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CORE-Hom: A powerful and exhaustive database of clinical trials in homeopathy



Jürgen Clausen^{1,*}, Sian Moss², Alexander Tournier², Rainer Lüdtkke³ and Henning Albrecht¹

¹Karl und Veronica Carstens-Stiftung, Am Deimelsberg 36, 45276 Essen, Germany

²Homeopathy Research Institute, International House, 39 Great Windmill Street, Piccadilly, London, UK

³DSZ – Deutsches Stiftungszentrum GmbH, im Stifterverband für die Deutsche Wissenschaft, Barkhovenallee 1, 45239 Essen, Germany

The CORE-Hom database was created to answer the need for a reliable and publicly available source of information in the field of clinical research in homeopathy. As of May 2014 it held 1048 entries of clinical trials, observational studies and surveys in the field of homeopathy, including second publications and re-analyses. 352 of the trials referenced in the database were published in peer reviewed journals, 198 of which were randomised controlled trials. The most often used remedies were *Arnica montana* ($n = 103$) and Traumeel[®] ($n = 40$). The most studied medical conditions were respiratory tract infections ($n = 126$) and traumatic injuries ($n = 110$). The aim of this article is to introduce the database to the public, describing and explaining the interface, features and content of the CORE-Hom database. Homeopathy (2014) 103, 219–223.

Keywords: Homeopathy; Clinical research; Database; Randomised controlled trials

Introduction

In homeopathy, diseases are treated according to the *similia principle* “let like be cured by like” (*similia similibus curentur*). This means that a certain drug is selected for treating a condition (usually in a low dose preparation called “potency”), which can evoke similar symptoms when given to healthy volunteers in higher doses. The low dose preparations are prepared according to a special procedure which includes serial dilution steps called “succussion” or “potentisation”. This way of preparation is thought to be required for the biological action of the remedies through a mechanism as yet not understood. The number of such dilution steps is not limited and many homeopathic remedies are diluted to such a degree that it is highly unlikely that a single molecule of the starting material is left.

Despite its central role in homeopathy, most of the criticism levelled at homeopathy has not focused on the *similia principle*, but on the absence of any active molecule in

some homeopathic remedies. The current difficulty in formulating a plausible working mechanism for homeopathy is the main point of concern for sceptics of homeopathy.^{1–4} Positive effects of homeopathy in human clinical trials are often disregarded as placebo effects, self-healing or regression to the mean by sceptics.^{3,4}

Systematic reviews and meta-analyses play an important role in the ongoing debate between supporters and sceptics of homeopathy^{3,5–10} (a list of hitherto published reviews in the field of Homeopathy can be found in the online supporting material).

In evidence-based medicine, a systematic review of randomised and controlled clinical trials, including a meta-analysis of the summarised data, is considered the highest grade of evidence with regard to a given medicinal intervention. A meta-analysis is a quantitative summary of the outcomes of two or more primary research studies that have been carried out on the same topic. By statistical pooling of data, a meta-analysis increases confidence in the direction and magnitude of effect size by including a greater total number of patients than each of the original studies alone. The compilation of such a systematic review is preceded by a rigorous literature search for appropriate publications. In conventional medicine, several specialised databases exist. The problem for review authors in the field of homeopathy is that the conventional databases usually

*Correspondence: Jürgen Clausen, Karl und Veronica Carstens-Stiftung, Am Deimelsberg 36, 45276 Essen, Germany. E-mail: info@Carstens-Stiftung.de

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only contain a fraction of the relevant studies.^{11,12} This is mostly due to the fact that many of these studies have been published without having gone through a “peer review process”. The peer review process strives to maintain standards of quality and to ensure the credibility of scientific publications.^{13,14} During peer review of a manuscript submitted to a scientific journal, independent reviewers from the same field (“peers”) judge its intrinsic quality, offering improvements as may be appropriate, and recommend to the journal editor whether it should be published or not. Publications in books, conference proceedings or reports are usually not covered by conventional databases. Moreover, several studies in homeopathy are published in languages other than English, French or Spanish, which can be an additional obstacle for inclusion in conventional databases.

