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# **The Trials of Homeopathy**

**Origins, Structure and Development**

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## Abstract

The controversial discipline of homeopathy is examined from three original perspectives.

*Conceptual background:* The structure and presentation of Hahnemann's research programme is contrasted with philosophical assumptions about medical science and emerging theoretical structures in German academic medicine circa 1800, and the subsequent rift between homeopathy and allopathy is explained at this level. The sources of homeopathic theory and method are located in mainstream eighteenth-century experiment. Alleged relationships to alchemical medicine are discounted, with the exception of certain pharmacy techniques introduced after 1816. Divergent schools and approaches within homeopathy are traced to their sources, and mapped onto a unified therapeutic field.

*Historical importance:* A systematic review of prospective clinical evaluations of homeopathy, 1821–1953, contends that these played an important but neglected part in the evolution of the clinical trial. Placebo-controlled trials by sceptics most probably originated in prior Hahnemannian use of within-patient placebo controls. Pragmatic trials of homeopathy versus allopathy in the mid nineteenth century show that judgements of homeopathic inefficacy made by influential nineteenth-century opponents, which have coloured debate ever since, were not evidence-based. Early twentieth-century clinical trials by homeopaths were methodologically in advance of biomedical trials in some respects.

*Clinical relevance:* A systematic review of 205 prospective controlled clinical trials published since 1940 found evidence of homeopathy's safety, and specific and global efficacy in trials of high internal validity. Implications for clinical research and practice are considered, founded on analysis of intra-homeopathic differences and trends. On the basis of trial evidence, the relative merits of placebo-controlled and pragmatic evaluations of homeopathy are discussed. Clinical relevance was found particularly in areas that pose problems for biomedicine, and proposals for pragmatic trials of homeopathy versus standard treatment are made in the following conditions: unexplained female infertility; postviral fatigue syndrome; influenza; atopy.

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# 1. Introduction

## 1.1. Rationale

Public demand for alternative and complementary medicine has never been greater, and homeopathy is high on the list of sought-after therapies (House of Lords 2000). Commissioners looking for evidence to justify funding naturally turn to published reports of clinical trials or reviews of those trials. At this point several problems emerge.

*Accessibility of information:* Because of homeopathy's isolation from mainstream medicine, most homeopathic trials have been published in grey literature, inaccessible through Medline, Embase or other standard databases.

*Representativeness of contemporary trials:* Many homeopaths claim theirs is a general therapy, applicable and successful in a wide range of conditions. Situated outside orthodox medicine, homeopathy has been starved of funds for research – Albrecht (1999) estimated spending no higher than \$1.5 million annually worldwide for all types of homeopathy. As a consequence, there are few contemporary clinical trials overall (fewer than 300 were found in the comprehensive literature search conducted for this thesis). Of these trials, the majority have used standardized treatments, on the lines of a conventional drug trial, even though the majority of homeopaths practise a therapy where treatments are tailored to the individual, particularly in chronic disease. Some conditions, such as bronchial asthma, for which homeopaths claim their therapy works particularly well, are very underrepresented in the trial record.

*Homeopathy's controversiality:* Like some other complementary therapies, homeopathy is regarded as a placebo therapy by many scientists, regardless of evidence of efficacy from clinical trials (Vandenbroucke 1997). Unlike most other complementary therapies, however, homeopathy began as part of orthodox western medicine, at the beginning of the nineteenth century. Its controversiality and present fringe status stem from judgements made about it in the nineteenth century by powerful opponents in orthodox medicine (e.g. Académie de Médecine 1835a; Holmes 1842; House of Commons 1854–55). Whether or not those judgements were scientifically valid, they still inform current debate (Ernst 1995b; Crellin 1997).

*Relevance of existing reviews:* Traditional review articles in homeopathy, as is the case in most fields, have generally been unsystematic and written by opponents or proponents of the therapy as a whole (or even of one approach within it). Monographs and textbooks containing reviews, which might be regarded as sources, are highly selective in their choice of examples (e.g. Aulas, Bordelay, Royer 1991; Meyer 1996). Well-conducted recent systematic reviews (with protocols) have used wide-ranging literature search strategies to answer the scientific question ‘Is homeopathy any more than a placebo effect?’ (e.g. Boissel, Cucherat, Haugh et al. 1996; Linde, Clausius, Ramirez et al. 1997). Because of the question posed, however, these reviews have tended to leave out study designs which might inform health services research and provision.

*Exclusion of historical evidence:* The widespread use of homeopathy in the nineteenth century has been acknowledged by medical historians (e.g. Kaufmann 1971; Nicholls 1988), but only rarely evaluated for evidence of effectiveness (e.g. Leary 1994). Since homeopathy tends to add to rather than replace its clinical treatments, and since the numbers involved in nineteenth-century trials were many times greater than the sum of all contemporary trial participants, exclusion of the historical record may also misrepresent the therapy.

For these reasons, a historical approach to the evaluation of homeopathy is proposed, one which connects the discipline to its past, and to that of orthodox medicine. In one sense this thesis contains two concise histories of important aspects of homeopathy: Part I accounts for the origins, characteristics and development of the content and methods of the therapy from before 1800 to the present day, while Part II examines evidence from clinical trials of homeopathy from the early nineteenth century up until the middle of the twentieth century. Part III is not historically oriented, but contains a systematic review of clinical trials from 1940 to the end of 1998, looking at issues of current concern including safety and clinical relevance.

Questions concerning the nature of highly diluted homeopathic medicines and the manner in which they are biologically active fall outside the scope of this thesis.

