Review 述评

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Improving the quality of randomized controlled trials in Chinese herbal medicine, part : applying a revised CONSORT checklist to measure reporting quality

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ABSTRACT Objective: To discuss the quality of reporting in randomized controlled trials (RCTs) of Chinese herbal medicine (CHM), and to provide suggestions for improving the reporting of future clinical studies in this therapeutic area . Methods: A search of the Cochrane Library was conducted to identify RCTs of CHM . A revised CONSORT checklist designed for CHM clinical studies was implemented . The revised CONSORT checklist contained 63 items, including the following new items added specifically for CHM: (1) syndrome of disease" based on Chinese medicine theories; (2) rationale of CHM formula; (3) formula composition; (4) preparation form of CHM; (5) quality control of CHM . Results: The overall reporting quality of the RCTs as assessed with the revised CONSORT checklist varied between 19% and 44% , with a median score of 32% (standard deviation 8%) . Conclusion: The overall quality of reporting of RCTs of CHM evaluated with a revised CONSORT checklist was poor, reflecting the need for improvements in reporting future clinical trials in this area . Recommendations: To improve the quality of reporting of RCTs of CHM, we recommend adopting

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a revised CONSORT checklist that includes items specific to CHM . We also recommend that editors of CHM journals require authors to use a structured approach to presenting their trials as a condition of publication .

KEY WORDS   randomized controlled trial; Chinese herbal medicine; methodology; quality assessment; reporting

1 INTRODUCTION

In this fourth part of our four-part series on improving the quality of randomized controlled trials (RCTs) in Chinese herbal medicine (CHM), we will review the common weaknesses traditionally found in the reporting format of RCTs of CHM . A revised CONSORT (Consolidated Standards of Reporting Trials) checklist was used to evaluate the quality of reporting of RCTs of CHM, and recommendations for improving the quality of reporting are discussed .

Methodological quality and execution are pivotal elements when conducting a RCT of CHM[1] . Both of these crucial elements are inherently dependent on how a study is reported in order to share this information with its readers . Although the method of reporting is not a direct measure of the inherent quality of a trial, quality methodology of quality reporting can not exist independently . In fact, the reporting of RCTs is often the only information available for readers to evaluate how a study was conducted, and is the primary source of information for systematic reviews on the safety and efficacy of an intervention . Therefore, it is incumbent upon investigators of RCTs to ensure that sound methodology and execution are paired with sound reporting . Inadequate reporting, for example, of randomization sequence generation, allocation concealment, blinding, and intervention protocol, can all lead to biased interpretation of a study' s results[2,3] .

In conventional medicine, reporting requirements for clinical trials have improved substantially since the 1960s, and the tangible outcome of such improvement is the revised CONSORT checklist[4] , endorsed by over 192 journals worldwide[5] . A comparative pre- and post-CONSORT evaluation reported that use of the CONSORT checklist did in fact improve the quality of reporting RCTs[6] . Based on the review of systematic reviews of CHM published in Cochrane Library and our undertaking the systematic review of CHM to treat irritable bowel syndrome, it became obvious to us that the quality of reporting RCTs in CHM was heterogeneous .

Hence, the primary aim of our research was to (1) systematically analyze the quality of reports of RCTs in CHM, as judged by whether they provide the minimum set of information describing the " design, conduct, analysis, and generalizability of the trial", and (2) provide suggestions for improving the quality of reporting in RCTs of CHM . This study was focused on the adequacy of reporting in RCTs and did not attempt to assess the overall methodological quality of the RCTs; that was reported in our previous study on this topic[1] .

2 METHODS AND MATERIALS

2 .1 Selection of RCTs

The search strategy used in this study was reported previously[1] . Briefly, the Cochrane Library Database was searched and yielded 11 systematic reviews about CHM involving 167 RCTs . The systematic review about type 2 diabetes mellitus reported on 66 RCTs, the largest number of RCTs about CHM in the Cochrane Library (up to July 2005) . All 66 RCT reports were obtained through electronic and hand searching, and formed the basis for this study evaluating the current state of the quality of reporting of RCTs with CHM .

