

## 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>.

*PubMed*: (Cochrane Highly Sensitive Search Strategy – Lefebvre et al., 2009):<sup>14</sup> “((homeopath\* OR homoeopath\*) AND ((randomized controlled trial[pt] OR (controlled clinical trial[pt] OR (randomized[tiab] OR (placebo [tiab] OR (clinical trials as topic[mesh:noexp] OR (randomly[tiab] OR (trial[ti]))) NOT (animals[mh] NOT humans[mh])))”).

*Science Citation Index*: “Topic = (homeopath\* randomized)”, plus all other pairs of terms using the variant spellings homoeopath\* and randomized.

*Scopus*: “(homeopath\* OR homoeopath\*) AND (random\* OR placebo\* OR singl\* blind\* OR doubl\* blind\* OR clinical trial\*)”.

*Other literature sources*: To the above findings we added references identified as an RCT of homeopathy (in humans) in a hand-search of reference lists or bibliography sections of systematic reviews (including Linde<sup>8</sup> and Shang<sup>9</sup>), original RCT papers, and key text-books.<sup>15,16</sup> We have also been in contact with other expert colleagues to minimise the chance of our missing any potentially relevant papers.

## Attributes of research design and publication

### (a) Placebo controlled versus OTP controlled:

Placebo controlled: A trial that describes the control group as ‘placebo’, ‘dummy’, ‘sham’, ‘inactive control’ or similar.

OTP controlled: A trial whose control is an active intervention (proven conventional and/or complementary, non-homeopathic, medicine) or is untreated.

### (b) Individualised versus non-individualised homeopathy:

Individualised homeopathy: Any description that refers clearly to an intervention that involves the individual prescription of homeopathic medication for each participant in the study (and whether or not a case-taking consultation or interview is described). The intervention may involve a change of prescriptions in response to changing individual symptoms. This category includes trials in which individualised prescribing is limited within a defined range of pre-selected homeopathic medicines.

Non-individualised homeopathy: The term includes all interventions that have involved the same, specified, homeopathic medication being allocated to each and every participant in the study: clinical homeopathy, complex homeopathy or isopathy.<sup>17</sup> This category includes trials for which eligibility requires subjects to match a particular set of characteristic symptoms, so that all trial subjects have been prescribed just one pre-defined homeopathic medicine.

### (c) PR versus NPR journal article:

The peer-review status of each relevant journal was identified by inspection of that journal’s published information (website and/or printed version): the statement ‘peer reviewed’ (or equivalent phrase) enabled the journal to be so designated for our review. We did not require the explicit statement that the peer review was external to the

editorial board of the journal concerned. In cases where relevant information about the journal was absent or equivocal, its historical peer-review status was identified from *The Serials Directory*,<sup>18</sup> where its presence in the *Peer Reviewed Index* enabled its designation ‘PR’; otherwise the journal was designated as ‘NPR’.<sup>c</sup>

## Data collection and categorisation of articles

*Screening: characterising search records as potentially eligible for systematic review*: At this stage, the full texts of articles were not sought: assessment was based solely on information available from each record’s title and/or abstract and/or database descriptor. Articles not reporting primary research were disregarded (except for the purpose of identifying references cited therein). Homeopathic pathogenetic (‘provings’) trials<sup>19</sup> were also disregarded.

Non-rejection of a record at this stage was based on evidence (explicit or implicit) that randomisation was used to determine group allocation and that there were control subjects. The salient details of all such non-rejected records were saved in an *Excel* spreadsheet.

The following publication types were excluded automatically from consideration for systematic review, though we did read the full texts sufficiently to characterise the research by study design and by type of homeopathy used:

- Not a journal article:
  - Book, book chapter, conference proceedings, thesis/dissertation, newsletter, report.

*Full text scrutiny: characterising journal articles as RCTs potentially acceptable for full data extraction in systematic review*: The full texts of all remaining articles (in PR and NPR journals) were obtained. The following records were excluded from further assessment:

- Minor journal-article:
  - Abstract, one-page paper, other minor article <500 words, letter.

Substantive journal-articles only (PR and NPR, and translated into English as required) were given further consideration:

- Short paper (2 pages AND ≥500 words)
- Full paper (≥3 pages).

Any record was then rejected if it became clear that it was a repeat of a retained record that had been published previously and/or more definitively elsewhere.

The next aim was to identify and reject records that, on full text appraisal, could not be defined as randomised and/or controlled and/or ‘homeopathic’:

- If it was obvious that a group randomisation procedure was not part of the study design; alternate allocation,

<sup>c</sup>The category ‘not peer-reviewed’ includes any paper published in *The British Homoeopathic Journal* up to and including 1986, after which date the journal became peer reviewed – Fisher P. A new editor. *Br Hom J* 1986; 75: 123.

for example, was regarded as a non-randomised procedure;

- If the study did not include a (non-homeopathy) control group of participants in the study design;
- If the research used a homeopathic dilution (including any component of complex formulations) of less than '1X' (or equivalent: e.g. 'D1');<sup>d, e</sup>
- If the research used formulation(s) not described by the authors as 'homeopathic'.<sup>f</sup>

The articles that remained were characterised as follows:

- PR or NPR journal;
- Placebo control or OTP control;
- Individualised homeopathy or non-individualised homeopathy;
- Medical condition investigated;
- Language used in main text of article.

At this stage, a paper reporting >1 RCT is listed once only and is identified, as appropriate, solely by the first-named of each of the following attributes: placebo control or OTP control; individualised or non-individualised homeopathy. Subsequent detailed analysis of such papers will reflect the full nature of the multiple-trial data.

Similarly, a paper reporting a single RCT comprising >2 groups of subjects is listed once only at this stage, and identified (prioritised for identification as above) by the attributes of just one pair of groups.

We are thus able to define the scope and nature of the literature of RCTs in homeopathy, categorising the potentially eligible journal papers primarily by:

- PR/NPR;
- Placebo control/OTP control;
- Individualised homeopathy/non-individualised homeopathy.

Our characterisation of the literature includes comparison of our search findings with those of two previous reviews of placebo-controlled RCTs.<sup>8,9</sup>

- We have taken account of the relevant cut-off dates<sup>g</sup> (reflecting acceptance criteria for the literature searches concerned and also our opportunity to detect 'repeat' publications), and comparing the numbers of records given in those two reviews.
- For Linde *et al.* (1997),<sup>8</sup> we have reflected the following references listed at the end of their paper: their no. 14 and nos. 36–138 inclusive ( $n = 104$ ).

<sup>d</sup> Mother tinctures are therefore excluded.

<sup>e</sup> Studies fulfilled the inclusion criteria if they used an explicitly labelled 'anthroposophic' or 'homotoxicologic' medicine prepared homeopathically and whose dilution (or that of each of its components) was  $\geq 1X$ .

<sup>f</sup> Research studies on explicitly 'anthroposophic' or 'homotoxicologic' medicine fell within the inclusion criteria if the authors used the term 'homeopathic' or 'homeopathically prepared' in their description of the medicine(s) used.

<sup>g</sup> Cut-off dates: Linde *et al.*<sup>8</sup>: October 1995; Shang *et al.*<sup>9</sup>: January 2003.

- For Shang *et al.* (2005),<sup>9</sup> we reflected all the references listed in their Web Appendix 1 ( $n = 105$ ). We have also reflected the records (enumerated in their Figure 1) in the categories 'could not be located', 'insufficient information', 'ineligible study design', 'multiple publication', 'no matching trial', 'no clinical outcome' or 'no homeopathic intervention' ( $n = 60$ ). Details of these 60 records became available, as a supplementary publication,<sup>20</sup> on the authors' institution's website 4 months after their paper's publication in *The Lancet*; those records are also accounted for in our analysis.