## 1.2. Overview

### 1.2.1. *Homeopathy's place in the history of therapeutics*

The historiography of homeopathy has tended to come from inside the profession. Where different evolutionary streams in homeopathy have been discussed, the treatment usually reflects the allegiances of the author, and tends to be antagonistic towards competing schools of thought (e.g. Coulter 1977; Demarque 1981). More recently, following trends within the 'new' non-medical academic historiography of medicine, the field has enlarged to include accounts and analysis from outside homeopathy: for example, studies of specific historical moments, regional microhistories, sociological analysis of casebooks of well-known homeopaths, and accounts of political and economic conflict between homeopathy and orthodox medicine. But, as in social constructionism generally, little attention has been paid to the content or theoretical and practical adequacy of homeopathy (e.g. Berliner 1982). Therefore, Part I (Chs 2–4) explores the discipline by means of explanatory coverage of its historical origins, conceptual foundation, pharmacological techniques and internal development, without any attempt to impose norms based on what is currently acceptable within any one area of the discipline.

Ch. 2 contrasts the structure of Hahnemann's research programme with emerging structures in German academic medicine around 1800, and is also innovative in attempting to account for Hahnemann's formal presentation of homeopathy by detailing his rhetorical use of academic conventions in his bid to overthrow them. Ch. 3 examines the generally assumed irrationality of homeopathic theory and method by a thorough exploration of Hahnemann's allegedly covert debt to alchemy. Ideas from alchemical medicine that are frequently presumed to survive in homeopathy – such as the doctrine of signatures (e.g. Flaherty 1995) – are shown to have been decisively rejected, yet an acknowledged but overlooked borrowing from Islamic alchemical pharmacy is shown to have transformed the preparation of homeopathic medicines after 1818. The probable origins of Hahnemann's avant-garde miasmatic and germ theory in a forgotten eighteenth-century treatise are also explored, again possibly for the first time. Ch. 4 recounts the post-Hahnemannian development of the principal schools and approaches within homeopathy, and is innovative in showing that allegedly irreconcilable theoretical and practical differences can be mapped and understood as a unified therapeutic field – one which is systematically traversed by many therapists in the present day.

### **1.2.2. Homeopathy and the development of clinical evaluation**

Part II (Chs 5–9) consists of a comprehensive and systematic review of prospective historical trials, 1821–1953. Ch. 5 presents the background against which such a review must take place, namely the neglect of the clinical trial in orthodox medical historiography, compounded by the even greater neglect of homeopathy's clinical record.

The great majority of historical trials found in the literature search fall neatly into three methodological groups corresponding to three chronological phases in the evaluation of homeopathy (and perhaps medicine generally): open observation, pragmatic comparison, and explanatory trial. Ch. 6 reviews mainly prospective case series from the period 1821–35, and the significance of the cut-off date will be apparent when it is remembered that 1835 was the year in which the Académie de Médecine issued its ostensibly evidence-based pronouncement against homeopathy, and the therapy's journey from centre to fringe began in earnest. Ch. 7 reviews mainly pragmatic comparisons with allopathy from the period 1844–86, some of which were clearly an embarrassment to the increasingly powerful medical establishment, as evidenced by attempts to prevent trials and comparisons from being carried out, or to suppress the results once completed. Ch. 9 looks at the increasing adoption of the orthodox explanatory research model in the years 1914–53, at a time when homeopathy had been almost entirely displaced by biomedicine. The evidence found in each chapter is reviewed along with the reception of the trials where found, and then synthesized in relation to the judgements made on homeopathy at the time.

A fourth group of historical trials is reviewed in Ch. 8. These are trials in which placebo controls were used in the period 1829–1903. Such a disparate group – only 2 placebo-controlled therapeutic trials, plus 5 placebo-controlled pathogenetic drug tests and 3 trials of placebo alone regarded as the rhetorical equivalent of homeopathy – deserves separate treatment from the therapeutic trials in Chs 6 and 7. This is in view of the importance accorded to the introduction of masked evaluation, including placebo controls, in the history of clinical evaluation, and again the evidence is synthesized in relationship to nineteenth-century (and current) opinion. All the reviews in Part II are innovative, but Ch. 8 particularly so. It contains the first detailed account of within-patient placebo controls in everyday homeopathic practice as used throughout the nineteenth and twentieth centuries. Evidence that this internal usage was imitated in the first external placebo-controlled evaluations of homeopathy is presented, in complete contrast to the normative view that homeopaths adopted placebo controls in trials as early as they did because of external prompting.

### **1.2.3. *Is homeopathy clinically relevant?***

In view of the problems of accessibility mentioned in 1.1 above, the development of a comprehensive database of controlled trials was paramount. This has been based on a search for every prospective controlled homeopathic clinical trial published between 1940 and the end of 1998, with controls including orthodox treatment or no treatment as well as placebo, as in an earlier systematic review (Kleijnen, Knipschild, ter Riet 1991). Part III (Chs 10–13) constitutes a systematic review of the contemporary trials found, split into chapters for convenience: Ch. 10 Rationale, Ch. 11 Methods, Ch. 12 Results, Ch. 13 Discussion. Exploratory rather than hypothesis-based, it is innovative in its inclusion of:

- more trials than any previous review;
- analysis of intrahomeopathic differences and trends;
- an evaluation of homeopathy's safety;
- the evaluation of a generic methodological quality assessment tool designed to allow meaningful inclusion and comparative evaluation of prospective controlled trials other than randomized placebo-controlled ones – as well as allowing other nonexperimental designs to be evaluated and added to the database at a later time;
- discussion of homeopathy's clinical relevance;
- identification of areas that appear to hold most clinical relevance and warrant further research.

### **1.2.4. *Retrospect and prospect***

The conclusions drawn in the thesis as a whole are summarized and extended in Ch. 14. These relate to empirical evidence concerning the origins of homeopathy's epistemology, pharmacognosy and theories of disease transmission; and to empirical evidence of its efficacy drawn from nearly two centuries of clinical trials.