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Revised Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): Extending the CONSORT statement☆

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A B S T R A C T

The Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) were published in five journals in 2001 and 2002. These guidelines, in the form of a checklist and explanations for use by authors and journal editors, were designed to improve reporting of acupuncture trials, particularly the interventions, thereby facilitating their interpretation and replication. Subsequent reviews of the application and impact of STRICTA have highlighted the value of STRICTA as well as scope for improvements and revision.

To manage the revision process a collaboration between the STRICTA Group, the CONSORT Group, and the Chinese Cochrane Centre was developed in 2008. An expert panel with 47 participants was convened that provided electronic feedback on a revised draft of the checklist. At a subsequent face-to-face meeting in Freiburg, a group of 21 participants further revised the STRICTA checklist and planned dissemination.

The new STRICTA checklist, which is an official extension of CONSORT, includes six items and 17 sub-items. These set out 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 interventions. In addition, and as part of this revision process, the explanations for each item have been elaborated, and examples of good reporting for each item are provided. In addition, the word "controlled" in STRICTA is replaced by "clinical", to indicate that STRICTA is applicable to a broad range of clinical evaluation designs, including uncontrolled outcome studies and case reports.

It is intended that the revised STRICTA, in conjunction with both the main CONSORT Statement and extension for nonpharmacologic treatment, will raise the quality of reporting of clinical trials of acupuncture.

1. Introduction

The STRICTA (Standards for Reporting Interventions in Clinical Trials of Acupuncture) reporting guidelines, first published in 2001 [1–9], were designed to improve the completeness and transparency of reporting of interventions in controlled trials of acupuncture, in order that such trials may be more accurately interpreted and readily replicated. STRICTA comprised a checklist that expanded the generic content of Item 5 of the CONSORT statement [10,11], which relates to the reporting of the intervention.

A survey of authors of clinical trials and systematic reviews was subsequently conducted to determine the usefulness of STRICTA in helping them write their reports [12]. In addition, a survey of 90 acupuncture trials was undertaken to assess whether use of the STRICTA checklist was associated with improved reporting over time [13]. The results of these initiatives led to conclusions that

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most STRICTA items were found to be necessary and easy to use, though some were seen as poorly reported, ambiguous or possibly redundant, and a number of suggestions were made for additional items. A revision of STRICTA was therefore proposed.

Meanwhile, extensions to CONSORT have been developed to cover the reporting of non-pharmacological treatments [14,15] and pragmatic trials [16]. Since there are acupuncture specific aspects to reporting not covered by these extensions, it was decided that STRICTA should be revised in a manner congruent with CONSORT and its extensions for non-pharmacological treatments and pragmatic trials.

The combination of these developments led to an agreement between the CONSORT Group and the STRICTA Group, in collaboration with the Chinese Cochrane Centre and the Chinese Centre for Evidence-based Medicine, to revise STRICTA as a formal extension to CONSORT. The revision processes have been described in more detail elsewhere [17]. This paper describes the outcome in terms of a new checklist, updated explanations, and published examples of good reporting.

2. Methods

In the summer of 2008, a group of 47 experts from the original STRICTA Group, the CONSORT Group, the World Federation of Acupuncture and Moxibustion Societies, the Acupuncture Trialists' Collaboration [18], the Society for Acupuncture Research [19], and clinical trial authors were surveyed [12]. The experts were from 15 countries, 41 had academic positions, 31 were acupuncturists, 18 were involved with journals, such as board members, 15 were physicians, and 11 had been involved previously in developing reporting guidelines. These experts were consulted in regard to a draft of revised STRICTA items that had evolved from previous research [12,13]. Feedback was collated and forwarded (with permission) to those invited to a consensus development workshop, the next phase of the revision process.

Twenty-one individuals attended a workshop in Freiburg, Germany, in October 2008. The attendees included experts in epidemiology, trial methodology, statistics, and medical journal editing. Just over half the participants were acupuncturists from a variety of backgrounds, including physician and non-physician. All attendees received collated feedback from the 47 experts, along with a draft revised STRICTA checklist for consideration.

The workshop comprised presentations about the history of STRICTA, CONSORT, and the then new CONSORT non-pharmacological treatments extension [14,15]. The results of two investigations into the utility and acceptability of STRICTA [12,13], and the subsequent consultation with the 47 experts, were also presented. A general discussion and agreement on generic issues relating to STRICTA were followed by a discussion of each nominated checklist item. The aim was to agree, where possible, on the content of the updated draft checklist as well as to develop a revised set of explanations for each included item.

Subsequent to the workshop, a small writing group edited drafts of the revised STRICTA checklist, identifying for each item one or more exemplars of good reporting, and developed text explaining the rationale and discussing relevant evidence. Taking into account further feedback from those attending the Freiburg workshop, the writing group finalised the STRICTA checklist, the explanations and the examples of good reporting.

3. Results

There was agreement that STRICTA should continue to function as a stand-alone guideline for reporting acupuncture studies, and be an official extension of CONSORT for reporting randomized controlled trials. There was also consensus on a minor change of name, in that the word "controlled" in STRICTA should be replaced by "clinical", to indicate that it was applicable for reporting a broad range of clinical evaluation designs, including uncontrolled outcome studies and case reports. The group agreed that the rationale behind reporting should be to provide the information needed to allow replication of a study, reduce ambiguity and enhance transparency. The group recognised that acupuncture trials inevitably differ in the degree of individualisation of care that is permitted, and agreed that the reporting guideline should acknowledge this and be applicable across the whole range of designs. The group also suggested that the revised STRICTA statement, when published, should be presented as embedded within the two-group parallel trial CONSORT checklist [10] and its non-pharmacological treatment extension checklist [14].

The revised STRICTA checklist comprises six items broken out into seventeen sub-items (Table 1). Table 2 presents how the revised STRICTA checklist fits within the CONSORT checklist [10] and its extension for non-pharmacological treatments [14]. Below we provide the checklist text for each of the six items and their sub-items, as well as explanations on the need for their adequate reporting and examples of good reporting from the published literature.

3.1. STRICTA item 1: acupuncture rationale

3.2. Item 1a

Style of acupuncture (e.g. Traditional Chinese Medicine, Japanese, Korean, Western medical, Five Element, ear acupuncture, etc.).

3.2.1. Explanation

Acupuncture has a long history in many cultures and is characterised by a broad diversity of styles and approaches in both East Asia and the West [20]. In order for the readers to contextualize the trial within the range of current clinical practices, researchers should state the overall style or approach on which they have based the treatments. If the researcher believes the treatment approach is completely novel, then this should be clearly stated.

3.2.1.1. Examples[2].

(i) We based the acupuncture point selections on Traditional Chinese Medicine meridian theory to treat knee joint pain, known as the "Bi" syndrome [21].
(ii) Participants were randomized to two styles of acupuncture: Japanese style (Kiiko-Matsumoto's Form) and Traditional Chinese Medicine style [22].
(iii) Four out of five of the acupuncturists primarily practised the Five Element style with a diagnostic focus on individual 'Causative Factors', (ref) and one used the Traditional Chinese Medicine (TCM) style with diagnosis primarily based on syndrome patterns (ref). Both styles are rooted in traditional acupuncture theory, and they are the most common traditional approaches used by professional acupuncturists in the UK today (ref) [23].
(iv) Each patient was treated with non-local needle acupuncture (according to the theory of channels of Traditional Chinese Medicine) at distant points, and dry needling of local myofascial trigger points [24].

[2] *Note*: In the Examples that follow, the embedded terms (ref) and (refs) refer to sources that are reported in the original published studies, but the details of these sources are not provided in this article for reasons of brevity.