Clinical Trials과 보고지침

Reporting Guideline of Clinical Trial Results

-CONSORT guideline-

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2011. 2. 10

Why reporting guideline for clinical research ?

- 부적절한 report로는 연구의 질과 의미(상관성)을 평가하기 어렵다.
- Publication bias
  - ✓ Study publication bias (Publisher)
  - ✓ Reporting bias (authors)
- Meta분석 등 연구결과의 활용이 어렵다.

임상연구분야의 국제 동향

임상연구의 윤리적 기준 강화 및 객관화

- 연구윤리 강화
  - 연구자 인증제
  - 사전등록에 대한 의무
- 출판bias의 최소화를 위한 등록시스템
- Reporting guideline

성과 활용 및 확산을 위한 표준화 추세

- 임상연구 정보의 상호 활용을 위한 표준화
  - CDISC, NCI CaBIG project
- Data Combining: for SR
- Data sharing policy

Evidence-Based Healthcare

Publication Bias

- Study not published
  - ✓ Not accepted by publisher
  - ✓ Selective publication (esp. company-sponsored trials)
- Only selected findings published
- Stopping a trial early for benefit

Publication Bias

- Study not published
  - ✓ Not accepted by publisher
  - ✓ Selective publication (esp. SIT)
- Only selected findings published
- Stopping a trial early for benefit

Publication Bias를 해결하려는 국제적 노력들은?

1. Clinical Trial Registration

2. Reporting Guidelines

Biased reporting is scientific misconduct

"In return for the altruism and trust that make clinical research possible, the research enterprise has an obligation to **conduct research ethically** and to **report it honestly**."

["Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors", September 2004]

Some history of reporting guidelines developed by consensus

1993-94	SORT	RCT
1994	Asilomar	RCT
1995-96	**CONSORT**	**RCT**
1996-99	QUOROM	SR/M-A of RCTs
1997-00	MOOSE	M-A of obs. studies
1999-01	**CONSORT II**	**RCT**
2000-03	STARD	Diagnostic test
2003-04	TREND	Non-RCT/Behavioural
2001-05	REMARK	Biomarker(cancer)
2004	**STROBE**	**Observational**
2005	QUOROM II	SR/M-A of RCTs
2010	**CONSORT2010**	**RCT**

SORT:Standardized Reporting of Trials, QUOROM;Quality of Reporting of Meta-analyses

Reporting Guidelines for Clinical Research

연구 종류에 따른 국제적인 research reporting guideline이 개발되었음

STROBE

- Strengthening the Reporting of Observational Studies in Epidemiology

STREGA

- Strengthening the Reporting of Genetic Association Studies

CONSORT

- CONsolidated Standards of Reporting Trials

STARD

- Reporting of diagnostic accuracy studies

PRISMA

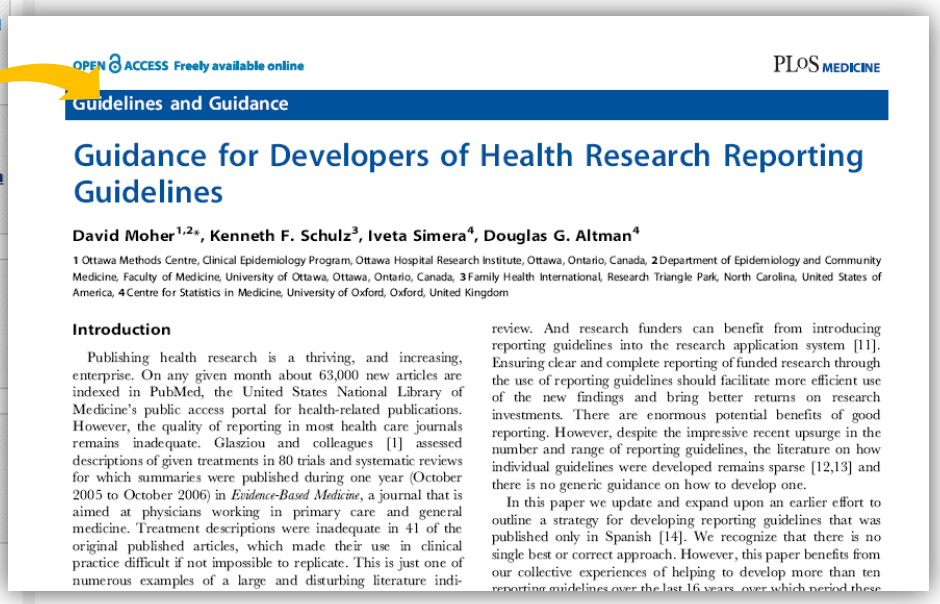
- Reporting of systematic reviews

MOOSE

- Reporting of meta-analyses of observational studies

EQUATOR

- Enhancing the Quality and Transparency of Health Research
- 국제적인 보건의료 reporting의 표준을 위한 networking



CONSORT statement와 관련된 설명 및 예시는 모두 공식사이트 및 publication된 논문으로부터 인용한 것입니다.

