Homeopathy (2007) 96, 42–45

doi:10.1016/j.homp.2006.11.006, available online at http://www.sciencedirect.com

EDUCATION AND DEBATE

Reporting data on homeopathic treatments (RedHot): a supplement to CONSORT ☆

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When homeopathy is tested in clinical trials, understanding and appraisal is likely to be improved if published reports contain details of prescribing strategies and treatments. An international Delphi panel was convened to develop consensus guidelines for reporting homeopathic methods and treatments. The panel agreed 28 treatment- and provider-specific items that supplement the Consolidated Standards of Reporting Trials (CONSORT) Statement items 2, 3, 4 and 19. The authors recommend these for adoption by authors and journals when reporting trials of homeopathy. *Homeopathy* (2007) **96, 42–45.**

Keywords: homeopathy; international cooperation; publishing/standards; quality control; randomized controlled trials/standards; reproducibility of results; research design/standards

Introduction

The Consolidated Standards of Reporting Trials (CONSORT) Statement[1] was developed to improve reporting of randomized controlled trials, and to aid evaluation of the literature by clinicians, researchers and patients. CONSORT includes a checklist and a flow diagram, and has been widely adopted. Problems of assuring methodological rigour in non-pharmacological or non-placebo-controlled trials have led to the subsequent creation of CONSORT-derived checklists in those areas.[2,3] However, CONSORT requires little or no information about treatments and those who give them. Of 22 items, only item 4 relates to interventions, and there is no item requesting information on care providers.

Absence of information on treatments can represent a particular problem when researching non-standard or complementary therapies. Sophisticated techniques and training might be under-reported because tacit knowledge of the field has been assumed by authors and journal editors. Conversely, CAM trials might not directly report that they were conducted with scant practical or theoretical knowledge.[4] Similar considerations have led to the creation of extensions to the CONSORT statement to improve reporting of some CAM therapies. A face-to-face conference of invited acupuncture experts followed by editorial intervention resulted in the STandards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) guidelines.[5] Pre-meeting telephone calls to generate items, a face-to-face consensus meeting, and post-meeting feedback were used in the creation of herbal reporting guidelines.[6]

Recent reviews of homeopathic trials have highlighted general problems of conduct[7] and trial design.[8] A comprehensive systematic review of controlled trials included the recommendation that published reports should in future contain sufficient information on theoretical models, case analysis strategies, pharmacy and prescriptions to aid independent appraisal or replication.[9] That recommendation led to the objective of developing a consensus on reporting standards for homeopathic treatments.

☆ This paper was jointly submitted to *Forschende Komplementärmedizin/Research in Complementary Medicine*, *JACM* and *Homeopathy*, and is published in these journals in parallel. A German translation of this paper is accessible at www.karger.com/doi/10.1159/000097073.

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Methods

An international email conference of 12 experts in the field was convened. Members of the panel were drawn from practitioners and non-practitioners who had published reports of homeopathic research, as trialists, authors of comprehensive systematic reviews, or CAM journal editors. We adopted a 3-stage Delphi consensus process. In round 1, panellists were provided with the CONSORT and STRICTA guidelines as prompts, and asked to produce items under headings borrowed from CONSORT and STRICTA. These were successively voted for and refined in rounds 2 and 3. Participation in each stage varied from 8 to 10 members. At the end of round 3, 57 items had been accepted by the majority of the panel (70% or greater). The items were then compiled as 28 brief items under 8 headings, cross-referenced to CONSORT items 2, 3, 4 and 19. Additional explanations of the criteria were created where multiple items had been compiled under a heading, along with examples. As an end-user quality measure, the checklist and explanatory text were sent to three CAM journal editors who sat on the original panel, to assess the acceptability and feasibility of implementing the guidelines.

Table 1 Checklist for reporting data on homeopathic treatments

Item	*Treatment (CONSORT item number)*	*Description*	*Reported on page number*
1	Rationale (2)	*Type of homeopathy*	
		Individualized (aka classical, constitutional)	
		Formula (aka clinical = single constituent, or complex = multi constituent)	
		Isopathy	
		Evidence base	
		Sources, references	
2	Participants (3)	Knowledge condition	
		Baseline health definition in provings	
3	Medications (4)	*Manufacture*	
		Manufacturer, Pharmacopoeia (or process), references	
		Potency and scale	
		Dilution method	
		Nomenclature	
		Individualized: list or frequency table	
		Formula: constituents, trade name	
		Dosage	
		Dose, timing, form	
4	Consultations (4)	Setting	
		Clinical history detail	
		Duration, frequency	
		Number needed to agree prescription	
		Group process or expert consultation	
		Confidence in prescriptions	
5	Practitioners (4)	Number in study	
		Experience, accreditation, qualifications	
		Current schools or styles of homeopathy	
6	Co-interventions (4)	*Included*	
		Rationale, intended effect, references	
		Duration, frequency	
		Excluded	
		Stopping of mainstream interventions	
		Antidotes	
7	Control interventions (4)	*Active*	
		Rationale, references	
		Placebo	
		Manufacturing process	
8	Adverse Events (19)	Aggravations	

Statement, to be included with checklist:
These guidelines are intended as a supplement to, not a substitute for, the CONSORT Statement, to improve the reporting of homeopathic treatments. We strongly recommend that reports of clinical trials of homeopathy follow the CONSORT guidelines, particularly the flowchart. The points above are specific to homeopathy. All points refer to controlled clinical trials, all but item 7 to uncontrolled outcome studies.

