

Facts About Homeopathy Research - An Overview:

1. Homeopathy research, although in its infancy when compared with conventional biomedicine, is an active and growing field of research worldwide (for further details, visit the Homeopathy Research Institute website, <https://www.hri-research.org>).
2. Universities and academic institutes are currently supporting not only clinical research, but also fundamental and basic laboratory research into homeopathy.
3. Over 1,000 clinical trials on homeopathy have been published – ranging from randomised controlled trials (RCTs) to observational studies. The more recent published clinical trials demonstrate the increasingly high quality of work done in the field.
4. The 2012-2015 National Health & Medical Research Council (NHMRC) Review of the evidence on homeopathy stated that it 'rigorously assessed over 1800 papers', whereas in fact only 176 papers were included in scope (less than 10% of the published research)¹.

Meta-analyses:

5. **5 out of 6 published meta-analyses (which combine the results from multiple studies) conclude effects for homeopathy beyond placebo.**

- *These were excluded from scope of the NHMRC Homeopathy Review.*

6. Only 1 has been negative; for more details about this study, go to: <https://www.hri-research.org/resources/homeopathy-the-debate/the-lancet-paper-by-shang-et-al/>

7. The most recent meta-analysis, a robust study by Mathie et al. (2014), found that homeopathic medicines, when prescribed during individualised treatment, are 1.5- to 2.0-times more likely to have a beneficial effect than placebo ($p=0.013$)².

This was the first meta-analysis to look solely at individualised homeopathic treatment i.e. as delivered by homeopaths in 'real world' practice. The findings of this meta-analysis passed a rigorous 'sensitivity analysis' to check the results were robust - i.e. no matter how the trials' analyses were changed, the result remained highly statistically significant ($p<0.001$).

There was also no evidence that lower-quality trials had larger treatment effects.

Randomised Controlled Trials (clinical 'efficacy' studies in humans):

8. **Around half of all clinical research trials into homeopathy report statistically positive outcomes, with only 5% being negative** - the same proportion as seen in conventional research³.
9. **Of 104 placebo-controlled RCTs published in peer-reviewed journals by the end of 2014, 41% were positive, 54% inconclusive and only 5% negative**⁴ - a strikingly similar proportion to that observed in published conventional medical research⁵.
10. There is evidence from several good quality, prospective controlled studies demonstrating effectiveness for homeopathic treatments in several conditions (eg. diarrhoea in children, sinusitis, allergic rhinitis, upper respiratory tract infections). See below for more specific examples.

¹ NHMRC Information Paper; NHMRC 2015 media release.

² Mathie, R. T. *et al.* (2014) Randomised placebo-controlled trials of individualised homeopathic treatment: systematic review and meta-analysis, *Syst Rev*, **3**:142

³ Australian Register of Homeopaths submission to NHMRC, 2013.

⁴ Faculty of Homeopathy (UK), <http://facultyofhomeopathy.org/research/>

⁵ El Dib RP, Atallah AN, Andriolo RB. Mapping the Cochrane evidence for decision making in health care. *J Eval Clin Pract*, 2007; **13**(4):689-92

The NHMRC's Review of 176 randomised controlled trials:

11. In 2012, NHMRC had commissioned and terminated a first review of the evidence on homeopathy, without disclosing this to the public. FOI documents reveal the first review was of high methodological quality⁶.

12. Of the 176 RCTs included in scope of the NHMRC Review comparing homeopathic interventions to placebo or another treatment of known efficacy, **50% report statistically positive outcomes with only 5% being negative**. How did NHMRC then conclude there was “no reliable evidence”?

NHMRC developed and applied a unique “reliable evidence” framework for the assessment of these 176 studies, consisting of criteria that were created and retrospectively applied to the data *after* the contractor (Optum) had already completed the evidence assessment in March 2013⁷.