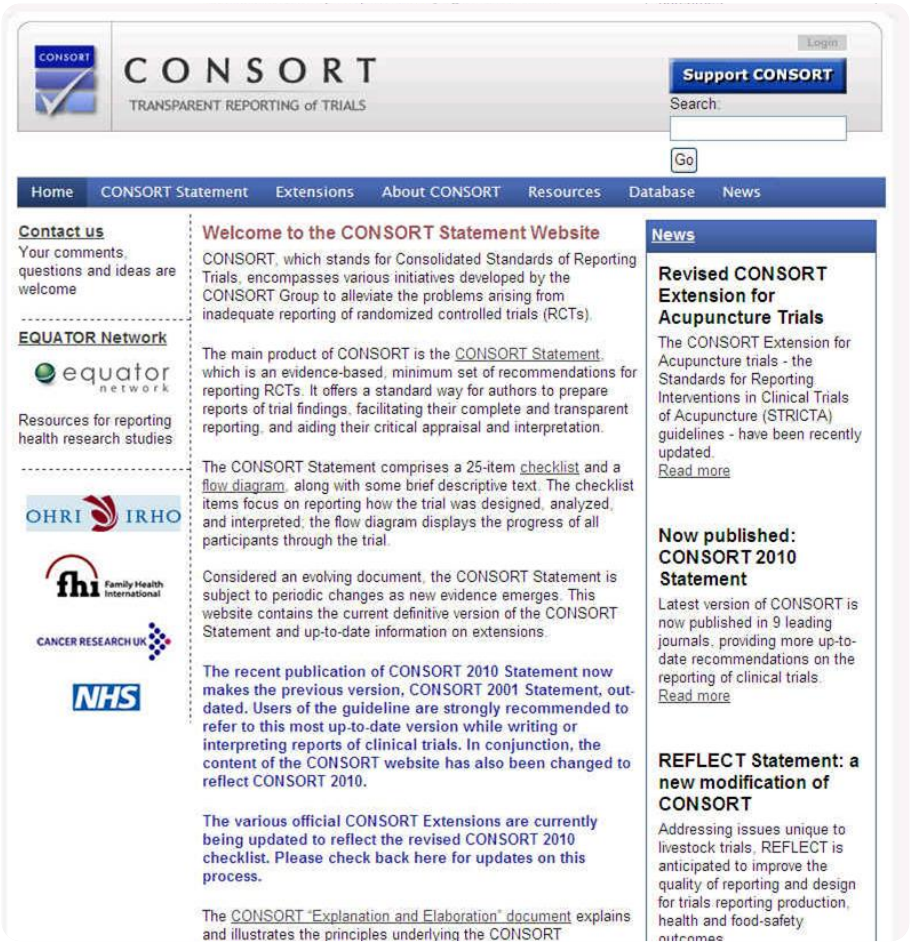
Using the CONSORT Statement

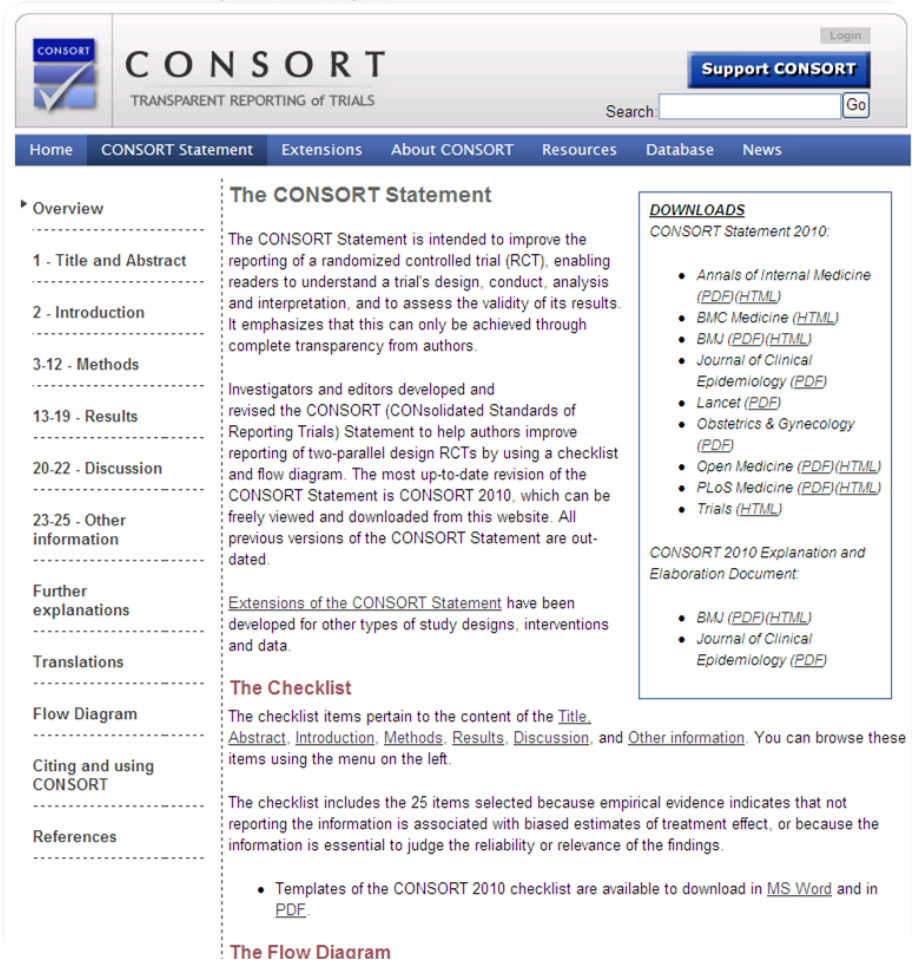
However, because the guidelines represent a consensus agreed through successive drafts by the CONSORT Group, they should not be edited or modified in any way, although it is acceptable to publish portions (e.g., the summary).

http://www.consort-statement.org/consort-statement/citing-and-using-consort/

CONSORT (CONsolidated Standards of Reporting Trials) Statement

http://www.consort-statement.org





CONSORT statement

- Object
  - ✓ To improve the reporting of a randomized controlled trial (RCT), enabling readers to understand a trial's design, conduct, analysis and interpretation
  - ✓ To assess the validity of its results.
- By using a checklist and flow diagram.

CONSORT 2010 checklist (25 items)

TITLE & ABSTRACT

INTRODUCTION

- Background & Objectives

METHODS

- Trial design
- Participants
- Interventions
- Outcomes
- Sample size
- Randomization
  - **Sequence generation**
  - **Allocation concealment**
  - **Implementation**
- Blinding
- Statistical methods

RESULTS

- Participant flow
- Recruitment
- Baseline data
- Numbers analyzed
- Outcomes and estimation
- Ancillary analyses
- Harms (Adverse events)

DISCUSSION

- Limitations
- Generalisability
- Interpretation

OTHRT INFORMATION

- Registration
- Protocol
- Funding

Title

- To help ensure that a study is appropriately indexed and easily identified, authors should use the word **“randomised”** in the title to indicate that the participants were randomly assigned to their comparison groups.
- Example
  - ✓ “Smoking reduction with oral nicotine inhalers: double blind, randomised clinical trial of efficacy and safety.”(BMJ. 2000;321:329-33.)

