

CONSORT in China and its extension to TCM

CONSORT 在中國及其擴展：中醫藥臨床試驗報告指南

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1 June 2013



CONSORT Statement

- ❖ “Improve the reporting of a RCT, enabling readers to understand a trial's design, conduct, analysis and interpretation, and to assess the validity of its results.”
- ❖ “改善臨床試驗的報告質量，使讀者能明白試驗的設計，實施和分析，從而評估結果數據的真實性”

Milestone of CONSORT

- ❖ **1996** **First publication of CONSORT 首次發表**
- ❖ **2001** **Revision of CONOSRT 修改內容**
- ❖ **2001-2013** **Development extensions on design,
intervention and data (CONSORT family)
發表針對不同領域的擴展**
- ❖ **2010** **Further revision of CONSORT
發表修訂版 CONSORT 2010**

CONSORT 的扩展

- ❖ **Design Extensions 關於試驗試計**
 - Cluster trials (2004)
 - Non-inferiority and equivalence trials (2006)
 - Pragmatic trials(2008)

- ❖ **Intervention Extensions 關於干預措施**
 - Herbal medicinal interventions (2006)
 - Non-pharmacological treatment(2008)
 - Acupuncture Interventions (2010)

- ❖ **Data Extensions 關於數據資料**
 - Harms (2004)
 - Abstracts (2008)
 - Patient-reported outcomes (2013)

“Use of the CONSORT statement is associated with improvements in the quality reports of RCTs”

“CONSORT聲明的實施,有助改善隨機對照試驗報告的質量”

Moher D, Jones A, Lepage L. for the CONSORT group. Use of the CONSORT statement and quality of reports of randomized trials. A comparative before and after Evaluation. JAMA, 2001, 285:1992-1995.

Plint AC, Moher D, Morrison A, Schulz KF, Altman DG, Hill C, Gaboury I. Does the CONSORT checklist improve the quality of reports of randomized controlled trials: a systematic review. Medical Journal of Australia 2006;185:263-267.

Over **50%** core medical journals on PubMed endorsed CONSORT (as of 4 August 2011)

超過50%主要醫學期刊使用CONSORT



The screenshot shows the CONSORT website interface. At the top, there is a navigation bar with links for Home, CONSORT Statement, Extensions, About CONSORT, Library of Examples, Resources, and News. The main content area is titled "CONSORT Endorsers - Journals" and features a sidebar on the left with sections for History, The CONSORT Group, CONSORT Endorsement, and CONSORT Endorsers - Journals. The main text states that CONSORT is endorsed by over 50% of the core medical journals listed in the Abridged Index Medicus on PubMed. A list of journals is provided, including Academic Emergency Medicine, Acta Neurologica Scandinavica, Advances in Neonatal Care, African Journal of Medicine, AIDS, and AIDS Research and Therapy. A red circle highlights the "50%" figure, and a red arrow points to the "African Journal of Medicine" entry in the list.

CONSORT
TRANSPARENT REPORTING of TRIALS

Support CONSORT

Search

Home CONSORT Statement Extensions About CONSORT Library of Examples Resources News

CONSORT Endorsers - Journals

The following journals have endorsed CONSORT.

CONSORT is endorsed by over 50% of the core medical journals listed in the *Abridged Index Medicus* on PubMed.

- [A](#) [B](#) [C](#) [D](#) [E](#) [F](#) [G](#) [H](#) [I](#) [J](#) [K](#) [L](#) [M](#) [N](#) [O](#) [P](#) [Q](#) [R](#) [S](#) [T](#) [U](#) [V](#) [W](#) [X](#) [Y](#) [Z](#)

Academic Emergency Medicine
[Acta Neurologica Scandinavica](#)
[Advances in Neonatal Care](#)
African Journal of Medicine
[AIDS](#)
AIDS Research and Therapy

CONSORT 在中国

- ❖ **TO calculate how many medical journals in China had adopted the CONSORT.**

統計採用CONSORT的醫學期刊的數目

- ❖ **TO investigate the the influence of CONSORT on the quality of RCT reports in Chinese medical journals**

探討CONSORT對臨床試驗報告質量的影響

First CONSORT exposure in China

- ❖ **Liu YX, Yao C, Chen F, Yang YC. Introduction of CONSORT statement of reporting randomized controlled clinical trials. National Journal of Andrology, 2001, Oct, 7(5):288-291**
- ❖ **Editorial Office of Chinese J of EBM, Revised CONSORT: a suggestion to improve the reporting quality of RCT. 2001, Oct, 1(3):182-184**

Full translation of 22 items and flow chart

- ❖ **汪謀岳, Formal Translation of CONSORT endorsed by CONSORT group (Date: 25 Oct 2007)**
- ❖ **CONSORT 2010 translation in Chinese**

Endorsement

中国循证医学杂志 2005年第5卷第8期

· 591 ·

建立 CONSORT声明中国传播协作网 提高中国临床试验报告质量

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- ❖ **Li YP, Li J, Liu XM. Establishing collaboration of dissemination of CONSORT statement in China to improve the quality of reporting of randomized clinical trials. Chinese Journal of Evidence based medicine; 2005; 5(8):591-593**
- ❖ **Around 50 journals participated**

ChengDu statement (17 April 2006)

- ❖ **Joint Statement of Establishing Chinese Clinical Trial Registration and Publishing System**
- ❖ **48 medical journals**
- ❖ **Majorly about CONSORT, not CONOSRT family**

METHODS

- **Collection of the “instruction to author” from all medical journals in China to calculate how many journals adopted the CONSORT**
查找作者須知中注明採用CONSORT醫學期刊
- To assess the quality of RCT reports from Journals adopting CONSORT, comparing with that without adopting CONSORT
比較採用與不採用CONSORT的醫學期刊,其臨床試驗報告的質量

How many medical Journals in China?