## Results: literature search findings

Four hundred and eighty-nine (489) records were identified as potentially eligible for systematic review (*PRISMA* flowchart – Figure 1).

### Records rejected from further analysis ( $n = 226$ )

Web Appendix 1 lists and characterises the 226 rejected records (see Figure 1 for numerical data):

Ninety-five of the 489 records lie in the non-journal literature (book chapters, theses, etc.); 34 of the 95 were identified as a repeat of a study present elsewhere in our lists, leaving 61 non-repeat records in this category – see Web Appendix 1 (sections *a* and *b*) for details. Amongst these 61 non-repeat, non-journal, records the largest category is research thesis ( $n = 30$ ). Fifty-four of the 61 non-repeat records included comparison with placebo; 51 of the 61 studied non-individualised homeopathy (Web Appendix 1, section *a*).

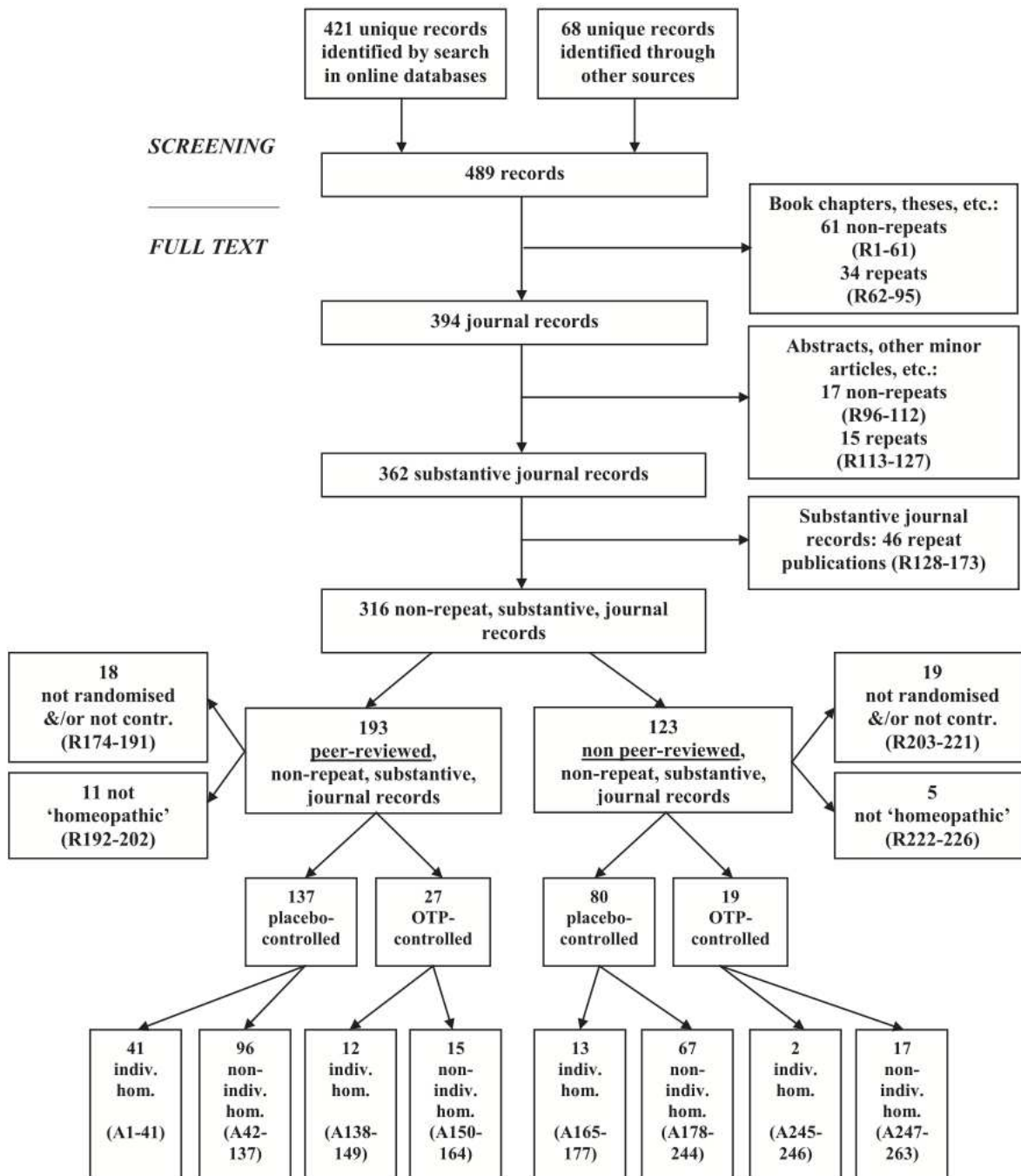
The non-journal records were typically retrieved from just a single electronic database (*CAM-Quest*, *Hom-Inform* or *LILACS*; data not shown); English is the majority language in these publications.

Also rejected are 32 non-substantive journal-records, 15 of which are repeat publications – see Web Appendix 1 (sections *c* and *d*) for details.

Each of 46 of the remaining 362 (substantive) records is the repeat of a publication given elsewhere in our lists (details in Web Appendix 1, section *e*), and so 316 are non-repeat records of substantive journal-records.

Full-text inspection of those latter 316 records revealed that the study design was not in fact randomised and/or controlled in 37 cases (18 PR, 19 NPR) – see Figure 1 (details in Web Appendix 1, sections *f* and *h*). Sixteen other journal-records (11 PR, 5 NPR) are also excluded from further assessment because they did not use a 'homeopathic' preparation – see Figure 1 (details in Web Appendix 1, sections *g* and *i*).

Thus  $34 + 15 + 46 = 95$  records in total have been rejected as 'repeat' publications (Figure 1), and so there are  $226 - 95 = 131$  non-repeat records in total that we have rejected from further analysis. More of those 131 rejected records reported placebo-controlled trials ( $n = 107$ ; 81.7%) than OTP-controlled trials ( $n = 24$ ; 18.3%) – details in Web Appendix 1 (sections *a*, *c*, *f*, *g*, *h*, *i*).



**Figure 1 PRISMA flowchart: inclusion and exclusion of records reporting RCTs in homeopathy.**  
Key to abbreviations: Indiv. = individualised; OTP = other-than-placebo.

### Records accepted for further analysis (n = 263)

We therefore accepted 263 substantive, non-repeat, journal articles (164 PR, 99 NPR; Figure 1); the full reference details are provided in Table 1. These 263 records will be the basis for the systematic review of study quality and outcome evaluation in our subsequent reports.

**Database retrieval:** The 263 records were each retrieved from a median of 3 databases (interquartile range [IQR], 1–6 databases); a higher retrieval rate was achieved for PR (median, 6; IQR, 3–7) compared to NPR journal articles (median, 1; IQR, 1–1). The online databases yielded a widely varying total of these 263 records; overall retrieval

rate was greatest in *CAM-Quest* (PR, 139/164; NPR, 76/99), *Embase* (119/164; 12/99) and *PubMed* (116/164; 3/99), and least in *CINAHL* (46/164; 0/99) and *LILACS* (2/164; 0/99) [data not shown]. Seventeen of the 263 records were retrieved solely from sources other than the online databases; 14 of those 17 were in the NPR literature (see Table 1).

**Language of publication:** The most common language of publication is English (PR, 79.3%; NPR, 24.2%), followed by German (15.9%; 46.5%), and French (1.8%; 17.2%) – see Figure 2. Six other languages comprise the remaining records (3.0%; 12.1%).