Method: Trial Design

- **Description of trial design (such as parallel, factorial) including allocation ratio**
- Example
  - ✓ This was a multicenter, stratified (6 to 11 years and 12 to 17 years of age, with imbalanced randomisation [2:1]), double-blind, placebo-controlled, parallel-group study conducted in the United States (41 sites) *(Pediatrics 2009;123:e770-e776)*

Method: Study settings

- **Settings and locations where the data were collected**
- Example
  - ✓ The study took place at the antiretroviral therapy clinic of Queen Elizabeth Central Hospital in Blantyre, Malawi, from January 2006 to April 2007. Blantyre is the major commercial city of Malawi, with a population of 1 000 000 and an estimated HIV prevalence of 27% in adults in 2004. *(BMJ 2009;338:1867-75)*

Method: Sample size

- **How sample size was determined**
- Example
  - ✓ To detect a reduction in PHS (postoperative hospital stay) of 3 days (SD 5 days), which is in agreement with the study of Lobo et al. with a **two-sided 5% significance level and a power of 80%,** a sample size of 50 patients per group was necessary, **given an anticipated dropout rate of 10%**. To recruit this number of patients a 12-month inclusion period was anticipated. *(Trials 2009;10:50)*

Method: Randomisation

sequence generation

- **Method used to generate the random allocation sequence**
- **Examples**
  - ✓ Independent pharmacists dispensed either active or placebo inhalers **according to a computer generated randomisation list**. *(BMJ.2000;321:329-33)*
  - ✓ “For allocation of the participants, a computer-generated list of random numbers was used. *(Obstet Gynecol 2008;111:639-47)*

Method: Blinding

- **If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how**
- **Example**
  - ✓ Whereas patients and physicians allocated to the intervention group were aware of the allocated arm, outcome assessors and data analysts were kept blinded to the allocation. *(Mayo Clin Proc 2008;83:747-57)*

Results: Participant Flow

- **A diagram is strongly recommended.**
- Item 13a - For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome

