

Australian government report on the clinical effectiveness of homeopathy: Analysis and proposals

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Available online ScienceDirect xxx

SUMMARY

The Australian government recently published a report investigating the effectiveness of homeopathy in many diseases, using as a source systematic reviews of clinical trials in homeopathy. The study of 57 systematic reviews enabled the analysis of 68 pathological conditions. However, this method leads to the exclusion of well conducted trials and sometimes to far too categorical analyses. Moreover, no homeopathic doctor with expertise on the subject took part in this work. Analysing each situation studied by the working group, we provide additional information and put forward proposals to determine in which areas controlled clinical trials or more pragmatic studies can be carried out.

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INTRODUCTION

The debate on the clinical evaluation of homeopathy and the modalities of study of this therapy have been the subject of regular controversy. There are three main explanations for this:

- methodological: the homeopathic treatment is an individualised prescription. It is adapted to the disease, but also to the patient, which makes the modalities of its evaluation difficult to carry out in placebo-controlled clinical trials or in reference treatment;
- scientific: homeopathy often, but not always, uses high dilutions that may be beyond the threshold of molecular presence, a fact which at best intrigues, but more often irritates the scientific community, which generally judges the action of high dilutions to be not very plausible, if not impossible;
- social and political: a considerable section of the population uses homeopathy, not only on the European continent, but also in India and in South America. There are many prescribing physicians wishing to avoid as much as possible the use of potentially iatrogenic therapeutics.

In Australia, the *National Health and Medical Research Council* [NHMRC], whose mission is to advise on methods of care, has identified

as a priority not yet accredited or evidence-based methods ["Evidence based medicine"]. Among these is homeopathy. Believing that there was contradictory data on the clinical effectiveness of this therapy, a review of the literature on the effectiveness of homeopathy under specific clinical conditions was carried out [1]. The authors used the synthesis method for analysing Reviews from the "Cochrane Handbook of Systematic Reviews of Interventions" [2]. The report [3] is very comprehensive and details the various systematic reviews or meta-analyses considering particular clinical situations as well as specific clinical trials.

Over a period from 1997 to 2013, the working group analysed 183 systematic reviews published in English, retained 60 of them, then excluded three. Of the remaining 57, eight relate to a broad assessment of homeopathy. Five studies concern specific clinical conditions: allergic and infectious respiratory pathologies [4], psychiatric pathology [5], dermatology [6], pains of the child [7], effectiveness of *Arnica* in trauma [8]. Three studies evaluate the effectiveness of homeopathy in all pathologies [9–11]. The report analyses, from clinical trials from these 57 systematic reviews, 15 therapeutic fields corresponding to 68 clinical situations, including seven for which no studies were performed.

The NHMRC analysis highlights:

KEYWORDS

Controlled clinical trials in homeopathy
National Health and Medical Research Council [NHMRC]
Systematic reviews on homeopathy

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<https://doi.org/10.1016/j.revhom.2018.01.019>

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- an often low number of participants compared to the threshold of 150 considered to be necessary for reliability: out of the 61 clinical conditions initially selected, there were fewer than 150 patients included in the trials for 36 pathologies, 15 other pathologies and more than 500 for 10 clinical conditions.
- low evidence level in all trials: in 31 conditions, only one controlled clinical trial was identified. The degree of confidence calculated for each pathology according to all the evidence retained [sample size, degree of accuracy and quality of evidence] was moderate for one pathology, moderate to low in four pathologies, and low to very low in the other 56 pathologies

This work was the subject of public consultations and the *Homeopathy Research Institute* [HRI] sent a document [12] asking 3 questions:

- Is the document easily understandable? The HRI has reservations.
- Does the document clearly show how the experts from the NHMRC committee analysed the studies? The HRI points out a lack of knowledge in homeopathy from the experts and has reservations about grouping studies.
- Are there other publications on the effectiveness of homeopathy which should be analysed? The HRI suggests several others.

