

Towards better reporting of interventions in clinical trials of acupuncture

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The STAndards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) provide guidelines for authors reporting clinical trials of acupuncture. The aim for STRICTA is to help authors of clinical trials to clearly report the specific components of treatment that are provided within an acupuncture trial. In published reports we need complete, accurate, and transparent information on the intervention in order to better interpret and critically appraise the findings.

The problem of poor reporting of trials in publications has been addressed by the CONSORT (Consolidated Standards of Reporting Trials) Group. First published in 1996^[1] and then revised in 2001^[2] and 2010^[3], the CONSORT Statement set out guidelines that have been designed to improve the reporting of parallel-group randomised controlled trials. The most recent version, CONSORT 2010, consists of a 25 item checklist and a flow diagram, along with a set of explanations and examples of good reporting^[3, 4]. One of these items, Item 5, relates to the quality of reporting of the intervention. It has been noted within the conventional medical field that there have been problems of reporting interventions in clinical trials. Only around a half of such trials that were scrutinised in one study were found to adequately describe the intervention^[5]. The problem has also surfaced with regard to acupuncture trials. Not all reports of acupuncture trials have reported sufficient information on the acupuncture provided within the trial, such that the interpretation of the trial is compromised, and replication would not be feasible.

To encourage clear and complete reporting of acupuncture within clinical trials, the STRICTA Group first developed a guideline for reporting in 2001^[6]. The guideline was designed to replace the

one item in the CONSORT checklist related to the intervention, essentially providing an expanded checklist which contained 6 sub-items. The intention was that authors reporting on acupuncture trials would follow CONSORT for all items except the one related to the intervention, and for this item, the STRICTA checklist with six sub-items should be followed. The original STRICTA was co-published in five journals, and also translated and published in Chinese^[7, 8], Korean^[9] and Japanese^[10].

In parallel with the updated CONSORT^[3, 4], known as the CONSORT 2010 Statement, the STRICTA Group have recently revised the STRICTA guidelines. The details of this revision process, which included a literature review^[11], a survey of authors of previous trials^[12], an elicitation of opinion from a group of 47 experts, and a consensus meeting in Freiburg in Germany in 2008, have been set out elsewhere^[13]. The revised STRICTA has now been published as an official extension to CONSORT^[14, 15]. In the revised STRICTA, we have retained the six sub-items as before, but have focussed on improving details of the reporting that our international group of collaborators have identified as redundant, ambiguous, lacking in clarity, or otherwise worth improving. The revised STRICTA guidelines are currently being published in six journals, all of which have agreed that the paper will have open access. The revised STRICTA guidelines comprise not only a six-item checklist but also explanatory text with examples of good reporting. Also included in the STRICTA paper is the checklist for CONSORT 2010^[3] and the variation of this checklist for non-pharmacological interventions^[16].

Both STRICTA and CONSORT are highly relevant

to current research endeavours in China. Chinese authors reporting on their acupuncture trials should use both STRICTA and CONSORT when writing up their studies for publication. Each item on both checklists should be adequately reported. This will facilitate higher quality reporting, which in turn will enhance the impact of research conducted in China. Some efforts are being made to extend the mission of improving reporting guidelines to include the improving of research itself through the EQUATOR Network (www.equator-network.org). In the same way, it would be good to see STRICTA also having an impact on trial quality. It is hoped that STRICTA will contribute to the growing trend for acupuncture trials conducted in China to be considered to be sufficiently methodologically rigorous that they can be included with confidence in the systematic reviews of say the Cochrane initiative. In this context, the decision of the *Journal of Chinese Integrative Medicine* to publish the revised version of STRICTA in this issue is therefore of great value to researchers worldwide.