2 .2 Assessment of reporting quality

The reporting of a RCT is the only tangible evidence of its execution that is available to those outside the study team to communicate the details of their research . To this effect, the question may arise of what should be included in the final report for a RCT ? A group of clinical scientists published their recommendation about a formal checklist for clinical trial reporting in 1996[7] and later revised it in 2001[4] . This checklist is known as the CONSORT statement . Subsequent evidence has shown that CONSORT has positive influence on the quality of trial reporting of conventional medicine[6,8] . The items from that checklist are summarized in Table 1 (http:// www .consort-statement .org/ Downloads/ Checklist .doc) .

Table 1   CONSORT checklist

SECTION/ Topic	Item	Description
TITLE & ABSTRACT	1	How participants were allocated to interventions .
INTRODUCTION		
Background	2	Scientific background and explanation of rationale .
METHODS		
Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected .
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered .
Objectives	5	Specific objectives and hypotheses .
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements .
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules .
Randomization Sequence generation	8	Method used to generate the random allocation sequence, including details of any restrictions .
Randomization Allocation concealment	9	Method used to implement the random allocation sequence, clarifying whether the sequence was concealed until interventions were assigned .
Randomization Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups .
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment . When relevant, how the success of blinding was evaluated .
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses .
RESULTS		
Participant flow	13	Flow of participants through each stage . Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome . Describe protocol deviations from study as planned, together with reasons .
Recruitment	14	Dates defining the periods of recruitment and follow-up .
Baseline data	15	Baseline demographic and clinical characteristics of each group .
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by" intention-to-treat" . State the results in absolute numbers when feasible .
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision .
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory .
Adverse events	19	All important adverse events or side effects in each intervention group .
DISCUSSION		
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes .
Generalizability	21	Generalizability (external validity) of the trial findings .
Overall evidence	22	General interpretation of the results in the context of current evidence .

In this study, the CONSORT checklist was evaluated as a basis for assessing the quality of reporting in RCTs of CHM . However, pilot testing of this list unearthed some concerns about its suitability for CHM, such as (1) many of the items presented in the list contained multiple components (e g . item 3 about participants, inclusion/ exclusion criteria, diagnosis, settings and locations), and (2) the items listed did not represent all of the details required of RCTs in CHM (e .g . preparation form of CHM) . Therefore, a revision of the CONSORT checklist was undertaken for RCTs of CHM .

At first, items with multiple components were further divided into individual items . The 22-item checklist therefore became a 58-item checklist that will likely be easier to score . Secondly, the following 5 items specific to CHM were added to the checklist: (1) syndrome of disease based on CHM; (2) rationale of CHM formulas; (3) CHM formula composition; (4) preparation form of CHM; and (5) quality control of CHM . These items were added based on our understanding of CHM for the following reasons: (1) the rationale of CHM treatment is different from that of conventional medicine;

(2) the composition of the CHM formula is a pivotal factor for its efficacy, as different compositions may produce different clinical results; (3) the preparation form of the CHM is variable, including decoction, tablet, powder, granule and capsule, and may reflect the quality of blinding to randomization; (4) quality control of CHM is essential for ensuring that all participants are receiving interventions with the same quality . Thus the revised checklist used for assessing the quality of reporting of RCTs of CHM in this paper involved 63 items (Table 2) .

Table 2   Revised CONSORT checklist (to be continued)