**Table 1** Records accepted for further analysis ( $n = 263$ ). Each tabulation is ordered alphabetically by first author name and then by year of publication

**(a) Peer reviewed ( $n = 164$ )**

Ref. No.	First author	Year	Total databases	Language	Category	Condition
<b>(1) Controlled by placebo: individualised homeopathy (<math>n = 41</math>)</b>						
A1	Andrade	1991	7	Eng.	Rheumatology	Rheumatoid arthritis
A2	Bell	2004	7	Eng.	Rheumatology	Fibromyalgia
A3	Bell	2004	7	Eng.	Rheumatology	Fibromyalgia
A4	Bell	2004	6	Eng.	Rheumatology	Fibromyalgia
A5	Bell	2004	7	Eng.	Rheumatology	Fibromyalgia
A6	Bonne	2003	6	Eng.	Mental Disorder	Anxiety
A7	Brien	2011	2	Eng.	Rheumatology	Rheumatoid arthritis
A8	Carlini	1987	5	Por.	Mental Disorder	Insomnia
A9	Cavalcanti	2003	8	Eng.	Dermatology	Uraemic pruritus
A10	Chapman	1999	7	Eng.	Neurology	Brain injury
A11	de Lange de Klerk	1994	7	Eng.	Respiratory Infection	URTI
A12	Fisher	2001	7	Eng.	Rheumatology	Rheumatoid arthritis
A13	Fisher	2006	7	Eng.	Dermatology	Eczema
A14	Frass	2005	7	Eng.	Surgery & Anaesthesiology	Sepsis
A15	Frei	2005	5	Eng.	Mental Disorder	ADHD
A16	Gaucher	1994	4	Eng.	Tropical Disease	Cholera
A17	Haila	2005	7	Eng.	Oral/Dental	Xerostomia
A18	Jacobs	1993	3	Eng.	Gastroenterology	Childhood diarrhoea
A19	Jacobs	1994	8	Eng.	Gastroenterology	Childhood diarrhoea
A20	Jacobs	2001	6	Eng.	Ear, Nose & Throat	Otitis media (acute)
A21	Jacobs	2000	8	Eng.	Gastroenterology	Childhood diarrhoea
A22	Jacobs	2005	8	Eng.	Obstetrics & Gynaecology	Menopause post breast cancer
A23	Jacobs	2005	8	Eng.	Mental Disorder	ADHD
A24	Jansen	1992	3	Eng.	Gastroenterology	Proctocolitis
A25	Kainz	1996	7	Eng.	Dermatology	Warts
A26	Katz	2005	6	Eng.	Mental Disorder	Depression
A27	Kuzeff	1998	5	Eng.	Immune Disorder	Immune function
A28	Lökken	1995	8	Eng.	Surgery & Anaesthesiology	Post-operative pain
A29	Mousavi	2009	8	Eng.	Oral/Dental	Aphthous ulcer
A30	Naudé	2010	6	Eng.	Mental Disorder	Insomnia
A31	Rastogi	1999	7	Eng.	Immune Disorder	HIV
A32	Sajedi	2008	5	Eng.	Neurology	Cerebral palsy
A33	Siebenwirth	2009	6	Ger.	Dermatology	Eczema
A34	Steinsbekk	2005	6	Eng.	Respiratory Infection	URTI
A35	Straumsheim	2000	7	Eng.	Neurology	Migraine
A36	Thompson	2005	8	Eng.	Obstetrics & Gynaecology	Menopause post breast cancer
A37	Walach	1997	5	Eng.	Neurology	Headache
A38	Weatherley-Jones	2004	6	Eng.	Mental Disorder	Chronic fatigue syndrome
A39	White	2003	7	Eng.	Allergy & Asthma	Childhood asthma
A40	Whitmarsh	1997	7	Eng.	Neurology	Migraine
A41	Yakir	2001	7	Eng.	Obstetrics & Gynaecology	Premenstrual syndrome
<b>(2) Controlled by placebo: non-individualised homeopathy (<math>n = 96</math>)</b>						
A42	Aabel	2001	7	Eng.	Allergy & Asthma	Seasonal allergic rhinitis
A43	Aabel	2000	8	Eng.	Allergy & Asthma	Seasonal allergic rhinitis
A44	Aabel	2000	7	Eng.	Allergy & Asthma	Seasonal allergic rhinitis
A45	Adkison	2010	4	Eng.	Musculoskeletal	Muscle soreness
A46	Baillargeon	1993	0	Eng.	Cardiovascular	Blood coagulation
A47	Baker	2003	9	Eng.	Mental Disorder	Anxiety
A48	Balzarini	2000	8	Eng.	Dermatology	Radiodermatitis
A49	Beer	1999	5	Ger.	Obstetrics & Gynaecology	Induction of labour
A50	Belon	2006	3	Eng.	Toxicology	Arsenic toxicity
A51	Belon	2007	6	Eng.	Toxicology	Arsenic toxicity
A52	Bergmann	2000	7	Ger.	Obstetrics & Gynaecology	Female infertility
A53	Bernstein	2006	3	Eng.	Dermatology	Psoriasis
A54	Bernstein	2011	6	Eng.	Ear, Nose & Throat	Non-allergic rhinitis
A55	Berrebi	2001	5	Fre.	Obstetrics & Gynaecology	Postpartum lactation
A56	Bignamini	1987	3	Eng.	Cardiovascular	Hypertension
A57	Brinkhaus	2006	7	Eng.	Surgery & Anaesthesiology	Post-operative swelling
A58	Brydak	1999	2	Eng.	Respiratory Infection	Influenza
A59	Cialdella	2001	6	Fre.	Mental Disorder	Withdrawal of benzodiazepines
A60	Clark	2000	2	Eng.	Musculoskeletal	Plantar fasciitis
A61	Cornu	2010	5	Eng.	Surgery & Anaesthesiology	Post-operative bleeding
A62	Diefenbach	1997	3	Ger.	Respiratory Infection	Bronchitis
A63	Ernst	1990	5	Eng.	Cardiovascular	Varicose veins
A64	Ferley	1989	4	Eng.	Respiratory Infection	Influenza
A65	Ferrara	2008	5	Eng.	Urology	Nocturnal enuresis
A66	Fisher	1989	5	Eng.	Rheumatology	Fibromyalgia
A67	Frass	2005	4	Eng.	Respiratory Infection	Tracheal secretions
A68	Freitas	1995	2	Por.	Allergy & Asthma	Childhood asthma

Table 1 (Continued)

(a) Peer reviewed (n = 164)

