Memorandum submitted by The British Homeopathic Association HO 12

1. Background

1.1 Homeopathic medicines are normally prescribed to patients by homeopathic practitioners and on an individualised basis, with importance placed on the unique character and lifestyle of the person concerned. Some randomised controlled trials (RCTs) of homeopathy have reflected this approach. Others have investigated a given, standardised, homeopathic medicine taken by the entire sample of eligible patients, and where the input of a homeopathic practitioner may or may not have been involved.

1.2 This document is a summary and update of the overview submitted jointly by the British Homeopathic Association and the Faculty of Homeopathy in 2008 to the Government Office for Science.[a] It is a factual account of best clinical research evidence in homeopathy published in peer-reviewed scientific journals up to and including October 2009. It focuses primarily on systematic reviews of published RCTs and reconciles those data with results obtained in the original RCT literature. Findings from non-randomised clinical studies are presented in brief. We conclude with a number of recommendations for future research development in homeopathy.

2 Systematic reviews of randomised controlled trials

2.1 Comprehensive systematic reviews (all medical conditions with homeopathy research)

Four out of five comprehensive systematic reviews of RCTs in homeopathy have reached the qualified conclusion that homeopathy differs from placebo.[1, 2, 3, 4] One of those four reviews also stated there was "insufficient evidence […] to draw conclusions about the efficacy of homeopathy for any specific medical condition".[4] The fifth systematic review concluded there was "weak evidence for a specific effect of homoeopathic remedies";[5] the methodology of that review and its conclusions have been challenged.[6] The value of any comprehensive systematic review, moreover, is limited by the small number of RCTs in homeopathy, the differing criteria used by reviewers for data extraction, the disparate modes of homeopathy investigated, the narrow focus typically on placebo controlled trials, and by the heterogeneous range of medical conditions being examined collectively.

2.2 Systematic reviews focusing on particular medical conditions

The issue of heterogeneity of medical condition has been avoided in each of 17 systematic reviews that have focused, to date, on homeopathy RCTs (individualised or standardised treatment) in one of 16 particular clinical conditions. Five reviews concluded there was positive evidence for homeopathy (childhood diarrhoea;[7] post-operative ileus;[8] seasonal allergic rhinitis;[9, 10] vertigo[11]); three concluded there was little or no evidence (attention-deficit hyperactivity disorder;[12] delayed-onset muscle

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[a] Fisher P, Mathie RT. The research evidence base in homeopathy. Government Office for Science, January 2008.

soreness;[13] headache and migraine prevention[14]); nine did not offer a clear conclusion either way (anxiety;[15] chronic asthma;[16] dementia;[17] depression;[18] headache and migraine treatment;[19] HIV/AIDS;[20] induction of labour;[21] influenza;[22] [b] osteoarthritis[23]).

2.3 Systematic reviews focusing on particular groups of diagnoses

There are seven systematic reviews in this category. Four of these reviews were positive (allergies;[24] upper respiratory tract infections;[25, 26] rheumatic diseases[27]); two were negative (ailments of childhood and adolescence;[28] cancer[29]); one was non-conclusive (cancer side-effects[30]). Homeopathic *Arnica montana* (often used in RCTs of post-operative pain or swelling) has itself been the subject of two systematic reviews: one was negative;[31] a more recent one was non-conclusive.[32]

3 Randomised controlled trials of homeopathy: the original peer-reviewed research literature

3.1 Criteria and methods for data extraction

3.1.1 We set clear criteria for including research papers in this overview. Non peer-reviewed research such as book chapters, conference proceedings and theses were excluded from consideration, as were papers in which the medicine tested had concentration greater than the homeopathic dilution 1X. This overview therefore contains references to all full papers of RCTs of homeopathy (any medical condition, treatment or prevention) that have been published in explicitly peer-reviewed journals in any country and in any language from 1950 to October 2009 inclusive. RCTs were categorised by whether: (a) they were controlled by placebo or by other than placebo (usual treatment or no treatment); and (b) the mode of homeopathic treatment was individualised or standardised.

3.1.2 A peer-reviewed trial was eligible for inclusion only if a minimum standard of intrinsic quality was met. A study was defined as an RCT if the paper unequivocally stated there had been prospective random assignment to treatment. In the case of placebo-controlled trials, explicit mention of double blinding was also required; for other-than-placebo controlled (including equivalence) trials, observer blinding was sufficient for inclusion. These and a number of additional criteria of quality were met by a total of 142 RCTs in 129 peer-reviewed journal papers.