SECTION/ Topic	Old item	New item	Description	Number of RCTs reported certain item (%)
TITLE & ABSTRACT	1	1	Identifies study as a RCT	3 (5)
		2	Has an abstract	36 (55)
		3	Has a structured format	23 (35)
		4	Gives hypothesis (or rationale)	0 (0)
		5	Gives number of patients	26 (39)
		6	States whether analysis was by intention-to-treat	0 (0)
		7	Gives method of randomization	0 (0)
		8	States results	36 (55)
INTRODUCTION				
Background	2	9	Scientific background	36 (55)
		10	Explanation of rationale	18 (27)
METHODS				
Participants	3	11	Diagnostic criteria	58 (88)
		12	Inclusion criteria	23 (35)
		13	Exclusion criteria	12 (18)
		14	Informed consent form	3 (5)
		15	Ethic committee approval	3 (5)
		16	Settings and locations where the data were collected	37 (56)
Intervention	4	17	Syndrome of disease based on CHM	30 (45)
		18	Rationale of CHM composition	66 (100)
		19	Composition of CHM formulas	57 (86)
		20	Preparation form of CHM	66 (100)
		21	Quality control of CHM	0 (0)
		22	Precise details of the interventions intended for each group	65 (98)
		23	States methods of administration	64 (97)
		24	States time of administration	62 (94)
		25	States duration of treatment	63 (95)
		26	States duration of follow-up	7 (11)
Objectives	5	27	Specific objectives	64 (97)
		28	Hypothesis	0 (0)
Outcomes	6	29	Defined primary outcome measures	65 (98)
		30	Defined secondary outcome measures	1 (2)
		31	Methods to enhance the quality of outcomes measurements	3 (5)
Sample size	7	32	Sample size	64 (97)
		33	States sample size calculation	1 (2)
		34	Explanation of any interim analyses	0 (0)
		35	Explanation of stopping rules	0 (0)
Randomization Sequence generation	8	36	States method to generate the random allocation sequence	9 (14)
		37	States whether sequence was concealed until interventions were assigned	0 (0)

Table 2 (continuation)　Revised CONSORT checklist

SECTION/ Topic	Old item	New item	Description	Number of RCTs reported certain item (%)
Randomization Allocation concealment	9	38	States method to implement the random allocation sequence	1 (2)
Randomization Implementation	10	39	States who generated the allocation sequence	0 (0)
		40	Who enrolled participants	0 (0)
		41	Who assigned participants to their groups	0 (0)
Blinding	11	42	States that the trial is blinded or open	7 (11)
		43	Participants were blinded to group assignment	7 (11)
		44	Investigators were blinded to group assignment	4 (6)
		45	Assessors were blinded to group assignment	0 (0)
		46	States how the success of blinding was evaluated	0 (0)
Statistical methods	12	47	Defines statistical methods	27 (41)
RESULTS				
Participant flow	13	48	Flow of participants through each stage	0 (0)
		49	Describes protocol deviations and reasons	1 (2)
Recruitment	14	50	Dates defined periods of recruitment	20 (30)
Baseline data	15	51	Baseline of clinical characteristics of each group	39 (59)
Numbers analyzed	16	52	Actual number of participants in each group	65 (98)
		53	"intention-to-treat" analysis	1 (2)
		54	States withdrawal/ dropout	5 (8)
Outcomes and estimation	17	55	Summary of results for each group with primary and secondary outcomes	66 (100)
		56	Estimates effect size	43 (65)
		57	Estimates precision of effect size (95% confidence interval)	0 (0)
Ancillary analyses	18	58	Addresses multiplicity by reporting any other analyses performed including subgroup analyses and adjusted analyses	2(3)
Adverse events	19	59	States important adverse events or side effects	13 (20)
DISCUSSION				
Interpretation	20	60	Interpretation of results / states dangers associated with multiplicity of analyses and outcomes	0 (0)
		61	Interpretation of the results / states sources of potential bias	0 (0)
Generalizability	21	62	Generalizability (external validity) of the trial findings	0 (0)
Overall evidence	22	63	Interpretation of results in context of current evidence	66 (100)
			Total/ mean	1368 (33)

Comparisons of reporting quality assessment scores for studies published prior to and after the year 2000, as well as compliance with old versus new items on the revised CONSORT checklist, were performed using the student's t test.

2.3　Data extraction and analysis

The report of each RCT included in this study was assessed independently by two reviewers (Hui-Min Zhang and Jiang-Xia Miao). Firstly, both reviewers underwent training in evaluating RCTs using a prepared checklist by discussing the definition of each item on the list. Secondly, a calibration exercise was conducted with 5 RCTs using the revised CONSORT checklist. Thirdly, all disagreements due to inaccurate data extraction were resolved through further review of the original articles. And fourthly, the two reviewers independently assessed each report with respect to its eligibility for the study. During the assessment, the discrepancies were resolved by consensus involving a third reviewer (Zhao-Xiang Bian).