- ❖ **Total Journals in China: 8200**
- ❖ **Total Medical journals: 1221 (50/1218=4.1%)**
 - **Preventive medicine and Hygiene (144)**
 - **Traditional Chinese Medicine(117)**
 - **Integrative medicine (17)**
 - **Basic biomedical science (76)**
 - **Clinical Medicine (91)**
 - **Internal medicine (108)**
 - **Neurology and psychology (29)**
 - **Surge ry, dermatology (107)**
 - **Obstetrics and Gyne cology, pediatrics (28)**
 - **Oncology and special medicine (71)**
 - **Otorhinolaryngology and Ophthalmology (52)**
 - **Pharmace utical Science (71)**
 - **Medicine (187)**
 - **Acta and Jourals in medicine (120)**

All the medical journals in China 所有在中國的醫學期刊

中國期刊全文數據庫 數為200,目前并裝數為7

查詢檢索系中 **期刊導航** 初級檢索 高級檢索 專業檢索

登錄 登錄並且有密碼
未登錄或者無密碼
檢索首飾分類

Navigation 搜索導航 專輯導航

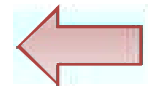
題名 卷期 檢索詞 詞頻 複合

日期 主題 請輸入您所需的檢索詞 檢索

從 1994 到 2012 更新 全部數據 範圍 全部期刊 匹配 模糊 排序 時間 每頁 20

中英漢語

Journal of Navigation



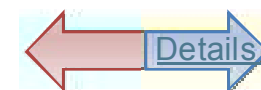
Collection of the “instruction to author” 採集“作者須知”

Official material 正式資料

- Homepages of journals
- Hard copies of the journals

Unofficial material 非正式資料

- Websites which had no relationship with each journal



Ranking of Journals 期刊评分

The screenshot shows the homepage of the Science China website. At the top left is the Science China logo with the text '中国科学文献服务系统'. The main header features the URL 'www.sciencechina.cn' and the title '中国科学文献服务系统'. Below the header are two main sections: '中国科学引文数据库' (Chinese Science Citation Database) and '中国科学文献计量指标' (Chinese Science Literature Metrics). The left sidebar contains a search box, a '立即检索' button, and a '公告栏' (Notice Board) with two items. The first item, '中科院引证报告(JCR)2009年数据已经更新, 欢迎访问', is circled in red. A blue box with a white border and the text 'CSCI: SSCI in China' is positioned below the sidebar, with a blue arrow pointing from the red circle to it. A red arrow points from the bottom right towards the blue box. Navigation buttons for '进入检索' and '详细介绍' are visible at the bottom of each main section.

Science China
中国科学文献服务系统

www.sciencechina.cn
中国科学文献服务系统

中国科学引文数据库

中国科学文献计量指标

快速检索
立即检索

公告栏

- 中科院引证报告(JCR)2009年数据已经更新, 欢迎访问
- 中国科学文献计量指标数据库(CSCI)数据库已经更新, 欢迎访问

中科院引文数据库 (Chinese Science Citation Database, 简称CSCI) 始建于1989年, 收录我国数学、物理、化学、天文学、力学、生物学、农林科学、医药卫生、工程技术、环境科学和信息科学等领域出版的中文科技核心期刊和优秀期刊1100种, 目前已积累从1989年到现在的论文记录800万条, 引文记录近1700万条。中科院引文数据库内容丰富...

科技论文的产出是一个国家科技水平的一种具体体现, 利用科技论文统计数据可以从一个方面勾勒出一个国家科技发展的大致状况。中科院引文数据库继美国ISI(美国科学引文数据库(Citation Indexes Citation Database, CSCI))和美国Science Citation Index数据库, 对我国科技论文进行了详细的统计, 为因多方位地体现我国科学研究成果, 本指标数据库...

进入检索 详细介绍

进入检索 详细介绍

CSCI:
SSCI in China

Targeted RCT reports

目標隨機對照臨床試驗報告

- Trials with intervention in **real-life human beings**
人體臨床試驗
- Trials with interventions as **chemical drugs** (chemical agents, biological agents and Traditional Chinese Medicine (TCM) herbs)
以化學藥、生物制劑或中藥為干預措施
- Trials with **acupuncture** or electroacupuncture
針刺或電針的試驗
- Trials with aim of testing the **treatment effects** of interventions
以測試干預措施治療效果的試驗

Search strategy for RCT reports 檢索方法

❖ Articles written in Chinese—VIP & CJN

The screenshot shows a search interface with two main sections: VIP and CJN. The VIP section has search criteria for journal name (中国药理学通报), subject (随机), and exclusion (鼠+兔). The CJN section has a search history table with columns for logic, search item, search term, word frequency, and expansion. The table contains three rows: '刊名' (China Journal of Pharmacology), '主题' (Random), and '主题' (Mice + Rabbits). Below the table, there are options for time range (2002 to 2002), update (全部数据), range (全部期刊), and matching mode (匹配). A blue box highlights the time range '2002,2004,2006,2008,2010' with arrows pointing to the '时间' field in the VIP section and the '从' and '到' fields in the CJN section.