The need for a publicly available and reliable source of information in the field of homeopathy clinical research was thus identified and the CORE-Hom database project was launched (<http://www.carstens-stiftung.de/core-hom>). It was created by the Karl und Veronica Carstens-Stiftung (www.carstens-stiftung.de) in collaboration with the Homeopathy Research Institute (<http://www.homeoinst.org>). CORE-Hom is the abbreviation for “Clinical Outcome REsearch in Homeopathy”. The interface of CORE-Hom is in English and access to CORE-Hom is free after a cost-free registration. Here we present the first overview of the CORE-Hom database, describing the search functionalities and providing some statistics.

Description of the database interface

The database interface (Figure 1) enables not only searching by the standard bibliographical data (author name, peer review status) but also through a number of characteristics of the studies themselves. The latter include the medical indication, the field of disease, the study design (Parallel/Crossover, Sequence generation and Blinding), the prescribed remedies and trial controls, and whether intention-to-treat analysis was used or not. Search for these items is limited to fixed drop-down lists. In contrast to this, the interface for the two fields “Indication” and “Author” is different from the other search items in the sense that the user may enter any combination of characters and the drop-down list is filtered according to the matching data entries.

In addition, the database offers the possibility of filtering database entries based on the scientific quality ratings of past systematic reviews. Currently the database offers the ratings assigned by Shang et al.,³ Linde et al.,^{5,15} and Dean et al.¹⁶

Moreover it is possible to filter for main publications only (see Figure 1, item “B”). This adjustment excludes (for example) all second publications, re-analyses, translations and interim-publications of cohort studies from the subsequent search result.

An extra field allows full text searches in the “reference field”. The “reference field” comprises the author information, the title, the publication date and the journal information.

The logical operator for combining search parameters is always AND.

The screenshot displays the search interface of the CORE-Hom database, organized into several sections:

- Box A:** A vertical list of search filters, each with a dropdown menu set to "any": Indication, Field, Homeopathic remedy, Control, Sequence generation, Blinding, Design, and Intention to treat.
- Box B:** A checkbox labeled "Show only main publications:" which is currently unchecked.
- Box C:** Bibliographical search fields including "Author:" (dropdown: any), "Peer reviewed:" (dropdown: any), "Year:" (range: 1941 - 2014), and "Full text search in references:" (dropdown: any).
- Box D:** Quality filter section with checkboxes and sliders for:
 - Shang's quality: dropdown (any)
 - Shang's OR: activate OR search [0 - 15.66] with a checked slider (X).
 - Dean's methodological quality: activate MQ search [0 - 96] % with a checked slider (X).
 - Dean's clinical relevance: activate CR search [0 - 100] % with a checked slider (X).
 - Linde's quality: activate IV search [-1 - 5] with a checked slider (X). Note: (-1 = not applicable)
 - Linde's OR: activate OR search [0 - 81] with a checked slider (X).
- Box E:** Output style selection: "View results as:" with radio buttons for "Table" (selected) and "File card". Below it, a search button and a status message: "Search Your search will generate 1048 hits."

Figure 1 Database interface of CORE-Hom. Box A contains detailed study information, while Box C contains the bibliographical data, including a full text search option (one single word) in the bibliographical summary (authors, title, journal information). The checkbox B allows search for main publications, only. The sliders (X) in Box C apply (when manually activated) filters based on the results of the three prominent reviews by Shang,³ Linde^{5,15} and Dean.¹⁶ Box E defines the output style of search results. OR = Odd ratio, MQ = Methodological quality, CR = clinical relevance, IV = Internal validity (Jadad Score).¹⁹

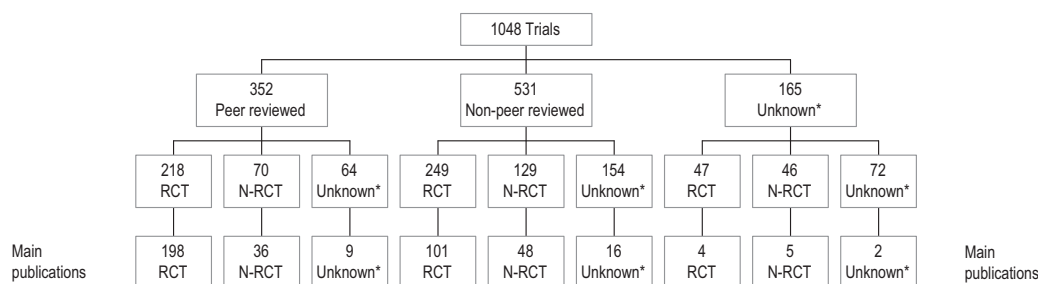


Figure 2 Breakdown of database entries between peer review status, sequence generation and main publications. Main publications: trials after exclusion of re-analyses and second publications (e.g. in other languages) etc. RCT = Randomised controlled trials (including quasi-randomised controlled trials). N-RCT = Non-randomised trials. * Unclear or not determined yet.