3.1.3 Fewer than half the eligible RCTs included a power calculation and the associated pre-defined minimum effect that would be regarded as clinically important. In view of this low proportion of properly powered trials, positive or negative RCT findings are described here in terms only of their statistical significance, not their clinical importance.[c]

3.1.4 A statistically conclusive trial result required that the 95% confidence interval (CI) of the mean difference in the outcome variable did not include 0 (or $P \leq 0.05$); a statistically non-significant trial result meant that the 95% CI included 0 (or $P > 0.05$). A study reporting statistically significant findings was either 'positive' or 'negative', depending on whether the homeopathy group was superior or inferior to control in at least one principal outcome. Relevant corresponding criteria were applied to other-than-placebo controlled trials.

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[b] The review reported that *Oscillococcinum* reduced the length of influenza illness by 0.28 days (95% confidence interval, 0.50 to 0.06). The authors concluded "though promising, the data are not strong enough to make a general recommendation to use *Oscillococcinum* for first-line treatment of influenza".

[c] This and further aspects of intrinsic trial quality in homeopathy are included in a new evaluation of the research literature that the British Homeopathic Association is currently pursuing.

3.1.5 To be regarded as statistically conclusive, we required at least one significant finding out of no more than three statistical analyses of a given study's principal outcomes. Secondary outcomes were disregarded. This approach avoided the possibility of interpreting a trial as statistically conclusive based on merely one statistically significant positive or negative result out of many.

3.2 Randomised controlled trial findings

3.2.1 Summary based on nature of control group: One hundred and twenty out of the total of 142 RCTs (85%) were placebo controlled. The other 22 RCTs (15%) were controlled by other than placebo. Of the 142 trials overall, the summary finding was positive in 44%, negative in 8% and statistically non-conclusive in 48%. Findings in the other-than-placebo controlled RCTs were conclusively positive or negative more frequently than those in placebo controlled RCTs:

Control group	**Summary trial finding: no. of RCTs** (%)			**Total**
	Positive	**Negative**	**Statistically non-conclusive**	
Placebo	**52** (43%)	**3** (3%)	**65** (54%)	**120**
Other than placebo	**11** (50%)	**8** (36%)	**3** (14%)	**22**
TOTAL	**63** (44%)	**11** (8%)	**68** (48%)	**142**

3.2.2 Summary based on mode of homeopathy: Forty out of the total of 142 RCTs (28%) have reflected the normal individualised mode of homeopathic treatment. Each of the other 102 RCTs (72%) has investigated a standardised homeopathic medicine. The percentage distribution of the summary findings does not differ between the two modes of treatment:

Mode of homeopathy	**Summary trial finding: no. of RCTs** (%)			**Total**
	Positive	**Negative**	**Statistically non-conclusive**	
Individualised	**18** (45%)	**3** (8%)	**19** (47%)	**40**
Standardised	**45** (44%)	**8** (8%)	**49** (48%)	**102**
TOTAL	**63** (44%)	**11** (8%)	**68** (48%)	**142**

3.2.3 The above RCTs represent research in a total of 80 different medical conditions. There is replicated research (≥2 peer-reviewed RCTs per medical condition) in each of 28 conditions (90 RCTs in total). There is a singleton RCT for each of the other 52 conditions.

3.2.4 Of the 28 conditions for which there is replicated research in RCTs, there are 13 that have not been the subject of formal systematic review to date. Viewed per condition, the balance of evidence from these RCTs is positive for fibromyalgia[33, 34, 35] and sinusitis,[36, 37, 38, 39] and non-conclusive for insect bites,[40, 41] menopause in breast cancer survivors,[42, 43] post-operative pain or swelling (*Arnica montana* used in the majority of trials),[44, 45, 46, 47, 48, 49, 50] stroke,[51, 52] and warts.[53, 54] There was no identifiable balance of evidence in dermatitis,[55] irritable bowel syndrome,[56, 57] leg ulcers,[58] otitis media[59, 60] or post-operative analgesic intake.[61]

4 Non-randomised research

4.1 Controlled trials

Non-randomised, controlled, parallel-group design has been applied to homeopathy. It has focused on homeopathy for either a particular medical condition (eczema;[62] insomnia;[63] otitis media;[64] vertigo[65]) or a specified range of complaints.[66, 67, 68] Results have been positive; in the absence of group randomisation, however, one cannot infer a clear causal relationship between the intervention and the clinical outcome in this type of trial.[69]