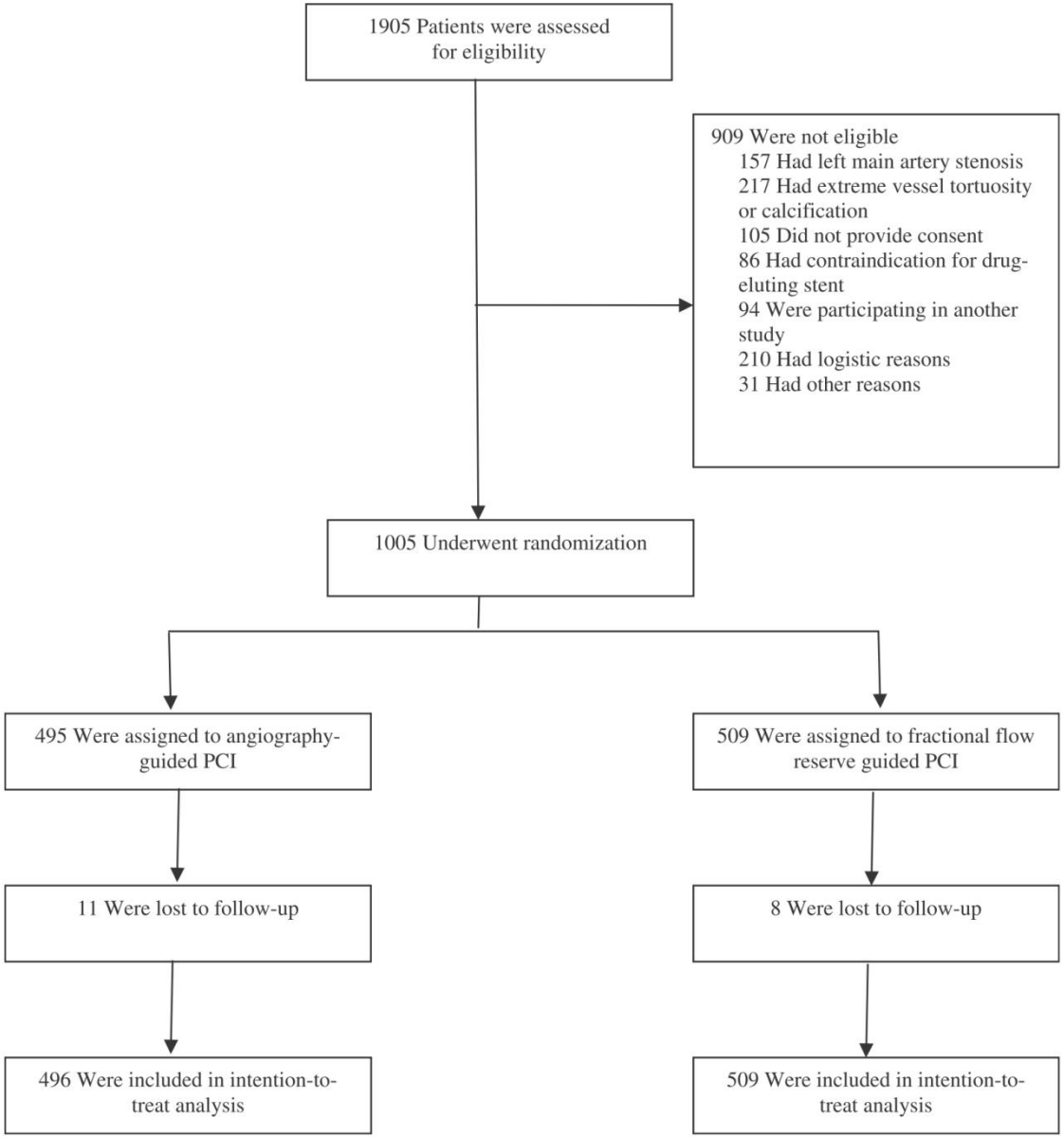
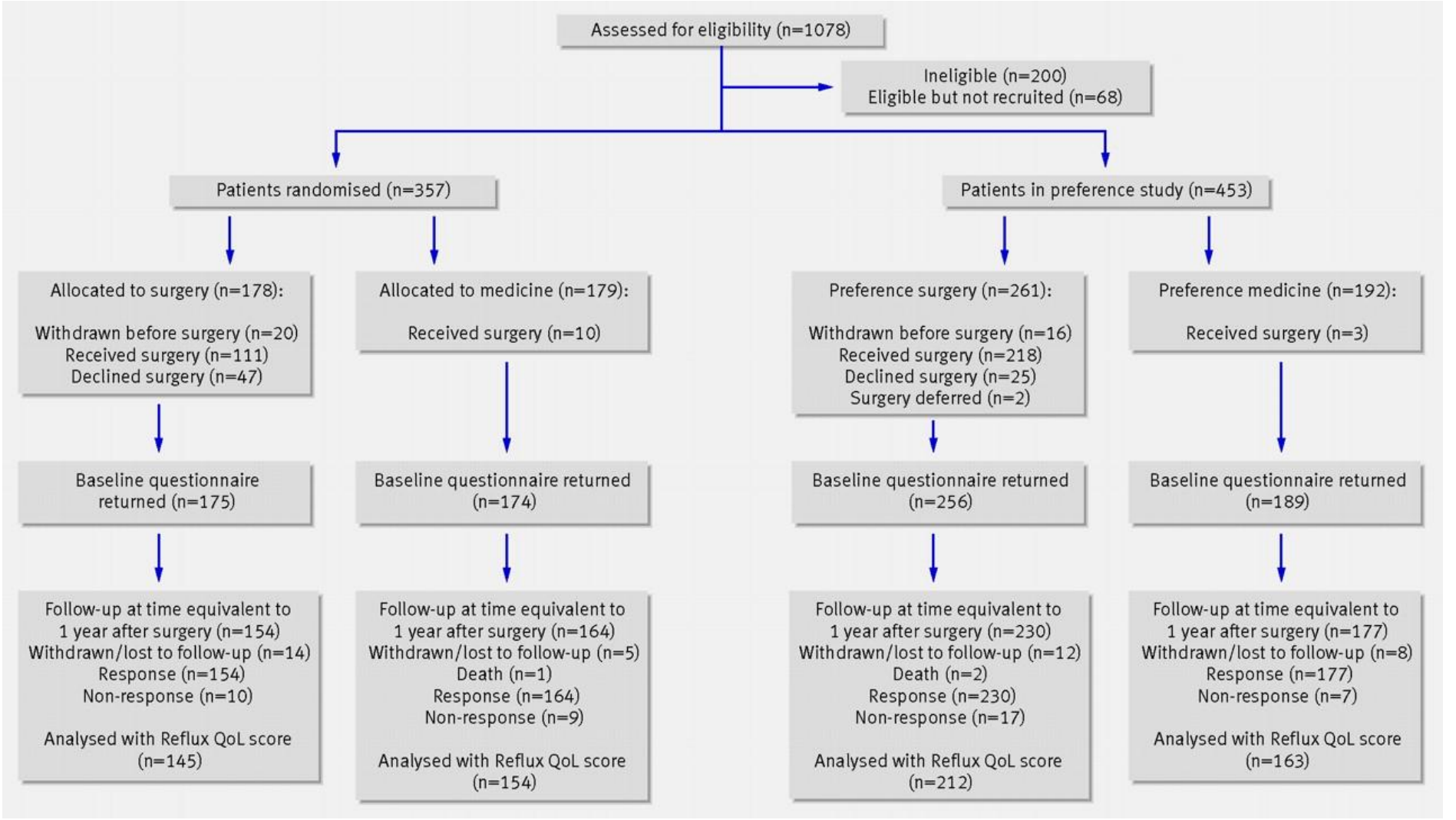


Fig. 2. Flow diagram of a multicentre trial of fractional flow reserve versus angiography for guiding percutaneous coronary intervention (PCI) (adapted from Tonino et al [313]). The diagram includes detailed information on the excluded participants.

Minimal access surgery compared with medical management for chronic gastro-oesophageal reflux disease: UK collaborative randomised trial



BMJ. 2008 Dec 15;337:a2664.

Results: Recruitment

- Dates defining the periods of recruitment and follow-up
- Example

  “Age-eligible participants were recruited … from February 1993 to September 1994 … Participants attended clinic visits at the time of randomisation (baseline) and at 6-month intervals for 3 years.”(Ann Intern Med. 2000;133:516-26)

Results: Outcome and estimation

- Item 17a - For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
- Examples

Table 5 | Example of reporting of summary results for each study group (binary outcomes).* (Adapted from table 2 of Mease et al[103])

Endpoint	Number (%)		Risk difference (95% CI)
	Etanercept (n=30)	Placebo (n=30)	
Primary endpoint			
Achieved PsARC at 12 weeks	26 (87)	7 (23)	63% (44 to 83)
Secondary endpoint			
Proportion of patients meeting ACR criteria:			
ACR20	22 (73)	4 (13)	60% (40 to 80)
ACR50	15 (50)	1 (3)	47% (28 to 66)
ACR70	4 (13)	0 (0)	13% (1 to 26)

*See also example for item 6a.
PsARC=psoriatic arthritis response criteria. ACR=American College of Rheumatology.

Table 6 | Example of reporting of summary results for each study group (continuous outcomes). (Adapted from table 3 of van Linschoten[234])

	Exercise therapy (n=65)		Control (n=66)		Adjusted difference* (95% CI) at 12 months
	Baseline (mean (SD))	12 months (mean (SD))	Baseline (mean (SD))	12 months (mean (SD))	
Function score (0-100)	64.4 (13.9)	83.2 (14.8)	65.9 (15.2)	79.8 (17.5)	4.52 (−0.73 to 9.76)
Pain at rest (0-100)	4.14 (2.3)	1.43 (2.2)	4.03 (2.3)	2.61 (2.9)	−1.29 (−2.16 to −0.42)
Pain on activity (0-100)	6.32 (2.2)	2.57 (2.9)	5.97 (2.3)	3.54 (3.38)	−1.19 (−2.22 to −0.16)

*Function score adjusted for baseline, age, and duration of symptoms.