邏輯	檢索項	檢索詞	詞頻	擴展
+ =	刊名	中国药理学通报		
并且	主题	随机		選擇最近輸入
不包含	主题	鼠+兔		

從 2002 到 2002 更新 全部數據 範圍 全部期刊 匹配 模

中英擴展

Ensure representative data

**2002,2004,2006
,2008,2010**

Quality assessment of RCT reports

Training workshop 培訓班

4 students 學生—2 groups 組

Revised CONSORT 2010 checklist (Re-definition)
使用修改後CONSORT 2010清單

Jadad scale

RESULTS

❖ **1221 medical journals**
(Feb. 2012)

❖ **Medical journals in
China**

❖ **1140 official
“instruction to
author”**

❖ **Collection of the
“instruction to
author”**

Only 7 Journals adopted CONSORT

只用7本醫學期刊採用CONSORT

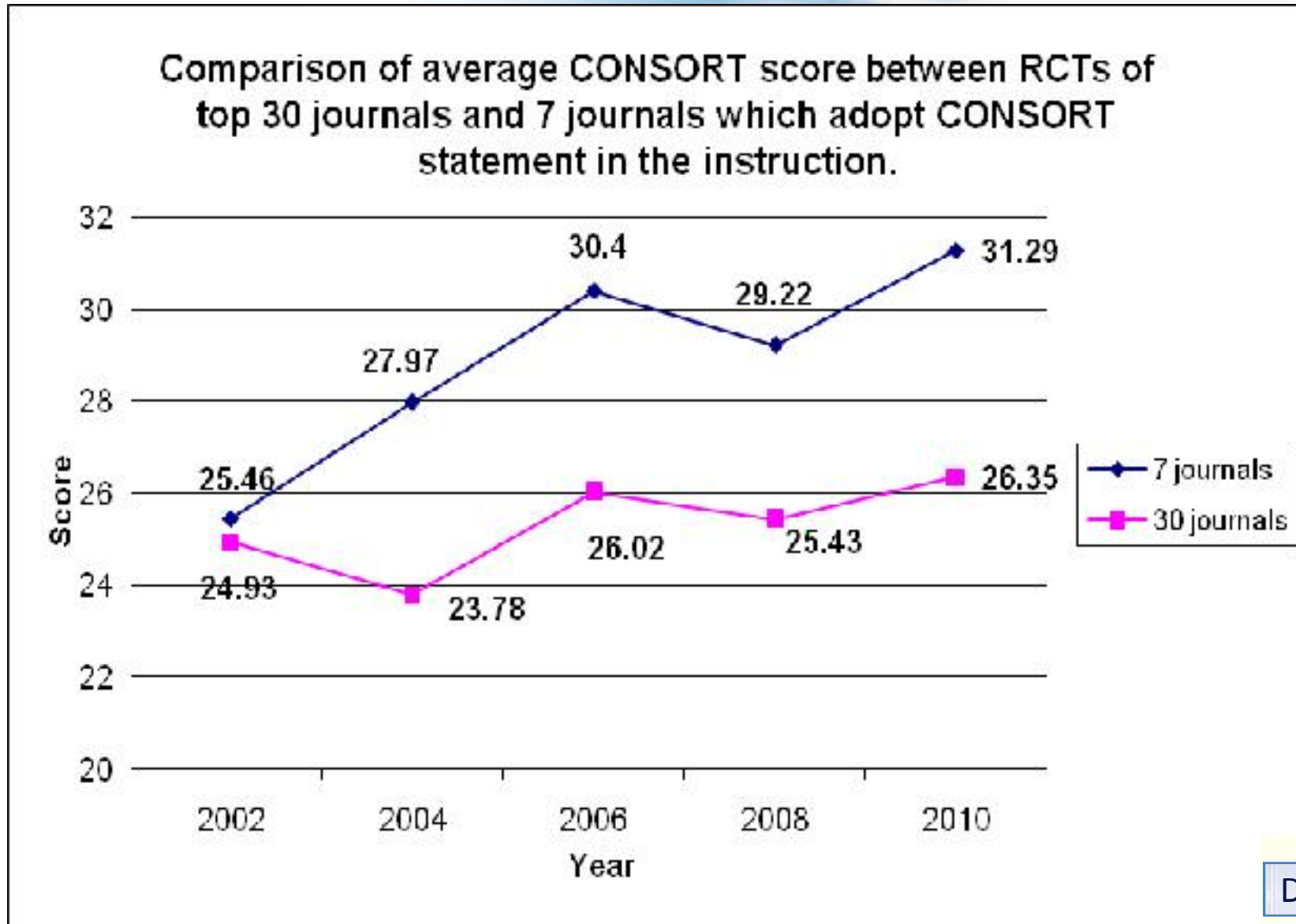
7 journals officially endorsed CONSORT statement

Chinese Journal of Cancer Biotherapy	中國腫瘤生物治療雜誌
Chinese Medical Journal	中華醫學雜誌(英文版)
Hepatobiliary & Pancreatic Diseases International	國際肝膽胰疾病雜誌(英文版)
Chinese Journal of Evidence-Based Medicine	中國循證醫學雜誌
Journal of Chinese Integrative Medicine	中西醫結合學報
Shanghai Archives of Psychiatry	上海精神醫學
Chinese Journal of Evidence-Based Pediatrics	中國循證兒科雜誌

RESULTS of quality of RCT papers

- ❖ Report from top 30 medical journals vs 7 journals (02, 04, 06, 08, 10)
與30本排名最高的醫学期刊的報告比較
- ❖ 403 articles (232 from 30 journals, and 171 from 7 journals)