Ref. No.	First author	Year	Total databases	Language	Category	Condition
A69	Friese	2007	6	Ger.	Ear, Nose & Throat	Sinusitis
A70	Friese	1997	7	Ger.	Ear, Nose & Throat	Adenoid
A71	Furuta	2003	3	Por.	Ear, Nose & Throat	Adenoid
A72	Furuta	2007	1	Por.	Ear, Nose & Throat	Tonsillitis
A73	Garrett	1997	4	Eng.	Dermatology	Leg ulcers
A74	Gerhard	1998	1	Ger.	Obstetrics & Gynaecology	Female infertility
A75	GRECHO	1989	6	Fre.	Surgery & Anaesthesiology	Post-operative ileus
A76	Hart	1997	7	Eng.	Surgery & Anaesthesiology	Post-operative pain
A77	Heusser	2009	4	Eng.	Cardiovascular	Blood coagulation
A78	Hitzenberger	2005	4	Ger.	Cardiovascular	Hypertension
A79	Hofmeyr	1990	4	Eng.	Obstetrics & Gynaecology	Postpartum pain
A80	Jacobs	2006	8	Eng.	Gastroenterology	Childhood diarrhoea
A81	Jacobs	2007	8	Eng.	Tropical Disease	Dengue fever symptoms
A82	Jawara	1997	3	Eng.	Musculoskeletal	Muscle soreness
A83	Kaziro	1984	2	Eng.	Surgery & Anaesthesiology	Post-operative pain/swelling
A84	Khuda-Bukhsh	2005	1	Eng.	Toxicology	Arsenic toxicity
A85	Khuda-Bukhsh	2011	4	Eng.	Toxicology	Arsenic toxicity
A86	Kim	2005	7	Eng.	Allergy & Asthma	Seasonal allergic rhinitis
A87	Kneis	2009	4	Eng.	Ear, Nose & Throat	Sinusitis
A88	Kolia-Adam	2008	0	Eng.	Mental Disorder	Insomnia
A89	Kotlus	2010	5	Eng.	Surgery & Anaesthesiology	Post-operative bruising
A90	La Pine	2006	6	Eng.	Mental Disorder	Shift lag
A91	Labrecque	1992	8	Eng.	Dermatology	Warts
A92	Leaman	1989	4	Eng.	Dermatology	Minor burns
A93	Lewith	2002	8	Eng.	Allergy & Asthma	Allergic asthma
A94	Lipman	1999	2	Eng.	Miscellaneous	Snoring
A95	McCutcheon	1996	5	Eng.	Mental Disorder	Anxiety
A96	Meissner	2011	1	Eng.	Cardiovascular	Blood pressure
A97	Merklinger	1995	1	Ger.	Dermatology	Eczema
A98	Mokkapatti	1992	1	Eng.	Ophthalmology	Conjunctivitis
A99	Mousavi	2009	8	Eng.	Oral/Dental	Oral lichen planus
A100	Oberbaum	2001	7	Eng.	Oral/Dental	Stomatitis
A101	Oberbaum	2005	8	Eng.	Obstetrics & Gynaecology	Postpartum bleeding
A102	Pach	2011	5	Eng.	Musculoskeletal	Low back pain
A103	Padilha	2011	7	Eng.	Toxicology	Lead poisoning
A104	Papp	1998	3	Eng.	Respiratory Infection	Influenza
A105	Paris	2008	6	Eng.	Surgery & Anaesthesiology	Post-op. analgesic intake
A106	Paris	2011	2	Eng.	Mental Disorder	Anxiety
A107	Plezbert	2005	2	Eng.	Musculoskeletal	Muscle soreness
A108	Rahlfs	1976	1	Ger.	Gastroenterology	Irritable bowel syndrome
A109	Rahlfs	1978	1	Ger.	Gastroenterology	Irritable bowel syndrome
A110	Ramelet	2000	7	Eng.	Surgery & Anaesthesiology	Post-operative haematoma
A111	Reilly	1986	7	Eng.	Allergy & Asthma	Seasonal allergic rhinitis
A112	Reilly	1994	6	Eng.	Allergy & Asthma	Allergic asthma
A113	Robertson	2007	8	Eng.	Surgery & Anaesthesiology	Post-operative pain
A114	Saruggia	1992	1	Eng.	Urology	Renal failure
A115	Schirmer	2000	6	Ger.	Musculoskeletal	Ankylosing spondylitis
A116	Schmidt	2002	7	Eng.	Miscellaneous	Body weight loss
A117	Seeley	2006	5	Eng.	Surgery & Anaesthesiology	Post-operative bruising
A118	Shipley	1983	5	Eng.	Rheumatology	Osteoarthritis
A119	Simpson	1998	6	Eng.	Ear, Nose & Throat	Tinnitus
A120	Singer	2010	4	Eng.	Surgery & Anaesthesiology	Post-operative pain
A121	Smith	2002	5	Eng.	Dermatology	Seborrhoeic dermatitis
A122	Stevinson	2003	6	Eng.	Surgery & Anaesthesiology	Post-operative pain/swelling
A123	Taylor	2000	8	Eng.	Allergy & Asthma	Perennial allergic rhinitis
A124	Tuten	1999	0	Eng.	Musculoskeletal	Muscle soreness
A125	Tveiten	1991	2	Nor.	Musculoskeletal	Muscle soreness
A126	Tveiten	1998	6	Eng.	Musculoskeletal	Muscle soreness
A127	Vickers	1997	9	Eng.	Musculoskeletal	Muscle soreness
A128	Vickers	1998	8	Eng.	Musculoskeletal	Muscle soreness
A129	von Hagens	2011	1	Eng.	Obstetrics & Gynaecology	Menopausal syndrome
A130	Weiser	1994	3	Ger.	Ear, Nose & Throat	Sinusitis
A131	Wiesenaue	1985	7	Eng.	Allergy & Asthma	Seasonal allergic rhinitis
A132	Wiesenaue	1989	7	Ger.	Ear, Nose & Throat	Sinusitis
A133	Wiesenaue	1990	1	Ger.	Allergy & Asthma	Seasonal allergic rhinitis
A134	Wiesenaue	1991	5	Ger.	Rheumatology	Rheumatoid arthritis
A135	Wiesenaue	1995	3	Eng.	Allergy & Asthma	Seasonal allergic rhinitis
A136	Wolf	2003	7	Ger.	Surgery & Anaesthesiology	Post-operative pain
A137	Zabolotnyi	2007	6	Eng.	Ear, Nose & Throat	Sinusitis

(Continued on next page)

**Table 1** (Continued)

**(a) Peer reviewed (n = 164)**

Ref. No.	First author	Year	Total databases	Language	Category	Condition
<b>(3) Controlled by OTP: individualised homeopathy (n = 12)</b>						
A138	Adler	2009	2	Eng.	Mental Disorder	Depression
A139	Gerhard	1997	1	Eng.	Obstetrics & Gynaecology	Female infertility
A140	Gmünder	2002	6	Ger.	Musculoskeletal	Low back pain
A141	Harrison	1999	8	Eng.	Ear, Nose & Throat	Otitis media (chronic)
A142	Hitzenberger	1982	7	Ger.	Cardiovascular	Hypertension
A143	Paterson	2003	1	Eng.	Gastroenterology	Dyspepsia
A144	Relton	2009	7	Eng.	Rheumatology	Fibromyalgia
A145	Schreier	1997	3	Ger.	Miscellaneous	Male infertility
A146	Steinsbekk	2005	6	Eng.	Respiratory Infection	URTI
A147	Thompson	2011	5	Eng.	Allergy & Asthma	Childhood asthma
A148	van Erp	1996	3	Eng.	Tropical Disease	Malaria
A149	Witt	2009	6	Eng.	Obstetrics & Gynaecology	Vulvo-vaginal candidiasis
<b>(4) Controlled by OTP: non-individualised homeopathy (n = 15)</b>						
A150	Gassinger	1981	5	Ger.	Ear, Nose & Throat	Common cold
A151	Issing	2005	7	Eng.	Nausea/Vertigo	Vertigo
A152	Jobst	2005	2	Ger.	Respiratory Infection	URTI
A153	Karow	2008	2	Eng.	Surgery & Anaesthesiology	Post-operative wound healing
A154	Kienle	1973	2	Ger.	Respiratory Infection	Respiratory insufficiency
A155	Maiwald	1988	7	Ger.	Ear, Nose & Throat	Common cold
A156	Shealy	1998	1	Eng.	Rheumatology	Osteoarthritis
A157	Stam	2001	8	Eng.	Musculoskeletal	Low back pain
A158	Stoffel	2007	1	Ger.	Ophthalmology	Eye infection
A159	Taylor	2011	4	Eng.	Ear, Nose & Throat	Otitis media (acute)
A160	Totonchi	2007	1	Eng.	Surgery & Anaesthesiology	Post-operative oedema
A161	van Haselen	2000	8	Eng.	Rheumatology	Osteoarthritis
A162	Weiser	1998	7	Eng.	Nausea/Vertigo	Vertigo
A163	Weiser	1999	8	Eng.	Allergy & Asthma	Seasonal allergic rhinitis
A164	Wiesnauer	1987	1	Ger.	Cardiovascular	Orthostatic hypotension

