

Item	Treatment (CONSORT item #)	Description	Reported on page #
1	Rationale (2)	<i>Type of homeopathy</i> – Individualized (aka classical, constitutional) – Formula (aka clinical = single constituent, or complex = multi constituent) –Isopathy <i>Evidence base</i> – Sources, references	_____ _____ _____ _____
2	Participants (3)	– Knowledge condition – Baseline health definition in provings	_____ _____
3	Medications (4)	<i>Manufacture</i> – Manufacturer, Pharmacopoeia (or process), references – Potency and scale – Dilution method <i>Nomenclature</i> – Individualized: list or frequency table – Formula: constituents, trade name <i>Dosage</i> – 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)	<i>Included</i> – Rationale, intended effect, references – Duration, frequency <i>Excluded</i> – Stopping of mainstream interventions – Antidotes	_____ _____ _____ _____
7	Control Interventions (4)	<i>Active</i> – Rationale, references <i>Placebo</i> – Manufacturing process	_____ _____
8	Adverse Events (19)	<i>Aggravations</i>	_____

Explanatory notes on page 2.

N.B. 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.

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\*Dean ME, Coulter MK, Fisher P, Jobst K, Walach H. "Reporting data on homeopathic treatments (RedHot): a supplement to CONSORT." *Forsch Komplementarmed.* 2006;13:368-71. *Homeopathy.* 2007;96:42-45. *J Altern Complement Med.* 2007;13:19-24.

## Notes

### 1. 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 (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 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 (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 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 non-medical, 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 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.

### 7. 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.

### 8. Adverse Events

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

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