Results

The Delphi and editorial processes resulted in a final checklist of 28 items under 8 headings (see Table 1). The checklist is designed to be used as an adjunct to CONSORT, when reporting randomized controlled trials. Because the list is specific to treatments and providers, it is intended to be equally applicable to reporting homeopathic treatments when used in other clinical studies, such as outcomes research and provings. Explanations and examples are given under each heading below.

Rationale

CONSORT item 2 asks for scientific background and explanation of rationale. The type of homeopathy should be defined as individualized (classical), formula (single- or multi-constituent), or isopathy. Analysis strategies should be stated and referenced. For example, individualized prescribing strategies include analysis methods (such as Kent, Bönninghausen), and tools (repertories, software). Formula strategies include traditional recommendations, reanalysis of collective symptoms or systematic approaches such as homotoxicology, and should also reference sources including repertories and software. The evidence base for the approach being tested should be included (eg personal experience, case series, clinical trial, systematic review) and referenced.

Participants

CONSORT item 3 requests general information on trial participants. Homeopathic trials should report participants' prior experience or knowledge of the treatment (eg whether primed to expect homeopathic aggravations from a trial information sheet). Reports of provings should state how the baseline state of 'healthy' was defined and measured.

Medications

Details of manufacturers and manufacturing processes should reference the Pharmacopoeia or guidelines used. The dilution method should be specified (eg Hahnemannian multi-vial, Korsakovian single-vial, continuous fluxion). The nomenclature of all medicines or constituents (and trade names), as well as potencies and scales, should be clearly stated. Lists or frequency tables of individual prescriptions in classical trials should be included. Where excessively lengthy, these can be published online as an appendix, or made available from authors. Dose, timing and form (eg liquid, globules, tablets) should be given.

Consultations

Study settings should be specified (eg country, primary or secondary care, public or private provision). The duration and frequency (planned and actual) of consultations should be reported. The number of homeopaths needed to agree the prescription should be stated, as well as mentioning whether a group process or expert consultation was used to determine the medicine. If providers rated their confidence in the prescribed medicines, this should be reported.

Practitioners

The number of practitioners in the study should be stated. Experience in clinical practice should be defined in years and hours per week. Accreditation and qualifications, including whether medical or non-medical, should be mentioned. Current schools or styles of homeopathy should be identified.

Co-interventions

Included co-interventions, whether CAM or mainstream, should be specified and documented. This includes diet, exercise, and life-style advice. If co-interventions consist of treatments, the frequency and duration of each treatment should be included. Excluded co-interventions, including any stopping of mainstream interventions, should be specified, as should prohibition of theoretical antidotes such as medications, toiletries, foods and beverages.

Control interventions

The rationale and intended effect of comparator treatments should be clearly stated. If placebo was used in the study, full details of the manufacturing process are required.

Adverse events

CONSORT item 19 concerns reporting of adverse events. Aggravations should be included in this category.

Conclusions

Although there is recent evidence that conduct and reporting of homeopathy trials is significantly better than randomly chosen trials matched for size and study condition,[10] detailed reporting of homeopathic approaches and treatments remains problematic. A group of CAM journals that regularly carry homeopathic trial reports has therefore adopted the RedHot guidelines and includes them in their Instructions to Authors. These are *Homeopathy*, *The Journal Of Alternative And Complementary Medicine*, and *Research in Complementary Medicine/Forschende Komplementärmedizin*. We would urge the general adoption of the guidelines by other journals. This can be done by registering with the lead author and RedHot coordinator (www.redhot-homeopathy.info). Users are encouraged to report their experience with the guidelines. This will help identify problems in areas such as clarity, feasibility and acceptability. All reports will be

registered, and fed back to the next consensus panel as part of the ongoing drafting and revision process.

We hope that adoption of the RedHot guidelines will not only augment the knowledge of what happened in individual trials, but will also help to increase general awareness and dispel misconceptions of what homeopathic treatment involves.

Acknowledgements

Mike Emmans Dean and Morag Coulter were funded by UK Department of Health Research Capacity Development awards.

Appendix

The Delphi panel consisted of:

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