

EDITORIAL FOR NOVEMBER 2016

EVIDENCE BASE FOR HOMOEOPATHY – A BIRD’S EYE VIEW.

Homeopathy is a system of medicine that involves treating the individual with highly diluted (potentized) substances with the aim of supporting the body’s immune system that leads to healing. Homoeopaths usually base their prescription on symptom similarity and prescribe a remedy that are prepared by Homoeopathic pharmacies using a careful process of dilution and succussion (a specific form of vigorous shaking).

Unfortunately, since 200 years our science has not been able to explain the mechanism of action of these ultra- high dilutions in the body, but laboratory experiments are increasingly showing that homoeopathically prepared substances can **cause biological effects**. There is also a growing body of research evidence suggesting that homeopathic medicines have **clinical effects** too. However, the scientific debate over the evidence base for and against homeopathy continues.

There are many different types of research methodology used to assess medical treatments. These research approaches vary in a number of key properties – size of the study, whether they are performed under ideal conditions or real-world conditions, whether they test a treatment for a specific condition or for safety, whether the patients are blinded to the treatment received.

The science of testing Homoeopathic medical treatment is complex and each approach provides a specific level of insight depending on the design of the investigation. When assessing evidence, the highest quality evidence that is available is considered first as it is generally believed to provide the most reliable information.

The most common studies conducted by Central council of Homoeopathy includes:

- Observational Studies
- Clinical Trials
- Systematic Reviews
- Safety Studies
- The Placebo Effect

1 Clinical trials

Clinical trials are experiments carried out on patients to compare the effects of homoeopathic treatments under highly controlled conditions. One type of clinical trial – the randomised controlled trial (RCT) – is considered by many scientists to be the ‘gold standard’ of research methods for determining whether medical treatments are effective, especially if the control group for comparison is a placebo and both patients and practitioners are blinded as to whether the treatment given is placebo or the test treatment. These are known as double blind – randomised controlled trials (DB-RCTs).

RCTs have been used to investigate various different aspects of homeopathy, such as how homeopathic medicines compare with placebo and how effective homeopathic treatment is for specific conditions.

“Up to the end of 2011, there have been 164 peer-reviewed papers reporting randomised controlled trials (RCTs) in homeopathy. This represents research in 89 different medical conditions. Of those 164 RCT papers, 71 (43%) were positive, 9 (6%) negative and 80 (49%) non-conclusive¹”.

The fact that 80 trials were inconclusive highlights the need for changes in the way homeopathy research is conducted in future to ensure that meaningful results are generated from clinical trials. Three key factors for improving the clinical trial evidence base for homeopathy are :

- the need for larger scale trials with larger sample sizes (commonly prevented by a lack of funding)
- the use of research methods that are better suited to the task of testing homeopathy as a complex individualised therapy.
- assess the value of homeopathy across a wider range of illnesses with repetition in each condition.

Given that homeopathy is a holistic therapy (treating the person as a whole rather than treating specific diseases) it can appear contradictory to have research trials testing homeopathic treatment of specific medical conditions. There are three main reasons why researchers are performing clinical trials that assess how effective homeopathic treatment is for a specific disease, working through this apparent clash of philosophies:

1. Patients considering seeing a homeopath often ask whether homeopathy can help with the health problem that is bothering them most (their chief complaint)
2. When another medical professional refers a patient to a homeopath they may want to know what track record the therapy has in treating that specific disease
3. The central government provides the majority of medical services according to disease categories esp. primary health centres, central government health employees scheme etc..

2. Systematic review

A systematic review is a summary of the total research evidence available on a particular subject, designed to provide more reliable information than single studies. Specific methods are used to search academic journals and identify which studies are suitable for inclusion in the review (e.g. those of suitably high quality). From these identified trials a smaller number may be found suitable to go into a meta-analysis. A meta-analysis is a statistical technique used to quantitatively analyse the combined results of multiple studies to generate a more meaningful overall result.

