
Randomized controlled trials of individualized homeopathy: a state-of-the-art review

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Authors' objectives

An overview of the methods and results of the available randomised clinical trials of individualised homeopathy.

Searching

The original literature search is described in Linde et al (1997). This update included searches of MEDLINE, EMBASE (from 1994 - search terms given), HOMINFORM and the Cochrane Trials Registry. Researchers in the field were also contacted. No language restrictions were applied.

Study selection

Study designs of evaluations included in the review

Controlled trials with either randomised or quasi-randomised allocation to conditions or a clear statement that the trial was double blind.

Specific interventions included in the review

Individualised homeopathic similimum. Included studies used a variety of potencies. One study specified Rhus tox C6, another specified sulphur C30 and also a serial application of C20, C200 and C1000. Controls included placebo, salicylate, chloroquine, salazopyrine plus ASA and dicyclomide hydroxide and faecal bulking agents.

Participants included in the review

Participants with a variety of conditions: migraine (3 studies); chronic headache (1 study); childhood diarrhoea (3 studies); rheumatoid arthritis (3 studies), recurrent upper respiratory tract infection (1 study); fibrositis (1 study); cholera (1 study); amebiasis and giardiasis (1 study); malaria (1 study); premenstrual syndrome (2 studies); postviral fatigue syndrome (1 study); heroin detoxification (1 study); insomnia (1 study); mild traumatic brain injury (1 study); proctocolitis (1 study); common warts (1 study); various (including mental health and rheumatological: 1 study); attention deficit (1 study); allergic asthma (1 study); irritable bowel syndrome (1 study); pain after oral surgery (1 study); Broca's aphasia in stroke patients (1 study); acne vulgaris (1 study); patients with dermatoses and the remedy picture of sulphur (1 study).

Outcomes assessed in the review

In order of preference: the study's predefined main outcome measure; patient's global assessment of efficacy; physician's global assessment of efficacy.

How were decisions on the relevance of primary studies made?

One reviewer assessed the relevance of the trials.

Assessment of study quality

The following checklist of questions was used: was allocation randomised? Was the study double blind? Was the study published in a journal listed in MEDLINE? Are there no other obvious flaws? If all questions were answered "yes", the study was classified as "likely to have good methodological quality". Trials not in MEDLINE listed journals with no major problems were classified as "unlikely to have major flaws". Trials with some problems but not fatally flawed were classified as "trials with obvious minor or moderate problems". The remaining trials were classified as "not assessable" or having "major flaws".

In addition a Jadad score (Jadad et al, 1996) and an internal validity score (Linde et al, 1997) were assigned. Most assessments were made by a single reviewer.

Data extraction

Information on methods (allocation to groups; concealment of allocation; blinding; selection bias after allocation), patients (number included/analysed; condition; demographics; setting), interventions (homeopathic; control) and results (overall assessment; number of patients assessed as globally improved) was extracted by one reviewer using a standardised spread sheet and special form. Information collected for the earlier review was used in part.

For each study a rate ratio ((number of responders in the treatment group/number of patients randomised to the treatment group)/(number of responders in the placebo group/number of patients randomised to the placebo group)) and 95% confidence intervals were calculated.

Methods of synthesis

How were the studies combined?

All the studies were summarised in tables and a "vote-counting" approach was used. The studies were discussed in terms of the conditions treated.

Nineteen placebo-controlled trials presented sufficient detail to be included in a quantitative meta-analysis. A pooled random-effects estimate was calculated for all studies and for quality subgroups. In addition analyses were performed using the odds ratio and a fixed-effect model.

How were differences between studies investigated?

The quality subgroups were analysed separately.

Results of the review

Thirty-one studies in tables (text says 32): 25 randomised controlled trials (1367 participants); 3 quasi-randomised controlled trials (sequential allocation) (286 participants); 3 studies of uncertain design (125 participants).

The homeopathy groups responded significantly better than controls in 8 trials.

The overall meta-analysis (19 trials) produced a rate ratio of 1.62 (95% CI: 1.17, 2.23) in favour of homeopathy. The pooled rate ratio of the methodologically best studies was not statistically significant: 1.12 (95% CI: 0.87, 1.44).

Authors' conclusions

The results of the available randomised trials suggest that individualised homeopathy has an effect over placebo. The evidence, however, is not convincing because of methodological shortcomings and inconsistencies. Further research should focus on replication of existing promising studies. New randomised studies should be preceded by pilot studies.

CRD commentary

This review is an update of an earlier review. Both general medical and specific complementary medicine databases were searched and researchers in the field were contacted. Consequently it is likely that this is a comprehensive review. Relevant details of all individual studies are presented in tables.

However, the review was not based on a well-defined question. Neither participants nor outcomes were specified and a broad class of therapies (individualised homeopathy) rather than particular interventions were reviewed. The inclusion criteria were clearly specified but the assumption that a double blind trial involves an unbiased method of allocation is questionable because blinding usually refers to assessment of outcomes rather than allocation concealment. Three different validity assessments were performed; the primary one was mainly based on the study's inclusion in a journal listed in MEDLINE. This seems an unusual requirement for studies of complimentary medicine, although the authors do mention that 6 journals dealing with complimentary therapies have been included since 1998. The authors recognise the shortcomings of having only one reviewer assess the papers. Less than half the studies are included in the quantitative meta-analysis. Although the trials were grouped by methodological quality, this is likely to be a heterogeneous set of studies: neither the main outcome, participants nor treatment were constant across studies.

Consequently the results of the meta-analysis should be treated with extreme caution. This is acknowledged by the authors.

Implications of the review for practice and research

Practice: The authors state 'it is likely that many homeopaths over-estimate both their overall success rates and the contribution of the specific remedy to success. Recommendations for homeopathic care itself can hardly be extrapolated from the clinical trials, as they seem rarely to reflect what happens in every day practice'.

Research: 'Future randomised trials should be preceded more often by pilot studies and researchers should be warned of being too optimistic in terms of feasibility and results. Suitably large sample sizes are a precondition for conclusive results. Unless positive findings are become independently replicated for at least two or three study models, the evidence will remain unconvincing. pragmatic research strategies going beyond placebo controlled trials are needed to provide basic evidence for decision making.'

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Bibliographic details

Linde K, Melchart D. Randomized controlled trials of individualized homeopathy: a state-of-the-art review. *Journal of Alternative and Complementary Medicine* 1998; 4(4): 371-388

Other publications of related interest

1. Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ, et al. Assessing the quality of reports of randomized clinical trials: is blinding necessary? *Control Clin Trials* 1996;17:1-12. 2. Linde K, Clausius N, Ramirez G, et al. Are the clinical effects of homoeopathy placebo effects? A meta-analysis of placebo controlled trials. *Lancet* 1997;350:834-43.

This additional published commentary may also be of interest. Kleijnen J. Unconvincing effect of individualised homoeopathy reported in randomised trials. *FACT* 1999;4:199-200.

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