The search results can be displayed either as a table or in file card style. Information is provided on the search fields mentioned above and on bibliographic data. Brief summaries of the study results are included. The data sets contain links to the abstracts of the publications, if available. Importantly, a given publication may describe the results of a numbers of trials. In order to distinguish these, such trials are differentiated from one another by Roman numerals (e.g. “Aabel 2000i”, “Aabel 2000ii”). Different publications by the same first author in the same year are discernible by lowercase letters (e.g. “Bell 2004a”, “Bell 2004b”, “Bell2004c”).

A special feature is the grouping of publications in the search results. This feature enables the user to retrieve all publications of certain authors on the same topic. If, for example, several publications belong to the same cohort study or if they are re-analyses of older publications, such attributes will be clearly visible. Similarly, another category indicates the number of review articles the individual studies was included in. Clicking on the hyperlinks (“Cohort”, “Reanalysis”, “Reviewed”) in the search result opens a new window that summarises all trials in a given cohort group/review/grouping of main publication and subsequent re-analyses. The grouping “Reanalysis” also includes identical second publications, conference abstracts, theses or translations into other languages.

Database content

In May 2014, the database held 1048 entries. At the time of writing, the database is still being curated, although the functionalities are completely operational. The high number of “unknown” items or missing numbers in the subsequent paragraphs is, to the most part, due to the continuing but still incomplete assessment of some of the characteristics of the publications. For example, for a given study most of the characteristics might have been already assessed while some of them still need to be assessed.

The peer reviewed part of the literature represents 352 trials in the database. 531 trials were non-peer reviewed, whilst for 165 of them the peer review status is unknown (either unclear or not determined yet).

475 of the listed records correspond to randomised, controlled trials (RCTs). In 245 trials, no randomisation procedure was applied. In 39 studies, sequence generation

was assigned as quasi-randomised; employing special methods for patient allocation like “Minimisation”^{17,18} or randomisation procedures that involve some systematic, non-random approach like alternating allocation or sequence generation based on the week of the month. In summary, 514 trials either employed a randomised or quasi-randomised design. After removal of secondary publications and re-analyses, 303 randomised or quasi-randomised, controlled trials remain; 198 of these appeared in peer reviewed journals and 101 in non-peer reviewed journals. In four randomised or quasi-randomised, controlled trials no information on peer review status of the respective journal was available. Figure 2 displays a breakdown of studies between various parameters starting from peer review status.

In 730 trials, the results were compared between study group and control group(s) (205 without controls, 113 as yet unassessed). 518 trials applied placebo controls, 163 used standard treatment as control and 42 used untreated participants as controls. 33 studies applied a three-arm design. 22 of these three-arm trials compared the homeopathic treatment to standard treatment and placebo treatment, nine to untreated control groups and placebo and another two to standard treatment and untreated groups. The majority of controlled trials applied parallel study designs ($n = 717$) rather than cross-over study settings ($n = 58$). 217 observational studies are included. Blinding was conducted in single blinded ($n = 53$) or double blinded manner ($n = 474$).

