

The Scientific Status of Homeopathy

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This paper gives a brief overview of the scientific status of homeopathy. It demonstrates that there is pre-clinical and clinical evidence for the effectiveness of homeopathy and that with professional and adequate application, it can be seen as safe.

1. The Status of Homeopathy

1.1 Definition

Homeopathy is often confused with the more general category of complementary and alternative medicine (CAM). CAM is an umbrella term that includes all therapeutic and diagnostic procedures which are not taught in conventional medical schools [1]. There is no generally accepted definition of CAM, and the term is used differently in different studies. It also changes with time. In a workshop held by the office of alternative medicine of the US National Institute of Health in 1995, the participants agreed on the following definition: 'A broad domain of healing resources that encompass all health systems, modalities and practices, and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period. It includes all such products and ideas self defined by their users as preventing or treating illness or promoting health and well-being. Boundaries within complementary and alternative medicine and between complementary and alternative medicine and the domain of the dominant system are not always sharp or fixed.' [2].

Thus it is that the Atkins diet, Chinese medicine, homeopathy, iris diagnosis, and phytotherapy all come under the umbrella of CAM despite the huge differences in their theoretical background, empirical observation and continuity of tradition and experience. Many patients consider the term homeopathy as an umbrella term for all kinds of alternative treatment – for example they may say 'I am going to my homeopath' when in fact they are visiting a herbalist.

To clarify this confusing use of terms: homeopathy was developed by Samuel Hahnemann in 1796 and is a medical therapy that intends to cure by stimulating the organism's own ability to re-establish health. Symptoms are carefully evaluated and remedies used. These are micro dose stimuli which would produce symptoms in healthy persons similar to those of the sick person. This is known as the 'simile principle' (let like be cured by like) and is described in Hahnemann's 'Organon' [3]. Most of these homeopathic therapies use so-called potencies, specially prepared dilutions, the extent of which may go beyond Avogadro's number (as yet unknown in Hahnemann's time) to enhance the homeopathic effect.

1.2 Scientific tradition

Homeopathy has a scientific tradition which dates back over 200 years. It has been based from the beginning on scientific thinking and accurate documentation. This has been maintained since both in classical homeopathy and in the majority of the different schools that have developed, such as complex homeopathy, clinical homeopathy, homotoxicology, anthroposophic medicine and isopathy.

Hahnemann was a leading contemporary scientist. He studied both medicine and chemistry. He turned his back on the medicine of his time because with its profusion of bloodlettings and enemas he thought it too crude and barbaric and actually more harmful to than beneficial for its patients. He was well-read and got impetus for his work from translating medical and chemistry books into German. The search for better understanding as to why quinine was effective in the treatment of malaria, inspired him to take quinine himself to establish its effect in healthy subjects. During this experiment on himself, he noted that he developed many symptoms, such as intermittent fever, similar to those of malaria. He described his empirical findings that medication which leads to special symptoms in healthy people could be helpful in treating patients with similar symptoms

(‘similia similibus curentur’ – let like be cured by like). He was too cautious and scientifically accurate to devise a theoretical working model, and simply stated that he could see the simile association although he was unable to explain it. He made many trials on himself, his family and colleagues to substantiate his simile hypothesis and carefully documented the many treatment successes with his patients. Subsequently he further refined his method by developing a special dilution method (involving successive dilution and succussion), called ‘potentisation’.

As early as the nineteenth century, followers of Hahnemann pioneered the use of placebo controls in homeopathic pathogenetic trials (often referred to as ‘drug provings’, wrongly translated from the German ‘Arzneimittelprüfung’) [4,5]. This was long before the widespread use of placebo studies in allopathic medicine which did not take place until after the Second World War.

1.3 A worldwide medical method

Homeopathy is now established worldwide as a medical method [6]. In many countries it is considered on equal terms as conventional medicine. Chile (end of the 19th century), Nigeria (1961), India (1973), Brazil (1979) and Cuba (1992) integrated homeopathy into their public health system [6,7]. In these countries the debate about “the end of homeopathy” in *The Lancet* [8] was noted with amazement. The state secretary for ayurveda, homeopathy and yoga in India commented on the debate: “How could a single study dismiss an entire system?”

In some European Countries, such as France, Germany, Austria, Switzerland and Latvia, homeopathy is acknowledged by the medical associations as an official specialisation for physicians. It is also acknowledged as a treatment option in many other countries such as Italy, Spain, and Greece. In the UK it is partly integrated into the public health system (National Health Service). Those homeopathic doctors who make treatment decisions are familiar with both homeopathic and conventional treatment options, and very often decide in favour of homeopathy.

2. Evidence Base

2.1 Research methodology

Homeopathy provides over 200 years of successful clinical experience (See Annex 1: Two Case Reports). However today’s ‘gold standard’ of evidence based medicine, the randomised controlled clinical trial (RCT), usually with double blinding, is not well suited to the specific nature in particular of highly individualised types of homeopathic treatment [9].

