Standards for reporting interventions in controlled trials of acupuncture: the STRICTA recommendations

H. MacPherson,[1] A. White,[2] M. Cummings,[3] K. Jobst,[4] K. Rose,[5] R. Niemtzow[6] for the STRICTA group

[1]Co-ordinator for the STRICTA* Group [2]Editor, Complementary Therapies in Medicine [3]Editor, Acupuncture in Medicine [4]Editor, Journal of Alternative and Complementary Medicine [5]Editor, Clinical Acupuncture and Oriental Medicine [6]Editor, Medical Acupuncture

SUMMARY. Acupuncture treatment and control group interventions in parallel-group randomised trials of acupuncture are not always precisely reported. In an attempt to improve standards, an international group of experienced acupuncturists and researchers devised a set of recommendations, designating them STRICTA: STandards for Reporting Interventions in Controlled Trials of Acupuncture. In a further consensus-building round, the editors of several journals helped redraft the recommendations. These follow the Consolidated Standards for Reporting Trials (CONSORT) format, acting as an extension of the CONSORT guidelines for the specific requirements of acupuncture studies. Participating journals are publishing the STRICTA recommendations and requesting prospective authors to adhere to them when preparing reports for publication. Other journals are invited to adopt these recommendations. The intended outcome is that interventions in controlled trials of acupuncture will be more adequately reported, thereby facilitating an improvement in critical appraisal, analysis and replication of trials.

INTRODUCTION

The need for more precise standards of reporting of interventions in controlled trials of acupuncture is evident from the difficulties associated with their interpretation and analysis.[1] Many of the more general problems have been addressed by the recently revised Consolidated Standards for Reporting Trials (CONSORT) statement.[2,3] Within acupuncture research, however, there remain specific aspects of controlled trials that are poorly documented, in particular those aspects that relate to interventions, for both the treatment and control groups. These are not sufficiently covered by CONSORT.

An international group of acupuncture researchers met at Exeter University, England, UK, from 2nd to 4th July 2001 to discuss the design of clinical trials of acupuncture. The group also drafted a set of recommendations for improved reporting of the interventions in parallel-group trials of acupuncture. These recommendations were designated **ST**andards for **R**eporting **I**nterventions in **C**ontrolled **T**rials of **A**cupuncture or STRICTA. They are intended for use in conjunction with CONSORT, as an extension to the CONSORT checklist item on intervention.

The editors of several key journals that publish clinical trials of acupuncture were invited to participate in re-drafting the recommendations. The overall aim was to achieve a broad set of recommendations that would cover the most common approaches to acupuncture and research design.

Dr Hugh MacPherson
Co-ordinator for the STRICTA group, c/o Foundation for Traditional Chinese Medicine, 122A Acomb Road, York YO24 4EY, UK.
E-mail: hugh@ftcm.org.uk

*Members listed in Appendix 1

doi:10.1054/ctim. 2001.0488, available online http://www.idealibrary.com on IDEAL®

The recommendations had to be appropriate for a range of styles, from western trigger point treatment to traditional Chinese acupuncture, and from electroacupuncture to auricular acupuncture. They also had to cover the spectrum of randomized controlled trial designs, from explanatory trials evaluating the specific effects of needling, to pragmatic trials evaluating the broader effects of acupuncture in routine practice.

The recommendations are being published by the editors of Acupuncture in Medicine, Clinical Acupuncture and Oriental Medicine, Complementary Therapies in Medicine, Journal of Alternative and Complementary Medicine and Medical Acupuncture as part of their Instructions to Authors. 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.[4] It may also help with some specific challenges, such as developing criteria for assessing the adequacy of acupuncture treatment in earlier studies.[5] It is hoped that, over time, use of the STRICTA recommendations will lead to more rigorous trial design, more robust conclusions and better data to determine future policy and practice.

