



Australian Government

National Health and Medical Research Council

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ADMINISTRATIVE REPORT

NHMRC advice on the effectiveness of
homeopathy for treating health conditions

March 2015

Publication Details

Publication title:	Administrative Report: NHMRC Advice on the effectiveness of homeopathy for treating health conditions
Published:	March 2015
Publisher:	National Health and Medical Research Council
NHMRC Publication reference:	CAM02B
Online version:	www.nhmrc.gov.au/guidelines-publications/cam02
ISBN Online:	978-1-925129-30-4
Suggested citation:	National Health and Medical Research Council. 2015 <i>Administrative Report: NHMRC Advice on the effectiveness of homeopathy for treating health conditions</i> . Canberra: National Health and Medical Research Council; 2015

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Administrative Report: NHMRC Advice on the effectiveness of homeopathy for treating health conditions

This administrative report refers to the development of the following documents:

- *Information Paper: Evidence on the effectiveness of homeopathy for treating health conditions*;
- *NHMRC Statement on Homeopathy*; and
- Background documents relating to the assessment of the evidence on the effectiveness of homeopathy for treating health conditions.

Background

Within our health system there are a number of products and practices that are based on little or no evidence of benefit beyond that of the placebo effect. There is a risk that patients may be misled into rejecting practices and treatments that are proven to be effective for those that have no evidence to substantiate the health claims they promote.

The NHMRC Strategic Plan 2010–2012 identified ‘examining alternative therapy claims’ as a major health issue for consideration by the organisation. This was broadened in the NHMRC Strategic Plan 2013-15 to *Claiming benefits for human health not based on evidence*. NHMRC aims to provide practitioners and patients with evidence based health advice on the effectiveness of a number of Complementary and Alternative Medicines (CAM). Homeopathy was the first CAM selected as it is commonly used, both in Australia and around the world and its underlying premise is not consistent with our current understanding of the biological, physiological and pharmacological sciences.

In late 2012, NHMRC commissioned an independent assessment of the evidence of effectiveness for homeopathy to treat clinical conditions. The *Information Paper: Evidence on the effectiveness of homeopathy for treating health conditions* provides a summary of this evidence. The *NHMRC Statement on Homeopathy* was prepared on the advice of Council, based on the evidence provided in the Information Paper. Both documents are defined as ‘advise the community’ as per section 7(1)(a) of the NHMRC Act 1992. They have been developed for the Australian community, health professionals and policy makers to guide healthcare choices, guide clinical practice or influence policy.

The documents were finalised in early 2015 following consideration by the Council of NHMRC.

Contributors

Homeopathy Working Committee

The Homeopathy Working Committee (HWC) was established in April 2012 and includes researchers and experts in clinical trials, evidence-based medicine, complementary and alternative medicine and a consumer representative. The role and functions of the HWC was guided by its Terms of Reference.

Terms of Reference

The Homeopathy Working Committee will guide the development of a review of the literature addressing the effectiveness of homeopathy (the Homeopathy Review) by providing advice to the Office of the NHMRC on:

- methods to identify relevant published guidelines, systematic reviews, government reports and evidence submitted by relevant bodies; and
- methods to evaluate relevant published guidelines, systematic reviews, government reports and evidence submitted by relevant bodies.

The Homeopathy Working Committee will consider the outcomes of the Homeopathy Review and use these findings to inform the development of:

- an Information Paper on homeopathy; and
- a Position Statement on homeopathy, for consideration by NHMRC Council.

The Homeopathy Working Committee will advise on the Homeopathy Review, Information Paper and Position Statement for NHMRC's Health Care Committee, before recommendation to Council.

The Homeopathy Working Committee is effective from 2 April 2012 and appointments were originally scheduled to conclude on 30 June 2013. Appointments have been extended to 2 April 2015. The Homeopathy Working Committee will report to NHMRC's Health Care Committee.

Membership

The HWC comprised experts in includes researchers and experts in evidence-based medicine and complementary medicine.