A precondition for RCTs in all kinds of studies on homeopathy as well as in conventional medicine is an equipoise regarding the therapies in question (test intervention and control) by patients and physicians. That means that neither patients nor physicians should favour one of the treatment alternatives (even in normal clinical studies this is almost impossible). There is nearly an ‘equipoise’ situation in phase III clinical trials, from which the RCT design originally derived, because of the balance between the hope for a better treatment and the risk of unknown adverse effects or even fatal outcome. But this is not the case in a homeopathic treatment: in visiting a homeopath, the patient is making an active choice and expects proper homeopathic treatment, and the homeopath takes into account the patient’s unique situation when choosing the remedy. In other words, strong preferences exist, which greatly decrease the likelihood of patients being prepared to enter a clinical trial in which they have a 50% chance of receiving a placebo. It may also be that ‘non-specific’ treatment effects are enhanced by the fact that the homeopathic practitioner takes an interest in the individual situation, health conditions and particular symptoms of the patient [10]. Consequently RCTs are less suitable for investigation of the efficacy of highly individualised homeopathic approaches. This is less of an issue in more ‘clinical’ homeopathic approaches where homeopathic medicines are prescribed for particular indications. These methodological concerns are confirmed by the available trial data which indicate that the percentage of positive trials of ‘clinical’ homeopathic approaches is higher than the percentage of positive results in ‘classical’ homeopathic studies [11].

2.2 Quality of studies

Despite these methodological issues, there are a considerable number of homeopathic clinical trials which fulfil the strictest criteria of evidence based medicine. Shang et al. [12] assessed 110 homeopathic RCT studies regarding their study quality and compared them with 110 (more or less) matched studies of conventional medicine. Only 6 of the 110 conventional studies and 8 of the homeopathic ones fulfilled all quality criteria (they chose only criteria of so called internal validity: sufficient number of cases, sufficient allocation concealment and others). From this result and the overall quality of the studies, the authors concluded that homeopathic studies were of better quality than conventional ones.

2.3 Evidence of effectiveness

The totality of research into homeopathy demonstrates that the majority of clinical trials in homeopathy are positive, including the majority of the more rigorous studies.

This statement might contradict the results of Shang et al [12], who calculated and compared so-called combined effect values of the best quality studies of homeopathy and allopathic medicine (see above), and found in favour of allopathic medicine. Calculating a combined value of studies from selective data containing such heterogeneous subjects as stroke and influenza or diarrhoea and warts is not an adequate approach even for evidence based medicine: "It's important to remember that whatever statistical model you choose, you have to be confident that clinical and methodological diversity is not so great that we should not be combining studies at all." [13]. When comparing the selected studies one by one, the results for conventional and homeopathic trials are quite comparable (see Annex 2 Table 1). Moreover, as Lütke demonstrated, results of meta-analyses are highly sensitive to the way the type and number of trials have been selected [14]. There is clear evidence to suggest that the Shang meta-analysis was disproportionately affected by the results of one single negative trial [15].

The most extensive and carefully collected review of homeopathic clinical trials to date has been done by Kleijnen et al. [16]. They systematically searched a total of 107 studies for three years and assessed them according to a panel of criteria predominantly of internal validity. 81 studies showed a result in favour of homeopathy (compared with placebo), 24 did not. Of the qualitatively highest rated studies 15 showed significant results in favour of homeopathy and only 7 did not. The authors stated: "The amount of positive evidence even among the best studies came as a surprise to us. Based on this evidence we would be ready to accept that homeopathy can be efficacious, if only the mechanism of action were more plausible."

The most recent comprehensive work about homeopathy consists in the results of a five year Health Technology Assessment, which was initiated by the Swiss authorities involving many independent and well-reputed international university researchers in order to evaluate the benefits of complementary medicine within the national health system. All available reviews as well as systematically searched studies in upper respiratory tract infection were evaluated. In addition to the usual criteria of internal validity the authors also considered external validity - that is whether study design and performance were in concordance with everyday homeopathic practice. Furthermore pre-clinical studies were reported as well as studies about economy, usage, and safety. The authors concluded: "effectiveness of homeopathy can be supported by clinical evidence and with professional and adequate application be seen as safe" [17-18].

Further, concise compilations of homeopathic research have been published [19-25]. In more recent homeopathic trials [26-27] as well as in methodological articles on homeopathic and CAM research in general [28-30], new and more appropriate approaches to research design are being successfully pursued in order to overcome some of the methodological problems mentioned above.

3. The Working Model (Potentisation)

The plausibility of the working model of homeopathy remains the greatest obstacle to its more widespread acceptance. The high dilutions used in some homeopathic medicines (approximately 25% of those sold) mean that in some cases the homeopathic medicines used no longer contain molecules of the starting material.

