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ORIGINAL ARTICLE

Improving the quality of reporting acupuncture interventions: describing the collaboration between STRICTA, CONSORT and the Chinese Cochrane Centre

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Abstract

Background First published in 2001, STRICTA (STandards for Reporting Interventions in Controlled Trials of Acupuncture) was designed to expand on the reporting of one item within the CONSORT (Consolidated Standards of Reporting Trials) Statement checklist, the item relating to the intervention. Two recent reviews had found that STRICTA was highly regarded in the field and that there was a need for minor revisions.
Objective To revise STRICTA within the CONSORT of family of reporting guidelines.
Design A collaborative effort involving the STRICTA Group, the CONSORT Group and the Chinese Cochrane Centre was agreed. A consultation process with 47 international experts provided detailed feedback on an initial draft of a revised checklist. These data, along with the two review studies, comprised the documentation for a consensus meeting in Freiburg, Germany in October 2008. A total of 21 participants attended the meeting, bringing their expertise as research methodologists, reporting guideline developers, acupuncturists, physicians and journal editors.
Results At the workshop, a revised draft checklist was agreed. There was general consensus that STRICTA should continue to function as a stand-alone guideline as well as an extension to CONSORT. It was agreed that STRICTA should be sufficiently broad to cover all type of clinical studies, from case reports through uncontrolled studies to randomised controlled trials. It was also decided that explanations and examples, as with other CONSORT reporting guidelines, would provide a useful way of supporting the uptake to the new recommendations when published.
Discussion The checklist will be subjected to further revision processes in order to further its impact and support wider dissemination. Journals that regularly publish acupuncture trials will be encouraged to adopt the revised STRICTA, include it in their guidelines for authors, and promote the adoption of its recommendations for clinical studies of acupuncture.

Background to CONSORT and STRICTA

Published in 1996 and revised in 2001, the CONSORT (Consolidated Standards of Reporting Trials) Statement, set out guidelines that are designed to improve the reporting of parallel-group randomised controlled trials (RCTs) (1, 2). The use of these guidelines has been associated with better quality of reporting in RCTs (3). To cover various reporting requirements for particular types of trial, the

CONSORT Statement has been extended for cluster randomised trials(4), non-inferiority and equivalence trials(5); herbal interventions(6); reporting of harms(7); non-pharmacological treatments(8); and pragmatic trials (9) (see www.consort-statement.org).

In 2001, the STRICTA (STandards for Reporting Interventions in Controlled Trials of Acupuncture) recommendations were published (see: www.stricta.info) (10). The initiative came about because of widespread dissatisfaction with levels of reporting within published reports of acupuncture trials. In addition, the CONSORT Statement did not adequately cover some aspects that are characteristic of acupuncture trials. Acupuncture is usually practiced in a way that is made up of multiple components, and as such can be viewed as a complex intervention (11). There are inherent difficulties in describing, standardising, delivering, and replicating complex treatments. For more pragmatic trial designs, where practitioners are instructed to do what they normally would, the complexity leads to the challenge of not knowing precisely what aspects of the intervention to associate outcomes with. For more explanatory trial designs, there are difficulties associated with providing an adequate sham intervention and ensuring the integrity of the blinding. For all trial designs, it was clear that a useful step would be to improve the reporting of the actual intervention that was delivered to patients.

The STRICTA guidelines were developed by an international group who met in Exeter, England and were subsequently refined by a group of five journal editors who co-published the final version. STRICTA was developed by expanding on one item from within CONSORT: item 4, which sets out the requirements for reporting the intervention. The six STRICTA items that were designed to replace this one item from CONSORT were the acupuncture rationale, the needling details, the treatment regimen, the co-interventions, the practitioner background and the control intervention(s). Most of these items had sub-items. The guiding principle was that better reporting of these STRICTA items and sub-items would improve the completeness and transparency of reporting of interventions in controlled trials of acupuncture, in order that they may be more accurately interpreted and more easily replicated.

Recent reviews of STRICTA's utility and impact

After six years had elapsed since the publication of STRICTA, it was thought timely to evaluate the recommendations to determine how well they were working, whether there were specific problems, and whether there seemed a need for a revision. We conducted two studies to help resolve these issues. First we surveyed 38 randomly selected authors of clinical trials and 14 authors of Cochrane acupuncture reviews and protocols to determine how useful the STRICTA items were to them (12). We sought their opinion in a questionnaire that asked them to rate the utility of each STRICTA item as well as provide qualitative feedback on their overall experiences of using STRICTA. The 28 respondents to the questionnaire tended to rate the utility of STRICTA items highly overall, with the exception of five sub-items: literature sources to justify the acupuncture rationale, intervention needle type, and the three items that pertained to details on the trial acupuncturist's background. Authors also identified several items that were unclear, ambiguous or redundant, and questioned the appropriateness of STRICTA for some trial designs. Because of word limits, some authors reported that they had to delete from their manuscripts some of the acupuncture intervention-specific reporting. We also noted that very few acupuncture studies were published in the five STRICTA-adopting journals.