THE STRICTA RECOMMENDATIONS (SEE TABLE 1)

Acupuncture rationale

The acupuncture rationale, the first item on the STRICTA checklist, should include a statement about the style of acupuncture used, whether for example traditional Chinese medicine or a western medical approach. It should also include an explicit rationale for the chosen treatment, including diagnosis, point selection and treatment procedures. Where a trial protocol includes individualisation of treatment, the rationale for the treatments should be documented. Whatever the active intervention, the sources that justify the underlying rationale must be explicit, whether these are from the literature, expert clinical and research panels, practitioner surveys or a combination of sources.

Needling details

The specific point locations, and whether unilateral or bilateral, should be described in terms of a standard nomenclature or in terms of anatomical location. The number of needle insertions should

Table 1 Checklist for STRICTA - standards for reporting interventions in controlled trials of acupuncture.

Intervention	Item	Description	Reported on page #
Acupuncture rationale	1	Style of acupuncture Rationale for treatment (e.g. syndrome patterns, segmental levels, trigger points) and individualisation if used Literature sources to justify rationale	
Needling details	2	Points used (uni/bilateral) Numbers of needles inserted Depths of insertion (e.g. *cun* or tissue level) Responses elicited (e.g. *de qi* 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, life-style advice)	
Practitioner background	5	Duration of relevant training Length of clinical experience Expertise in specific condition	
Control intervention(s)	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 non-penetrating 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	

Checklist of items to include when reporting on the interventions in a randomized controlled trail of acupuncture.

be reported as either a simple total where a formula of points is used, or as the mean and range where the number of needles varies between patients. The depth of insertion, and whether standardised or individualized, should be expressed using the Chinese measurement of the *cun*; in terms of anatomical depth, for example subcutaneous tissue, fascia, muscle or periosteum; or in millimetres. If the study protocol requires that specific responses to needling be elicited, for example the *de qi* sensation in traditional Chinese acupuncture, the muscle twitch in trigger point treatment or muscle contraction in electroacupuncture, these responses should be documented. Needle stimulation techniques, where used, should be clearly described. For manual stimulation such techniques include lifting, thrusting or rotating the needle to manipulate the de qi sensation. For electrical stimulation the current, amplitude and frequency settings should be recorded. Needle retention times should be reported, as either a standard or a mean and range. Details should be given of the types of needles used, including the gauge and length as well as the manufacturer and/or the material.

Treatment regimen

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

Co-interventions

Co-interventions refer to the auxiliary techniques and prescribed self-treatment and lifestyle advice carried out by the patient as an adjunct to the acupuncture needling itself. All co-interventions should be clearly reported. Examples of auxiliary techniques include moxibustion, cupping, plum-blossom needling and Chinese herbs. If the protocol specifies the option of prescribed self-help treatments such as Qigong or muscle stretching exercises, and lifestyle advice such as dietary changes based on diagnostic criteria, then these too must be reported.

Practitioner background

The background of acupuncture practitioners will influence the nature of the acupuncture treatment given and is therefore a variable that may significantly affect the outcome. For this reason reporting should include the duration of relevant training, length of clinical experience, and details of expertise in treating the specific condition being evaluated, as well as any other experience that may be relevant to the trial.

Control intervention(s)

The choice of control and its intended effect should be presented and justified in relation to the research question and the methodology. Sources that led to the choice of control, such as literature, should be provided. In particular, where the control is intended to mimic acupuncture in all but the specific needle puncture effect, care must be taken to describe precisely what the sham acupuncture is intended to control for, e.g. for point specificity or for the type and duration of stimulation. Control procedures may involve an active comparator, such as physiotherapy, for which the intended action is therapeutic. However control procedures involving invasive or non-invasive sham needling techniques may be minimally active, evoking a neurophysiological and/or neurochemical response. Other control procedures can be assumed to be inert, such as an inactivated TENS machine, however these procedures may not have the same total psychological impact as acupuncture, thereby compromising outcome. The information that the patient receives regarding the treatment and control intervention should be provided, including relevant wording on the information leaflet. Describing a sham acupuncture control as 'a type of acupuncture' may affect outcome differently than saying it is 'not acupuncture, but will involve a similar experience to acupuncture'. The credibility of the control, which often depends on the inclusion of acupuncture-naïve patients, needs to be tested and reported. Finally, a precise description of the control intervention itself should be presented, including needling details, and regimen if different from that used in the acupuncture group.