**(b) Non peer reviewed (n = 99)**

Ref. No.	First author	Year	Total databases	Language	Category	Condition
<b>(1) Controlled by placebo: individualised homeopathy (n = 13)</b>						
A165	Awdry	1996	2	Eng.	Mental Disorder	Chronic fatigue syndrome
A166	Benzécri	1991	1	Fre.	Mental Disorder	Withdrawal of benzodiazepines
A167	Brigo	1991	3	Eng.	Neurology	Migraine
A168	Campistrous-Lavaut	1999	1	Spa.	Cardiovascular	Hypertension
A169	Chapman	1994	1	Eng.	Obstetrics & Gynaecology	Premenstrual syndrome
A170	Fisher	1986	4	Eng.	Rheumatology	Fibromyalgia
A171	Gaus	1997	1	Ger.	Neurology	Headache
A172	Grover	2009	1	Eng.	Miscellaneous	Opium addiction
A173	Ledermann	1954	1	Eng.	Tropical Disease	Tuberculosis
A174	Riveron-Garrote	1998	2	Spa.	Allergy & Asthma	Bronchial asthma
A175	Solanki	1995	2	Eng.	Gastroenterology	Intestinal amoebiasis
A176	Strauss	2000	1	Eng.	Mental Disorder	ADHD
A177	Sutherland	1954	1	Eng.	Tropical Disease	Tuberculosis
<b>(2) Controlled by placebo: non-individualised homeopathy (n = 67)</b>						
A178	Albertini	1984	2	Fre.	Oral/Dental	Dental neuralgia
A179	Alibeu	1990	6	Fre.	Surgery & Anaesthesiology	Post-operative agitation
A180	Aulagnier	1985	1	Fre.	Surgery & Anaesthesiology	Post-operative ileus
A181	Bekkering	1993	1	Dut.	Obstetrics & Gynaecology	Menopausal syndrome
A182	Böhmer	1992	1	Ger.	Musculoskeletal	Sprain
A183	Bordes	1986	1	Fre.	Respiratory Infection	Cough
A184	Bornoroni	1997	0	Ita.	Respiratory Infection	URTI
A185	Campbell	1976	1	Eng.	Trauma	Blunt injury
A186	Chakraborty	2009	0	Eng.	Tropical Disease	Leprosy
A187	Chirila	1984	1	Fre.	Allergy & Asthma	Seasonal allergic rhinitis
A188	Davies	1971	1	Eng.	Respiratory Infection	URTI
A189	Dexpert	1987	1	Fre.	Nausea/Vertigo	Seasickness
A190	Dorfman	1985	1	Fre.	Miscellaneous	Sports pathology
A191	Dorfman	1987	1	Fre.	Obstetrics & Gynaecology	Postpartum pain
A192	Dorfman	1988	1	Fre.	Surgery & Anaesthesiology	Post-operative haematoma
A193	Dorfman	1992	1	Fre.	Surgery & Anaesthesiology	Post-operative ileus
A194	Ferley	1987	1	Fre.	Respiratory Infection	Influenza
A195	Guillemain	1983	1	Fre.	Miscellaneous	Mental and physical stress
A196	Hariveau	1987	1	Fre.	Musculoskeletal	Muscle cramp
A197	Hariveau	1992	1	Fre.	Nausea/Vertigo	Seasickness
A198	Heilmann	1992	1	Ger.	Ear, Nose & Throat	Common cold



**Table 1** (Continued)

**(b) Non peer reviewed (n = 99)**

Ref. No.	First author	Year	Total databases	Language	Category	Condition
A199	Hildebrandt	1984	1	Ger.	Musculoskeletal	Muscle soreness
A200	Hildebrandt	1983	1	Ger.	Musculoskeletal	Muscle soreness
A201	Hildebrandt	1983	0	Ger.	Musculoskeletal	Muscle soreness
A202	Hildebrandt	1983	1	Ger.	Musculoskeletal	Muscle soreness
A203	Kennedy	1971	1	Eng.	Surgery & Anaesthesiology	Post-operative chest infection
A204	Köhler	1991	0	Ger.	Rheumatology	Rheumatoid arthritis
A205	Kulkarni	1988	2	Eng.	Miscellaneous	Radiation protection
A206	Kurz	1993	2	Ger.	Urology	Overactive bladder
A207	Lecocq	1985	1	Fre.	Respiratory Infection	Influenza
A208	Lepaisant	1995	2	Fre.	Obstetrics & Gynaecology	Premenstrual syndrome
A209	Macedo	2005	3	Eng.	Surgery & Anaesthesiology	Post-operative pain/swelling
A210	Manchanda	1997	1	Eng.	Dermatology	Warts
A211	Matusiewicz	1995	1	Ger.	Allergy & Asthma	Bronchial asthma
A212	Matusiewicz	1999	1	Ger.	Allergy & Asthma	Bronchial asthma
A213	Matusiewicz	1997	1	Ger.	Allergy & Asthma	Bronchial asthma
A214	Mössinger	1973	0	Ger.	Ear, Nose & Throat	Pharyngitis
A215	Mössinger	1980	1	Ger.	Dermatology	Pyoderma
A216	Mössinger	1982	1	Ger.	Ear, Nose & Throat	Common cold
A217	Mössinger	1976	1	Ger.	Ear, Nose & Throat	Pharyngitis
A218	Mössinger	1976	0	Ger.	Musculoskeletal	Muscle cramp
A219	Mössinger	1976	1	Ger.	Dermatology	Pyoderma
A220	Mössinger	1977	1	Ger.	Ear, Nose & Throat	Pharyngitis
A221	Mössinger	1977	1	Ger.	Ear, Nose & Throat	Pharyngitis
A222	Mössinger	1985	1	Ger.	Ear, Nose & Throat	Otitis media (acute)
A223	Niederle	2001	1	Ger.	Ear, Nose & Throat	Tonsillitis
A224	Raschka	2006	4	Ger.	Musculoskeletal	Muscle soreness
A225	Reilly	1985	1	Eng.	Allergy & Asthma	Seasonal allergic rhinitis
A226	Ritter	1966	0	Ger.	Gastroenterology	Gastritis
A227	Rottey	1995	1	Dut.	Respiratory Infection	Influenza
A228	Ruff	1992	0	Dut.	Allergy & Asthma	Seasonal allergic rhinitis
A229	Salenko	2006	3	Rus.	Nausea/Vertigo	Seasickness
A230	Savage	1977	1	Eng.	Neurology	Stroke
A231	Savage	1978	1	Eng.	Neurology	Stroke
A232	Schmidt	1996	2	Eng.	Musculoskeletal	Muscle soreness
A233	Schwab	1990	0	Ger.	Dermatology	Various skin diseases
A234	Selkova	2005	0	Rus.	Respiratory Infection	Influenza
A235	Tétau	1993	1	Eng.	Surgery & Anaesthesiology	Post-operative haematoma
A236	Thiel	1991	2	Ger.	Musculoskeletal	Haemarthrosis
A237	Torbicka	1998	0	Ger.	Respiratory Infection	Resp. syncytial virus infection
A238	Ustianowski	1974	1	Eng.	Obstetrics & Gynaecology	Post-coital cystitis
A239	Villatoro Cadena	1991	1	Spa.	Gastroenterology	Childhood diarrhoea
A240	Werk	1994	3	Ger.	Miscellaneous	Obesity
A241	Wiesenauer	1983	2	Ger.	Allergy & Asthma	Seasonal allergic rhinitis
A242	Wolf	1992	1	Ger.	Mental Disorder	Insomnia
A243	Zell	1988	6	Ger.	Musculoskeletal	Sprain
A244	Zicari	1992	2	Ita.	Ophthalmology	Diabetic retinopathy
<b>(3) Controlled by OTP: individualised homeopathy (n = 2)</b>						
A245	Gerhard	1993	1	Ger.	Obstetrics & Gynaecology	Female infertility
A246	Gerhard	1999	1	Ger.	Obstetrics & Gynaecology	Female infertility
<b>(4) Controlled by OTP: non-individualised homeopathy (n = 17)</b>						
A247	Beer	1995	1	Ger.	Obstetrics & Gynaecology	Menopausal syndrome
A248	Bononi	2001	1	Ita.	Surgery & Anaesthesiology	Post-operative infection
A249	Casper	1967	1	Ger.	Trauma	Acute trauma
A250	Colombo	2007	0	Eng.	Respiratory Infection	Influenza
A251	Geiger	1968	1	Ger.	Trauma	Soft tissue contusion
A252	Maiko	2002	1	Ger.	Rheumatology	Osteoarthritis
A253	Maronna	2000	0	Ger.	Rheumatology	Osteoarthritis
A254	Mergen	1969	1	Ger.	Trauma	Acute trauma
A255	Nahler	1996	2	Ger.	Rheumatology	Osteoarthritis
A256	Prinzing	1948	1	Ger.	Trauma	Acute trauma
A257	Ricciotti	2005	2	Ita.	Ear, Nose & Throat	Sinusitis
A258	Stippig	1996	1	Ger.	Respiratory Infection	URTI
A259	Strösser	2000	3	Ger.	Rheumatology	Osteoarthritis
A260	Strösser	2000	2	Ger.	Nausea/Vertigo	Dizziness
A261	Supino	2002	0	Eng.	Respiratory Infection	URTI
A262	Wiesenauer	1986	1	Ger.	Allergy & Asthma	Seasonal allergic rhinitis
A263	Wolschner	2001	1	Ger.	Nausea/Vertigo	Vertigo