Results: Outcome and estimation

- Item 17b - For binary outcomes, presentation of **both absolute and relative effect sizes** is recommended
- Example

  "The risk of oxygen dependence or death was reduced by 16% (95% CI 25% to 7%). The absolute difference was -6.3% (95% CI -9.9% to -2.7%); early administration to an estimated 16 babies would therefore prevent 1 baby dying or being long-term dependent on oxygen" (also see table 7).

Table 7 | Example of reporting both absolute and relative effect sizes. (Adapted from table 3 of The OSIRIS Collaborative Group[242])

	Percentage (No)			
Primary outcome	Early administration (n=1344)	Delayed selective administration (n=1346)	Risk ratio (95% CI)	Risk difference (95% CI)
Death or oxygen dependence at "expected date of delivery"	31.9 (429)	38.2 (514)	0.84 (0.75 to 0.93)	−6.3 (−9.9 to −2.7)

Discussion

- Item 20 - Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
- Item 21 - Generalisability (external validity, applicability) of the trial findings
- Item 22 - Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

Other Information

- Registration
  - ✓ Registration number and name of trial registry
- Protocol
  - ✓ Where the full trial protocol can be accessed, if available
- Funding
  - ✓ Sources of funding and other support (such as supply of drugs), role of funders

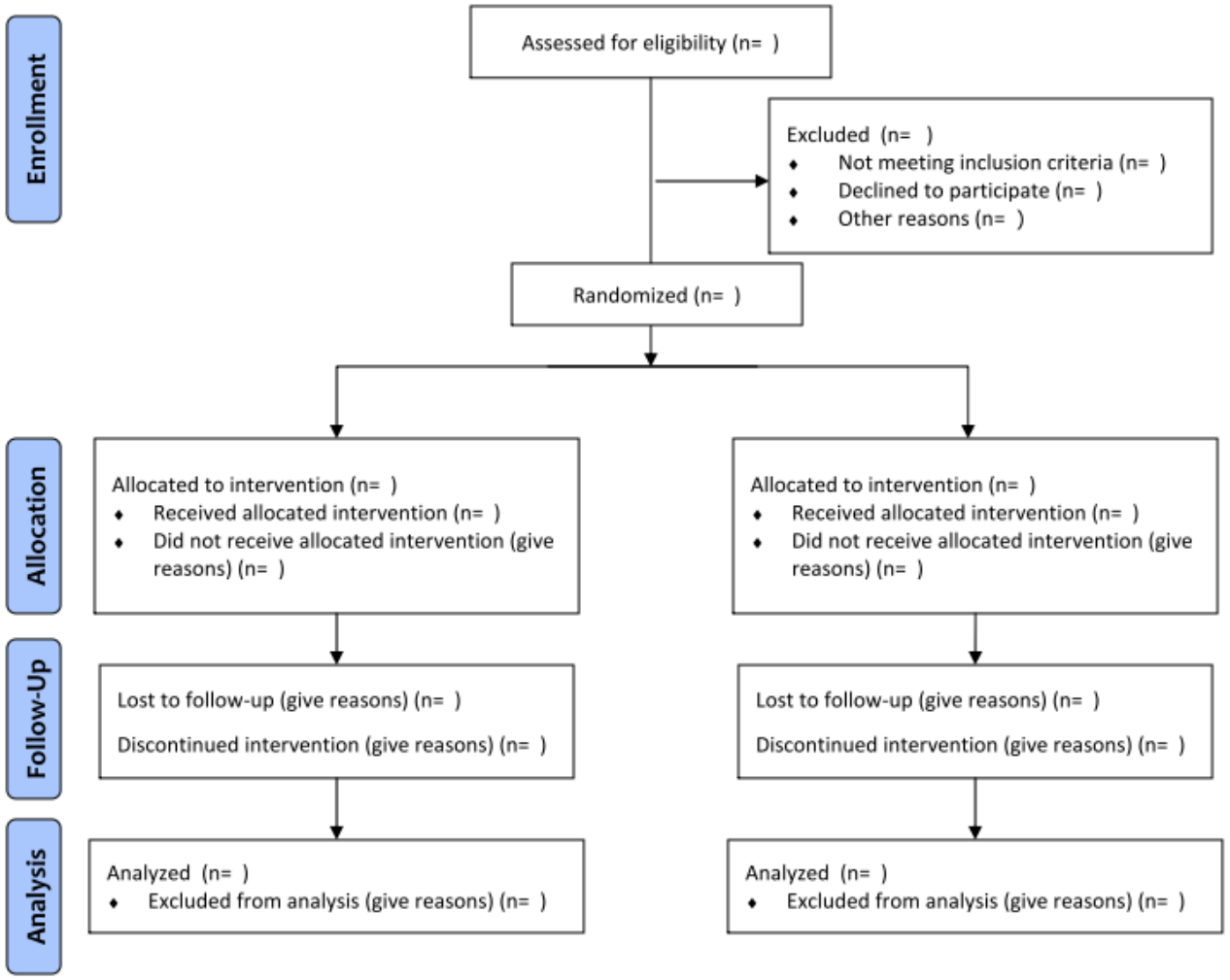
CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT Statement 2010 Flow Diagram



Impact of CONSORT

- More than 400 journals have endorsed CONSORT.
- **How to endorse the CONSORT Statement (Journal)**
  - ✓ Include mention of the CONSORT Statement and refer to the CONSORT web link (www.consort-statement.org) in the journal's instructions to authors for reporting of randomized trials, or in the organization's resource section.
  - ✓ Include an editorial in the journal to this effect along with the journal's policy on helping to improve the quality of reporting clinical trials.
  - ✓ Allow us to add your journal's name to its list of journal endorsers by contacting us.