Member	Area of expertise
Chair Professor Paul Glasziou MBBS, PhD, FRACGP	General practitioner; Professor and Director of the Centre for Research into Evidence-Based Practice, Bond University, Queensland; Expert in evidence-based medicine.
Professor Peter Brooks AM, MBBS, MD (Lund), FRACP, FAFRM, FAFPHM, MDHonCausa, FRCP (Glas, Edin)	Rheumatologist; Director of the Australian Health Workforce Institute, University of Melbourne, Victoria (to September 2013); Executive Director Research, Northern Hospital, Epping, Victoria; Former board member, Australian Centre for Complementary Medicine Education and Research, University of Queensland.
Professor Frederick Mendelsohn, AO, MB BS, PhD, MD, FRACP	Neuroscientist; Former Chair in Medicine and Director of the Howard Florey Institute, University of Melbourne, Victoria.
Dr Nikolajs Zeps, BSc(Hons), PhD:	Research scientist; Director, St John of God Subiaco Hospital Research network; Adjunct Professor School of Health Sciences, Curtin University; Adjunct Professor, Centre for Comparative Genomics, Murdoch University; Adjunct Associate Professor, School of Surgery and School of Pathology and Laboratory Medicine, University of Western Australia; Adjunct Associate Professor, Faculty of Medicine, University of Notre Dame, Western Australia; Founding Director, Australian Clinical Trials Alliance; Member, Research Committee, NHMRC; Member, Australian Health Ethics Committee, NHMRC Triennium 2010–2012.

Member	Area of expertise
Associate Professor Evelin Tiralongo, BPharm(Hons), PhD, GradCertHigherEd	Pharmacist; Discipline head for complementary medicine teaching and research, School of Pharmacy and Griffith Health Institute, Griffith University, Gold Coast, Queensland; Member, Clinical Trials Coordinating Centre, Griffith University; Member, Society for Medicinal Plant and Natural Product Research.
Mr John Stubbs, BA, DipAcct	Consumer; Executive Officer, canSpeak; Honorary Associate, School of Medicine, University of Sydney, New South Wales; Member, Australian Health Ethics Committee, NHMRC; Member, Consumer Consultative Group, NHMRC.
Professor Chris Baggoley, AO, BVSc(Hons), MBBS, BSocAdmin, FACEM, FIFEM (Member May 2012–March 2013. Observer March–June 2013)	Australian Government Chief Medical Officer.

Declaration of conflict of interest process

Members of the HWC were required to declare their interests in writing prior to appointment, in accordance with NHMRC's Declaration of Interest policy.

Members were reminded of their obligation to consider any interest that may have arisen since the last meeting or with any particular agenda items at every meeting of the HWC. A record of interests was managed by the Office of NHMRC and updates were made to the NHMRC website as required which is available at www.nhmrc.gov.au/health-topics/complementary-medicines/membership-homeopathy-working-committee.

Declared Interest	Actions/Management strategy
Professor Peter Brooks—member of Friends of Science in Medicine (from January to April 2012).	Stepped down as Chair of HWC. Previously involved in establishing the Australian Centre for Complementary Medicine Education and Research at the University of Queensland, in association with Southern Cross University. No formal management plan implemented.

Decision making process

A consensus based approach was used for developing the key evidence statements of the Information Paper. All discussions were robust and open with decision-making being majority-based.

One member of the HWC recorded a dissenting view regarding the absence of a homeopath on the committee. This was not supported by either NHMRC or the remaining committee membership, for the following reasons:

- The composition of committees for clinical guidelines is different from the composition of committees for Health Technology Assessments (HTA). Clinical guideline working committees typically include representatives from the target clinical disciplines that will use the final guideline. In contrast, HTA committees typically include experts in research methods and technical fields, who need not be experts in the particular branch of medicine in which the technology will be used.
- This approach is consistent with other HTA committees such as the Medical Services Advisory Committee, the Pharmaceutical Benefits Advisory Committee (PBAC) and the Therapeutic Goods

Administration Statutory Advisory Committees. (NB: Whilst several PBAC members are clinicians, they are not selected to match the discipline in which a medicine will be used, rather they are selected for their expertise in assessing risk/benefit etc).

- The purpose of NHMRCs assessment of homeopathy was to find and interpret evidence for whether or not homeopathic medicines are effective – not to develop a clinical guideline for practising homeopaths.

Meetings

The HWC met once face to face and three times by teleconference in 2012 to discuss the scope of the project and the assessment of the evidence. In 2013, two face to face meetings and seven teleconferences were held to consider: the results of the evidence review; methodological review comments; the criteria for developing the evidence statements; and the draft Information Paper. Following release of the draft document for public consultation from 9 April 2014, the HWC met on 30 July to discuss additional evidence along with public consultation and expert review comments. Two subsequent teleconferences were held to finalise the Information Paper and related documents.

NHMRC Project Team

The project was undertaken by a small team within the Environmental Health and Complementary and Alternative Medicines Section of Research and Operations Group.