Quality assessment information was collected from the study reports and entered independently by each reviewer into separate Excel spreadsheets (Microsoft; Mac version 5 .0a); trials were entered in random order. The resulting spreadsheets were then manually cross referenced to ensure agreement. Disagreements about interpretation of the information in the report were discussed and, if necessary, resolved by the third reviewer (Zhao-

Xiang Bian) .

Descriptive statistics were computed for each checklist item . For each article, the quality of its reporting was determined by the total number of items it included on the 63-item checklist . For example, a RCT reporting 40 of the 63 items on the checklist would score a 63 .5% . Each item on the checklist was also evaluated by tabulating the number of RCTs that reported the item . For example, if 33 of 66 RCTs reported item 2 on the checklist, that item would score a 50% compliance score overall .

3 RESULTS

3 .1 Literature search

A total of 66 RCTs on CHM for type 2 diabetes mellitus were included for assessment . The first RCT was published in 1988, and only 6 (9 .1%) RCTs were published in English in 5 different journals whose full texts were found using www . medline .com . Two RCTs were published in the journal *Diabetes Care* (2004 impact factor 7 .071), one paper was published in *Brazilian J Med Res* (2004 impact factor 0 .842), and three papers were published in journals that could not be found in " Journal citation reports" . Non-English articles published after 1998 were obtained through the subscription site www .wangfandata .com .

3 .2 Revised CONSORT checklist

The items in the revised CONSORT checklist that the independent raters had to discuss most often were primary and secondary outcome measurement and actual number of participants in each group . The raters resolved most coding discrepancies by consensus . A third independent rater was required to make the final decision about the actual number of participants in each group for 2 (3%) of the 66 articles .

3 .3 Assessment of reporting quality using revised CONSORT checklist

Compliance with reporting each item on the revised CONSORT checklist varied between 0% and 100% , with a median score of 33% for each item . Table 2 provides a summary of scores for each item in the checklist . The overall reporting quality of the RCTs as assessed with the revised CONSORT checklist varied between 19% and 44% , with a median score of 32% (standard deviation 8%) . Table 3 provides a summary of reporting quality for each RCT . There were no significant differences in the quality of reporting of RCTs between those published prior to and after the year 2000 (*P* >0 .05) .

3 .4 Title and abstract

Of 66 articles, only 3 (5%) identified their studies as RCTs in the title . Only 36 (55%) papers provided abstracts, including 23 (35%) with a structured format . None of the abstracts included a hypothesis, intention-to-treatment analysis statement, or methods for randomization . Only 26 (39%) papers provided the sample size in the abstract . Only 36 (55%) papers included a report of study results in the abstract .

3 .5 Introduction

Not all papers provided a clear explanation about the context in which their RCT was conducted . Only 36 (55%) papers provided a scientific background for their study, and only 18 (27%) gave an explanation of the rationale for conducting the trial .

3 .6 Methods

3 .6 .1 Participants   Although 58 (88%) of RCTs reported diagnostic criteria, only 23 (35%) reported inclusion criteria, and only 12 (18%) reported exclusion criteria . Just 3 studies (5%) provided information about informed consent and approval of the study by a research ethics committee . A majority (56%) of the papers provided the settings and locations where data were collected .

3 .6 .2 Intervention

Only 30 (45%) of RCTs reported the syndrome of disease based on Chinese medicine theories . All (100%) reported the rationale of the chosen CHM formula (66/ 66) . A strong majority (86%) reported the composition of the CHM formula (57/ 66) . All (100%) reported the preparation form of the CHM (66/ 66) . However, none of the studies provided any information about quality control of the CHM products used . Overall, the mean compliance with these 5 items across the 66 studies was 66% . Compliance with reporting of the interventions was generally satisfactory . The interventions intended for each group were reported in 65 (98%) of studies, method of administration in 64 (97%), duration of treatment in 63 (95%), and time of administration in 62 (94%) . Only 7 (11%) provided readers with the duration of the follow-up period .