Designs
Interventions
Data

Extensions of the CONSORT Statement

Due to the recent publication of CONSORT 2010, work is underway to update the various CONSORT extensions to reflect the 2010 checklist.

The main CONSORT Statement is based on the 'standard' two-group parallel design. However, there are several different types of randomized trials, some of which have different designs (e.g., cluster), interventions (e.g., herbals) and data (e.g., harms).

To help improve the reporting of these trials the CONSORT Group has been involved in extending and modifying the main CONSORT Statement for application in these various areas, and the resulting CONSORT extensions are presented in this section. This list is, by no means, exhaustive; and work is constantly in progress.

Please note that modifications to the CONSORT checklist or flow diagram that are not developed with the involvement of the CONSORT Group do not have permission to name their work 'CONSORT'.

Some work, however, has been done to modify the CONSORT Statement without the involvement of the Group. These unofficial extensions of the CONSORT Statement can be found in the CONSORT database.

Shortcuts:

Design Extensions

- *Cluster trials*
- *Non-inferiority and equivalence trials*
- *Pragmatic Trials*

Intervention Extensions

- *Herbal medicinal interventions*
- *Non-pharmacological treatment interventions*
- *Acupuncture Interventions*

Data Extensions

- *Harms*
- *Abstracts*

Page last edited: 24 January 2011

Cluster Trials

Extension of CONSORT statement to cluster trials

To accommodate the reporting of the special features of the cluster randomised trial, we have extended the CONSORT statement to include the following information:

- The rationale for adopting a cluster design
- How the effects of clustering were incorporated into the sample size calculations
- How the effects of clustering were incorporated into the analysis
- The flow of both clusters and individuals through the trial, from assignment to analysis.

Title and abstract

Item 1: How participants were allocated to interventions (eg random allocation, randomised, or randomly assigned), *specifying that allocation was based on clusters.*

Example

Title: "Self help smoking cessation in pregnancy: cluster randomised trial."[21]

Abstract (design): "Pragmatic cluster randomised controlled trial with community midwife as the unit of randomisation."[21]

Sample size

Item 7: How total sample size was determined *(including method of calculation, number of clusters, cluster size, a coefficient of intracluster correlation (ICC or k), and an indication of its uncertainty)* and, when applicable, explanation of any interim analyses and stopping rules.

Example

We calculated sample size with a method that takes into account the intracluster correlation coefficient, the number of events, the expected effect, and the power of the study. We assumed an intracluster correlation of $\rho = 0.2$, a minimum of 25 patients for each practice, and a worst case control rate of 50%. Under these assumptions we anticipated a power of 87% to detect a difference of 15% in rates between the two groups with $\alpha = 0.05$ with 60 practices for each intervention group.[29]

Paper section and topic	Item	Descriptor
Title and abstract		
Design	1*	How participants were allocated to interventions (eg random allocation, randomised, or randomly assigned), *specifying that allocation was based on clusters*
Introduction		
Background	2*	Scientific background and explanation of rationale, *including the rationale for using a cluster design*
Methods		
Participants	3*	Eligibility criteria for participants *and clusters* and the settings and locations where the data were collected
Interventions	4*	Precise details of the interventions intended for each group, *whether they pertain to the individual level, the cluster level, or both*, and how and when they were actually administered
Objectives	5*	Specific objectives and hypotheses *and whether they pertain to the individual level, the cluster level, or both*
Outcomes	6*	Report clearly defined primary and secondary outcome measures, *whether they pertain to the individual level, the cluster level, or both*, and, when applicable, any methods used to enhance the quality of measurements (eg multiple observations, training of assessors)
Sample size	7*	How *total* sample size was determined *(including method of calculation, number of clusters, cluster size, a coefficient of intracluster correlation (ICC or k), and an indication of its uncertainty)* and, when applicable, explanation of any interim analyses and stopping rules
Randomisation:		
Sequence generation	8*	Method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, *matching*)
Allocation concealment	9*	Method used to implement the random allocation sequence, *specifying that allocation was based on clusters rather than individuals and* clarifying whether the sequence was concealed until interventions were assigned
Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups
Blinding (masking)	11	Whether participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated
Statistical methods	12*	Statistical methods used to compare groups for primary outcome(s) *indicating how clustering was taken into account*; methods for additional analyses, such as subgroup analyses and adjusted analyses
Results		
Participant flow	13*	Flow of *clusters and* individual participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of *clusters and* participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed 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 information for each group *for the individual and cluster levels as applicable*
Numbers analysed	16*	Number of *clusters and* 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 (eg 10/20 not 50%)
Outcomes and estimation	17*	For each primary and secondary outcome, a summary of results for each group *for the individual or cluster level as applicable*, and the estimated effect size and its precision (eg 95% confidence interval) *and a coefficient of intracluster correlation (ICC or k) for each primary outcome.*
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified 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.
Generalisability	21*	Generalisability (external validity) *to individuals and/or clusters (as relevant)* of the trial findings
Overall evidence	22	General interpretation of the results in the context of current evidence

*Addition to CONSORT guidelines 2001[2]

