

## DEBATE

# 'Homeopathy': Untangling the debate

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**There are active public campaigns both for and against homeopathy, and its continuing availability in the NHS is debated in the medical, scientific and popular press. However, there is a lack of clarity in key terms used in the debate, and in how the evidence base of homeopathy is described and interpreted.**

**The term 'homeopathy' is used with several different meanings including: the therapeutic system, homeopathic medicine, treatment by a homeopath, and the principles of 'homeopathy'. Conclusions drawn from one of these aspects are often inappropriately applied to another aspect. In interpreting the homeopathy evidence it is important to understand that the existing clinical experimental (randomised controlled trial) evidence base provides evidence as to the efficacy of homeopathic medicines, but not the effectiveness of treatment by a homeopath. The observational evidence base provides evidence as to the effectiveness of treatment by a homeopath. We make four recommendations to promote clarity in the reporting, design and interpretation of homeopathy research. *Homeopathy* (2008) 97, 152–155.**

**Keywords:** Homeopathy; Evidence base; Observational studies; RCTs; Homeopathic medicines; Treatment by a homeopath; Therapeutic system of homeopathy

## Introduction

Despite its popularity among the general public<sup>1,2</sup> homeopathy has struggled to gain legitimacy within the medical and scientific establishments.<sup>3,4</sup> There are active public campaigns both for and against homeopathy, particularly its continuing availability in the NHS.<sup>2</sup> Those 'for' cite the popularity of homeopathy and evidence from observational studies of treatment by homeopaths in clinics and hospitals and systematic reviews of trials.

Those 'against' also cite the evidence from systematic reviews of trials,<sup>3,5</sup> and highlight the alleged implausibility of 'homeopathy' and question its continued provision in the National Health Service (NHS).<sup>3</sup> Professor Gustav Born and colleagues last year wrote to the Director of NHS commissioning and all 472 NHS Primary Care Trusts repeating their concerns about "...the continued provision to patients

*of 'alternative' medicine including 'homeopathy', in the absence of evidence of efficacy, across the NHS".<sup>6</sup>*

In this article we attempt to contribute to this debate by clarifying some of the key terms used and exploring the evidence base available. Recommendations are made to clarify the issues and enhance understanding in this debate.

## Defining terms

### 'Homeopathy': multiple meanings

Within any debate, it is important to define the key terms. What exactly is meant by the term "homeopathy" in this debate?

The MeSH<sup>1</sup> term for 'Homeopathy' describes it as "A system of therapeutics founded by Samuel Hahnemann (1755–1843), based on the Law of Similars where "like cures like". Diseases are treated by highly diluted substances that cause, in healthy persons, symptoms like those of the disease to be treated. The dilutions are repeated so

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<sup>1</sup> MeSH terms were developed by the United States National Library of Medicine to index articles in Index Medicus and Medline in order to provide a standardised way to describe diseases, symptoms, treatments, drugs etc. [http://www.nlm.nih.gov/cgi/mesh/2007/MB\\_cgi](http://www.nlm.nih.gov/cgi/mesh/2007/MB_cgi).

many times that there is less than one molecule per dose and it is suggested that benefit is from the energetic life force of the original substance.” and alludes to two principles of homeopathy and homeopathic ‘doses’. However, the term ‘homeopathy’ is not just used to refer to the ‘system of therapeutics’ but often to refer to one or more of the following:

1. Homeopathic medicine (pillules, etc.).
2. Treatment by a homeopath (care by a homeopath, consultation(s) with a homeopath).
3. The principles of ‘homeopathy’ (Principle of similars, minimum dose, etc.).

Ambiguity in the use of the term ‘homeopathy’ is common, with the term being used to denote two or more different meanings in the same conversation or article. Conclusions drawn from research on one aspect of homeopathy (e.g., homeopathic medicines) are often applied to another meaning of the term<sup>3</sup> (e.g., the therapeutic system of homeopathy). This confounding of meanings is most obvious in systematic reviews of ‘homeopathy’<sup>5,7,8</sup> and reviews of systematic reviews of ‘homeopathy’.<sup>9,10</sup> For example, in a review entitled ‘A systematic review of systematic reviews of homeopathy’<sup>9</sup> where the evidence reviewed was systematic reviews of trials of homeopathic medicines, the author switches between the following terms: ‘homeopath’, ‘homeopathy’, ‘homeopathic medicines’, ‘homeopathy’ s... two principles’, resulting in confusion as to which of these conclusions the review might refer to.