4.2 Non-controlled studies

Non-randomised, non-controlled, studies can make a useful contribution to developmental research in complementary medicine including homeopathy.[70, 71] Findings from studies in this category may be considered as an adjunct to research evidence obtained from RCTs and from non-randomised controlled trials; they do not in themselves constitute research evidence. Findings have been strongly positive, including those for dysmenorrhoea,[72] headache,[73] menopausal flushes[74] and sinusitis.[75] A cross-sectional survey undertaken collectively by the five NHS homeopathic hospitals reported improved patient-reported outcome whose extent and timing varied between the different principal medical complaints (eczema, chronic fatigue syndrome, menopausal symptoms and osteoarthritis).[76] This paper emphasised homeopathy's contribution to the healthcare of patients with multiple, complex, morbidities.

5 Summary of clinical research in homeopathy to date

5.1 Most comprehensive systematic reviews of RCTs in homeopathy (individualised or standardised treatment) have concluded there is evidence that the homeopathic intervention differs from placebo treatment.

5.2 Condition-specific systematic reviews have indicated effectiveness of homeopathy (individualised or standardised treatment) in childhood diarrhoea, post-operative ileus, seasonal allergic rhinitis, and vertigo. They indicate non-effectiveness in attention-deficit hyperactivity disorder, delayed-onset muscle soreness, and in prevention of headache and migraine. Findings are non-conclusive for all other conditions that have been the subject of review.

5.3 Homeopathy research has focused on a total of 80 different medical conditions, in which there is a total of 142 peer-reviewed RCTs that met a number of key quality criteria for this overview. Findings in 44% of those RCTs reported positive findings, 8% were negative and 48% were non-conclusive. The majority of trials have examined standardised homeopathy and used placebo-controlled design. There has been replicated RCT research in each of only 28 medical conditions; of those without formal systematic review to date, there is a balance of positive RCT evidence for fibromyalgia and sinusitis.

6 Recommendations

6.1 New and independently conducted RCTs are essential to confirm or refute the currently available research evidence in homeopathy for specific conditions. There is a need to enhance the quantity and the quality of research on the effectiveness of individualised homeopathy, particularly in chronic conditions, as well as on efficacy of specific homeopathic medicines compared with placebo. Future trials must be statistically powered to ensure conclusions may be made about clinically relevant effects.

6.2 Greater collaboration between homeopathic practitioners, conventional physicians and basic scientists would enhance the scope and quality of homeopathy research. Integration of homeopathic research in existing academic and clinical settings (by practitioners of homeopathy working within the NHS, where regulated and safe clinical practice is assured) raises standards of research in homeopathy, encouraging mutual understanding and promoting agreement on the interpretation of findings. An example of this approach recently has been the effective collaboration between the Universities of Leeds and Sheffield with Barnsley Hospital NHS Foundation Trust in an RCT of individualised homeopathy for fibromyalgia.[35]

6.3 In focusing research on areas in homeopathy where positive findings from RCTs might be corroborated, the most promising targets include those with already replicated findings, such as fibromyalgia, seasonal allergic rhinitis, sinusitis, and vertigo. Attention must also be paid to areas where there is mainly non-conclusive or negative trial evidence to date.

6.4 Moreover, emphasis should be placed on those clinical areas where RCT evidence is currently scanty but where homeopathy is frequently used in NHS practice,[76, 77] particularly in diagnoses that are difficult to treat using conventional medicine and that have promising data from non-randomised studies. In this respect, especially worthwhile research targets include atopic eczema, chronic fatigue, depression, irritable bowel syndrome, menopausal symptoms, otitis media and premenstrual syndrome. Patients with complex medical predicaments are not normally eligible for RCT research but should be included in suitable clinical outcome studies, most notably in the clinical context of the homeopathic hospitals.

6.5 The above recommendations for research development are consistent with comments made about homeopathy in the GO-Science Review of the Department of Health:

> *"A programme for a stronger evidence base would necessitate agreement between practitioners, patients and researchers on what should be evaluated, and on relevant endpoints. Flagship trials should be run in the most promising areas, chosen on plausibility, and patient demand. These should be well planned, including pre-defined agreement on what constitutes a minimally important clinical effect, and adequate resource, so that the results were clear-cut. […] The Health Technology Assessment Programme provided a framework that should be as applicable to research on homeopathy as to any other therapy."*
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> GO-Science Review of the Department of Health, Annex 1 (2008). Government Office for Science: Department for Innovation, Universities and Skills; Paragraph 3.16.