Pragmatic Clinical Trials

Section	Item	Standard CONSORT description	Extension for pragmatic trials
Title and abstract	1	How participants were allocated to interventions (eg, "random allocation," "randomised," or "randomly assigned")	
Introduction			
Background	2	Scientific background and explanation of rationale	Describe the health or health service problem that the intervention is intended to address and other interventions that may commonly be aimed at this problem
Methods			
Participants	3	Eligibility criteria for participants; settings and locations where the data were collected	Eligibility criteria should be explicitly framed to show the degree to which they include typical participants and/or, where applicable, typical providers (eg, nurses), institutions (eg, hospitals), communities (or localities eg, towns) and settings of care (eg, different healthcare financing systems)
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered	Describe extra resources added to (or resources removed from) usual settings in order to implement intervention. Indicate if efforts were made to standardise the intervention or if the intervention and its delivery were allowed to vary between participants, practitioners, or study sites
			Describe the comparator in similar detail to the intervention
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 (eg, multiple observations, training of assessors)	Explain why the chosen outcomes and, when relevant, the length of follow-up are considered important to those who will use the results of the trial
Sample size	7	How sample size was determined; explanation of any interim analyses and stopping rules when applicable	If calculated using the smallest difference considered important by the target decision maker audience (the minimally important difference) then report where this difference was obtained
Randomisation—sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (eg, blocking, stratification)	
Randomisation—allocation concealment	9	Method used to implement the random allocation sequence (eg, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned	
Randomisation—implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups	
Blinding (masking)	11	Whether participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment	If blinding was not done, or was not possible, explain why
Statistical methods	12	Statistical methods used to compare groups for primary outcomes; methods for additional analyses, such as subgroup analyses and adjusted analyses	

Steinsbekk A, Fonnebo V, Lewith G, Bentzen N. Homeopathic care for the prevention of upper respiratory tract infections in children: a pragmatic, randomised, controlled trial comparing individualised homeopathic care and waiting-list controls. *Complement Ther Med* 2005;13:231-8.

Item 7: methods; sample size

How sample size was determined; when applicable, explanation of any interim analyses and stopping rules

Extension for pragmatic trials: If calculated using the smallest difference considered important by the target decision maker audience (the minimally important difference) then report where this difference was obtained.

Example—"There were no previous data using the main outcome measure on which to base the sample size calculation, and therefore the sample size was calculated on the number of days with URTI [upper respiratory tract infection]. It was decided, in line with other rigorous pragmatic studies that the smallest difference worth detecting was a 20% reduction in number of days with URTI."[67]

Explanation—The minimally important difference (MID) is the size of a change in the primary outcome which would be important to the key decision making audience. The MID may differ between settings, consequently readers need to know what MID was considered important in the trial setting, and by whom, to contrast with their own expectations.

Acupuncture Interventions

Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines

STRICTA 2010 checklist of information to include when reporting interventions in a clinical trial of acupuncture (Expansion of Item 5-Interventions from CONSORT 2010 checklist)

Item	Detail
1. Acupuncture rationale	1a) Style of acupuncture (e.g. Traditional Chinese Medicine, Japanese, Korean, Western medical, Five Element, ear acupuncture, etc)
	1b) Reasoning for treatment provided, based on historical context, literature sources, and/or consensus methods, with references where appropriate
	1c) Extent to which treatment was varied
2. Details of needling	2a) Number of needle insertions per subject per session (mean and range where relevant)
	2b) Names (or location if no standard name) of points used (uni/bilateral)
	2c) Depth of insertion, based on a specified unit of measurement, or on a particular tissue level
	2d) Response sought (e.g. de qi or muscle twitch response)
	2e) Needle stimulation (e.g. manual, electrical)
	2f) Needle retention time
	2g) Needle type (diameter, length, and manufacturer or material)
3. Treatment regimen	3a) Number of treatment sessions
	3b) Frequency and duration of treatment sessions
4. Other components of treatment	4a) Details of other interventions administered to the acupuncture group (e.g. moxibustion, cupping, herbs, exercises, lifestyle advice)
	4b) Setting and context of treatment, including instructions to practitioners, and information and explanations to patients
5. Practitioner background	5) Description of participating acupuncturists (qualification or professional affiliation, years in acupuncture practice, other relevant experience)
6. Control or comparator interventions	6a) Rationale for the control or comparator in the context of the research question, with sources that justify this choice
	6b) Precise description of the control or comparator. If sham acupuncture or any other type of acupuncture-like control is used, provide details as for Items 1 to 3 above.

WILEY-BLACKWELL

Journal of Gastroenterology and Hepatology JGHF

Registration of Clinical Trials

We strongly recommend, as a condition of consideration for publication, registration in a public trials registry. Trials register at or before the onset of patient enrolment. This policy applies to any clinical trial starting enrolment after July 1, 2008. For trials that began enrolment before this date, we request registration by December 1, 2008, before considering the trial for publication. We define a clinical trial as any research project that prospectively assigns human subjects to intervention or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Studies designed for other purposes, such as to study pharmacokinetics or major toxicity (e.g., phase 1 trials) are exempt.

We do not advocate one particular registry, but registration with a registry that meets the following minimum criteria:

(1) accessible to the public at no charge;
(2) searchable by standard, electronic (Internet-based) methods;
(3) open to all prospective registrants free of charge or at minimal cost;
(4) validates registered information;
5) identifies trials with a unique number; and
(6) includes information on the investigator(s), research question or hypothesis, methodology, intervention and comparisons, eligibility criteria, primary and secondary outcomes measured, date of registration, anticipated or actual start date, anticipated or actual date of last follow-up, target number of subjects, status (anticipated, ongoing or closed) and funding source(s).

Registries that currently meet these criteria include, but are not limited to:

(1) the registry sponsored by the United States National Library of Medicine (www.clinicaltrials. gov);
(2) the International Standard Randomized Controlled Trial Number Registry (http://www.controlled-trials.com);
(3) the Australian Clinical Trials Registry (http://www.actr.org.au);
(4) the Chinese Clinical Trials Register (http://www.chictr.org); and
(5) the Clinical Trials Registry - India (http://www.ctri.in); (6) University hospital Medical Information Network (UMIN) (http://www.umin.ac.jp/ctr/).

Randomized Controlled Trials

Reporting of randomized controlled trials should follow the guidelines of The CONSORT Statement: http://www.consort-statement.org Any experiments involving animals must be demonstrated to be ethically acceptable and where relevant conform to international standards for animal usage in research. These include but are not limited to the NHMRC of Australia, NIH and European Union.

www.strobe-statement.org/

STROBE Statement

Strengthening the reporting of observational studies in epidemiology

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What is STROBE?

STROBE stands for an international, collaborative initiative of epidemiologists, methodologists, statisticians, researchers and journal editors involved in the conduct and dissemination of observational studies, with the common aim of **STrengthening the Reporting of OBservational studies in Epidemiology**.