Assessment of the Evidence

The NHMRC assessment of the evidence utilised a combination of three main sources of information about the effectiveness of homeopathy:

- an evidence review (the ‘overview of systematic reviews’), comprising a systematic review of published systematic reviews (summarised in the Overview Report)¹;
- evidence provided by homeopathy interest groups and the public at the beginning of the process, before the commissioned overview of evidence (preliminary submitted literature)² and during following public consultation on the draft Information Paper (public consultation submitted literature)³; and
- evidence-based clinical practice guidelines, government reports on homeopathy published in other countries, and other reports.

The assessment of the evidence is presented in three documents: the Overview Report, a systematic review of available systematic reviews (an overview) on the effectiveness of homeopathy in treating a range of clinical conditions in humans; the Review of Submitted Literature, a review of evidence submitted to NHMRC from homeopathy stakeholder groups and members of the public prior to the commencement of the evaluation; and the Review of Literature from public submissions, a review of evidence submitted to NHMRC from homeopathy stakeholder groups and members of the public during public consultation on the draft Information Paper.

Effectiveness of Homeopathy for Clinical Conditions: Evaluation of the Evidence (Overview Report)

In October 2012, NHMRC commissioned OptumInsight (Optum) to conduct a review to summarise the evidence from systematic reviews regarding the effectiveness of homeopathy as a treatment for any clinical condition in humans. The approach, of using published systematic reviews, was recommended as an effective way of identifying the body of evidence for homeopathic treatments.

The scope and parameters of the assessment was guided by NHMRC's HWC.

The methodology used to conduct the review was based on that described in Chapter 22 of the Cochrane Handbook of Systematic Reviews of Interventions. Optum sought to identify systematic reviews of studies that compared homeopathy with no homeopathy, or with other treatments (prospective, controlled studies), and measured effectiveness in patients with any health condition. Literature addressing the use of homeopathy for preventative/prophylactic use and in conjunction with other therapies, where the design of the study confounds the results (i.e. where the specific effect of homeopathy cannot be determined) was considered 'out of scope'.

Literature searches were performed to identify all relevant systematic reviews of controlled clinical trials of homeopathy in humans published in English between January 1997 and 3 January 2013. A total of 57 systematic reviews were identified that met the criteria for inclusion within this Overview Report. The reviews examined the evidence for a total of 68 clinical conditions and included seven clinical conditions for which no relevant primary studies were identified.

From each included systematic review, data was extracted from the individual studies included in the review by a single reviewer and checked by a second reviewer. In addition, the quality of each included systematic review was assessed using the AMSTAR measurement tool by a single reviewer and checked by a second reviewer. The overall conclusion of the systematic review authors was also recorded. The evidence for each clinical condition was summarised and evidence statements were formulated after consultation and agreement with the HWC. Full details are provided at www.nhmrc.gov.au/health-topics/complementary-medicines/homeopathy-review.

Effectiveness of homeopathy for any clinical condition: evaluation of the evidence

Review of submitted literature

Interest groups and the public provided a total of 343 articles on homeopathy prior to the commencement of the overview. The independent contractor, Optum, used similar methods of assessment to that of the overview, whereby only prospectively designed and controlled studies conducted in humans (including randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials and prospective cohort studies) were considered.

A review of titles and abstracts found 234 articles were of the wrong research or publication type and 79 articles had already been included or considered in the overview. On application of the inclusion criteria to the remaining 30 articles a total of nine studies were identified for critical appraisal. Full details are provided at www.nhmrc.gov.au/health-topics/complementary-medicines/homeopathy-review.

Effectiveness of homeopathy for clinical conditions: evaluation of the evidence

Review of evidence from public submissions

NHMRC commissioned a professional research group (Australian Research Centre for Health of Women and Babies [ARCH]) to assess studies submitted during public consultation that had not already been included in the overview.

During public consultation, 153 articles were provided by consumers, consumer groups, health care professionals, homeopathy practitioners and homeopathy organisations. 94 articles were excluded because they did not meet criteria for the NHMRC review (e.g. they did not investigate treatment of health conditions in humans, they had already been considered in an earlier stage of the NHMRC review, or they were not published studies). The remaining 58 studies, which had not been included in the overview report or preliminary submitted literature report, were assessed against pre-determined criteria for consideration. After this assessment, 17 more of these studies were

excluded because they did not meet the inclusion criteria. A total of 40 published studies assessing the effectiveness of homeopathy for the treatment of health conditions were examined in detail.

For each study, the ARCH reviewers assessed the risk of bias systematically using a standardised method (the Cochrane Collaboration's tool for assessing risk of bias) and analysed the study results.