7 Declaration of interest

The author of this overview is Robert T Mathie PhD, Research Development Adviser, British Homeopathic Association; he is not a homeopathic practitioner. The sole aim of this document is to provide a transparent, balanced and constructive summary of the clinical research evidence in homeopathy.

References

[1] Kleijnen J, Knipschild P, ter Riet G (1991). Clinical trials of homoeopathy *British Medical Journal*, **302**: 316–323.

[2] Boissel JP, Cucherat M, Haugh M, Gauthier E (1996). Critical literature review on the effectiveness of homoeopathy: overview of data from homoeopathic medicine trials. In: *Homoeopathic Medicine Research Group, Report of the Commission of the European Communities, Directorate-General XII – Science, Research and Development, Directorate E – RTD Actions: Life Sciences and Technologies* – Medical Research, Brussels, Belgium.

[3] Cucherat M, Haugh MC, Gooch M, Boissel JP (2000). Evidence of clinical efficacy of homeopathy – A meta-analysis of clinical trials. *European Journal of Clinical Pharmacology*, **56**: 27–33.

[4] Linde K, Clausius N, Ramirez G, *et al* (1997). Are the clinical effects of homoeopathy placebo effects? A meta-analysis of placebo-controlled trials. *Lancet*, **350**: 834–843.

[5] Shang A, Huwiler-Muntener K, Nartey L, *et al* (2005). Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy. *Lancet*, **366**: 726–732.

[6] Lüdtke R, Rutten ALB (2008). The conclusions on the effectiveness of homeopathy highly depend on the set of analyzed trials. *Journal of Clinical Epidemiology*, **61**: 1197–1204.

[7] Jacobs J, Jonas WB, Jimenez-Perez M, Crothers D (2003). Homeopathy for childhood diarrhea: combined results and metaanalysis from three randomized, controlled clinical trials. *Pediatric Infectious Disease Journal*, **22**: 229–234.

[8] Barnes J, Resch K-L, Ernst E (1997). Homeopathy for postoperative ileus? A meta-analysis. *Journal of Clinical Gastroenterology*, **25**: 628–633.

[9] Wiesenauer M, Lüdtke R (1996). A meta-analysis of the homeopathic treatment of pollinosis with Galphimia glauca. *Forschende Komplementärmedizin und Klassische Naturheilkunde*, **3**: 230–236.

[10] Taylor MA, Reilly D, Llewellyn-Jones RH, *et al* (2000). Randomised controlled trials of homoeopathy versus placebo in perennial allergic rhinitis with overview of four trial series. *British Medical Journal*, **321**: 471–476.

[11] Schneider B, Klein P, Weiser M (2005). Treatment of vertigo with a homeopathic complex remedy compared with usual treatments: a meta-analysis of clinical trials. *Arzneimittelforschung*, **55**: 23–29.

[12] Coulter MK, Dean ME (2007). Homeopathy for attention deficit/hyperactivity disorder or hyperkinetic disorder *(Cochrane Review)*. In: The Cochrane Library. Chichester, UK: John Wiley & Sons, Ltd. CD005648.

[13] Ernst E, Barnes J (1998). Are homoeopathic remedies effective for delayed-onset muscle soreness? – A systematic review of Placebo-controlled trials. *Perfusion (Nürnberg)*, **11**: 4–8.

[14] Ernst E (1999). Homeopathic prophylaxis of headaches and migraine? A systematic review. *Journal of Pain and Symptom Management*, **18**: 353–357.

[15] Pilkington K, Kirkwood G, Rampes H, *et al* (2006). Homeopathy for anxiety and anxiety disorders: A systematic review of the research. *Homeopathy*, **95**: 151–162.

[16] McCarney RW, Linde K, Lasserson TJ (2004). Homeopathy for chronic asthma *(Cochrane Review).* In: The Cochrane Library. Chichester, UK: John Wiley & Sons, Ltd. CD000353.

[17] McCarney R, Warner J, Fisher P, van Haselen R (2004). Homeopathy for dementia *(Cochrane Review).* In: The Cochrane Library. Chichester, UK: John Wiley & Sons, Ltd. CD003803.