Key to abbreviations: Ref. No. = Reference number; ADHD = attention-deficit hyperactivity disorder; HIV = human immunodeficiency virus; Post-op. = post-operative; Resp. = respiratory; URTI = upper respiratory tract infection; Dut. = Dutch; Eng. = English; Fre. = French; Ger. = German; Ita. = Italian; Nor. = Norwegian; Por. = Portuguese; Rus. = Russian; Spa. = Spanish.

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**Table 1 (Continued)**

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**(a) PR (n = 164)**

**(1) Controlled by placebo: individualised homeopathy (n = 41)**

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(b) NPR (n = 99)

(1) Controlled by placebo: individualised homeopathy (n = 13)

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**Table 1 (Continued)**

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**Table 1** (Continued)

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**(3) Controlled by OTP: individualised homeopathy (n = 2)**

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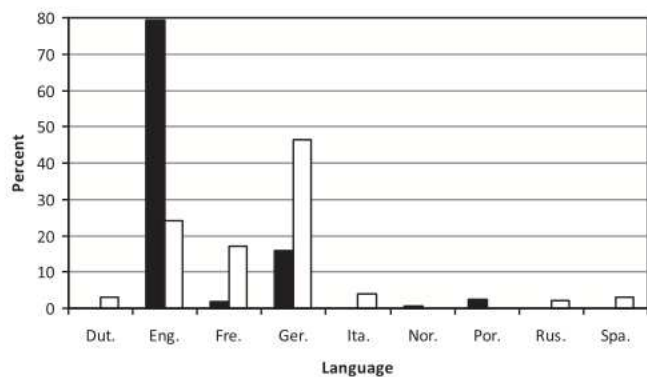
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*Placebo-controlled versus OTP controlled:* Of the 263 accepted records, more have reported placebo-controlled trials ( $n = 217$ ; 82.5%) than OTP-controlled trials ( $n = 46$ ; 17.5%) – Figure 1 and Table 1. For PR records, the number focused on placebo is 137/164 (83.5%); for NPR records the number focused on placebo is 80/99 (80.8%).

*Individualised versus non-individualised homeopathy:* As Figure 1 and Table 1 illustrate, the accepted RCT literature ( $n = 263$ ) has focused less on individualised homeopathy (total of 68 records; 25.9%) than on non-individualised homeopathy (total of 195 records; 74.1%).

For PR records, the proportion that has investigated individualised homeopathy is 53/164 (32.3%), of which 41 are placebo-controlled; the proportion for non-individualised homeopathy is 111/164 (67.7%), of which 96 are placebo-controlled (Figure 1). For NPR records, the proportion that investigated individualised homeopathy is only 15/99 (15.2%), of which 13 are placebo-controlled; the proportion focused on non-individualised homeopathy is 84/99 (84.8%), of which 67 are placebo-controlled (Figure 1).

*Publication timeline:* For PR research, the peak period of publication was 1997–2001, when a rapid increase from



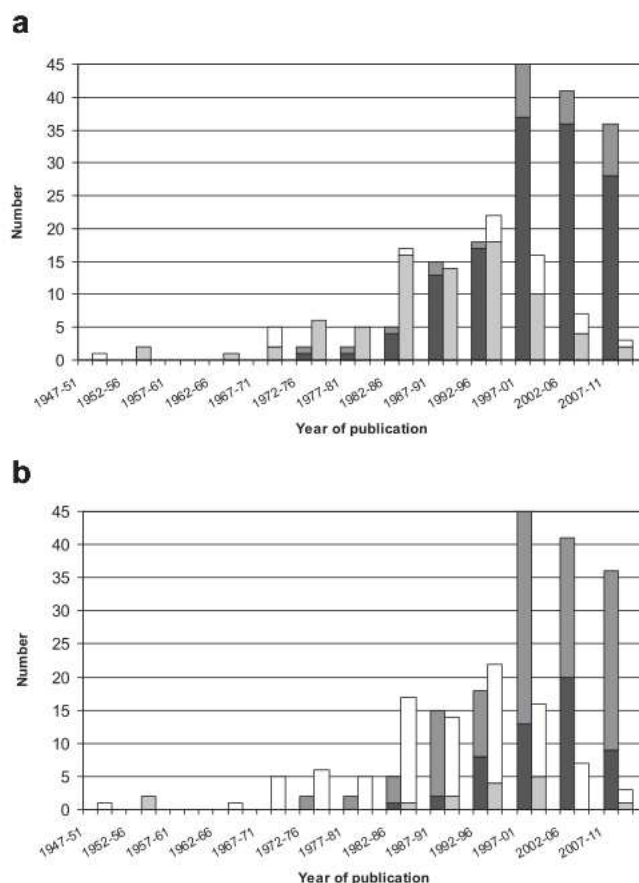
**Figure 2 Language of publication.**  
Filled bars: PR records; unfilled bars: NPR records.  
Key to abbreviations: Dut. = Dutch; Eng. = English; Fre. = French; Ger. = German; Ita. = Italian; Nor. = Norwegian; Por. = Portuguese; Rus. = Russian; Spa. = Spanish.

the previous publication rates occurred (Figure 3a/b); the median year of publication is 2001 (IQR, 1996–2006). The first PR record was published in 1973. For NPR research, the peak period of publication was 1992–1996; the median year of publication is 1991 (IQR, 1983–1997). The first NPR record was published in 1948. There has been a marked decrease in NPR-published research over the past decade.

Figure 3a and b show the timelines for placebo/OTP control and individualised/non-individualised homeopathy respectively. OTP trials have been published more frequently in the past 15–20 years, though numbers remain small (Figure 3a). Trials of individualised homeopathy started to become prominent, in the PR literature only, from the period 1992–97; recently there has been a decline in the numbers of trials of individualised homeopathy, from a peak during the period 2002–06 (Figure 3b).

