

The STRICTA Recommendations: Improving Standards in Acupuncture Research

By Editorial Staff

First published in 1996, the Consolidated Standards for Reporting Trials statement, also known as CONSORT, set a benchmark for the way randomized, controlled trials should be conducted by the scientific community.

While many of the general problems previously associated with controlled trials have been addressed by the CONSORT statement, there remain issues regarding clear documentation in certain areas of trial design and implementation, most notably the lack of precise standards for reporting interventions in treatment and control groups, which are not covered by CONSORT. A lack of these standards has frequently been cited as a concern in reviews of controlled acupuncture trials.

Last year, a group of internationally-respected acupuncture researchers met at the United Kingdom's Exeter University to address the situation, and to discuss the design of clinical acupuncture trials in general. The group was faced with a rather daunting task: creating a set of recommendations that would cover a wide range of treatment styles and trial designs without being too weak or too stringent.

The result of the group's work was the drafting of a new set of recommendations known as the Standards for Reporting Interventions in Controlled Trials of Acupuncture, or STRICTA, which have been finalized and are being incorporated into the guidelines of several acupuncture and complementary medicine journals. Implementing these recommendations, the researchers feel, will improve the overall quality of acupuncture trials, which is hoped will lead to better study designs, more convincing results, and less criticism of randomized, controlled acupuncture studies.

The STRICTA Recommendations: A Closer Look

The STRICTA recommendations consist of a six-item checklist that covers all aspects of study interventions, including: acupuncture rationale; needling details; treatment regimen; co-interventions; practitioner background; and control interventions. They are intended to be used in conjunction with CONSORT as an extension to that statement's intervention checklist.

Checklist for STRICTA Recommendations			
Intervention	Item	Description	Reported on page #
Acupuncture rationale	1	Style of acupuncture Rationale for treatment (e.g., syndrome patterns, segmental levels, trigger points) and individualization if used Literature sources to justify rationale	
Needling details	2	Points used (bilateral/unilateral) Numbers of needles inserted Depths of insertion (e.g., <i>cun</i> or tissue level) Responses elicited (e.g., <i>de qi</i> or twitch response) Needle stimulation (e.g., manual or electrical) Needle retention time Needle type (gauge, length, and manufacturer or material)	
Treatment regimen	3	Number of treatment sessions Frequency of treatment	
Co-interventions	4	Other interventions (e.g., moxibustion, cupping, herbs, exercises, lifestyle advice)	
Practitioner background	5	Duration of relevant training Length of clinical experience Expertise in specific condition	
Control interventions	6	Intended effect of control intervention and its appropriateness to research question and, if appropriate, blinding of participants (e.g., active comparison, minimally active penetrating or nonpenetrating sham, inert) Explanations given to patients of treatment and control interventions, details of control intervention (precise description, as for Item 2 above, and other items if different) Sources that justify choice of control	

Acupuncture Rationale

The acupuncture rationale should include a statement about the style of acupuncture being used, along with an explicit rationale for the chosen treatment, including diagnosis, point selection and treatment procedures. If treatment is individualized, the rationale for those treatments should be documented. The sources that

justify the use of treatment must also be explicit.

Needling Details

Among the features that should be clearly documented:

- Specific point locations, whether unilateral or bilateral, should be described using standard nomenclature and/or anatomical locations;
- The number of needles inserted should be reported either as a simple total in cases where a specific formula is used, or as a mean and range in cases where the number of needles varies between patients;
- The depth of needle insertion, whether standardized among a treatment group or individualized between subjects, should be expressed in terms of Chinese units (*cun*), tissue level, or millimeters;
- Responses to needling, such as *de qi*, muscle twitch or muscle contraction should be noted, if the study design requires the elicitation of these responses;
- Needle stimulation techniques, whether manual or electrical, should be clearly described;
- Needle retention times - either as a standard for all patients or a mean/range between patients - should be recorded;
- Other needle details, such as the gauge and length of the needle, the manufacturer of the product, and the material the needle is made of - are of great importance and must be included.

Treatment Regimen

The number and frequency of treatment sessions should be clearly documented. If there is variation in the treatment regimen between patients, the mean and range numbers should be reported.

Co-interventions

Cointerventions refer to any auxiliary techniques (e.g., moxibustion, cupping, herbal remedies), prescribed self-treatment (such as *qigong*, *tai chi* or stretching exercises) and lifestyle practices (such as changes in diet or exercise routines) carried out by a patient as an adjunct to acupuncture. Any cointerventions must be reported clearly. If the treatment protocol includes the option of lifestyle and self-help treatments, these options must be reported as well.

Practitioner Background

The STRICTA recommendations recognize that an acupuncturist's background and experience can have a significant impact on the outcome of the type of treatment given. For this reason, it is suggested that authors provide a variety of information on the person providing treatment, including the duration of relevant training, length of clinical experience, and any details on the practitioner's expertise in treating the condition being studied.

Control Interventions

A precise description of the control intervention being used should be presented, including any aspects of the trial (needling details, treatment regimen) that may be different from those used on the acupuncture group. The credibility of the control should also be tested and reported, and any sources that led the investigators to choose a particular type of control should be provided.

The choice of control used in a study, as well as its intended effect, should be presented and justified in relation to the research question (or questions) the trial is attempting to answer and, if appropriate, whether the study participants are being blinded. Particular care should be taken if the control group will be subject to sham acupuncture; in these instances, investigators must describe precisely what sham acupuncture is being used to control for.

Finally, the recommendations state that all information given to a patient, whether in a control or treatment group, should be documented, including any relevant wording that may influence the outcome of care.

STRICTA and its Meaning to Future Trials

Research has shown the CONSORT statement to have a positive effect on the reporting of randomized, controlled trials since it was first published six years ago.^{1,2} In a report published in the *Journal of Alternative and Complementary Medicine*,³ two members of the STRICTA Group, along with the editors of several leading acupuncture and complementary medicine journals, emphasized their belief that the STRICTA recommendations will have a similar positive influence on the reporting of acupuncture trials.

"It is intended that implementation of the STRICTA recommendations will reduce inadequate reporting of acupuncture trials, facilitating an improvement in their critical appraisal and interpretation," the authors wrote. "It is hoped that over time, use of the STRICTA recommendations will read to more rigorous trial design, more robust conclusions, and better data to determine future policy and practice."

The Foundation for Traditional Chinese Medicine, located in the United Kingdom, has posted the STRICTA recommendations on its website at www.ftcm.org.uk/stricta.htm. As with the CONSORT statement, the STRICTA recommendations are deemed a work-in-progress and are subject to change. To help improve these guidelines, interested parties are welcome to review the document and send their comments to Hugh McPherson, STRICTA group coordinator, at hugh@ftcm.org.uk.

References

1. Moher D, Jones A, Lepege L. Use of the CONSORT statement and quality of reports of randomized trials: a comparative before-and-after evaluation. *JAMA* 2001a;285:1992-1995.
2. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet* 2001b;357:1191-2001.
3. MacPherson H, White A, Cummings M, et al. Standards for reporting interventions in controlled trials of acupuncture: the STRICTA recommendations. *Journal of Alternative and Complementary Medicine* 2002;8(1):85-89.



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