Systematic reviews are intended to draw conclusions from data collected from multiple similar studies, yet the set of trials used in the more famous systematic reviews of homeopathy vary widely in both the type of homeopathic treatment given and the medical conditions being investigated. Particularly, the term 'homeopathy' has been interpreted several different ways in the context of homeopathy research¹. This means that studies investigating very different approaches are all described as trials of 'homeopathy' and are frequently (and inappropriately) analysed together in systematic reviews.

For example, trials pooled for systematic reviews have studied very different aspects of homeopathy making it inappropriate to directly compare them. These different aspects of homeopathy include:

- A standard single homeopathic medicine given to all participants
- A standard combination of several homeopathic medicines given to all participants
- Individualised prescribing without a homeopathic consultation
- Treatment by a homeopath including individualised prescription and consultation
- Isopathic trials e.g. homeopathic pollen for treatment of hay fever

A small number of systematic reviews have confirmed that homeopathy can be effective for a small number of specific conditions, but much more research of this kind is needed to investigate a wider range of conditions before we can be sure how effective homeopathy may be under idealised research conditions.

3 Safety Studies

No medical intervention is risk free, but homeopathy, as a treatment option is generally considered to have an excellent safety record¹. But what is the evidence supporting this belief?

When assessing the safety of homeopathy, there are three discrete issues to consider:

1) Safety of homeopathic medicines

One of the main differences between homeopathic medicines and conventional medicines is that the latter can be associated with significant toxicity problems and unwanted side effects known as 'adverse drug reactions'. The highly-diluted nature of homeopathic medicines means that they are considered to be highly unlikely to lead to this type of toxic side-effect².

It is the collective experience of homeopaths and patients alike over decades that homeopathic treatment is safe and many patients say that they choose homeopathic treatment rather than conventional treatment because it does not have the side-

effects associated with many conventional drugs. However, it must be appreciated that there is a need to continue to carry out formalised research to test the accuracy of these observations; the safety of homeopathic medicines has been identified as a key area for further work by researchers in the field³.

2) Safety of treatment by a homeopath

Several systematic reviews of the evidence base for homeopathy have been carried out to look at the published rate of adverse events during, but not necessarily caused by, treatment by a homeopath.

The most comprehensive study reviewed the evidence from 1970–1995, including clinical trials, case reports and information provided by manufacturers and regulatory bodies¹. Adverse effects reported during clinical trials testing homeopathic medicines were found to be mild and transient e.g. headaches, tiredness, skin eruptions, dizziness and diarrhoea. These adverse effects occurred more often in the groups given a homeopathic medicine than in the control groups given placebo, which is further evidence that homeopathic medicines are different from placebo.

These true side-effects are easy to differentiate from what homeopaths refer to as 'aggravations'. A homeopathic aggravation is considered to be a brief intensification of pre-existing symptoms that is sometimes seen soon after taking a homeopathic medicine³. When this initial reaction is followed by significant improvement in the patient's overall sense of wellbeing, it is considered to be part of the healing process and therefore classed as a positive therapeutic outcome⁴.

A report by the European Council for Clinical Homeopathy reviewed the results of observational studies assessing the safety of homeopathic treatment since 1995. Observational studies are less reliable than randomised clinical trials because they do not attempt to determine precisely what caused any adverse events.

3) The appropriateness of homeopathic treatment

It is sometimes stated that homeopathic treatment may carry indirect risks of harm by delaying necessary conventional medical treatment. However, in practice it is rare for a patient to seek help who has not already tried everything the conventional approach has to offer.

Risk of harm to the patient in homeopathy may also arise from poorly qualified or unregulated practitioners rather than the practice itself and if homeopathy is used

instead of essential conventional medical treatments where it may not be appropriate to do so: not all conditions are appropriate for homeopathic treatment.

Registered members of Central Council Of Homoeopathy (indicated by the letters BHMS) have met stringent academic requirements, completed a registration process, and agree to abide by a Code of Ethics & Practice.

In Europe the European Council for Classical Homeopathy (ECCH), the Society of Homeopaths has a clear and transparent complaints procedure. The ECCH member associations represent over 5,000 practitioners in 24 countries.