[18] Pilkington K, Kirkwood G, Rampes H, *et al* (2005). Homeopathy for depression: a systematic review of the research evidence. *Homeopathy*, **94**: 153–163.

[19] Owen JM, Green BN (2004). Homeopathic treatment of headaches: A systematic review of the literature. *Journal of Chiropractic Medicine*, **3**: 45–52.

[20] Ullman D (2003). Controlled clinical trials evaluating the homeopathic treatment of people with human immunodeficiency virus or acquired immune deficiency syndrome. *Journal of Alternative and Complementary Medicine*, **9**: 133–141.

[21] Smith CA (2004). Homoeopathy for induction of labour *(Cochrane Review).* In: The Cochrane Library. Chichester, UK: John Wiley & Sons, Ltd. CD003399.

[22] Vickers A, Smith C (2006). Homoeopathic Oscillococcinum for preventing and treating influenza and influenza-like syndromes *(Cochrane review).* In: The Cochrane Library. Chichester, UK: John Wiley & Sons, Ltd. CD001957.

[23] Long L, Ernst E (2001). Homeopathic remedies for the treatment of osteoarthritis: a systematic review. *British Homeopathic Journal*, **90**: 37–43.

[24] Bellavite P, Ortolani R, Pontarollo F, *et al* (2006). Immunology and homeopathy. 4. Clinical studies – Part 2. *Evidence-based Complementary and Alternative Medicine: eCAM*, **3**: 397–409.

[25] Bornhöft G, Wolf U, Ammon K, *et al* (2006). Effectiveness, safety and cost-effectiveness of homeopathy in general practice – summarized health technology assessment. *Forschende Komplementärmedizin*, **13** Suppl 2: 19–29.

[26] Bellavite P, Ortolani R, Pontarollo F, *et al* (2006). Immunology and homeopathy. 4. Clinical studies – Part 1. *Evidence-based Complementary and Alternative Medicine: eCAM*, **3**: 293–301.

[27] Jonas WB, Linde K, Ramirez G (2000). Homeopathy and rheumatic disease. *Rheumatic Disease Clinics of North America*, **26**: 117–123.

[28] Altunç U, Pittler MH, Ernst E (2007). Homeopathy for childhood and adolescence ailments: systematic review of randomized clinical trials. *Mayo Clinic Proceedings*, **82**: 69–75.

[29] Milazzo S, *et al* (2006). Efficacy of homeopathic therapy in cancer treatment. *European Journal of Cancer*, **42**: 282–289.

[30] Kassab S, Cummings M, Berkovitz S, *et al* (2009). Homeopathic medicines for adverse effects of cancer treatments *(Cochrane Review)*. In: The Cochrane Library. Chichester, UK: John Wiley & Sons, Ltd. CD004845, 2009.

[31] Ernst E, Pittler MH (1998). Efficacy of homeopathic arnica. A systematic review of placebo-controlled clinical trials. *Archives of Surgery*, **133**: 1187–1190.

[32] Lüdtke R, Hacke D (2005). On the effectiveness of the homeopathic remedy Arnica montana. *Wiener Medizinische Wochenschrift*, **155**: 482–490.

[33] Fisher P (1986). An experimental double-blind clinical trial method in homoeopathy. Use of a limited range of remedies to treat fibrositis. *British Homeopathic Journal*, **75**: 142-147.

[34] Bell IR, Lewis DA 2nd, Brooks AJ, *et al* (2004). Improved clinical status in fibromyalgia patients treated with individualized homeopathic remedies versus placebo. *Rheumatology*, **43**: 577–582.

[35] Relton C, Smith C, Raw J, *et al* (2009). Healthcare provided by a homeopath as an adjunct to usual care for fibromyalgia (FMS): results of a pilot randomised controlled trial. *Homeopathy*, **98**: 77–82.

[36] Weiser M, Clasen B (1994). [Randomized, placebo-controlled, double-blind study of the clinical efficacy of the homeopathic Euphorbium compositum-S nasal spray in cases of chronic sinusitis]. *Forschende Komplementärmedizin*, **1**: 251–259. *[Reports results of two trials]*

[37] Friese K-H, Zabalotnyi DI (2007). [Homeopathy in acute rhinosinusitis. A double-blind, placebo controlled study shows the efficiency and tolerability of a homeopathic combination remedy]. *HNO*, **55**: 271–277.

[38] Zabolotnyi DI, Kneis KC, Richardson A, *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 (NY)*, **3**: 98–109.