**Medical conditions:** For the categories of medical condition represented by RCT research, several are prominent in both the PR and the NPR literatures: Surgery & Anaesthesiology (PR, 10.4%; NPR, 8.1%); Allergy & Asthma (9.1%; 9.1%); Ear Nose & Throat (9.1%; 9.1%); Musculoskeletal (7.9%; 11.1%). Studies on Mental Disorders are more frequently seen in the PR than in the NPR literature (8.5% cf. 4.0%), whilst those on Respiratory Infection are less frequent in the PR literature (6.1% cf. 11.1%). See Figure 4 for further details.

The 263 papers reported findings in 122 different medical conditions. The PR and NPR literatures include a similar publication rate per medical condition (PR, 164 records reporting 91 conditions [1.8 records per condition]; NPR, 99 records reporting 59 conditions [1.7 records per condition]). In 45 conditions more than a single RCT has been reported in either the PR or the NPR literature; Table 2 lists the 22 conditions for which there have been at least 3 PR and/or NPR records per condition. The most frequently reported conditions in both the PR and NPR literature are muscle soreness (PR, 8 records; NPR, 6 records), seasonal allergic rhinitis (PR, 9;



**Figure 3 (a) Number of records published per 5-year period: Placebo- versus OTP-controlled RCTs.**

Dark grey bars = PR records (placebo-controlled RCTs); mid grey bars = PR records (OTP-controlled RCTs); pale grey bars = NPR records (placebo-controlled RCTs); unfilled bars = NPR records (OTP-controlled RCTs).

**(b) Number of records published per 5-year period: Individualised versus non-individualised homeopathy.**

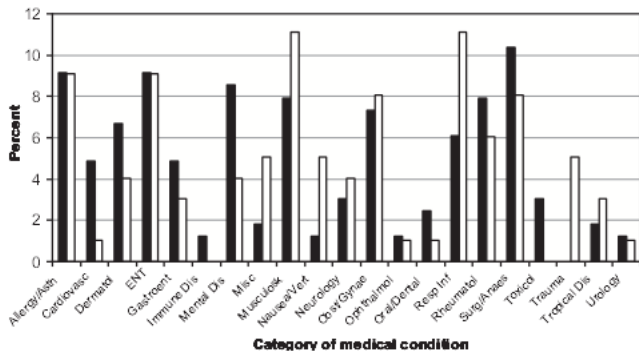
Dark grey bars: PR records (individualised homeopathy); mid grey bars: PR records (non-individualised homeopathy); pale grey bars: NPR records (individualised homeopathy); unfilled bars: NPR records (non-individualised homeopathy).

NPR, 5), influenza (PR, 3; NPR, 5), and upper respiratory tract infection (PR, 4; NPR, 4).

**Comparison with two previous systematic reviews of placebo-controlled RCTs**

Web Appendix 2 (A and B) focus on placebo-controlled research only; they list and characterise our rejected records (repeat or non-repeat) and our accepted records of placebo-controlled trials, and in comparison with the systematic reviews carried out by Linde *et al.* (1997)<sup>8</sup> and Shang *et al.* (2005).<sup>9</sup> Our literature search strategy retrieved additional sets of records that might potentially have been included in those previous reviews:

*Rejected records of placebo-controlled trials* (n = 195; Web Appendix 2A): Of the 195 records (repeat or non-repeat) of placebo-controlled research that we rejected, we regard 53 and 161 as having been potentially eligible for Linde and Shang respectively (see Web Appendix 2A,



**Figure 4 Categories of medical condition.**

Filled bars: PR records; unfilled bars: NPR records.  
Key to abbreviations: Allergy/Asth = Allergy/Asthma; Cardiovasc = Cardiovascular; Dermatol = Dermatology; ENT = Ear, Nose & Throat; Gastroent = Gastroenterology; Immune Dis = Immune disorder; Mental Dis = Mental disorder; Misc = Miscellaneous; Musculosk = Musculoskeletal; Nausea/Vert = Nausea/Vertigo; Obst/Gynae = Obstetrics & Gynaecology; Ophthalmol = Ophthalmology; Resp Inf = Respiratory Infection; Rheumatol = Rheumatology; Surg/Anaes = Surgery & Anaesthesiology; Toxicol = Toxicology; Tropical Dis = Tropical disease.

*Grand Totals*).<sup>h</sup> Those records actually listed in the previous review papers were 32 (of which Linde accepted 20 for analysis) and 50 (of which Shang accepted 21 for analysis). Compared to the numbers in this category that we regard as having been *potentially listed* in each of the previous reviews, we thus identified 21 records more than Linde and 111 records more than Shang.<sup>i</sup>

Thus, we have rejected 20 (Linde) and 21 (Shang) records, comprising a total of 25 *unique* records whose data were included for analysis by Linde and/or Shang. These 25 unique records include 2 that we regard as not randomised and/or controlled (records ‘R175’ and ‘R213’) and 2 that we judge to be not ‘homeopathic’ (‘R194’ and, as did Shang, ‘R222’). Another 5 of the 25 records are among those we rejected as repeat publications. The remaining 16 unique records are from either non-journal ( $n = 13$ ) or minor journal ( $n = 3$ ) sources. See [Web Appendix 2A](#) for details.

*Accepted records of placebo-controlled trials* ( $n = 217$ ; [Web Appendix 2B](#)):

*Potentially eligible for Linde*: In total, we accepted 96 (34 PR, 62 NPR) compared with 71 (32 PR, 39 NPR) records that were also listed by Linde – an additional 25 (2 PR, 23 NPR) in our case. Of these 71 records also listed by Linde, 59 were included in their data analysis and 12 were not.

*Potentially eligible for Shang*: In total, we accepted 151 (77 PR, 74 NPR) compared with 110 (63 PR, 47 NPR) records that were also listed by Shang – an additional 41 (14

**Table 2** Medical conditions with replicated RCT research ( $n > 3$  records) in at least the PR or the NPR journal literature

	PR		NPR	
	n	% of PR	n	% of NPR
Acute trauma			3	3.0
Anxiety	4	2.4		
Arsenic toxicity	4	2.4		
Bronchial asthma			4	4.0
Childhood asthma	3	1.8		
Childhood diarrhoea	4	2.4		
Eczema	3	1.8		
Female infertility	3	1.8	2	2.0
Fibromyalgia	6	3.7		
Hypertension	3	1.8		
Influenza	3	1.8	5	5.1
Insomnia	3	1.8		
Low back pain	3	1.8		
Muscle soreness	8	4.9	6	6.1
Osteoarthritis	3	1.8	4	4.0
Pharyngitis			4	4.0
Post-operative pain	5	3.0		
Rheumatoid arthritis	4	2.4		
Seasickness			3	3.0
Seasonal allergic rhinitis	9	5.5	5	5.1
Sinusitis	5	3.0		
URTI	4	2.4	4	4.0

PR, 27 NPR) in our case. Of these 110 records also listed by Shang, 83 were included in their data analysis and 27 were not.<sup>j</sup>

The above-identified 71 (Linde) and 110 (Shang) comprise a total of 121 (70 PR, 51 NPR) of our unique records that were also listed by Linde and/or Shang. And the above-identified 25 and 41 additional records comprise a total of 30 (7 PR, 23 NPR) unique records that were potentially eligible for, but not listed by, Linde or Shang.<sup>k</sup> For further details, see [Web Appendix 2B](#).

Thus we retrieved, and accepted,  $217 - 121 = 96$  unique, substantive, journal records of placebo-controlled research that were not listed by Linde or Shang. Of those 96 additional records, 66 were published between a previous cut-off date and ours (given in italics in [Web Appendix 2B](#)), and 30 were records potentially eligible for (but not listed by) Linde or Shang. Our newly identified 96 records of placebo-controlled trials comprise 67 in the PR literature. (The 67 may be verified as the difference between the total number of PR records of placebo-controlled trials that we accepted minus the number listed by Linde/Shang: i.e.  $41 - 17 = 24$  that studied individualised homeopathy [[Web Appendix 2B](#), section *a1*] plus  $96 - 53 = 43$  that studied non-individualised homeopathy [[Web Appendix 2B](#), section *a2*]).