NHMRC created the ‘rule’ that for a trial to be “reliable” it had to⁸:

- *Have more than 150 participants* - irrespective of the trial’s statistical significance or quality; AND/OR
- *Be given an unusually high 100% ‘quality rating’* (5/5 on the Jadad or equivalent scale)

This directly resulted in **the results of 171 out of the 176 studies being dismissed from any consideration in the Review’s findings, reducing the number of eligible trials to only 5 “reliable” trials**. By dismissing the results of 97% of the trials from contributing to the Review’s findings, NHMRC was therefore able to conclude there was “no reliable evidence”.

These “reliable evidence” thresholds are unique and not justified against any recognised scientific standards. Neither NHMRC nor any other research group in the world has ever applied them, before or since. The Therapeutic Goods Administration (TGA) does not recognise or apply them. They were also developed and applied to the data post-hoc between April-July 2013, after the contractor had already completed the assessment in March 2012. This process and the changes to the methodology were not disclosed.

13. NHMRC withheld independent expert advice from the Australasian Cochrane Centre (released under Freedom of Information) that its findings did not accurately reflect the evidence, noting that a substantial proportion of the studies reported positive outcomes for homeopathy⁹:

“If the intent is to provide general statements about the effectiveness of homeopathy, then ‘no reliable evidence’ may not adequately reflect the research. For example, when a substantial proportion of small (but good quality) studies show significant differences, [...] ‘no reliable evidence’ does not seem an accurate reflection of the body of evidence.”

14. NHMRC state in their Executive Summary that, “...no good-quality, well-designed studies with enough participants for a meaningful result reported either that homeopathy caused greater health improvements than placebo, or caused health improvements equal to those of another treatment” (Information Paper, p.6).

This is not true. The following studies met NHMRC’s definition of good quality, are well-designed with enough participants for a meaningful result (the results are statistically significant).

The following good quality studies reported that ‘homeopathy caused greater health improvements than placebo’:

- Two trials showed individualised homeopathic treatment to be better than placebo for treating **diarrhoea in children** (N=92¹⁰ and N=126¹¹)

⁶ NHMRC FOI 2016/17 016-13

⁷ As confirmed by Freedom of Information documents (see <http://www.nhmrc.homeopathy.com/incaccuratereporting.html>).

⁸ NHMRC Information Paper, pp.34-35.

⁹ 2013-07-09 - Australasian Cochrane Centre Methodological Review - FOI 2015-16 008-13-Doc 13

- Homeopathic over-the-counter remedy Sinfrontal was found to be better than placebo for **sinusitis** (N=113) (p<0.0001)¹²
- Homeopathic combination remedy Pollen C30 was found to be better than placebo for treating **hay fever** (allergic rhinitis) (N=144) (p=0.02)¹³
- Individualised immunotherapy (using homeopathic medicines made from the substance a patient is allergic to e.g. house dust mite or cat hair) worked better than placebo for **hay fever** (allergic rhinitis) (N=51)(p=0.0001)¹⁴
- Homeopathic cough syrup was found to be better than placebo for **cough** caused by upper respiratory tract infection (URTIs) (N=80)¹⁵

The following good quality studies reported that a homeopathic treatment caused '*health improvements equal to those of another treatment*':

- Homeopathic over-the-counter remedy Luffa compositum S nasal spray for **hay fever** (allergic rhinitis) (N=146)¹⁶
- Homeopathic gel Sprioflor SRL was found to be equally effective as the standard treatment Cremor Capsici Composites for **lower back pain** (N=161).¹⁷

It is important to note that the positive findings of these trials are un-refuted by any other trials testing the same treatments for these conditions.

Laboratory research:

15. Around 75% of *in vitro* experiments on ultra-high dilutions (where there is no 'placebo effect') show the substance having an effect, and nearly 75% of replications have been positive¹⁸.