Independent methodological review

The Australasian Cochrane Centre conducted an independent Methodological Review of the Overview Report and its supporting documents to confirm that an appropriate and rigorous approach had been taken.

Optum considered all the reviewer's comments and suggestions in consultation with the HWC, and amended the report accordingly to ensure there was transparency in the processes used for identifying and considering the evidence.

Development of the Information Paper

The *Information Paper: Evidence on the effectiveness of homeopathy for treating health conditions* provides Australians with a summary of evidence from research on the effectiveness of homeopathy in treating health conditions in humans. The Information Paper explains how NHMRC considered the findings of the assessment of the evidence in forming its conclusions. This work was guided by the HWC.

Technical writing of the Information Paper was contracted by the Office of NHMRC to Meducation.

Public consultation

A public consultation process on the draft Information Paper was undertaken from 9 April–2 June 2014. The independent systematic review of the evidence and the review of submitted literature undertaken by Optum were released at the same time as background information.

A media release was issued by NHMRC on 9 April 2014 and information on the public consultation process was provided on the NHMRC website. Invitations were also sent to various key stakeholders.

The public was invited to provide comment on the clarity of the draft Information Paper and the how the evidence was reviewed and interpreted by the HWC. Submission of any additional evidence was also sought. In order for any additional evidence to be considered, the following criteria were required to be met:

- be a prospectively designed and controlled study (including randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials or prospective cohort studies) OR a systematic review of prospectively designed and controlled studies;
- be publicly available in English;
- include participants with a particular clinical condition;
- evaluate the effectiveness of homeopathy for the treatment of that clinical condition or the treatment of the clinical side effects of another intervention;
- include a comparison group (placebo, no homeopathy or other treatment); and
- report on clinically relevant outcomes.

A total of 48 submissions were received from consumers, consumer groups, health care professionals, homeopathy practitioners and homeopathy organisations. The evaluation of the 153 citations

submitted is discussed in *Effectiveness of homeopathy for clinical conditions: evaluation of the evidence. Review of evidence from public submissions*, available at www.nhmrc.gov.au/guidelines-publications/cam02.

In considering the feedback received during public consultation, a number of key themes/common issues were identified across many of the submissions. The HWC developed a series of Frequently Asked Questions (FAQs) to address these. The feedback from public consultation informed the further development of the draft Information Paper. A summary of those considerations and the FAQ document, can be found at www.nhmrc.gov.au/guidelines-publications/cam02.

Submissions from respondents who agreed to have their submission published (in full or redacted where necessary), are available on the NHMRC Public Consultation website at <http://consultations.nhmrc.gov.au>.

Independent Expert Review

Three experts (two Australian and one international) in the fields of complementary medicine research and evidence based medicine provided comment on the draft Information Paper to ensure that the evidence had been appropriately interpreted and synthesised. Expert reviewers were required to declare any interests as per NHMRC standard processes.

The feedback from expert review informed the further development of the draft Information Paper. A summary of those considerations can be found at www.nhmrc.gov.au/guidelines-publications/cam02.

Development of Statement

In response to its Terms of Reference, the HWC guided the assessment of the evidence on the effectiveness of homeopathy and interpreted its findings in developing the Information Paper.

The NHMRC Statement was considered by Council, out of session in December 2014 and again in March 2015 and was finalised in early 2015. The Statement provides advice to the community and to policy makers, utilising evidence from the Information Paper.

Governance

Throughout the project, the HWC provided advice to Council and the Chief Executive Officer (CEO) of NHMRC through the Health Care Committee (HCC). The final Information Paper and key themes for the Statement were considered by HCC, out of session in November 2014 and by Council at its meeting on 27 November 2014. Further consideration of the Statement by Council occurred, out of session, in early December 2014, and in March 2015.

Council has a broad range of experience and expertise in health and medical research as well as consumer issues. Council's final approval and recommendation to the CEO ensures that material issued by NHMRC is evidence-based, robust and meets international standards.

The CEO agreed to issue the Information Paper and Statement under Section 7(1)(a) of the *NHMRC Act* in March 2015.

References

- 1 Optum. Effectiveness of homeopathy for any clinical condition: evaluation of the evidence. Overview report. Canberra: NHMRC; 2013.
- 2 Optum. Effectiveness of homeopathy for any clinical condition: evaluation of the evidence. Review of submitted literature. Canberra: NHMRC; 2013.
- 3 Australian Research Centre for Health of Women and Babies. Effectiveness of homeopathy for clinical conditions: evaluation of the evidence. Review of evidence from public submissions. 2014