<sup>h</sup>Within this set of 195 rejected records, 12 that were listed (though excluded from analysis) by Linde were not listed by Shang (see [Web Appendix 2A](#) for details).

<sup>i</sup>20 of these 21 (Linde) and 111 (Shang) records were not listed by both previous reviews. In total there are 112 unique records that were not listed by, though potentially eligible for, Linde or Shang ([Web Appendix 2A](#)).

<sup>j</sup>Within our total set of 217 accepted records, 11 that were listed (though excluded from analysis) by Linde were not listed by Shang ([Web Appendix 2B](#)). With the 12 such instances that we rejected (footnote<sup>h</sup>), there are 23 records in total that were listed by Linde but not by Shang.

<sup>k</sup>Combining the numbers from our lists of those potentially eligible for Linde and Shang, the grand totals of our additional records are:  $21 + 25 = 46$  more than Linde;  $111 + 41 = 152$  more than Shang. We identified  $112 + 30 = 142$  unique records that were potentially eligible for Linde and/or Shang, but not listed by either.

## Discussion

Our search findings and initial data extraction provide a greatly clarified, expanded and refined view of the clinical trial literature in homeopathy. In addition to its importance in informing the research community about the full details of the RCT literature in homeopathy, the key findings will directly inform our forthcoming programme of systematic reviews. Only a few previous reviews have separated treatment from prophylaxis (e.g.<sup>21</sup>) or OTP- from placebo-controlled trials (e.g.<sup>22</sup>) or individualised from non-individualised homeopathy (e.g.<sup>23</sup>).

Our literature search strategy retrieved and *accepted* a set of unique, time-relevant records of placebo-controlled trials that is 30 more than were listed by Linde or Shang.<sup>8,9</sup> We will not explore in depth the reasons for these discrepancies, but they may include: (a) differences in the precise inclusion criteria for the different searches and for the listing of records retrieved; (b) the difficulty of attributing month-specific publication dates for archived records; (c) the fact that we have benefited from the more complete and accessible bibliographic resources that are now available. In any event, we cannot regard our literature search as having been completely successful, though we believe we have not missed significant publications, in the PR literature in particular. Moreover, our comparisons with Linde/Shang are intended primarily to define the additional records that we have accepted for subsequent review.<sup>1</sup>

The records of placebo-controlled RCTs that we retrieved (121 included by Linde/Shang; 66 published after Linde/Shang; 30 not included by Linde/Shang) provide a total of 217 journal papers for our planned programme of systematic reviews. Along with the 46 records that reported OTP trials, there are altogether 263 records for our review programme overall; 164 of these are in the PR literature (Figure 1).

Given our prior experience with the homeopathy research literature, we are not surprised to have identified 95 repeat publications and 37 substantive journal records that do not include randomisation and/or controls. And it is notable that 16 substantive records that were retrieved using the search term 'homeopath\*' did not use a truly 'homeopathic' medicine. It is important to be aware of these issues in the categorisation of research in the relevant electronic databases. Because of our prospective focus on the journal literature only, we do not know how many of the 61 non-repeat records of book chapters and theses etc. were truly randomised or controlled or 'homeopathic' in

nature. However, we do know that 54 of these 61 records included a placebo group, and that 51 of the 61 studied non-individualised homeopathy (Web Appendix 1).

It is also noteworthy that we *rejected* from subsequent analysis a total of 25 unique records of placebo-controlled trials whose data were analysed by Linde and/or Shang.<sup>8,9</sup> This difference between the previous reviews and ours is largely accounted for by our automatic exclusion of book chapters, theses, conference proceedings, etc. In addition, Linde included several references that subsequently were published as full journal articles and which we have designated 'repeat' records. Of perhaps more concern is our identification of 4 records from Linde and/or Shang that we do not regard as randomised and/or controlled and/or 'homeopathic' in nature.

The 263 substantive journal publications that we identified and accepted are split 164/99 in the PR/NPR literature. Compared to the NPR records, the accepted PR literature is more frequently English-language and recently published, with each record retrieved typically from a much larger number of databases. With their relatively low rate of record retrieval (e.g. 116/164 PR papers and 3/99 NPR papers found in PubMed), it is apparent that the normal medical bibliographic databases are not suitable for identifying all RCTs in homeopathy; specialist resources such as CAM-Quest (Carstens-Stiftung) are therefore an essential source of information. But even CAM-Quest failed to yield 48 out of 263 accepted records; it now includes, or has re-categorised, those 48 records. If the last 15 years' improvement in the numbers of PR papers in the international literature is sustained, the proportion of easily retrievable articles from the standard databases would be likely to increase correspondingly.

Comparing the accepted PR and NPR journal research in homeopathy, the medical categories and conditions are broadly similar. RCTs on muscle soreness and seasonal allergic rhinitis are prominent in both domains of literature. Nevertheless, there is considerable heterogeneity in both the PR and NPR records, with research on a number of medical conditions being reported in only one or the other domain: e.g. 5 PR but no NPR records on post-operative pain, and 4 NPR but no PR records on pharyngitis. The fact that the 263 records reflect research on as many as 122 different medical conditions illustrates the considerable challenge this brings to data synthesis, analysis and reporting in the context of systematic review.

It is also striking that the majority of the accepted literature is placebo-controlled research and involves non-individualised homeopathy. There are broadly similar proportions in each sub-set of the accepted literature: placebo-controlled (PR, 83.5%; NPR, 80.8%); non-individualised homeopathy (PR, 67.7%; NPR, 84.8%). These statistics reinforce the growing view<sup>24,25</sup> that research development in complementary medicine, including homeopathy, should focus additional effort on pragmatic trials and on individualised homeopathy. There is evidence of a recent increase in the relative numbers of OTP trials but a decrease in trials on individualised homeopathy (Figure 3).

The findings from the full data extraction and assessment of this large and complex literature will be reported

<sup>1</sup>Although our comparative search findings are not focused on questioning the previous reviews' detailed literature retrieval, we identified many records that might potentially have been eligible for, but were not listed in, the reviews by Linde and/or Shang: an additional 142 unique records in total (112 of which we rejected from our forthcoming reviews). Furthermore, given that Shang's review was designed explicitly to update the entire review material provided by Linde, it was with interest that we noted 23 records that were listed (though rejected) by Linde but that were not listed anywhere by Shang (even amongst the latter group's list of rejected records).

subsequently in two main components: (1) treatment trials; (2) prophylaxis trials. As previously advocated by others,<sup>26</sup> the trials that are published in the NPR journal literature will not be prioritised for appraisal in our forthcoming programme of systematic reviews. The peer-review process undoubtedly raises the standard of published research, and prominent authorities see little or no worth in science that is disseminated outside this domain.<sup>27</sup> Nevertheless, NPR research should not be dismissed entirely – both Linde and Shang included substantial numbers of such records – and it is our intention in the future to appraise that literature. The fact that the records in the PR and NPR domains of the homeopathy literature have broadly similar characteristics suggests that our initial focus solely on PR publications will not misrepresent the balance of the literature overall.

The next stage of our review programme, including appropriate meta-analysis, will focus specifically on the 137 PR papers of placebo-controlled RCTs: 41 on individualised homeopathy and 96 on non-individualised homeopathy. This will reflect the 24 PR records of individualised homeopathy and 43 PR records of non-individualised homeopathy that have never previously been included in a comprehensive systematic review.

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## Supplementary data: Web Appendices

Supplementary data related to this article (Web Appendix 1, 2A, 2B) can be found at <http://dx.doi.org/10.1016/j.homp.2012.10.002>.

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