The HRI reiterated these reservations in two successive documents after publication of the NHMRC report [13,14], a brief summary being made in the second document, highlighting the following major problems:

- For each disease, the trial results were analysed as a whole, with negative trials being considered as negating positive results, even if they evaluated completely different treatments;
- Studies showing the effectiveness of homeopathy in real life have not been included;
- Only essays published in English were analysed;
- Trials with fewer than 150 patients were considered unreliable even though the results were in favour of homeopathy. The NHMRC does not justify this threshold;
- Trials reproduced by the same team but not reproduced by independent teams were considered to be insufficient;
- Some studies were wrongly excluded. So the HRI notes that the chosen method of selection led to the exclusion of meta-analyses evaluating the effectiveness of homeopathy in specific pathologies: infantile diarrhoea [15], allergic rhinitis [16], vertigo [17].

The HRI summarizes its reservations in the proposed summary paragraph amendment. According to the NHMRC, "*there were no health conditions for which there was reliable evidence that homeopathy was effective. No good-quality, well designed studies with enough participants for a meaningful result reported either that homeopathy caused greater health improvements than a substance with no effect on the health condition (placebo), or that homeopathy caused health improvements equal to those of another treatment*" [12 p.3]. The HRI proposes: "*For the 61 health conditions considered, if we consider only prospective, controlled trials published in English and discount all trials with less than 150 participants (even if they had positive statistically significant results), and if we discount positive trials that have not yet been repeated by other teams of researchers, and if we combine all trial results for each condition, we can say that there was no reliable evidence demonstrating that homeopathy was effective*" [12 p.3].

Reading these conflicting documents, two elements stand out:

- On the one hand, the very important work of the NHMRC which analysed a great number of works by classifying them by clinical situation studied,
- But also on the other hand, reservations can actually be made concerning, in particular
 - the absence of experts familiar with clinical research in homeopathy,
 - the joint analysis of trials with very different treatments,
 - the threshold of 150 patients that does not take into account the singularity of homeopathy,
 - the exclusion of well-conducted studies for reasons that are not always clearly justified.

We propose here to briefly analyse the different clinical conditions and diseases considered in the NHMRC report, in the light of the general reviews and meta-analyses already carried out. [9–11,18,19], a synthesis work published in French [20] and a recent analysis of clinical research work [21].

We will summarise the main data arising from this report. Differences of interpretation will be reported, as will the surprising nature of certain clinical indications. For greater clarity, we will follow the order of the clinical indications studied, without modification, as it appears in the 301- page general report [3], a summary of this list being given in Table VI [3, pages 23-25]

PATHOLOGIES STUDIED

Ear and eye disorders

Acute otitis media/Children with otitis media

In this indication, the NHMRC looks at three systematic reviews and four controlled clinical trials with a total of 365 participants. The study carried out in Seattle on 75 children aged 18 months to 6 years is the only selected randomised trial. [22] In this pilot study for ear infections that started less than 36 hours beforehand, individualised homeopathic treatment given three times daily for five days resulted in a decrease in the symptom score compared with placebo at 24 and 64 hours, in favour of homeopathy. Based on the results obtained, the authors of this study estimated that a new trial following this study would require 243 children in each group, which shows the difficulty of carrying out controlled trials in homeopathy.

More recently, another randomised study [23] without a placebo group was carried out in India and is assessed in the supplementary report [24]. The evaluation was performed on the symptom score and on the examination of the eardrums by an ENT specialist. Individualised homeopathic treatment in fifty millesimal potency [LM] proved as effective as the conventional treatment which used antipyretics, analgesics and anti-inflammatories. Symptomatic improvement was faster under homeopathic treatment. The use of antibiotic therapy was required in 39 of the 40 cases under conventional treatment, whereas it was not necessary in any of the 40 cases treated with homeopathy. The NHMRC only retains in its analysis of this essay the difference in the third day between the homeopathy group [four healed patients] and conventional treatment [one patient cured] and does not retain the equivalence of effectiveness of the two treatments.

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