- *This evidence was excluded from scope of the NHMRC Homeopathy Review.*

¹⁰ Jacobs, J., Jiménez, L. M., Gloyd, S. S., Gale, J. L. & Crothers, D. (1994) Treatment of acute childhood diarrhea with homeopathic medicine: a randomized clinical trial in Nicaragua, *Pediatrics*, **93**:719-725

¹¹ Jacobs, J., Malthouse, S. & et al. (1997) Childhood diarrhea: Results from Nepal and combined analysis, *Proceedings of the 52nd Congress of LMHL, Seattle, WA*

¹² Zabolotnyi, D. I. et al. (2007) Efficacy of a complex homeopathic medication (Sinfrontal) in patients with acute maxillary sinusitis: a prospective, randomized, double-blind, placebo-controlled, multicenter clinical trial, *Explore (New York, N.Y.)*, **3**:98-109

¹³ Reilly, D. T., Taylor, M. A., McSharry, C. & Aitchison, T. (1986) Is homoeopathy a placebo response? Controlled trial of homoeopathic potency, with pollen in hayfever as model, *Lancet (London, England)*, **2**:881-886

¹⁴ Taylor, M. A., Reilly, D., Llewellyn-Jones, R. H., McSharry, C. & Aitchison, T. C. (2000) Randomised controlled trial of homoeopathy versus placebo in perennial allergic rhinitis with overview of four trial series, *BMJ (Clinical research ed.)*, **321**:471-476

¹⁵ Zanasi, A. et al. (2014) Homeopathic medicine for acute cough in upper respiratory tract infections and acute bronchitis: a randomized, double-blind, placebo-controlled trial, *Pulmonary Pharmacology & Therapeutics*, **27**:102-108

¹⁶ Weiser, M., Gegenheimer, L. H. & Klein, P. (1999) A randomized equivalence trial comparing the efficacy and safety of Luffa comp.-Heel nasal spray with cromolyn sodium spray in the treatment of seasonal allergic rhinitis, *Forschende Komplementärmedizin*, **6**:142-148

¹⁷ Stam, C., Bonnet, M. S. & van Haselen, R. A. (2001) The efficacy and safety of a homeopathic gel in the treatment of acute low back pain: a multi-centre, randomised, double-blind comparative clinical trial, *The British Homoeopathic Journal*, **90**:21-28

¹⁸ Witt CM, Bluth M, Albrecht H, Weissshuhn TE, Baumgartner S, Willich SN. The in vitro evidence for an effect of high homeopathic potencies—a systematic review of the literature. *Complement Ther Med.*, 2007; 15(2): 128-38

Reproducibility of the results is increasing as scientists gain more experience and gradually understand what factors are influencing the results¹⁹.

16. Many laboratory studies have shown ultra-high dilution homeopathic medicines having biological effects, for example basophil (white blood cell) degranulation experiments:
- 28 scientific papers have been published on this topic, 23 of which report positive results.
 - 11 publications were judged to be of high quality, of which 8 report positive results²⁰.

Observational ('effectiveness') studies:

17. Observational studies examining the 'effectiveness' of homeopathic interventions in real-world clinical settings consistently report positive outcomes for patients²¹.

- *This evidence was excluded from scope of the NHMRC Homeopathy Review.*

Examples include:

18. A 500-patient survey at the Royal London Homeopathic Hospital showed that many patients were able to reduce or stop conventional medication following homeopathic treatment.²²
19. A study in Germany looking at 493 patients treated by GPs for chronic conditions showed that homeopathy produced better clinical outcomes than conventional medicine, for similar costs.²³
20. A multi-centre, 8-year longitudinal cohort study that followed over 3,500 adults and children receiving routine homeopathic care from GPs, found that "*patients who seek homeopathic treatment are likely to improve considerably*" - experiencing steady, long-term health benefits²⁴.
21. Four published observational studies carried out from 1999 to the present day have tracked the outcome of patients being treated at UK National Health Service (NHS) homeopathic hospitals.

These studies consistently show that patients improve clinically following homeopathic treatment (often from chronic, difficult to treat conditions); some also highlight areas of potential economic benefit in terms of reduced prescribing of conventional drugs.

- The largest study at Bristol Homeopathic Hospital followed over 6,500 consecutive patients with over 23,000 attendances in a six-year period²⁵. 70% of follow-up patients reported improved health; 50% reported major improvement.

