Reporting Data on Homeopathic Treatments (RedHot): A Supplement to CONSORT

MIKE EMMANS DEAN, Ph.D., MORAG K. COULTER, M.Sc.,
and HARALD WALACH, Ph.D.

ABSTRACT

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 on 28 treatment- and provider-specific items that supplement the CONSORT (Consolidated Standards of Reporting Trials) Statement items 2, 3, 4, and 19. The authors recommend these for adoption by authors and journals when reporting trials of homeopathy.

INTRODUCTION

The CONSORT (Consolidated Standards of Reporting Trials) Statement 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 methodologic rigor in nonpharmacologic or non-placebo-controlled trials have led to the subsequent creation of CONSORT-derived checklists in those areas. 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 nonstandard or complementary therapies. Sophisticated techniques and training might be underreported because tacit knowledge of the field has been assumed by authors and journal editors. Conversely, complementary and alternative medicine (CAM) trials might not directly report that they were conducted with scant practical or theoretic knowledge. 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 STRICTA (STandards for Reporting Interventions in Controlled Trials of Acupuncture) guidelines. Premeeting telephone calls to generate items, a face-to-face consensus meeting, and postmeeting feedback were used in the creation of herbal reporting guidelines.

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

METHODS

An international e-mail conference of 12 experts in the field was convened. Members of the panel were drawn from practitioners and nonpractitioners who had published reports of homeopathic research, as trialists, authors of comprehensive systematic reviews, or CAM journal editors. We adopted a three-stage Delphi consensus process. In round 1, panelists 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.

RESULTS

The Delphi and editorial processes resulted in a final checklist of 28 items under 8 headings (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.

1. Rationale

CONSORT item 2 asks for scientific background and explanation of rationale. The type of homeopathy should be defined as individualized (classic), formula (single- or multiconstituent), 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 (e.g., personal experience, case series, clinical trial, systematic review) and referenced.

2. Participants

CONSORT item 3 requests general information on trial participants. Homeopathic trials should report participants’ prior experience or knowledge of the treatment (e.g., 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.

3. Medications

Details of manufacturers and manufacturing processes should reference the Pharmacopoeia or guidelines used. The dilution method should be specified (e.g., Hahnemannian multivial, 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 classic trials should be included. Where excessively lengthy, these can be published online as an appendix, or made available from authors. Dose, timing, and form (e.g., liquid, globules, tablets) should be given.

4. Consultations

Study settings should be specified (e.g., 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 on 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.

5. 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 nonmedical, should be mentioned. Current schools or styles of homeopathy should be identified.

6. Co-interventions

Included co-interventions, whether CAM or mainstream, should be specified and documented. This includes diet, exercise, and lifestyle 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.
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.

8. 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, 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.

ACKNOWLEDGMENTS

Mike Emmans Dean, Ph.D., and Morag K. Coulter, M.Sc., were funded by the U.K. Department of Health Research Capacity Development awards.

REFERENCES


Address reprint requests to:
Mike Emmans Dean, Ph.D.
Department of Health Sciences
University of York
Seebohm Rowntree Building
York YO10 5DD
United Kingdom.

E-mail: med5@york.ac.uk
APPENDIX

The Delphi panel included:

Iris R. Bell, M.D., Ph.D., University of Arizona, Tucson, AZ, USA
Sarah Brien, Ph.D., University of Southampton, Southampton, UK
Mike Emmans Dean, Ph.D., University of York, York, UK
Jennifer Jacobs, M.P.H., Ph.D., University of Washington School of Public Health and Community Medicine, Seattle, WA, USA
Jos Kleijnen, Ph.D., Kleijnen Systematic Reviews, York, UK
George T. Lewith, M.A., D.M., F.R.C.P., M.R.G.C.P., School of Community Clinical Sciences, University of Southampton, Southampton, UK
Klaus Linde, M.A., Technical University, Munich, Germany
Robert Mathie, Ph.D., British Homeopathic Association, Luton, UK
David Reilly, F.R.C.P., F.F.Hom., Glasgow Homoeopathic Hospital, Glasgow, UK
Harald Walach, Ph.D., Forschende Komplementärmedizin, University of Northampton, Northampton, UK