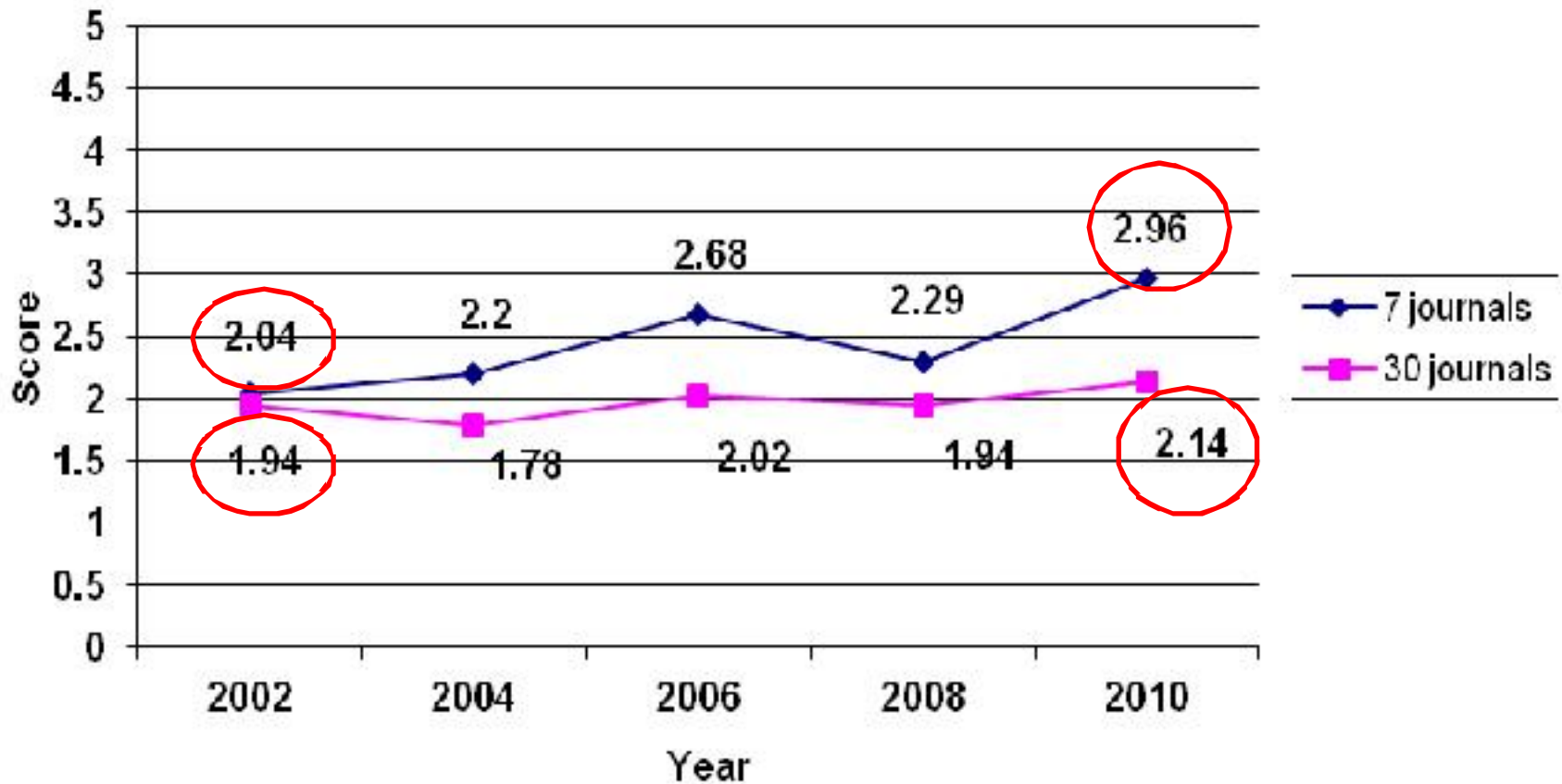
Quality of RCT reports



Year(no.) Items		Average sub item score from 7 Journals(171 articles)					
		02(13)	04(39)	06(35)	08(36)	10(48)	5 years (ratio)
Title		0.08	0.26	0.43	0.53	0.48	0.40 (40%)
Abstract		5.31	4.95	5.17	5.25	5.21	5.16(86%)
Introduction		2.54	2.69	2.83	2.78	2.81	2.76(92%)
Method		7.92	9.00	9.89	9.36	9.92	9.43(25.49%)
Results		6.54	8.18	8.63	8.08	9.02	8.36(34.83%)
Discussion		2.85	2.49	3.20	2.67	3.06	2.86(35.75%)
Other Information		0.31	0.33	0.26	0.56	0.79	0.49(9.8%)
Year(no.) Items		Average sub item score from the top 30 journals(232 articles)					
		02(15)	04(32)	06(56)	08(63)	10(66)	5 years(ratio)
Title		0	0.13	0.27	0.22	0.09	0.08(8%)
Abstract		5.5	5.09	4.66	4.68	4.92	4.85(80.83%)
Introduction		2.67	2.56	2.77	2.60	2.77	2.69(89.67%)
Method		7.87	6.94	8.21	8.37	8.65	8.18(22.11%)
Results		6.60	6.34	7.36	7.03	7.17	7.03(29.29%)
Discussion		1.93	2.31	2.39	2.06	2.18	2.20(27.5%)
Other Information		0.40	2.41	0.36	0.46	0.56	0.43(8.6%)
Total		24.93	23.78	26.02	25.43	26.35	25.57(30.44%)

Quality of RCT reports

Comparison of average JADAD score between RCTs and top 30 journals and 7 journals which adopt CONSORT statement in the instruction.



Conclusion

- **Very small part of journals among Chinese medical journals have adopted CONSORT.**
只有非常少量中文醫學期刊採用CONSORT
- **The overall quality of RCT reports in journals of China, though **increasing**, was **poor****
雖然臨床試驗報告質量有提升,但整體質量仍然偏低
- **Quality質量: 7 journals > top 30 journals.**

Extension of CONSORT

❖ Design Extensions 關於試驗試計

- Cluster trials (2004)
- Non-inferiority and equivalence trials (2006)
- Pragmatic trials(2008)

❖ Intervention Extensions 關於干預措施

TCM???