The lack of differentiation between the various possible uses of the term is perpetuated by ‘homeopathy’ being the only MeSH term available for searching the research evidence of homeopathy. We suggest that it is of fundamental importance to distinguish between the multiple possible meanings of the term ‘homeopathy’.

### Efficacy or effectiveness

Two terms used in the debate that would benefit from clarification are ‘efficacy’ and ‘effectiveness’. In clinical epidemiology ‘efficacy’ refers to ‘the extent to which a specific intervention, procedure, drug, regimen, or service produces a beneficial result under ideal conditions’.<sup>10</sup> Evidence of efficacy is usually interpreted as requiring evidence from placebo-controlled randomised controlled trials (RCTs). Whereas ‘effectiveness’ is a ‘measure of the extent to which a specific intervention, procedure, drug, regimen or service, when deployed in the field in routine circumstances does what it is intended to do for a specific population’.<sup>10</sup> Evidence of effectiveness requires pragmatic RCTs and well conducted observational studies of routine clinical practice.

## Evidence

### Evidence called for...

The editor of the Lancet called on the National Institute for Clinical Excellence (NICE) to evaluate ‘homeopathy’<sup>3</sup> an offer which was subsequently declined. Professor Born and colleagues called for ‘evidence of efficacy’ in their letter to the Director of NHS commissioning, that is, evidence

that the treatment offers therapeutic benefits greater than placebo, and not evidence of effectiveness. However, is evidence of efficacy rather than effectiveness required to justify NHS spending?

### Evidence required...

Since 2002 NHS Primary Care Trust commissioners have been required to follow guidance from NICE.<sup>11</sup> This guidance is primarily based on evidence of clinical and cost effectiveness. Cost effectiveness is calculated by NICE using cost utility analysis which estimates the ratio between the cost of a health intervention and the benefit it produces in terms of the number of years lived in full health by the beneficiary. From an NHS commissioning perspective the primary question is one of clinical effectiveness and cost effectiveness – benefits and costs – rather than efficacy. Leading Complementary and alternative medicine researchers<sup>12–15</sup> concur with NICE on the importance of establishing evidence of effectiveness before seeking evidence of efficacy.

### NHS spending on ‘homeopathy’

In 1998 there were an estimated 120,000 visits to homeopaths in the NHS with an NHS expenditure of £3.3 million.<sup>1</sup> What was this spent on? The total NHS spending on homeopathic medicines probably does not amount to much more than 5% of this, the bulk of the cost of ‘homeopathy’ in the NHS is the cost of the treatment by a homeopath i.e., consultation(s) with the homeopath and the infrastructure to facilitate this. Thus the evidence that is required to inform the debate regarding NHS spending on what is termed ‘homeopathy’ is largely evidence of the clinical and cost effectiveness of treatment by a homeopath.

### Experimental evidence

Let us consider the evidence which might inform the debate. Broadly speaking there are two types of evidence, experimental and observational.

Experimental evidence is derived from situations where subjects have been randomly assigned to one of two groups, for instance in a randomised controlled trial (RCT). The experimental evidence base comprises published reports of trials, systematic reviews of RCTs, meta-analyses of RCTs and reviews of systematic reviews.

Since 1940 over 150 RCTs of ‘homeopathy’ and 26 systematic reviews have been published.<sup>16</sup> All these RCTs are trials of homeopathic medicines (including the 32 RCTs of classical/individualised ‘homeopathy’ where patients have had in depth consultations with a homeopath in order to identify the ‘simillimum’ as well as homeopathic medicines). All ‘homeopathy’ RCTs have treated the homeopathic medicine as the sole ‘active’ ingredient along pharmacological lines. What sort of evidence do these RCTs of homeopathic medicines aim to provide? In over 140 RCTs patients were randomised to receive a placebo or verum medicine and thus provide information on the efficacy of homeopathic medicines, only 14 RCTs compared homeopathic medicine to orthodox treatment and thus

provided information on the comparative effectiveness of homeopathic medicines.