Concurrently with this review of attitudes to STRICTA, we conducted a before-and-after systematic review of 90 acupuncture trials to determine whether STRICTA had had an impact on the reporting of these trials over time (13). We randomly sampled acupuncture studies that were published in three distinct time periods: 1994–1995 (before the publication of the original CONSORT(14)), 1999–2000 (before the publication of the revised version of CONSORT (1) and before the publication of original STRICTA) and 2004–2005 (for sufficient time to pass). We detected a statistically significant improvement in the reporting of CONSORT items over time for these acupuncture trials. We found no evidence of any change in the levels of reporting of STRICTA items. We also obtained useful information on which STRICTA items were well reported and which ones were not. The conclusion from these two reviews was that STRICTA was highly valued, that there was considerable interest in a revision, and that we had obtained highly relevant data that would help guide such a process.

Methods for revising STRICTA as an extension to CONSORT

As a result of the evaluations discussed above, a meeting was arranged between members of the CONSORT Executive and the STRICTA Group. It was decided that working together would be helpful in revising STRICTA, with the intention that it should be an official extension to CONSORT. Subsequent to this initial agreement, the Chinese Cochrane Centre and the Chinese Centre for Evidence-based Medicine were invited to join the collaboration, as they had already been working on a "CONSORT for Traditional Chinese Medicine (TCM)"(15) and had an interest in developing reporting guidelines for acupuncture research. The need for a Steering Group for the revision process was agreed, and comprised two members of the STRICTA Group, two members of the CONSORT Executive and two members from the Chinese Cochrane Centre.

The revision process was thought to benefit from the recent publication of the extension to CONSORT for the reporting of non-pharmacological interventions (8,16). To some extent this extension covers similar ground to STRICTA, as acupuncture is a non-pharmacological intervention. However, there are acupuncture specific aspects to reporting that are not covered by the non-pharmacological interventions extension. The decision was taken therefore to revise STRICTA in a manner that would be congruent with both this extension and CONSORT more generally. It was agreed that the combination of these various developments provided an excellent platform for developing a revision to STRICTA.

The next step towards revising STRICTA took place in the summer of 2008 when we consulted a group of 47 experts from across the field. We elicited feedback on a draft of potential revisions that had been developed by the Steering Group taking account of findings from the afore-mentioned two reviews (12, 13). These experts were drawn from many groupings, including the STRICTA Group, the CONSORT Group, the World Federation of Acupuncture and Moxibustion Societies, the Acupuncture Trialists' Collaboration (17), the Society for Acupuncture Research (18), trial authors who had been consulted in a previous study (12), and others recommended by respondents. The respondents were drawn from 15 different countries. Forty-one had academic positions, 31 were acupuncturists, 18 had journal connections (for example as editors or editorial board members), 15 were physicians, and 11 had been previously involved in developing reporting guidelines. We collated a complete set of feedback from these respondents, which was to form one of the working documents for the next phase, the consensus workshop.

Held in Freiburg, Germany in October 2008, a consensus-building workshop was designed with the aim of reaching agreement on appropriate revisions to the STRICTA items. The 21 attendees were drawn from the STRICTA Group, the CONSORT Group and the Chinese Cochrane Centre, as well as others with an interest in the field. Their expertise included epidemiology, trial methodology, statistics, and acupuncture. Many were physicians, and several had additional roles such as journal editors and peer reviewers. At this workshop, a revised checklist developed by the Steering Group was presented, which incorporated the additional feedback from the previous round with the 47 experts. Some generic issues relating to the revised STRICTA were agreed from the outset. First, that STRICTA should continue to function as both a stand-alone guideline and to function as an extension to CONSORT. Second, that the new checklist for STRICTA should be shown as embedded within the checklists of CONSORT and its non-pharmacological extension. Third, it was agreed that the question: "Is the information sufficient to replicate this study?" should guide the thinking on reporting interventions. Fourth, there was agreement that the word "controlled" within the title of STRICTA should be changed to "clinical" on the basis that the recommendations should cover all types of clinical studies, from case reports through uncontrolled studies to randomised controlled trials. Fifth, it was decided that explanations and examples, as with other CONSORT reporting guidelines, would provide a useful way of supporting the uptake of the new recommendations when published.

Next steps for finalising the revision of STRICTA within CONSORT

To complete the revision of STRICTA, a few further steps will be required. Agreement among collaborators on the new checklist is necessary and the associated explanations and examples must be developed, with the intention that these improve the take-up of STRICTA when published. Then there are the challenges of publication and wider dissemination. A number of journals have indicated an interest in co-publishing the revised version, and it is hoped that all adopting journals will include the requirement in their instructions to potential authors of acupuncture studies that they follow STRICTA as an extension to CONSORT. The first English language version of STRICTA was translated into Chinese, Japanese and Korean, and it is intended that the revised STRICTA will also be published and disseminated in these and other languages. To conclude, it is hoped that the promotion of this extension will improve the quality of reporting of acupuncture studies, which in turn will enhance interpretation and ease replication.

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