[39] Wiesenauer M, Gaus W, Bohnacker U, Häussler S (1989). [Effectiveness trial of homeopathic drug combinations for the treatment of sinusitis. Results of a randomized double-blind study in primary care]. *Arzneimittelforschung*, **39**: 620-625.

[40] Hill N, Stam C, Tuinder S, van Haselen RA (1995). A placebo controlled clinical trial investigating the efficacy of a homeopathic after-bite gel in reducing mosquito bite induced erythema. *European Journal of Clinical Pharmacology*, **49**: 103–108.

[41] Hill N, Stam C, van Haselen RA (1996). The efficacy of Prrrikweg gel in the treatment of insect bites: a double-blind, placebo-controlled clinical trial. *Pharmacy World and Science*, **18**: 35–41.

[42] Jacobs J, Herman P, Heron K, *et al* (2005). Homeopathy for menopausal symptoms in breast cancer survivors: a preliminary randomized controlled trial. *Journal of Alternative and Complementary Medicine*, **11**: 21–27.

[43] Thompson EA, Montgomery A, Douglas D, Reilly D (2005). A pilot, randomized, double-blinded, placebo-controlled trial of individualized homeopathy for symptoms of estrogen withdrawal in breast-cancer survivors. *Journal of Alternative and Complementary Medicine*, **11**: 13–20.

[44] Robertson A, Suryanarayanan R, Banerjee A (2007). Homeopathic Arnica montana for post-tonsillectomy analgesia: a randomised placebo control trial. *Homeopathy*, **96**: 17–21.

[45] Brinkhaus B, Wilkens JM, Lüdtke R, *et al* (2006). Homeopathic arnica therapy in patients receiving knee surgery: results of three randomised double-blind trials. *Complementary Therapies in Medicine*, **14**: 237–246.

[46] Kaziro GS (1984). Metronidazole (Flagyl) and Arnica montana in the prevention of post-surgical complications, a comparative placebo controlled clinical trial. Britis*h Journal of Oral & Maxillofacial Surgery*, **22**: 42–49.

[47] Lökken P, Straumsheim PA, Tveiten D, *et al* (1995). Effect of homoeopathy on pain and other events after acute trauma; placebo controlled trial with bilateral oral surgery. *British Medical Journal*, **310**: 1439–1442.

[48] Hart O, Mullee MA, Lewith G, Miller J (1997). Double-blind, placebo-controlled, randomized clinical trial of homoeopathic arnica C30 for pain and infection after total abdominal hysterectomy. *Journal of the Royal Society of Medicine*, **90**: 73–78.

[49] Wolf M, Tamaschke C, Mayer W, Heger M (2003). [Efficacy of Arnica in varicose vein surgery: results of a randomized, double-blind, placebo-controlled pilot study]. *Forschende Komplementärmedizin und Klassische Naturheilkunde*, **10**: 242–247.

[50] Stevinson C, Devaraj VS, Fountain-Barber A, *et al* (2003). Homeopathic arnica for prevention of pain and bruising: randomized placebo-controlled trial in hand surgery. *Journal of the Royal Society of Medicine*, **96**: 60–65.

[51] Savage RH, Roe PF (1977). A double blind trial to assess the benefit of Arnica montana in acute stroke illness. *British Homeopathic Journal*, **66**: 207–220.

[52] Savage RH, Roe PF (1978). A further double blind trial to assess the benefit of Arnica montana in acute stroke illness. *British Homeopathic Journal*, **67**: 210–222.

[53] Labrecque M, Audet D, Latulippe LG, Drouin J (1992). Homoeopathic treatment of plantar warts. *Canadian Medical Association Journal*, **146**: 1749–1753.

[54] Kainz JT, Kozel G, Haidvogl M, Smolle J (1996). Homoeopathic versus placebo therapy of children with warts on the hands: a randomized, double-blind clinical trial. *Dermatology*, **193**: 318–320.

[55] Fisher P, McCarney R, Hasford C, Vickers A (2006). Evaluation of specific and non-specific effects in homeopathy: feasibility study for a randomised trial. *Homeopathy*, **95**: 215–222. *[Reports results of two trials]*

[56] Rahlfs VW, Mössinger P (1976). [On the treatment of irritable colon] *Arzneimittelforschung*, **26**: 2230–2234.