3 .6 .3 Objectives

Only 64 (97%) of RCTs gave a clear explanation about specific study objectives . No studies provided the hypothesis of the study .

3 .6 .4 Outcomes

While 65 papers (98%) defined outcomes measurement, only one (2%) paper mentioned secondary outcomes, and only 3 (5%) papers reported methods to enhance the quality of outcomes measurement .

Table 3   Quality assessment of reporting of RCTs of CHM

Studies published prior to the year 2000				Studies published after the year 2000			
Author	Year	Items reported	Score	Author	Year	Items reported	Score
Wang	1988	17	27%	Lan	2000	17	27%
Russo	1990	25	40%	Li	2000	21	33%
Chen	1993	22	35%	Ni	2000	21	33%
Wang	1993	20	32%	Wang	2000	26	41%
Chen	1995	27	43%	Wen	2000	18	29%
Peng	1995	21	33%	Chen	2001	17	27%
Sotaniemi	1995	28	44%	Li	2001	16	25%
Vray	1995	26	41%	Namdul	2001	26	41%
Agrawal	1996	28	44%	Qing	2001	22	35%
Guo	1996	17	27%	Shao	2001	26	41%
Wu	1996	16	25%	Zeng	2001	18	29%
Xie	1996	22	35%	Zhang	2001	26	41%
Cao	1997	16	25%	Zhao	2001	20	32%
Chen	1997	24	38%	Zheng	2001	14	22%
Hua	1997	18	29%	Zhou	2001	18	29%
Pan	1997	26	41%	Zhou	2001	19	30%
Xu	1997	20	32%	Zhou	2001	18	29%
Zhou	1997	17	27%	Agrawal	2002	25	40%
Zhu	1997	25	40%	Li	2002	21	33%
Chang	1998	23	37%	Mao	2002	23	37%
Feng	1998	25	40%	Pang	2002	21	33%
Guo	1998	16	25%	Tao	2002	17	27%
Shen	1998	26	41%	Yang	2002	14	22%
Wang	1999	14	22%	Chen	2003	14	22%
You	1999	16	25%	Deng	2003	12	19%
Zhang	1999	17	27%	Hou	2003	13	21%
				Hu	2003	15	24%
				Huang	2003	20	32%
				Li	2003	21	33%
				Miao	2003	18	29%
				Ren	2003	22	35%
				Tong	2003	20	32%
				Wang	2003	23	37%
				Wei	2003	19	30%
				Wu	2003	25	40%
				Xu	2003	17	27%
				Yang	2003	22	35%
				Yao	2003	23	37%
				Zhang	2003	14	22%
				Zhang	2003	17	27%
Mean		21	34%	Mean		19	31%

3 .6 .5   Sample size, randomization, blinding and statistical methods

Reporting of statistical methodology was poor overall . Only one (2%) paper reported sample size calculation, and none of the papers provided an explanation about interim analyses and information about stopping rules . Only 9 (14%) papers reported methods to generate random allocation sequences, and only one (2%) paper stated the method used to implement the random allocation sequences, but no RCTs stated whether sequence was concealed until interventions were assigned . No RCTs reported details of randomization implementation . Though 4 (6%) trials were described as double blinded and 3 (5%) trials were single blinded, none of the papers mentioned how the success of blinding was evaluated . There were defined statistical methods in only 27 (41%) papers . Only one (2%) paper carried out intention-to-treat analysis .

3 .7   Results

None of the papers reported a clear flow of participants from screening to discharge . A single (2%) paper described protocol deviations with clear explanations of reasons for deviating . Only 20 (30%) papers provided dates for defined periods of recruitment . More than half (59%) papers provided a

baseline comparison of the clinical characteristics for each group . Though 65 (98%) papers reported the actual number of participants in each group, only 5 (8%) papers provided information about withdrawal and dropout . All papers summarized the results for each groups using the primary outcome . Although 43 (65%) papers estimated the effect size, none estimated the precision of the effect size . Only 2 (3%) papers reported ancillary analyses . As for adverse events, only 13 (20%) papers reported important adverse events or side effects .