When testing drugs for their effects on healthy people, Hahnemann wanted to avoid adverse and toxic effects. Therefore he started to dilute the test substances. He developed a method to sequentially dilute the original substance (in 1:10 or 1:100 steps), shaking the solution vigorously in each dilution step, a process called potentisation. This stepwise vigorous shaking, also known as succussion, is different from dilution by stirring. When administering these potentised substances to healthy subjects and patients, he noticed that the treatment effect was enhanced whereas the toxic or adverse effects were diminished. This favourable safety profile of homeopathic medicines still applies and there are very few published reports of adverse events.

Hahnemann called this procedure 'potentisation' because it enhanced (potentised) the desired effect. He stated that he could not explain the working mechanism, but just observed the therapeutic effect.

Two hundred years later, the situation remains more or less the same. There are a number of hypotheses to explain the effect of potentisation. The more recent ones, with nuclear magnetic resonance and ultra-violet spectroscopy as well as with electrochemical and thermodynamic measurements, show differences between homeopathic potencies and controls [31-33] that are significant.

However we are still far from understanding what happens during the potentisation procedure. What can be stated with some certainty is that there is an interactive effect between potentised high dilutions and a living organism. For instance, in recent studies,

Scherr et al. [34] observed highly significant reactions of yeast cells to homeopathic potencies, which were modified by as yet unknown influencing factors.

Annex 1: Two Case Reports

Gypser (1990) [35]:

A fifty-six year old woman with severe and hindering pain in both legs lasting a week described spontaneously, “as if deep in the legs, beginning at the feet, the tendons were being pulled up and out”. According to the corresponding description by Ward [36] and Hering [37] *Crotalus horridus* was applied and the pains vanished completely within one hour. They returned the next day in a milder form but had never returned since. The patient was under observation for 8 months.

Wegener (1990) [38]:

A forty-one year old woman reported the following complaints:

For 3 years Nightly cramping in the stomach, annually recurring gastritis and depressed mood

11 years ago Hepatitis from which she hasn't actually recovered yet

21 years ago Cholecystectomy (gall stones) – at age 21

Since childhood Frequent diarrhoea from excitement

According to the patient's central symptom “melancholy during gastritis” *podophyllum* was applied. After an aggravation on the second day, the complaints gradually disappeared within two weeks. They now return sometimes in a considerably milder form.

Annex 2: Table1. Comparison of the results of the best quality studies of homeopathy currently available and selected studies of conventional medicine

| Indication | Conventional Medicine | | Homeopathy | |
|---|--|--------|--|---|
| | Study | Result | Study | Result |
| Bacterial vaginosis post abortion | Crowley et al. 2001 [39]: prophylactic treatment with antibiotics | n.s. | | |
| Stroke | Horn et al. 2001 [40]: therapeutic treatment with nimodipine | n.s. | | |
| Seasonal allergic conjunctivitis | Möller et al. 1994 [41]: therapeutic treatment with nedocromil (children); significance in favour of nedocromil in 2 of 3 investigated outcome parameters; high placebo effect | sign. | | |
| Influenza | De Flora et al. 1997 [42]: preventive long-term treatment with N-acetylcysteine; significant reduction of disease symptoms but no prevention of A/H1N1 virus influenza infection | sign. | | |
| | Nicholson 2000 [43]: therapeutic treatment with oseltamivir | sign. | Papp et al. 1998 [44]: therapeutic treatment with Oscillococtinum® Rottey et al. 1995 [45]: therapeutic treatment with microorganisms | sign. sign. |
| Acute diarrhea (children) | Kaplan et al. 1999 [46]: therapeutic treatment with loperamide; significantly more total adverse events in loperamide group | sign. | Jacobs et al. 2000 [47]: therapeutic homeopathic treatment (children in Nepal); low incidence of adverse events | sign. |
| Chronic sinusitis | | | Weiser & Clasen 1994 [48]: therapeutic treatment with Euphorbium comp. | sign. |
| Chronic Headache | | | Walach et al. 1997 [49]: classical homeopathic treatment | n.s. |
| Plantar warts | | | Labrecque et al. 1992 [50]: therapeutic homeopathic treatment outcome: complete disappearance of warts | n.s. |
| Muscle soreness after long-distance running | | | Vickers et al. 1998 [51]: preventive treatment (after long-distance running) with Amica 30X | n.s. (trend in favour of placebo) ¹ |
| Fasting | | | Schmidt & Ostermayr 2002 [52]: promotion of body weight reduction in fasting patients by Thyroidinum 30cH | n.s. (trend in favour of placebo; without adjustments: significance) ² |

¹This study shows an experimental design and can be interpreted as homeopathic remedy proving in which homeopaths could expect more symptoms in the verum group.

²The interpretation of this study is also somewhat ambiguous because some effects could be due to a homeopathic "treatment" of the fasting condition in which one also would expect results in favour of the control intervention.

Abbreviations: n.s. nonsignificant, sign.: significant

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