

Studying the studies: Meta-Analysis

Pooling the results

Homeopathy has generated a relatively small number of clinical studies compared to conventional medicine; furthermore these studies have tended to show only weak evidence of the clinical efficacy of homeopathic remedies.

When faced with a number of studies, each offering but a small amount of evidence for a certain hypothesis, one needs to be able to gather the results in a way that will provide an overall result. Meta-analysis is a set of techniques that enables statistical pooling together of the results of many studies, thus producing one final score of treatment effect. In practice, the quality and size of the individual trials differ greatly and the meta-analysis method needs to somehow take account of this.

Publication bias and trial quality

Meta-analyses face two major problems; the first being publication bias, the second being the quality of the trials being pooled together. Publication bias is the tendency for trials with negative results to be shelved by authors and if they are submitted, to be then ignored by publishers. This can lead to a situation where only positive results are published, hence the publication bias.

The quality of trials is also a problem as it is often difficult to determine the quality of a trial from the publication itself. So, trials of low quality can end up being assigned the same weight as trials of high quality.

The power of systematic reviews

Another powerful tool in weighing the evidence for or against homeopathy is the systematic review of trials in specific clinical conditions. A systematic review is a literature review focused on a single question which tries to identify, appraise, select and synthesize all high quality research evidence relevant to that question. These systematic reviews often include a meta-analysis of the trials investigated.

To date, twenty three such systematic reviews of homeopathic treatment exist. Ten of these

yielded positive results for treatments using homeopathic remedies, covering pathologies such as: allergies and upper respiratory tract infections, childhood diarrhoea, influenza, rheumatic diseases, hay-fever and vertigo.

In scientific terms, these systematic reviews carry a lot of weight, so it could be said that homeopathic remedies have been 'proven to be effective' for the conditions stated above.

Lack of evidence, not lack of effect

In many cases the systematic reviews point to a lack of evidence rather than a lack of effect so that, if more trials are performed which produce positive results, then more pathologies will be added to the list of conditions considered treatable through the use of homeopathic remedies.

Results of meta-analyses to date

There have been six meta-analyses of the efficacy of homeopathic remedies to date. Of these six meta-analyses, five concluded in favour of the effect of homeopathic remedies being more than placebo, whereas the last one concluded that the effects were probably due to placebo. Generally the meta-analyses have highlighted the weakness of the evidence and hence the need for more high-quality trials.

The first meta-analysis published in 1991 by Kleijnen et al, reported on one hundred and five trials and concluded that "The evidence of clinical trials is positive but not sufficient to draw definitive conclusions because most trials are of low methodological quality and because of the unknown role of publication bias" (*Kleijnen et al BMJ 1991*).

In 1996, Boissel et al reported on fifteen high-quality trials and concluded that "There is evidence that homeopathic medicine is more effective than placebo". (*Boissel et al 1996 Rep Eur Comm*).

In 1997, Linde et al performed a comprehensive meta-analysis, reporting on eighty nine trials of sufficient methodological quality (*Linde et al, Lancet 1997*). After a thorough statistical analysis

they concluded, “The results of our meta-analysis are not compatible with the hypothesis that the clinical effects of homeopathy are completely due to placebo”.

This paper generated a heated debate in the scientific literature with different people taking sides for or against homeopathy.

The need for more high-quality trials

Linde and Melchart published another meta-analysis in 1998. Using more stringent inclusion criteria, they concentrated on thirty two trials of homeopathy and concluded in favour of an effect of homeopathy, but stressed the weakness of the evidence and the need for more high-quality trials of homeopathy (*Linde & Melchart JACM 1998*).

In 2000, Cucherat et al also concentrated on the trials of highest quality, reporting on sixteen trials which met their criteria. They concluded in favour of an effect of homeopathy and also highlighted the weakness of the evidence and hence the need for more high-quality trials (*Cucherat et al, Eur J Clin Pharma 2000*).

In 2005 Shang et al published the results of their meta-analysis (*Shang et al Lancet 2005*). They performed a comparison of one hundred and ten trials of homeopathy matched with one hundred and ten allopathic trials of similar size. Their findings - widely reported in the press at the time - “heralded the end of homeopathy”. They concluded, “This finding is compatible with the notion that the clinical effects of homeopathy are placebo effects”. However, their paper has been at the centre of a great amount of controversy.

Of these six meta-analyses, only three were included in the Database of Abstracts of Reviews of Effects (DARE) held by The Cochrane Library. These three being the Linde et al 1997, Linde & Melchart 1998 and Cucherat 2000. All three concluded in favour of the existence of an effect of homeopathy and stressed the need for more high-quality research in the field.

The Shang et al 2005 meta-analysis

The meta-analysis at the centre of the controversy is based on 110 placebo-controlled clinical trials of homeopathy and 110 clinical trials of conventional medicine. It was published in The Lancet in 2005. In terms of the quality of the trials, 19% of homeopathy trials were considered to be of ‘higher quality’ compared to only 8% of the conventional medicine trials. In this paper, the analysis was finally restricted to large trials and trials with higher methodological

scores. When restricted in this way, the results showed a clear effect for conventional medicine but no significant effect appeared for the homeopathy trials. The paper’s main conclusion is that the clinical effects of homeopathy are probably those of placebo.

Criticisms of this publication.

Misleading information

The authors perform a meta-analysis but only base their conclusion on the analysis of eight trials of homeopathy against six of conventional medicine.

No precise trial choice criteria

The final conclusions were based on the analysis of the ‘larger and higher reported methodological quality’ trials, yet no precise criteria were given as to how this choice was made.

Quality assessment not adapted to homeopathy

It is also clear that the criteria for quality assessment were not adapted to homeopathy: e.g. large placebo-controlled studies of single remedies were considered of higher quality although they did not apply the homeopathic principle of individualisation.

Quality of the meta-analysis

The meta-analysis does not follow the Quality of Reporting of Meta-Analyses (QUOROM) guidelines, published by The Lancet in 1999. It was not included in the Database of Abstract of Reviews of Effects (DARE) held by The Cochrane Library.

Questionable endorsement by The Lancet

This study has done very little to clarify the issues with homeopathy and it is left to future studies to steer away from the serious limitations of this study and analyse the data afresh.

Authors: Dr A Tournier PhD and C Relton.

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