral, reporting of this item should include whether the side of the body used for sham acupuncture treatment is identical to the part of the body for real acupuncture treatment. If the points used for sham acupuncture is bilateral, reporting of this item should include whether this is 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. Describe the reason for the chosen location of sham acupuncture

Reporting the reasons for the selected location refers to the main goal that the study aimed to achieve by applying sham acupuncture on the specific point. Reason for the chosen location may include reduced therapeutic effect, sufficient distance from the meridians, or similarities to the acupoints used in 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 correspond 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.”

2.4. Treatment regimen

Item 4a. Report the number of treatment sessions

Using numbers is recommended when reporting this item. 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 by different ranges of treatment periods is suggested for clarification.

Examples: “The MwoA patients in 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 min...”

Item 4b. Report whether the number of sessions were identical between real and sham acupuncture treatments

Any difference between the two groups of real and sham

acupuncture treatment regimen should be reported if the study is a two-arm trial. If trial design is pragmatic and treatment regimen in the real acupuncture group is tailored by individual condition, the study should specify whether the same approach was taken to 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. Report the frequency and duration of treatment sessions

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

Examples: “Needles were left in place for 20 min 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. Report the total trial period

The total treatment period of sham acupuncture group should be documented in numbers. If any variation is allowed in the trial protocol, it should be reported to understand 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.”

2.5. Practitioner

Item 5a. Report whether the same practitioner is administering both real and control treatments (interventions)

In the context of non-specific effects induced by sham acupuncture, individual approach to patients by practitioners, multiplied by the number of practitioners involved in the trial, could lead to a manifold effect. Absence of practitioner details is not an indication of the trial's

lower 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 both real and sham needling.

Examples: “The same practitioner provided both 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. 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

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 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 interaction with the participants...”

2.6. Protocol and settings

Item 6a. Report the information regarding sham acupuncture provided to participants

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 control group using sham acupuncture. In some studies, participants may be informed that they will be randomized into different “types” of acupuncture treatment; other studies may provide unanimous instructions to both real and sham acupuncture groups altogether. It's noteworthy that incomplete disclosure does not imply low quality of the trial⁸⁶; for some studies measuring the placebo effect, the information may have been omitted on purpose. However, this procedure should be demonstrated to understand the participant's awareness on 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 randomised 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 randomised trial in which they could be treated with real acupuncture or an inactive treatment that looked like real acupuncture.”

Item 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”)

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 both 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 by their study objectives. Reporting the exact term or phrase to describe sham acupuncture are recommended.

Examples: “All patients were provided with a patient information sheet which informed them that they were taking part in a randomised 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. Describe how sham device was blinded from patients, and if done, how the blinding was assessed

Reporting how blinding was carried out in sham acupuncture procedure would help understand whether the procedure was applied as intended. Many studies show use simple statements to describe blinding in the trial; however, this item suggests using blinding index such as 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. If done, report any modification in the sham acupuncture treatment procedure, and reason for the modification

Reporting this item includes modification in sham acupuncture treatment protocol created with the intention to provide additional cues, other than the information regarding sham acupuncture directly presented to patients. Such cues usually aim to blur the discrepancy between 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. Report any difference in the treatment settings between real and sham acupuncture

For studies with identical settings between real and sham acupuncture, a clear statement is recommended. For studies which involved 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 that in the real acupuncture.”, “Procedures, electrode placements, and other treatment settings were the same.”

Conclusion

This paper presents the ACURATE checklist, an extension of the CONSORT, to be used along the STRICTA when both

real and sham acupuncture needles are used in a clinical study. This checklist focuses on a clear depiction of sham needling procedures to endorse a transparent description of its components in the future studies and to enable a precise assessment of the effects. Doing so will allow a deeper understanding on 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. The researchers are invited to provide feedbacks and comments on the ACURATE, as this guideline will be updated based on the feedbacks.

Author Contributions

Methodology, Investigation, Formal analysis, Writing - original draft: YL. Investigation, Writing - original draft: SYK. Methodology, Writing - review & editing: HL. Conceptualization, Writing - review & editing: YC. Supervision, Writing - review & editing: ML.

Conflicts of Interest

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Ethical Statement

This study was approved by the ethical review committee at Gachon University, Republic of Korea (Approval no: 1,044,396-202008-HR-159-01).

Data Availability

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

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