3 .8　Discussion

None of the papers discussed weaknesses associated with conducting multiple analyses and outcomes, none reported sources of potential bias, and none discussed the external validity of the trial findings . All papers gave a summary of interpreting results in the context of current evidence, but the quality of most interpretations was low .

4　DISCUSSION

Our assessment of the quality of reporting of RCTs of CHM revealed that most papers reviewed were not adequately reporting the recommended methodological details required for proper interpretation of study results . This weakness extended to all aspects of the studies, from inadequate information in the title, abstract and introduction, through incomplete information in the statistical analysis and discussion of the study .

4 .1　Why CONSORT should be applied in RCTs with CHM

It should be reiterated here that the main reason for undertaking clinical trials in CHM is to inform and alter the practice of CHM . Since details of a study can only be obtained from its published reports, it was disappointing to note that investigators seemed to pay scant attention to how their study was reported . This situation largely mirrors that found in studies assessing the quality of reporting in RCTs in obstetrics, pediatrics, and general medicine[9-13], as well as breast cancer[14] and rheumatoid arthritis[15] .

Although some readers may have other channels to access details about a particular RCT, the vast majority of study end users rely exclusively on published reporting to understand how a study was conducted to properly interpret its results . Readers of RCTs have a right to obtain better information about a trial, and it is thus imperative that the authors provide sufficient details in their published reports . Though some researchers have suggested that the quality of reporting of a RCT is not indicative of the quality of its execution[16], our review found that bad reporting simply reflected the bad method-

ology and design of the trials .

Since scientific journals are the gatekeepers for the publication of the vast majority of RCTs, it is essential for editors of these journals to require that authors adhere to these reporting requirements and they, in turn, publish all of this information on a routine basis . Inadequately reporting information concerning clinical trials may mislead readers about the importance of the results, cover shortcomings of trial design and methodology . It may also affect the judgment of key stakeholders such as practitioners, patients, researchers, and policy makers, who are unable to make a clear decision because they lack the required information . Clear reporting of RCTs will allow effective use of trial results to know what works, in whom, and under what conditions .

In the absence of generally accepted standards about the reporting of clinical trials, it is difficult for authors, peer reviewers, and journal editors to adequately report all of the important elements of a RCT . Though a checklist may not be the best way to improve reporting, it does provide the important elements of reporting trials to readers in a simple format[17] . Such checklists can not only build up a platform and smooth the communication between authors, peer reviewers, editors, and readers, but they may also help to consolidate the reporting quality[6,18] . Thus, we believe it is essential to apply the revised CONSORT checklist to the reporting of RCTs with CHM .

The title and abstract of a report are the elements that readers first encounter . But most of the papers reviewed failed to identify the study as a RCT in the title to attract the attention of readers, and nearly half of the papers in our reviews didn't provide an abstract to let readers quickly capture the important information on a trial . Even those papers with abstracts did not routinely include pivotal information such as trial aims, sample size, groups, interventions, results, and conclusions . In the introduction part, most papers just gave very short explanation about the scientific background and their rationale, but this was often too brief for readers to understand .

As for the reporting of the methodology of clinical trials, the situation was mostly unsatisfactory . Most of important elements, such as diagnosis criteria, inclusion/ exclusion criteria, setting and location of trials, sample size calculation, randomization, and blinding were not reported clearly . These aspects of methodological quality were discussed in a prior study[1] . Precise details regarding the intervention for different arms of the study such as how and when they were actually administered are necessary to understand a RCT . For the reporting of outcome,

the majority of papers focused on the primary outcomes . Very few papers reported a secondary outcome, and just a few authors mentioned methods to enhance the quality of outcomes measurement . None of the studies reviewed reported the flow of participants throughout each stage of the RCT, from screening to discharge . This is typically accomplished by using flowcharts, which have been associated with improved quality of reporting of randomized controlled trials[3] . In fact, this chart not only improves the reporting of the RCT but may improve how a trial is conducted .

