

## ORIGINAL PAPER

# Randomised controlled trials of homeopathy in humans: characterising the research journal literature for systematic review

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**Introduction:** A new programme of systematic reviews of randomised controlled trials (RCTs) in homeopathy will distinguish important attributes of RCT records, including: placebo controlled *versus* other-than-placebo (OTP) controlled; individualised *versus* non-individualised homeopathy; peer-reviewed (PR) *versus* non peer-reviewed (NPR) sources.

**Aims:** (a) To outline the methods used to search and categorise the RCT literature; (b) to report details of the records retrieved; (c) to compare our retrieved records with those reported in two previous systematic reviews (Linde *et al.*, 1997; Shang *et al.*, 2005).

**Methods:** Ten major electronic databases were searched for records published up to the end of 2011. A record was accepted for subsequent systematic review if it was a substantive report of a clinical trial of homeopathic treatment or prophylaxis in humans, randomised and controlled, and published in a PR or NPR journal.

**Results:** 489 records were potentially eligible: 226 were rejected as non-journal, minor or repeat publications, or lacking randomisation and/or controls and/or a 'homeopathic' intervention; 263 (164 PR, 99 NPR) were acceptable for systematic review. The 263 accepted records comprised 217 (137 PR, 80 NPR) placebo-controlled RCTs, of which 121 were included by, 66 were published after, and 30 were potentially eligible for, but not listed by, Linde or Shang. The 137 PR records of placebo-controlled RCTs comprise 41 on individualised homeopathy and 96 on non-individualised homeopathy.

**Conclusion:** Our findings clarify the RCT literature in homeopathy. The 263 accepted journal papers will be the basis for our forthcoming programme of systematic reviews. *Homeopathy* (2013) 102, 3–24.

**Keywords:** Homeopathy; Literature search strategy; Randomised controlled trials; Systematic review

## Introduction

Some randomised controlled trials (RCTs) in homeopathy are well known (e.g.<sup>1–5</sup>). Such RCTs are included among the 140 papers we identified in a semi-systematic overview of the peer-reviewed (PR) literature published up to and including 2011.<sup>6</sup> In our approach to the RCT evidence, we consider it important to distinguish between placebo-controlled and other-than-placebo (OTP) controlled trials, and to differentiate between individualised

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and non-individualised homeopathy; these distinctions were made in evidence submitted to the United Kingdom Parliament's Science & Technology Committee.<sup>7</sup> In common with most other reviewers of RCTs in homeopathy to date, however, we have not separated the analysis of treatment trials from that of prophylaxis trials, and our definition of 'PR' had not been precisely formulated.

No systematic review of the RCT evidence in homeopathy has ever comprised all the following attributes of: (a) treatment *versus* prophylaxis; (b) placebo *versus* OTP control; (c) individualised *versus* non-individualised (standardised) homeopathy; (d) PR *versus* non peer-reviewed (NPR) journal sources. Most of the existing comprehensive systematic reviews (including the most recent<sup>8,9</sup>) have addressed only (b) above, and by focussing solely on placebo-controlled trials. Moreover, the methods and the conclusions of those two systematic reviews have been challenged.<sup>10,11</sup>

The homeopathy RCT literature has significant inadequacies: for example, some studies described as 'randomised trials' turn out, on detailed reading, not to contain randomised groups; some papers report the same data as another publication (sometimes in a different language). Indeed, the multi-language nature of the homeopathy RCT literature is a major consideration, and many articles have been published in journals that are difficult to obtain.

An up-to-date, comprehensive and thorough systematic review of the entire international RCT literature in homeopathy is therefore needed. Our group has access to an established and contemporary library of research papers and books in homeopathy (Karl und Veronica Carstens-Stiftung, Essen, Germany), and we therefore have the optimum resources with which to undertake a major programme of systematic reviews of the relevant literature. The search strategy we report in this paper has ensured complete coverage of the world science literature.

In the review programme, we shall distinguish, as above, the four principal attributes of research design and publication in homeopathy: (a) treatment/prophylaxis; (b) placebo controlled/OTP controlled; (c) individualised homeopathy/non-individualised homeopathy; (d) PR/NPR journal sources. An 'eligible' record for full data extraction is defined as a substantive report of a homeopathic treatment or prophylaxis trial in humans that is randomised and controlled and is published in a PR or NPR journal. Each eligible RCT will ultimately be appraised for internal validity (risk of bias) against robust criteria, using Cochrane methods,<sup>12</sup> and included in appropriate meta-analysis of pre-defined outcomes. For the same RCTs we will also appraise model validity using recently defined criteria.<sup>13</sup>

The objectives of the present paper are: (a) to outline the methods used to search and categorise the research literature; (b) to report the categorisation of the records we have retrieved, particularly those eligible as acceptable for full systematic review; (c) to compare the number and identity of records with those reported by two previous groups of systematic reviewers (Linde *et al.*, 1997;<sup>8</sup> Shang *et al.*, 2005<sup>9</sup>). Methods of data extraction, assessment (including internal validity and model validity) and analysis

that are specific to a given systematic review will be described as appropriate in the series of papers planned to follow this one. In those subsequent papers, RCTs will be categorised as 'treatment' or 'prophylaxis'. In addition to informing our own programme of systematic reviews in humans, the findings reported here provide a uniquely detailed source of references that clarify the literature for those interested in homeopathy and its research.

## Methods: literature search and identification of studies

### Criteria for study eligibility

All randomised and controlled trials of homeopathic intervention (treatment and/or prophylaxis of disease in adults or children) were eligible for review. 'Disease' is defined as any medical condition or disorder classified in the World Health Organization (WHO) International Classification of Disease (ICD version 2007).

### Search methods for the identification of RCTs published in journal articles

The search aimed to target the entire world literature of RCTs in homeopathy (including NPR articles); it was not limited by language of publication.

*Electronic searches:* The following databases were searched from their inception up to and including December 2011: AMED (records available from 1985); CAM-Quest<sup>®</sup> (Karl und Veronica Carstens-Stiftung; from 1822); CINAHL (from 1981); Cochrane Central Register of Controlled Trials (CENTRAL; from 1908); Embase (from 1980); Hom-Inform<sup>a</sup> (from 1836); LILACS; PubMed (from 1950); Science Citation Index (from 1900); Scopus (from 1823).

The main searches were carried out during the period 30 March to 11 April 2011. A supplementary search for later 2011 publications was carried out on 9–12 January 2012.

The search strategy per database was as follows:

*AMED:* "(homeopath\* OR homoeopath\*) AND (random\* OR placebo\* OR singl\* blind\* OR doubl\* blind\* OR clinical trial\*).af".

*CAM-Quest<sup>®</sup> (Carstens-Stiftung):* "Homöopathie UND randomisierte".

*CINAHL:* "(homeopath\* OR homoeopath\*) AND random\* AND trial\*"

*CENTRAL (Clinical Trials Register):* "homeopathy (MeSH)".

*Embase:* "(homeopath\$ OR homoeopath\$)" together with the Scottish Intercollegiate Guidelines Network (SIGN) search strategy<sup>b</sup> for Embase.

*LILACS:* "(homeopath\$ AND random\$)".

*Hom-Inform:* "(homeopath\* OR homoeopath\*) AND random\* AND Article Type = Controlled Clinical Trial".

<sup>a</sup>The Hom-Inform database comprises records of articles published up to 2004.

<sup>b</sup><http://www.sign.ac.uk/methodology/filters.html>.

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