DISCUSSION

The CONSORT statement was first published in 1996[6] and subsequent evidence has shown it to be associated with a positive influence on the quality of trial reporting.[7] It is intended that these STRICTA recommendations will have a similarly positive influence on the reporting of acupuncture trials and thus help critical appraisal, analysis and interpretation of future controlled trials.

The STRICTA recommendations have been adopted by several participating journals that regularly publish in the field of acupuncture research. They have all agreed to recommend the STRICTA guidelines in their Instructions for Authors. Journals that have not yet adopted STRICTA may do so by registering with the lead author who is the co-ordinator of the STRICTA group. A full list of journals that have adopted STRICTA is available at: www.ftcm.org.uk/stricta.htm.

Like CONSORT, the STRICTA recommendations are a work-in-progress that will be updated. As with the CONSORT checklist, *ad hoc*

modifications to the STRICTA criteria are not encouraged because the process of generating consensus may differ from that used by the STRICTA participants. To help improve these guidelines, readers are invited to comment on the STRICTA checklist directly to the STRICTA group coordinator, identifying gaps or areas of ambiguity and suggesting improvements and additions. These contributions will be fed into the next round of re-drafting.

APPENDIX 1

Members of the STRICTA Group

An international group of experienced acupuncturists and researchers met July 2nd to 4th 2001 at Exeter University, Exeter, England, UK. This group first drafted these recommendations, designating them STRICTA, and initiated the plan to encourage journals in the field to adopt them. Participating in this group were Steve Birch, Stichting for Traditional East Asian Medicine, Amsterdam, Holland; Mark Bovey, University of Exeter, UK; Sarah Budd, University of Exeter, UK; Richard Hammerschlag, Oregon College of Oriental Medicine, Portland, USA; Val Hopwood, Acupuncture Association of Chartered Physiotherapists, Coventry, UK; Kenji Kawakita, Meiji University of Oriental Medicine, Japan; Lixing Lao, University of Maryland, USA; George Lewith, University of Southampton, UK; Hugh MacPherson, Foundation for Traditional Chinese Medicine, York, UK; Simon Mills, University of Exeter, UK; Marco Romoli, Federazione Italiana Società di Agopuntura, Prato, Italy; Karen Sherman, Centre for Health Studies, Seattle, USA; Sonya Pancucci, KST Health Services, Hamilton, Canada; Kien Trinh, McMaster University, Canada; Adrian White, University of Exeter, UK; and Chris Zaslawski, University of Technology, Sydney, Australia.

ACKNOWLEDGEMENTS

The authors would like to thank Professor JW Thompson for his useful comments on the STRICTA checklist and Dr Jaqueline Filshie for her contribution to the article.

REFERENCES

1. Ter Riet G, Kleijnen J, Knipschild P. Acupuncture and chronic pain: a criteria-based meta-analysis. J Clin Epidemiol 1990; 43(11): 1191–1199.
2. Moher D, Schulz KF, Altman DG, for the CONSORT Group. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. Lancet 2001; 357(9263): 1191–1194.
3. Altman DG, Schulz KF, Moher D, Egger M, Davidoff F, Elbourne D *et al.* The revised CONSORT statement for reporting randomized trials: explanation and elaboration. Ann Intern Med 2001; 134(8): 663–694.
4. Jobst KA and Eskinazi D (Eds). United States National Institutes of Health Report for the FDA on the status of Acupuncture in the USA. J Altern Complement Med 1996; 2(1): 1–353.
5. White AR, Ernst E. A trial method for assessing the adequacy of acupuncture treatments. Altern Ther Health Med 1998; 4(6): 66–71.
6. Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I et al. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. JAMA 1996; 276(8): 637–639.
7. Moher D, Jones A, Lepage L. Use of the CONSORT statement and quality of reports of randomized trials: a comparative before-and-after evaluation. JAMA 2001; 285(15): 1992–1995.