- Herbal medicinal interventions (2006)
- Non-pharmacological treatment(2008)
- Acupuncture Interventions (2010)

❖ Data Extensions 關於數據資料

- Harms (2004)
- Abstracts (2008)
- Patient-reported outcomes (2013)

Reporting Quality of RCT with TCM

中醫藥隨機臨床試驗報告質量

- ❖ A systematic review about CHM for type 2 diabetes mellitus with 66 RCTs published in Cochrane Library
- ❖ Appraising with revised CONSORT checklist, **compliance** varied between **0%** and **100%**, with a median score of **33%** for each item
- ❖ The **overall reporting quality** assessed with the revised CONSORT checklist varied between **20%** and **47%**, with a median score of **32%** (standard deviation 8%).
- ❖ no significant differences in the quality of reporting published prior to and after the year 2000 ($p>0.05$)

--Bian ZX, Moher D, Dagenais S, Li YP, Wu TX, Liu L, Miao JX, Song L, Zhang HM, Improving the quality of RCT with Chinese herbal medicine Part IV: applying a revised CONSORT checklist to measure quality of reporting, Journal of integrative medicine, 2006, 4,233-242

➔ **Necessity for the extension of CONSORT for TCM**
整體質量偏底, 有必要擴展及制訂CONSORT for TCM

Milestone of CONSORT for TCM

- ❖ **2005** Initial discussion to establish CONSORT for TCM 首次討論
Leaded by Prof Liu YP and Prof David Moher
- ❖ **2006** Formation of international working group for CONSORT for TCM
Key members: Wu T, Li Y, Bian Z, Li T, Li J, Dagenais S, Moher D
成立 CONSORT for TCM 國際工作小組
- ❖ **2007** Publication draft of CONSORT for TCM (Chi & Eng Version)
發表中英文版的中醫藥臨床對照試驗報告規範 (徵求意見稿)

Consolidated Standards for Reporting Trials of Traditional Chinese Medicine (CONSORT for TCM) (For Solicitation of Comments) 中医药临床随机对照试验报告规范（征求意见稿）

WU Tai-xiang¹, LI You-ping^{1*}, BIAN Zhao-xiang², LI Ting-qian¹, LI Jing¹, Simon Dagenais³,
David Moher^{3*}, for CONSORT for TCM working group

中国循证医学杂志, 2007, 7(9): 625-630.

中医药临床随机对照试验报告规范（征求意见稿） Consolidated Standards for Reporting Trials of Traditional Chinese Medicine (CONSORT for TCM)

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代表CONSORT for TCM工作组

中国循证医学杂志, 2007, 7(8): 601-605.

Major contents of CONSORT for TCM

- ❖ **Necessity for the extension of CONSORT for TCM**

擴展 CONSORT for TCM的重要性

- ❖ **History & process of development of CONSORT for TCM**

制訂CONSORT for TCM 的歷史和進程

- ❖ **Changes of CONSORT for TCM from CONSORT**

CONSORT for TCM 的內容修改

- ❖ **Discussion**

Major Changes from CONSORT 主要修改內容

(1) Title & abstract: standardized format with TCM specificity

題目和文摘: 加入中醫特色

(2) Background: rationale of formulation of TCM intervention by 1) TCM theory; and/or 2) modern pharmacological evidence of each active ingredient

背景: 增加中醫藥干預措施制訂的依據

(3) Inclusion & exclusion criteria: on the basis of 1) conventional medicine; 2) TCM disease name; 3) TCM 'zheng'; or 4) both TCM and conventional medicine diagnostic criteria

納入和排除標準: 基於西醫, 中醫, 或中西醫結合的考慮

(4) Interventions: details of treatment and control interventions, including ingredients, product name, dosage form, dose, usage, treatment regimen, duration, etc.

干預措施: 列明具體內容

(5) Outcome assessment: 1) specialty, practicability and necessity of effectiveness assessment of TCM outcomes; 2) measures of TCM 'zheng', e.g. symptom scoring, health related quality of life, etc. Recommended using flow diagram.

結局評估: 具中醫特色的結局評估報告規範

(6) Study design: Identify study design, 1) 'equivalence', 2) 'non-inferiority' or 3) 'superiority' design

研究設計: 註明設計的具體內容

(7) Others: Additional of ethics approval number and trial registration number

其他: 增加道德倫理委員會的審批編號及臨床試驗註冊編號

Implementing of CONSORT for TCM

CONSORT for TCM 實施情況

- ❖ Searching databases: CKNi & PubMed
- ❖ Searching words: “CONSORT for TCM” or “中醫藥臨床隨機對照試驗報告規範”
- ❖ Results:
 - CKNi: 116 papers
 - PubMed: 16 papers



(A) Explanation / discussion papers published by CONSORT for TCM group 工作小組發表評述性的文章

❖ **Total: 23 articles**

❖ **Selected publications**

1. Cheng CW, Bian ZX, Li YP et al. CONSORT Serial 1: Describing and transparently reporting the rationale for RCTs of TCM. Chin J EBM. 2008, 8(3): 152-154.

2. Bian ZX, Moher D, Li YP et al. CONSORT Serial 2: Concise and Precise Reporting of Intervention in RCTs of TCM. J Chin Integ Med. 2008, 6(7): 661-667.

3. Bian ZX, Moher D, Li YP et al. CONSORT Serial 3: Appropriately selecting and concisely reporting the outcomes of RCTs with TCM. J Chin Integ Med. 2008, 6(8): 771-775.

4. Cheng CW, Bian ZX, Li YP et al. CONSORT Serial 4: Transparently reporting the adverse effects of TCM drug interventions in RCT. J Chin Integ Med. 2008, 6(9): 881-886.

CONSORT 系列一

中医药临床研究报告中应清晰阐述试验设计理念

CONSORT Serial 1: How to Explain the Methodological Rationale of Randomized Controlled Trial on Traditional Chinese Medicine?