The most common diagnostic groups were Dermatology, Neurology, Rheumatology, Gastroenterology, Psychiatry and Ear, Nose & Throat. The largest improvements were reported in childhood eczema or asthma, and in inflammatory bowel disease, irritable bowel syndrome, menopausal problems and migraine.

¹⁹ Endler P, Thieves K, Reich C, Matthiessen P, Bonamin L, Scherr C, Baumgartner S. Repetitions of fundamental research models for homeopathically prepared dilutions beyond 10(-23): a bibliometric study. *Homeopathy*, 2010; **99**(1):25-36

²⁰ Witt CM, Bluth M, Albrecht H, Weissshuhn TE, Baumgartner S, Willich SN. The in vitro evidence for an effect of high homeopathic potencies—a systematic review of the literature. *Complement Ther Med.*, 2007; 15(2):128-38

²¹ <https://www.hri-research.org/resources/homeopathy-the-debate/essentialevidence/observational-studies/>

²² Sharples F, van Haselen R, Fisher P. NHS patients' perspective on complementary medicine. *Complement Ther Med*, 2003; 11: 243-248

²³ Witt C, Keil T, Selim D, et al. Outcome and costs of homeopathic and conventional treatment strategies: a comparative cohort study in patients with chronic disorders. *Complement Ther Med*, 2005;13: 79-86

²⁴ Witt, C. M., Lütke, R., Mengler, N. & Willich, S. N. How healthy are chronically ill patients after eight years of homeopathic treatment?—Results from a long term observational study. *BMC Public Health* 8, 413 (2008).

²⁵ Spence D, Thompson E A, Barron S J. Homeopathic treatment for chronic disease: a 6-year university-hospital outpatient observational study. *J Altern Complement Med*, 2005; 5: 793-798

22. A recent randomised controlled trial carried out in a public research hospital in Mexico City assessed two treatments for moderate to severe depression in 133 menopausal women²⁶. This study, published in 2015, found that both individualised homeopathic treatment and Fluoxetine (a.k.a. Prozac) were safe and more efficacious than placebo. However, homeopathy resulted in greater clinical improvement in symptoms of depression than fluoxetine, and also improved the patients' menopausal symptoms, whereas fluoxetine did not.
23. For further examples, go to: <https://www.hri-research.org/resources/homeopathy-the-debate/essentialevidence/observational-studies/>

Animal & plant studies:

24. **Placebo-controlled clinical trials in animals and plants show that homeopathy is not just due to 'placebo'.**
- *This evidence was excluded from scope of the NHMRC Homeopathy Review.*
25. For example, a rigorous research study found that a homeopathic medicine can prevent *E. coli* diarrhoea in piglets²⁷ – a major problem in commercial farming.
26. High quality experiments have demonstrated homeopathic ultra high dilutions having biological effects (see 'laboratory research' above).
27. In amphibians, the hormone thyroxine stimulates metamorphosis. Over almost 20 years, various teams have tested homeopathic dilutions of thyroxine on frogs by adding it to the bathing water tadpoles are kept in.
- An independent meta-analysis of these trials identified 22 experiments – 15 carried out by the original team in Austria and 5 by independent researchers²⁸. All 22 experiments found the same trend – that thyroxine 30X (diluted beyond Avogadro's limit using the homeopathic manufacturing process) inhibits metamorphosis, though the exact results varied.
 - This effect has now been observed by 7 researchers from Austria, Germany, Switzerland and the Netherlands.
28. There is also good quality evidence in plant models demonstrating the specific biological effects of highly diluted homeopathic preparations. For further details, go to: www.hri-research.org/wp-content/uploads/2014/08/HRI_ResearchArticle_16_Baumgartner_PlantModels.pdf

Swiss Health Technology Assessment report:

29. A comprehensive Swiss Health Technology Assessment (HTA) report ('Homeopathy in Healthcare') officially concluded that evidence from laboratory studies and clinical research shows that homeopathy is clinically effective, cost effective and safe, concluding:

"There is sufficient evidence for the preclinical effectiveness and the clinical efficacy of homeopathy and for its safety and economy compared with conventional treatment."