Table 1 Medicinal fields and their number of assigned trials

Field	n	Field	n
Respiratory tract disorders	126	Cancer	21
Traumatic injuries	110	Ear disorders	18
Mental disorders	93	Other (rare) fields	16
Gynaecology and obstetrics	83	Eye disorders	14
Infections	76	Urology	9
Dermatology	68	Dentistry	9
Allergies	58	Toxicology	8
Neurology	57	Various indications	6
Primary care	53	Pain	6
Gastroenterology	53	Homeopathic pathogenic trial	1
Musculoskeletal disorders	47	Safety	1
Rheumatology	33	Circulatory system	1
Cardiovascular system	33	Not assigned	26
Metabolism	22		

Table 2 Top ten of most often investigated substances/remedies

Substance/remedy	n
<i>Arnica montana</i>	103
Traumeel®	40
<i>Rhus toxicodendron</i>	19
<i>Galphimia glauca</i>	14
Sulphur	13
<i>Nux vomica</i>	13
<i>Arsenicum album</i>	12
Engystol®	11
Vertigoheel®	11
<i>Pulsatilla pratensis</i>	11

Trials are grouped in 26 different therapeutic areas. Most studies were performed in the field of “Respiratory tract disorders” ($n = 126$), “Traumatic injuries” ($n = 110$) and “Mental disorders” ($n = 93$); see Table 1. In six trials, a number of clinical indications were investigated at the same time (categorised as “Various”). Studies investigating rather rare condition were grouped together (“Other”; $n = 16$). Separate from this category “Other”, we created two further categories to which more trials are expected to be assigned after completion of the data assessment and inclusion of future studies (“Safety” $n = 1$; “Homeopathic pathogenetic trial” $n = 1$).

In total, 276 different substances were prescribed in patient treatment. *Arnica montana* is the remedy most often used ($n = 103$), followed by the complex preparation Traumeel® ($n = 40$) and *Rhus toxicodendron* ($n = 19$). The ten most often administered remedies are listed in Table 2. Among these, three trademarked remedies of the company Heel are found (Traumeel®, Engystol®, Vertigoheel®). Trademarked complex remedies were not broken down into their constituent parts. In 370 trials, more than five different remedies were used, denoted “Various” in the field “Homeopathic remedy”.

In 265 trials, fixed remedies (“clinical homeopathy”⁵) or complex remedies ($n = 214$) were used and in 34 trials remedies were selected according to the principles of isopathy. In 343 studies, remedy prescription was individualised (often termed “classical homeopathy”⁵).

Perspectives

The CORE-Hom database is still being curated. It is already in use, there are however studies which have not yet been indexed completely. In some studies, indexing is as yet quite rudimentary. Currently, most gaps exist for the number of included and analysed patients. In addition, some of the mentioned special features have been only partially implemented to date (e.g. assignment to previous review articles). Having gone over the current limitations of the database, it is worth mentioning that we concentrated on the 198 peer reviewed RCTs as they would be of most interest to the majority of users. Therefore, most of these have already been fully characterized in the database.

The interface of CORE-Hom is likely to undergo some modifications in future in order to make its use more comfortable and self-explanatory. Moreover, the database

will also be accessible via the homepage of the Homeopathy Research Institute (<http://www.homeoinst.org/>).

The most recent review of randomised controlled trials of homeopathy in humans, which was supervised by the British Homeopathic Association (<http://www.britishhomeopathic.org/evidence/>), identified 263 randomised, controlled trials in the peer reviewed literature ($n = 164$) and non-peer reviewed literature ($n = 99$).¹² In contrast to this, the CORE-Hom database lists 198 randomised (or quasi-randomised) trials in peer reviewed and 101 trials in non-peer reviewed publications (sum = 299; only main publications considered). The differences in numbers are due to the continuous updating of CORE-Hom database (new publications) and slightly different criteria for the definition of ‘main publication’. All studies listed in Mathie et al. 2013¹² are indexed completely in CORE-Hom. As soon as they are available, the quality ratings of this systematic review programme will also be included in the database.

CORE-Hom is curated and regularly updated by the Carstens-Stiftung in collaboration with the Homeopathy Research Institute: new publications are added, missing information is completed and errors in the existing records are corrected. Users of the databases are encouraged to inform the Karl and Veronica Carstens-Stiftung about any publications missing from the database or any errors of content they might identify.

The database was designed with the strongest scientific rigour in mind, to offer researchers and the general public a solid foundation from which to assess the quality of homeopathy randomised controlled trials, as well as the many clinical fields to which they relate. In future, we believe the database will be a valuable asset for scientists, health professionals and patients alike.

Conflict of interest statement

None declared.

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Appendix A

Supplementary data

Supplementary data related to this article can be found at [doi:10.1016/j.homp.2014.07.001](https://doi.org/10.1016/j.homp.2014.07.001).

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