Recommendations:

- 1. Rationale for the selection of study model**
- 2. Rationale for the selection of formula**
- 3. Rationale for the selection of dosage and treatment course**
- 4. Rationale for the selection of control intervention**
- 5. Rationale for the selection of outcome measurement index**

建議：闡述選擇 1) 研究模型(西醫病名/中醫證型/中西醫結合), 2) 中藥組方, 3) 劑量/療程, 4) 對照組, 5) 結局評價指等內容的依據。

Precise reporting of traditional Chinese medicine interventions in randomized controlled trials

Recommendations

- 1 Single Chinese herbal medicine-based/ formula-based/extraction-based intervention includes 1) Name, dosage format and registration; 2) The composition and quality of intervention; 3) Pharmaceutical processing and quality control; 4) Stability of final product and quality control; 5) Function and safety description; 6) Dosage and treatment course; 7) Control group.
2. Active compound-based TCM drug intervention includes 1) Name of active compound(s) ; 2) Original source of active compound(s) ; 3) The brief process obtaining active compound(s) ; 4) Percentage of active compound(s) in final product; 5) Added materials and its quality and quantity control.
3. The detailed information of intervention published as online supplementary in website .

建議: 提供不同類型中藥干預措施的報告方法

Editorial 专论

Appropriately selecting and concisely reporting the outcome measures of randomized controlled trials of traditional Chinese medicine

Recommends

- 1) Identifying the primary and secondary outcomes based on the purpose and hypothesis of the trial;**
 - 2) Defining the primary and secondary outcomes clearly;**
 - 3) Reporting the rationale of selection;**
 - 4) Reporting the method with aims to standardize the assessment process;**
 - 5) Reporting the method to improve the reliability of assessment; and**
 - 6) Stating the termination criteria in the trial**
- 建議：提供結局指標的報告方法和內容**



Transparently reporting adverse effects of traditional Chinese medicine interventions in randomized controlled trials

Recommendations:

- 1. Provide the background information on side effects of each CMM constituents and/ or the study intervention, specific outcome assessment on AEs,**
- 2. The details of reported AEs**
- 3. The interpretation of the AEs occurrence in a structural RCT report**

建議：提供中醫藥臨床試驗中關於不良反應的報告方法和具體內容。

(B) Systematic reviews using CONSORT for TCM as assessment tool

以CONSORT for TCM清單的條目作為試驗質量評價的系統綜述

❖ Total: 14 articles

❖ Selected publications

1. Chen J, Suo J, Zeng XM et al. Quality evaluation of randomized controlled trials involving traditional Chinese medicine for Cholelithiasis. *Chin J Evid-based Med.* 2008, 8(5):370-374.
2. Fu SF, Zhang JH, Liu Y et al. Reporting quality assessment of Huangqi injection for chronic heart failure randomized clinical trials. *Liaoning J TCM.* 2009, 36(10): 1713-1715.
3. Min J, Mao B, Liu AR. Quality assessment of randomized controlled trials related to traditional Chinese medicine published in the Chinese journal of evidence-based medicine. *Chi J EBM.* 2010, 10(03):362-366.
4. Luo H, Liu JP, Li Q. Methodological issues and suggestions for improvement in randomized controlled trials of Chinese herbal

Reporting Quality Assessment of Huangqi Injection for Chronic Heart Failure Randomized Clinical trials

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Abstract Objective To assess the reporting quality of Huangqi Injection for chronic heart failure randomized clinical trials. **Methods** An extensive search including PubMed, Cochrane Central Register of Controlled Trials, EMBASE, and other Chinese literature databases was performed up to July 2008. Clinical trials about Huangqi injection for the treatment of chronic heart failure were searched. The reporting quality of each trial was assessed according to the Consolidated Standards for Reporting Trials of Traditional Chinese Medicine (CONSORT for TCM) (For Solicitation of Comments). **Results** There are 107 reports included in the assessment according to the 22 items of the CONSORT for TCM. All the statements of the titles were not complete. 54 (50.5%) reports included abstracts. Only 26 (24.3%) reports included introduction. There were not clearly statements of the inclusion and exclusion criteria in 77 (72.0%) studies. The diagnostic criteria of the disease were not mentioned in 11 (10.3%) reports. All the studies reported without the informed consent and ethics committee approval of the situation. None of the studies explain the rationale of sample size determined and the principle of study termination. The methods used to generate the random allocation sequence were not mentioned in 91 (85.0%) studies. 32 (29.9%) studies did not report the statistical methods. Baseline demographic and clinical characteristics were reported in 79 (73.8%) studies. All important adverse events and side effects were mentioned in the 54 (50.5%) studies. 30 (28.0%) studies reported the external validity. The conflict of interest between investigators and study were not mentioned in all of the studies. **Conclusion** Through the assessment of 107 reports it indicated that most of the study design and implementation were not clear especially the methodology.

Key words Huangqi Injection; Chronic heart failure; CONSORT for TCM; Standards for Reporting Trials

(C) Citation / recommendation of CONSORT for TCM **引用或建議採用CONSORT for TCM的文章**

❖ **Total: 21 articles**

❖ **Selected publications**

1. Yang ZX, Shi XM. Systematic review of traditional Chinese medicine in treating stroke. Shanghai J TCM. 2009, 43(7): 82-85.
2. Qiao B, Yuan WL, Zhang Y et al. Protective effects of decoction plus radiotherapy on nasopharyngeal carcinoma: a meta-analysis of randomized controlled trials. West China Med J. 2011, 26(3): 391-398.
3. Yu S, Wang SC, Han XM et al. Study on literatures in treatment guidelines of common disease in TCM paediatrics. J Nanjing Univer of TCM. 2012, 28(6): 583-585.