The STROBE Statement is being endorsed by a growing number of biomedical journals. Click here for full list.

For STROBE-related entries in PubMed click here.

What's new in the STROBE Initiative?

Monday 29. of March 2010

The CONSORT 2010 Statement

The CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Ransomised Trials was published simultaneusly last 24th March in nine leading biomedical journals PLoSMedicine, BMJ, The Lancet, Obstetrics & Gynecology,...

[more]

Thursday 25. of February 2010

Guidance for Developers of Health Research Reporting Guidelines

In the article, recently published in PLosMed, David Moher et al aim at providing guidance for developing reporting guidelines.

STROBE checklist (22 items)

TITLE & ABSTRACT

INTRODUCTION

- Background /Rationale

METHODS

- Study design
- Setting
- Participants
- Variables
- Data sources/measurement
- Bias
- Study size
- Quantitative variables
- Statistical methods

RESULTS

- Participants
- Descriptive data
- Outcome data
- Main results
- Other analyses

DISCUSSION

- Key results
- Limitations
- Interpretation
- Generalizability

OTHRT INFORMATION

- Funding

STROBE checklist

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Annals of Internal Medicine

ACADEMIA AND CLINIC

Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): Explanation and Elaboration

Jan P. Vandenbroucke, MD; Erik von Elm, MD; Douglas G. Altman, DSc; Peter C. Gøtzsche, MD; Cynthia D. Mulrow, MD; Stuart J. Pocock, PhD; Charles Poole, ScD; James J. Schlesselman, PhD; and Matthias Egger, MD, for the STROBE initiative

Much medical research is observational. The reporting of observational studies is often of insufficient quality. Poor reporting hampers the assessment of the strengths and weaknesses of a study and the generalizability of its results. Taking into account empirical evidence and theoretical considerations, a group of methodologists, researchers, and editors developed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations to improve the quality of reporting of observational studies.

The STROBE Statement consists of a checklist of 22 items, which relate to the title, abstract, introduction, methods, results, and discussion sections of articles. Eighteen items are common to cohort studies, case–control studies, and cross-sectional studies, and 4 are specific to each of the 3 study designs. The STROBE Statement provides guidance to authors about how to improve the reporting of observational studies and facilitates critical appraisal and interpretation of studies by reviewers, journal editors, and readers.

This explanatory and elaboration document is intended to enhance the use, understanding, and dissemination of the STROBE Statement. The meaning and rationale for each checklist item are presented. For each item, 1 or several published examples and, where possible, references to relevant empirical studies and methodological literature are provided. Examples of useful flow diagrams are also included. The STROBE Statement, this document, and the associated Web site (www.strobe-statement.org) should be helpful resources to improve reporting of observational research.

Ann Intern Med. 2007;147:W-163–W-194. www.annals.org

For author affiliations, see end of text.

STROBE extension

- **Diagnostic Test: STARD**
  - ✓ The STARD Initiative
  - ✓ Standards for Reporting of Diagnostic Accuracy. Towards complete and accurate reporting of studies of diagnostic accuracy (Ann Intern Med. 2003;138:40)
- **Tumor markers: REMARK**
  - ✓ Statistics Subcommittee of the NCI-EORTC Working Group on Cancer Diagnostics.
  - ✓ REporting recommendations for tumour MARKer prognostic studies (REMARK). (Br J Cancer. 2005;93:3)
- **Genetic Association:STREGA**
  - ✓ Human Genome Epidemiology Network and the Network of Investigator Networks.
  - ✓ A road map for efficient and reliable human genome epidemiology. (Nat Genet. 2006;38:3)

ACADEMIA AND CLINIC | Annals of Internal Medicine

STrengthening the REporting of Genetic Association Studies (STREGA): An Extension of the STROBE Statement

Julian Little, PhD; Julian P.T. Higgins, PhD; John P.A. Ioannidis, MD, PhD; David Moher, PhD; France Gagnon, PhD; Erik von Elm, MD; Muin J. Khoury, MD, PhD; Barbara Cohen, PhD; George Davey-Smith, MD; Jeremy Grimshaw, MBChB, PhD; Paul Scheet, PhD; Marta Gwinn, MD; Robin E. Williamson, PhD; Guang Yong Zou, PhD; Kim Hutchings, MSc; Candice Y. Johnson, MSc; Valerie Tait, PhD; Miriam Wiens, MSc; Jean Golding, DSc; Cornelia van Duijn, PhD; John McLaughlin, PhD; Andrew Paterson, MD; George Wells, PhD; Isabel Fortier, PhD; Matthew Freedman, MD; Maja Zecevic, PhD; Richard King, MD, PhD; Claire Infante-Rivard, MD, PhD; Alex Stewart, PhD; and Nick Birkett, MD

Making sense of rapidly evolving evidence on genetic associations is crucial to making genuine advances in human genomics and the eventual integration of this information into the practice of medicine and public health. Assessment of the strengths and weaknesses of this evidence, and hence the ability to synthesize it, has been limited by inadequate reporting of results. The STrengthening the REporting of Genetic Association studies (STREGA) initiative builds on the STrengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement and provides additions to 12 of the 22 items on the STROBE checklist. The additions concern population stratification, genotyping errors, modeling haplotype variation, Hardy-Weinberg equilibrium, replication, selection of participants, rationale for choice of genes and variants, treatment effects in studying quantitative traits, statistical methods, relatedness, reporting of descriptive and outcome data, and issues of data volume that are important to consider in genetic association studies. The STREGA recommendations do not prescribe or dictate how a genetic association study should be designed but seek to enhance the transparency of its reporting, regardless of choices made during design, conduct, or analysis.

Ann Intern Med. 2009;150:206-215. www.annals.org

For author affiliations, see end of text.

“The whole of medicine depends on the transparent reporting of clinical trials”

Rennie D. CONSORT revised—improving the reporting of randomized trials. *JAMA* 2001;285:2006.


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