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更好地报告针刺临床试验中的干预措施

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“针刺临床试验干预措施报告的标准”(STandards for Reporting Interventions in Clinical Trials of Acupuncture, STRICTA)为作者报告针刺临床试验提供指南。STRICTA旨在帮助临床试验的作者明晰地报告针刺临床试验中所提供的治疗的特定组成部分。我们需要从已发表的试验报告中得到有关干预措施的完整、准确而又透明的信息,从而更好地解释并严格评价其研究结果。

CONSORT(Consolidated Standards of Reporting Trials, 临床试验报告的统一标准)工作组已着手应对发表的临床试验报告质量低下的问题。CONSORT声明于1996年首次发表^[1],之后于2001年^[2]和2010年^[3]作了修订,该声明为提高平行对照随机临床试验的报告质量制定了指南。最近的修订版即CONSORT 2010,包括一份含25项条目的对照检查清单和一张流程图,以及对全部条目的解释和良好报告的实例^[3, 4]。清单中的条目5涉及干预措施的报告质量。在西医领域中,临床试验干预措施的报告存在诸多问题并已引起注意。有一项研究对这类临床试验报告作了仔细审读,发现所核查的试验报告中仅约一半对干预措施进行了恰当的描述^[5]。在针刺临床试验报告方面这一问题也已引起注意。并非所有的针刺临床试验报告都充分地报告了有关试验中所用针刺方法的信息,这会影响对试验的解释,也使得试验结果难以重复。

为促进清晰而完整地报告临床试验中的针刺方法,STRICTA工作组最初于2001年制定了一份报告指南^[6]。该指南的目的实际上是制定一份包含6条二级条目的扩展清单以替代CONSORT清单中一项涉及干预措施的条目。其意图是,除了关于干预措施的一项以外,作者在报告针刺临床试验时要遵循CONSORT的其他所有条目,而对于该条目,则应该遵循STRICTA清单中的6条二级条目。原版STRICTA同时在5种期刊上发表,还被译成中文^[7, 8]、韩文^[9]和日文^[10]发表。

为了与CONSORT的更新版(即所谓“CONSORT

2010声明”)^[3, 4]同步,STRICTA工作组于近期修订了STRICTA指南。有关这次修订过程,包括文献回顾^[11]、对既往临床试验报告作者的调查^[12]、47位专家意见的汇总,以及2008年在德国弗莱堡(Freiburg)召开的共识会议等详情已在他处有过介绍^[13]。现在,修订版STRICTA已经被作为CONSORT的正式扩展版发表^[14, 15]。在修订版STRICTA中,我们像以前一样保留了6条二级条目,但主要针对如何改进报告的细节问题,包括我们这个国际性协作组成员认为冗长和含糊不清之处,或其他需要改进之处。修订版STRICTA指南目前在6种期刊上发表,这些期刊都已同意该文可以公开获取。修订版STRICTA指南不仅包含一份有6项条目的对照检查清单,而且还包含说明文字,并附有报告良好的实例。在STRICTA一文中还收入了CONSORT 2010对照检查清单^[3],以及针对非药物干预措施而对该清单所作的改动^[16]。

STRICTA和CONSORT两者都与当前中国的研究工作密切相关。报告针刺临床试验的中国作者在将其研究工作写成文章准备发表时应该同时使用STRICTA和CONSORT,对两份清单中的每一项条目都应予以充分报告。这将有助于提高报告质量,进而提高在中国开展的 research 的影响力。借助“提高医疗卫生研究的质量和透明性工作网”(Enhancing the Quality and Transparency of Health Research Network, EQUATOR Network; www.equator-network.org),人们正在作出一些努力以使完善报告指南的任务扩展到包括提高研究本身的质量。同样,我们也希望看到STRICTA对临床试验的质量产生影响。希望STRICTA将有助于在中国开展的日益增多的针刺临床试验在方法学上做到足够严谨,从而使其因为可信而能被纳入系统综述,比如Cochrane系统综述。居于这样的背景之下,《中西医结合学报》决定在本期发表STRICTA修订版对于全世界的研究人员都具有重大价值。

(李霄茜、周庆辉翻译,刘建平审校)