[57] Rahlfs VW, Mössinger P (1978). [Asa foetida in the treatment of the irritable colon – a double-blind trial]. *Deutsche medizinische Wochenschrift*, **104**: 140–143.

[58] Garrett B, Harrison PV, Stewart T, Porter I (1997). A trial of homoeopathic treatment of leg ulcers. *Journal of Dermatological Treatment*, **8**: 115–117. *[Reports results of two trials]*

[59] Harrison H, Fixsen A, Vickers A (1999). A randomized comparison of homoeopathic and standard care for the treatment of glue ear in children. *Complementary Therapies in Medicine*, **7**: 132–135.

[60] Jacobs J, Springer DA, Crothers D (2001). Homeopathic treatment of acute otitis media in children: a preliminary randomized placebo-controlled trial. *Pediatric Infectious Disease Journal*, **20**: 177–183.

[61] Paris A, Gonnet N, Chaussard C, *et al* (2008). Effect of homeopathy on analgesic intake following knee ligament reconstruction: a phase III monocentre randomized placebo controlled study. *British Journal of Clinical Pharmacology*, **65**: 180–187. *[Reports results of two trials]*

[62] Keil T, Witt CM, Roll S, *et al* (2008). Homoeopathic versus conventional treatment of children with eczema: A comparative cohort study. *Complementary Therapies in Medicine*, **16**: 15–21.

[63] Waldschütz R, Klein P (2008). The homeopathic preparation Neurexan vs. valerian for the treatment of insomnia: an observational study. *Scientific World Journal*, **8**: 411–420.

[64] Friese K-H, Kruse S, Lüdtke R, Moeller H (1997). The homoeopathic treatment of otitis media in children – comparisons with conventional therapy. *International Journal of Clinical Pharmacology and Therapeutics.* **35**: 296–301.

[65] Klopp R, Niemer W, Weiser M (2005). Microcirculatory effects of a homeopathic preparation in patients with mild vertigo: an intravital microscopic study. *Microvascular Research*, **69**: 10–16.

[66] Haidvogl M, Riley DS, Heger M, *et al* (2007). Homeopathic and conventional treatment for acute respiratory and ear complaints: A comparative study on outcome in the primary care setting. *BMC Complementary and Alternative Medicine*, **7**: 7.

[67] Rabe A, Weiser M, Klein P (2004). Effectiveness and tolerability of a homoeopathic remedy compared with conventional therapy for mild viral infections. *International Journal of Clinical Practice*, **58**: 827–832.

[68] Witt C, Keil T, Selim D, *et al* (2005). Outcome and costs of homeopathic and conventional treatment strategies: a comparative cohort study in patients with chronic disorders. *Complementary Therapies in Medicine*, **13**: 79–86.

[69] Behi R, Nolan M (1996). Quasi-experimental research designs. *British Journal of Nursing*, **5**: 1079–1081.

[70] White A, Ernst E (2001). The case for uncontrolled clinical trials: a starting point for the evidence base for CAM. *Complementary Therapies in Medicine*, **9**: 111–115.

[71] Walach H, Jonas WB, Lewith GT (2002). The role of outcomes research in evaluating complementary and alternative medicine. *Alternative Therapies in Health and Medicine*, **8**: 88–95.

[72] Witt CM, Lüdtke R, Willich SN (2009). Homeopathic treatment of patients with dysmenorrhea: a prospective observational study with 2 years follow-up. *Archives of Gynecology and Obstetrics*, **280**: 603–611.

[73] Muscari-Tomaioli G, Allegri F, Miali E (2001). Observational study of quality of life in patients with headache, receiving homeopathic treatment. *Homeopathy*, **90**: 189–197.

[74] Bordet MF, Colas A, Marijnen P, *et al* (2008). Treating hot flushes in menopausal women with homeopathic treatment – results of an observational study. *Homeopathy*, **97**: 10–15.

[75] Witt CM, Lüdtke R, Willich SN (2009). Homeopathic treatment of patients with chronic sinusitis: a prospective observational study with 8 years follow-up. *BMC Ear, Nose, and Throat Disorders*, **9**: 7.

[76] Thompson EA, Mathie RT, Baitson ES, *et al* (2008). Towards standard setting for patient-reported outcomes in the NHS homeopathic hospitals. *Homeopathy*, **97**: 114–121.

[77] Mathie RT, Robinson TW (2006). Outcomes from homeopathic prescribing in medical practice: a prospective, research-targeted, pilot study. *Homeopathy* **95**: 199–205.

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