中药复方联合放射疗法治疗鼻咽癌疗效的 Meta 分析

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目前中药复方配合放射治疗治疗鼻咽癌临床试验设计质量较低,研究方法有待科学规范,试验结果可信度较低,还不能为临床应用提供可靠的准确证据。建议学者们以后按照国际规范合理设计、严谨实施多中心、大样本的随机对照、双盲试验,尽量避免低水平重复;采用充分随机、充分实施分配隐藏等科学方法;按照临床试验报告的统一标准(consolidated standards of reporting trials, CONSORT)真实报告试验结果;长期随访,报道终点指标(如生存率等)以利于临床证据采集;重视阴性结果临床试验的报道。此外,简单运用西医的治疗标准、研究方案来评价、研究中医药,将难以得出满意结果,故迫切需要学者们将中医证候的规范、客观化体系进一步深化、完善,使中医“辨证论治”的标准变得可测、可重复,将有利于中医药临床试验研究的科学化、国际化。

(D) Comments / related studies on CONSORT for TCM

評論CONSORT for TCM或相關研究的文章

❖ **Total: 5 articles**

❖ **Selected publications**

1. Guo XF, Lai SL. Key methodological and insitiutional issues on how to promote the evidence based traditional Chinese medicine. Chin J Evid-based Med. 2008, 8(1): 10-12.
2. Fei YT, Liu JP. Improving the quality of reporting Chinese herbal medicine trials: an elaborated checklist. J Chin Integr med. 2008, 6(3):233-238.
3. Liu YT, Liang WX. Quality assessment of noninferiority and equivalence randomized controlled trials of traditional Chinese medicine. Tradit Chin Drug Research & Clinical Pharmacol. 2011, 22(5): 573-576.

表 1 (續 1) 改良中藥品質檢驗指南的參考表目

項目	編碼	附則
1. 總則	4	環境潔淨程度的「預清潔」(包括動物名稱、飼養、消毒控制、給飼時間和方法、中藥加工及包裝等策略)。其包括(4-1)至(4-11)。
中成藥	4A, 4B, 4C, 4D, 4E	<p>4A. 中成藥的藥品名、生產商和藥品標準</p> <p>4B. 中成藥在試驗室應與標品進行比對</p> <p>4C. 中成藥與原料藥的標品、來源和標品標準</p> <p>4D. 中成藥的劑型(複方劑型/單味藥劑型/參照藥物等)、劑型和規格</p> <p>4E. 如果藥品為從植物、動物、礦物等原料中提取的有效成分或有效部位或其劑型, 應在報告或有效成分或有效部位的名稱(同時報告中文、拉丁文和英文名)</p> <p>4F. 否為中西藥或單味藥劑型, 它不能與劑型名稱的自提下, 說明其方劑全藥的劑名稱(同時報告中文名及其拼音、拉丁名、英文名)及含量(或比例)</p>
原料藥	4B, 4C, 4D, 4E, 4F, 4G, 4H, 4I, 4J, 4K, 4L, 4M, 4N, 4O, 4P, 4Q, 4R, 4S, 4T, 4U, 4V, 4W, 4X, 4Y, 4Z	<p>4B. 檢驗方法、時間、劑量、劑型及注意事項</p> <p>4C. 原料藥在試驗室應與標品進行比對</p> <p>4D. 原料藥的標品(中文名稱及其拼音、拉丁名、英文名、劑量(或數量及單位))</p> <p>4E. 原料藥的標品(產地、來源、劑量、劑型)及相關文件</p> <p>4F. 原料藥的標品(來源、劑量、劑型)</p> <p>4G. 原料藥的標品(來源、劑量、劑型)</p> <p>4H. 原料藥的標品(來源、劑量、劑型)</p> <p>4I. 原料藥的標品(來源、劑量、劑型)</p> <p>4J. 原料藥的標品(來源、劑量、劑型)</p> <p>4K. 原料藥的標品(來源、劑量、劑型)</p> <p>4L. 原料藥的標品(來源、劑量、劑型)</p> <p>4M. 原料藥的標品(來源、劑量、劑型)</p> <p>4N. 原料藥的標品(來源、劑量、劑型)</p> <p>4O. 原料藥的標品(來源、劑量、劑型)</p> <p>4P. 原料藥的標品(來源、劑量、劑型)</p> <p>4Q. 原料藥的標品(來源、劑量、劑型)</p> <p>4R. 原料藥的標品(來源、劑量、劑型)</p> <p>4S. 原料藥的標品(來源、劑量、劑型)</p> <p>4T. 原料藥的標品(來源、劑量、劑型)</p> <p>4U. 原料藥的標品(來源、劑量、劑型)</p> <p>4V. 原料藥的標品(來源、劑量、劑型)</p> <p>4W. 原料藥的標品(來源、劑量、劑型)</p> <p>4X. 原料藥的標品(來源、劑量、劑型)</p> <p>4Y. 原料藥的標品(來源、劑量、劑型)</p> <p>4Z. 原料藥的標品(來源、劑量、劑型)</p>
4. 4. 1	4C, 4D, 4E, 4F, 4G, 4H, 4I, 4J, 4K, 4L, 4M, 4N, 4O, 4P, 4Q, 4R, 4S, 4T, 4U, 4V, 4W, 4X, 4Y, 4Z	<p>4C. 定性或定量檢驗</p> <p>4D. 定性或定量檢驗</p> <p>4E. 定性或定量檢驗</p> <p>4F. 定性或定量檢驗</p> <p>4G. 定性或定量檢驗</p> <p>4H. 定性或定量檢驗</p> <p>4I. 定性或定量檢驗</p> <p>4J. 定性或定量檢驗</p> <p>4K. 定性或定量檢驗</p> <p>4L. 定性或定量檢驗</p> <p>4M. 定性或定量檢驗</p> <p>4N. 定性或定量檢驗</p> <p>4O. 定性或定量檢驗</p> <p>4P. 定性或定量檢驗</p> <p>4Q. 定性或定量檢驗</p> <p>4R. 定性或定量檢驗</p> <p>4S. 定性或定量檢驗</p> <p>4T. 定性或定量檢驗</p> <p>4U. 定性或定量檢驗</p> <p>4V. 定性或定量檢驗</p> <p>4W. 定性或定量檢驗</p> <p>4X. 定性或定量檢驗</p> <p>4Y. 定性或定量檢驗</p> <p>4Z. 定性或定量檢驗</p>
4. 4. 2	4C, 4D, 4E, 4F, 4G, 4H, 4I, 4J, 4K, 4L, 4M, 4N, 4O, 4P, 4Q, 4R, 4S, 4T, 4U, 4V, 4W, 4X, 4Y, 4Z	<p>4C. 聯合管理及反應</p> <p>4D. 聯合管理及反應</p> <p>4E. 聯合管理及反應</p> <p>4F. 聯合管理及反應</p> <p>4G. 聯合管理及反應</p> <p>4H. 聯合管理及反應</p> <p>4I. 聯合管理及反應</p> <p>4J. 聯合管理及反應</p> <p>4K. 聯合管理及反應</p> <p>4L. 聯合管理及反應</p> <p>4M. 聯合管理及反應</p> <p>4N. 聯合管理及反應</p> <p>4O. 聯合管理及反應</p> <p>4P. 聯合管理及反應</p> <p>4Q. 聯合管理及反應</p> <p>4R. 聯合管理及反應</p> <p>4S. 聯合管理及反應</p> <p>4T. 聯合管理及反應</p> <p>4U. 聯合管理及反應</p> <p>4V. 聯合管理及反應</p> <p>4W. 聯合管理及反應</p> <p>4X. 聯合管理及反應</p> <p>4Y. 聯合管理及反應</p> <p>4Z. 聯合管理及反應</p>
4. 4. 3	4C, 4D, 4E, 4F, 4G, 4H, 4I, 4J, 4K, 4L, 4M, 4N, 4O, 4P, 4Q, 4R, 4S, 4T, 4U, 4V, 4W, 4X, 4Y, 4Z	<p>4C. 研究人員</p> <p>4D. 研究人員</p> <p>4E. 研究人員</p> <p>4F. 研究人員</p> <p>4G. 研究人員</p> <p>4H. 研究人員</p> <p>4I. 研究人員</p> <p>4J. 研究人員</p> <p>4K. 研究人員</p> <p>4L. 研究人員</p> <p>4M. 研究人員</p> <p>4N. 研究人員</p> <p>4O. 研究人員</p> <p>4P. 研究人員</p> <p>4Q. 研究人員</p> <p>4R. 研究人員</p> <p>4S. 研究人員</p> <p>4T. 研究人員</p> <p>4U. 研究人員</p> <p>4V. 研究人員</p> <p>4W. 研究人員</p> <p>4X. 研究人員</p> <p>4Y. 研究人員</p> <p>4Z. 研究人員</p>