Intention-to-treat analysis specifies that data from all allocated participants in the clinical trial should be included in the data analysis for the group to which they were originally assigned, regardless of compliance with the intervention protocol . This process is thought of as a general approach that can best serve the goals of randomization, i .e . to ensure comparability of the intervention and control groups[19] . On one hand, it may also be argued that adding results from participants who did not complete the intervention might dilute the true effect of the treatment in participants with full compliance . On the other hand, participant noncompliance with the intervention may have caused by the intervention itself and results must reflect this potential effect . Therefore, when a trial is conducted, attention to these factors and efforts to limit their occurrence are necessary to preserve study integrity and optimal analysis of data . Only one study of CHM reported an intention-to-treat analysis .

As for discussion and conclusion sections in reviewed articles, the situation was not satisfactory . Normally, this part should focus on analyzing the sources of potential bias that may have skewed their results, and stating the final conclusion . Most of RCTs of CHM just focused on their primary outcome, and considered it as a conclusion without discussion or explanation of potential bias and/ or dangers associated with multiplicity of analyses . Without this broad perspective, readers may justifiably remain skeptical about the validity of results .

4 . 2　Why is modification necessary when applying CONSORT to RCTs with CHM

As mentioned in the introduction of this paper, we found that the CONSORT checklist did not cover all necessary aspects of RCTs of CHM . After all, Chinese herbal medicine possesses many different characteristics than conventional medicine, such as treatment rationale, treatment method and evaluation system . Therefore we added 5 items to the checklist for evaluating the quality of reporting of RCTs with CHM . Compliance with the additional items was generally very good, confirming that

RCTs of CHM are already reporting content-specific trial methodology . However, none of the RCTs of CHM reviewed discussed quality control of the herbal medicine used . The improvement is necessary in this aspect, as discussed in the third part of our series[20] .

Recently, an international group of CHM doctors, editors, and epidemiologists led by Prof . You-Ping Li and David Moher began working together to deal with the revision of CONSORT for RCTs with CHM . We are working on the checklist of CONSORT of Chinese herbal medicine, and hope this revised CONSORT checklist will become available in June 2007 . We would like to highly recommend that editors of CHM journals require authors to use a structured approach to presenting their trials as a condition of publication . Such requirement may eventually force investigators to organize their protocols at an early stage of their research with an eye toward publication . A standardized combination of flowchart, checklist, and report formatting should tangibly enhance the quality of reporting of RCTs in CHM .

5　LIMITATIONS

Our study on the reporting quality of RCTs of CHM has two important limitations that need to be discussed . First, our review was on only 66 of the 167 RCTs of CHM identified by our search strategy, all related to type 2 diabetes mellitus . It is possible that our study sample is not representative of all RCTs of CHM for other conditions and that our results cannot be generalized to all RCTs of CHM . Second, our review was based on a revised CONSORT checklist adding five items relevant to CHM, which we believed were very important elements for RCTs with CHM . However, this revised checklist did not undergo extensive assessment and may not be appropriate as a rating tool for reporting quality of RCTs . It is therefore suggested simply as a starting point for future research on this topic .

6　CONCLUSION

In general, the quality of reporting of RCTs with CHM using a revised CONSORT checklist was low . More attention should be given to the reporting of RCTs with CHM to ensure that all necessary items are clearly delineated to provide information on a study that is necessary for all key stakeholders to make informed decisions based on its findings .

7　RECOMMENDATION

To improve the quality of reporting of RCTs of CHM we recommend adopting the CONSORT checklist as the reporting quality standard since it includes

all of the basic elements of RCT reporting and there is evidence to suggest that using this checklist can improve the quality of reporting of RCTs . We also believe that revision of the CONSORT checklist is necessary to reflect items that are specific to CHM such as: (1) syndrome of disease based on Chinese medicine theories; (2) rationale of CHM formula; (3) formula composition; (4) preparation form of CHM; and (5) quality control of CHM .

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