However, the majority of NHS 'homeopathy' is delivered by a homeopath. Van Hootegem<sup>18</sup> in relating the case of a 23 year old woman with chronic fatigue syndrome who was cured with a course of 'homeopathic' treatment states:

*"the action of the homeopathic medicine was intimately woven with the relationship I had with her as a therapist. It is impossible to separate these two influences"*

Does the homeopathic remedy mediate the activity of the relationship or does the therapeutic relationship mediate the activity of the remedy?

Thompson and Thompson<sup>19,20</sup> have suggested that interpreting what homeopaths do as solely identifying and prescribing the 'simillimum', has impoverished our understanding of homeopathy. They used qualitative research to identify what might be the 'active ingredients' of the homeopathic approach. Through a process of direct observation and modelling in a real world context, they attempted to "identify the components of the intervention and underlying mechanisms by which they will influence outcome". Six putative active ingredients were identified which might contribute to the effectiveness of homeopathic care: patient's openness to the mind body connection, consultational empathy, in depth enquiry into bodily complaints, disclosure, the remedy matching process, homeopathic remedies. Other authors have discussed the difficulties of separating out the effects of the homeopathic medicine from the consultation effects.<sup>21,22</sup> Until we are clear as to what actually the active ingredients in homeopathic treatment are and how all the ingredients relate to each other, treatment by a homeopath should be viewed as a complex intervention<sup>23</sup> rather than reduced to a homeopathic medicine. In assessing the effectiveness of 'homeopathy', the component parts of treatment by a homeopath should not be separated out – instead 'homeopathy' should be assessed as a package of care, as delivered.

### Observational evidence

In addition to experimental evidence, there is a large body of observational evidence. The observational evidence base consists of observational studies (of groups of patients) and case studies (single or case series) of treatment by homeopaths.

There are at least 22 observational studies (12 of which were conducted in the NHS) which report the outcomes of 15,703 patients receiving treatment by a homeopath. In addition there are several hundred thousand published single<sup>24</sup> case reports.<sup>2</sup>

The evidence from this substantial body of literature relates directly to questions of clinical effectiveness of treat-

ment by a homeopath. Unfortunately the research methods used to collect observational data mean that the evidence is vulnerable to substantial biases including regression to the mean, patient selection bias, outcome measurement bias.<sup>25-27</sup> Individual case studies are often vulnerable to other forms of additional bias: observer bias, recall bias, and analysis assessment bias. Any bias may exaggerate or deflate the true effect of the treatment. Since observational evidence is prone to many types of bias, it is regarded as weaker than experimental evidence, and is generally disregarded in systematic reviews of evidence. However, this type of evidence does acknowledge the homeopath i.e., focuses on treatment by a homeopath in contrast to the experimental evidence which focuses only on the homeopathic medicine.

## Recommendations

The implementation of the recent 'RedHot' supplement to CONSORT guidelines<sup>28</sup> will improve future reporting of 'Homeopathy' trials through the inclusion of information on consultations, practitioners, theoretical models, case analysis strategies etc.

We make a further four recommendations in order to promote clarity in the reporting, design and interpretation of 'homeopathy' research:

1. In reporting research, the term 'Homeopathy' should be solely used to refer to the 'therapeutic system of homeopathy'.
2. That the MeSH term 'homeopathy' has additional sub-headings to help differentiate various aspects of the therapeutic system of 'homeopathy': 'homeopathic medicines', 'treatment by a homeopath', 'the principles of homeopathy' etc. and that these are used in the reporting of research e.g., 'RCT of the efficacy of homeopathic medicine for...' or 'An observational study of treatment by a homeopath'.
3. The exact aspect of 'homeopathy' being discussed is made explicit.
4. The evidence referred to matches the evidence required by the nature of the question being debated.

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