Major changes: Interventions

- i) Decoction and proprietary Chinese medicine
- ii) Quality control with quantity or quantitative index

主要是針對修訂干預措施內容的建議

(E) Endorsement by medical journals

部份採用CONSORT for TCM的醫學期刊

- Chinese Journal of Evidence-based Medicine
- Chinese Journal of Evidence Based Pediatrics
- Journal of Practical Traditional Chinese Internal Medicine





❖ **What is the next?**
下一步工作?

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REVIEW

Consolidated standards of reporting trials (CONSORT) for traditional Chinese medicine: current situation and future development

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Major changes in CONSORT 2010

CONSORT 2010主要修訂內容

- ❖ **New subitem to clarify the basic trial design (i.e. parallel group, crossover, cluster) and the allocation ratio;**
新增有關試驗設計及分配比例的副條目
- ❖ **New subitem to address any important changes to methods after trial commencement, with a discussion of reasons;**
新增有關試驗開展後重要改動的副條目
- ❖ **Additional subitem on identifying any changes to the primary and secondary outcome (endpoint) measures after the trial has commenced;**
新增有關試驗開展後改動主要和次要結局的副條目

- ❖ **Addition specification of how blinding was done and also, if relevant, a description of the similarity of interventions and procedures. Eliminated: how success of blinding was assessed;**

加強盲法實施的內容及刪除有關盲法成功率的描述

- ❖ **Replacement of “intention to treat” analysis with a more explicit request for information about retaining participants in their original assigned groups; Addition of “For binary outcomes, presentation of both relative and absolute effect sizes is recommended”;**

修改統計方法和建議

- ❖ **New items on trial registration, availability of trial protocol, and funding**

新增有關臨床試驗註冊編號, 獲取研究方案和研究基金等內容的條目

Challenges ahead for CONSORT for TCM

❖ Finalization of the CONSORT for TCM

CONSORT for TCM的完善和修訂

- CONSORT 2010
- TCM characteristics 中醫特色
 - Rationale of study design 研究設計理念
 - TCM interventions (herbs, mineral and animals drugs)
中藥干預措施 (草藥, 礦物藥和動物藥)
 - Outcome measures 結局指標
 - Adverse effects 不良反應

❖ Dissemination 傳播及推廣

- Co-publication (journals & medical-related websites)
聯合刊載 (學術期刊/醫學網站)
- Promotion and training 教育培訓
 - Workshop 研修班
 - Conference 會議
- Endorsement from medical journals 醫學期刊支持
 - Publication guidelines 投稿須知
- Endorsement from funding agencies / research institutes 研究基金會及研究員支持
 - Special grants 特別研究基金
 - Awards 獎項

- ❖ **The application of CONSORT for TCM will encourage more insights into its modification, thus making it more practical.**
- ❖ **Practicality is an important factor for this guideline because there should be a balance between what should be done and what can be done currently.**
- ❖ **Periodic revision will be necessary and is perhaps the only means to improve it!!**

增加CONSORT for TCM的使用度, 定期修訂更新, 進一步提升中醫藥臨床隨機對照試驗報告的質量!!



Thank you for your attention.