THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 17, Number 2, 2011, pp. 1–2

DOI: 10.1089/acm.2010.0353

Revised STRICTA as an Extension of the CONSORT Statement: More Items Should Be Involved in the Checklist

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Dear Editor:

The revised standards for reporting interventions in clinical trials of acupuncture (STRICTA) as a formal extension to Consolidated Standards of Reporting Trials (CONSORT) has been published in *PLoS Medicine* recently.[1] It includes 6 items and 17 subitems, which set the reporting guidelines for the acupuncture rationale, the details of needling, the treatment regimen, other components of treatment, the practitioner background, and the control or comparator intervention. Also, the examples for the explanation of each item have been provided. The aim of this revision is first, to extend the STRICTA under the CONSORT roof, and second, to help authors of acupuncture trials provide readers with a clear, accurate, and transparent account of their acupuncture protocols as well as their control and/or comparator procedures. To some extent, we believe that it will provide help in improving the quality of reporting. Based on the nature of acupuncture and the necessity of reporting, however, some additional key elements should be involved in the reporting about acupuncture trials. These additional key elements are as follows.

Acupuncture Rationale

In the list of revised STRICTA, acupuncture rationales include (1) style of acupuncture; (2) reasoning for treatment provided, based on historical content, literature sources, and/or consensus methods, with references where appropriate; and (3) extent to which treatment was varied. As a reader, however, it is necessary to know why this trial should be conducted. Probably, many preparatory works have been done, and the authors themselves know why this trial is necessary, but for the readers, they may not have the chance to know such a rationale. Thus, besides those items in the revised STRICTA, "why the trial should be conducted" may need to be added in the "acupuncture rationale" part.

Needling Details

The revised STRICTA indicates that (1) number of needle insertions per subject per session; (2) names (or location if no standard name) of points used (uni/bilateral); (3) depth of insertion, based on a specified unit of measurement, or on a particular tissue level; (4) response sought (e.g., *de qi*, or twitch response), (5) needle stimulation (manual or electrical), (6) needle retention time, and (7) needle type (diameter, length, and manufacture or material) should be involved in the reporting. This revised version about the needling is clearer than that of the old version of STRICTA. Some additional details about needling should be involved in the reporting, though.

Points used

Theoretically, if the points used are reported, the reader should know precisely where the patient is being treated. However, the true situation is that there is no worldwide standard of acupoints. It was reported that acupuncturists differed by up to 25% in the location of acupuncture points they used.[2] The World Health Organization Western Pacific Regional Office initiated a project to reach consensus on acupuncture point locations and set guidelines. Their publication, Standard Acupuncture Point Locations in the Western Pacific Region,[2] stipulates the methodology for locating acupuncture points on the surface of the human body, and gives the locations of 361 acupuncture points. One could argue whether these standards apply elsewhere in the world. Unfortunately, that publication has no mandatory power to ensure that all those conducting acupuncture trials adhere to these standards. Discrepancies between regions can cause much trouble for readers, and also can cause much trouble in the interpretation and comparison of trial results. In order to avoid this problem, listing the location of each acupoint used in the trial and methods used to identify the location of the acupoints might be a more appropriate and expedient recommendation.

Insertion

Regarding the insertion, only one factor mentioned in the revised STRICTA is depth of insertion, based on a specified unit of measurement, or on a particular tissue level. Also, the revised version mentioned in the explanation part that "For some trials, the protocol might specify the angle and direction of insertion along with depth of insertion, in which case these should also be reported." It is known that the elements

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about insertion involve, at least, the following: (1) the angle/direction of insertion; (2) the manipulation method involving thrusting, lifting, and rotating techniques; and (3) intensity of these manipulation methods. These factors seem to play an important role because they will affect the efficacy of acupuncture based on Traditional Chinese Medicine theories.[3,4] For example, based on these theories, a different direction/angle of acupuncture stimulation will result in different efficacy,[5] while different density of stimulation will also result in a different effect.[6] Therefore, to list the angle of insertion and the direction of twitch may help the readers to repeat the trial results. It is not enough to list these elements just in the trials that specify the angle and direction of insertion in the protocol. It is essential for all the trials with acupuncture.

Control Intervention(s)

The items listed in the revised STRICTA statement involve (1) rationale for the control or comparator in the context of the research question, with sources that justify this choice; and (2) precise description of the control or comparator. Furthermore, we believe that the patients' experience of acupuncture treatment and the success rate of blinding may be helpful, if not necessary.

Why is a patient's experience of acupuncture treatment relevant to the outcome of the trial? In a sham acupuncture control trial, patients' experiences can affect the result of the trial; that is, if a patient knows how effective acupuncture feels and he or she does not feel it, the patient will suspect they are receiving sham, not true, acupuncture. One (1) study concluded that potential factors that influence the applicability of "placebo" needling include not only intertester variability but also the patient's knowledge and experience of acupuncture, acupuncture point selection, the visual impact of needling, and so on.[7] However, another study in a Korean population showed the opposite result (i.e., that previous experience does not affect people's expectation and does not hinder people from experiencing *de qi*).[8] Based on these contradictory results, whether experienced people can identify sham acupuncture, and whether that affects the outcome deserve further study. For this reason, it is necessary to list the patients' experiences of acupuncture treatment in the report.

With regard to the successful rate of blinding in sham-acupuncture controlled trials, reporting such a rate will let the reader know patients' perceptions toward the treatment they received.[9] We also noted that the CONSORT 2010 did not list "how the success of blinding (masking) was assessed" as a necessary item, "because of a lack of empirical evidence supporting the practice as well as theoretical concerns about the validity of any such assessment."[10] However, as to the acupuncture trial, patients' experience of acupuncture will affect the results of the trial. Also, the sham design of acupuncture and whether a patient can identify the true and sham acupuncture will affect the results of the trial, especially those trials for which the outcomes are connected with subjective judgment, such as pain. Therefore, it is recommended to list the success of blinding in the trial report.

In conclusion, the suggested points for the revised STRICTA are as follows: (1) to explain why the trial should be conducted; (2) to list the location of each acupoint used in the trial and methods used to identify the location of the acupoints; (3) to list the angle of insertion and the direction of twitch in each trial; (4) to list the patients' experiences of acupuncture treatment in the report; and (5) to list the successful rate of blinding. These items will add important information about the trials, and help readers to understand and repeat the trial.

Disclosure Statement

No competing financial interests exist.

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