The Swiss HTA report authors state that it:

²⁶ Macías-Cortés, E. d. C., Aguilar-Faisal, L. & Asbun-Bojalil, J. (2013) Efficacy of individualized homeopathic treatment and fluoxetine for moderate to severe depression in peri- and postmenopausal women (HOMDEP-MENOP): study protocol for a randomized, double-dummy, double-blind, placebo-controlled trial, *Trials*, **14**:105

²⁷ Camerlink I, Ellinger L, Bakker EJ, Lantinga EA. Homeopathy as replacement to antibiotics in the case of *Escherichia coli* diarrhoea in neonatal piglets. *Homeopathy*, 2010;99: 57–62

²⁸ Harrer B. Replication of an experiment on extremely diluted thyroxine and highland amphibians. *Homeopathy*, 2013;102(1):25-303

“Confirms homoeopathy as a valuable addition to the conventional medical landscape – a status it has been holding for a long time in practical health care.”

The Swiss HTA report found that 20 out of 22 systematic reviews of clinical trials into homeopathy showed a positive direction of evidence in favour of homeopathy.

30. The findings of the Swiss HTA report were entirely ignored by the NHMRC review of the evidence on homeopathy, with the report not being assessed or its findings not reported as part of the Review.

Switzerland is one of Australia’s closest medicines regulatory partner, part of the Australia-Canada-Singapore-Switzerland (ACSS) Consortium administered by the TGA²⁹. The goal of the ACSS Consortium is to:

“maximise international cooperation, reduce duplication, and increase each agency's capacity to ensure consumers have timely access to high quality, safe and effective therapeutic products.”

From 1 August 2017, Switzerland is fully integrating homeopathy and four other complementary medicine (CM) therapies into its national healthcare system. The Swiss Federal Government has acknowledged that these CM therapies meet the regulations of the Swiss Federal Health Insurance Act (HIA, 1996) when it comes to effectiveness. By law, only those services that are effective, appropriate and cost-effective can be covered (article 32 of the requirements of the Federal Act on Health Insurance)³⁰.

2017 German report:

31. A recent report by Bundesverband der Pharmazeutische Industrie e.v (BPI) from Germany³¹, has declared that: *“Homeopathy is a recognized and effective therapy for patients,”* and expressed its support for homeopathy. According to the report, homeopathy is a *“recognized and accepted therapy for the German patients and the first choice for many of them.”*

It further states that this affirmation derives from the results of a poll commissioned by BPI, conducted by the Institute for Social Investigation and Statistical Analysis (FORSA), one of the leaders in the field of research and sociological matters in Germany. According to the results of the study, approximately half of the respondents had taken homeopathy, of which 70% were satisfied or very satisfied with its efficacy and tolerability.

Good sites for further reading:

- Homeopathy Research Institute (HRI) - <https://www.hri-research.org>
- Australian Homoeopathic Association (AHA) - <http://www.homeopathyoz.org>
- British Homeopathic Association (BHA) - <http://www.britishhomeopathic.org>
- NHMRC Homeopathy Review information website: www.nhmrc.homeopathy.com
- NHMRC Homeopathy Review HRI site: <https://www.hri-research.org/resources/homeopathy-the-debate/the-australian-report-on-homeopathy/>
- NHMRC Homeopathy Review HRI FAQ webpage: <https://www.hri-research.org/resources/homeopathy-the-debate/the-australian-report-on-homeopathy/australian-report-faqs/>

²⁹ <https://www.tga.gov.au/australia-canada-singapore-switzerland-acss-consortium>

³⁰ <https://www.yourhealthyourchoice.com.au/news-features/complementary-medicine-in-switzerland-now-a-mandatory-health-insurance-service/>

³¹ ‘Patients Trust Homeopathic Medicines’, <http://www.bpi.de/home/nachrichten/nachrichten/patienten-vertrauen-homoeopathischen-arzneimitteln/>