

RESEARCH REVIEW

Clinical outcomes research: contributions to the evidence base for homeopathy

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Introduction

There are two principal categories of research design: experimental and observational. In a typical experimental study, the researcher investigates the effect of a pre-defined intervention in comparison with responses in at least one other randomised (control) group of subjects; any inter-group difference in a specified outcome may thus be causally linked with the intervention. In an observational study, on the other hand, the researcher collects information on the measurement/s of interest in a group or groups of subjects, but does not influence events; research of this type is essentially descriptive in nature. Each of these forms of research — with its particular strengths and weaknesses¹ — has importance in the field of homeopathy.

The randomised controlled trial (RCT) is the most highly respected form of experimental research in clinical science. Its methods, especially those involving a placebo control group, have been applied to investigation in homeopathy. The aggregate results of such RCTs published to date have enabled the conclusion overall that homeopathy has an effect that is statistically significantly greater than placebo.² However, there is insufficient volume of research in homeopathy to allow such clear conclusions about whether it has statistically significant — or, more crucially, clinically important — effects in any specific medical condition.

Observational research includes surveys, case-control investigations and clinical outcomes (also called cohort) studies. The design of clinical outcomes studies (like that of RCTs) involves prospective rather than retrospective data collection, and typically characterises the responses of a single group of patients to a therapy over a defined period of time. This form of research has featured prominently in the recent outflow of published investigation in homeopathy. The present

review summarises the key findings and conclusions of these papers, and comments on some implications to be drawn from them.

Principal findings of recent clinical outcomes studies in homeopathy

Five recently published clinical outcomes studies in homeopathy focus on diverse medical conditions: headache,³ acute otitis media,⁴ attention-deficit hyperactivity disorder (ADHD) in children,⁵ respiratory tract and ear complaints, including allergies,⁶ and male infertility.⁷ An account of the individually prescribed homeopathic remedies was offered in all five papers. Outcome measures were patient-centred in three studies^{3,4,6} and investigator-assessed in three.^{5–7} The relative effectiveness or consumption or costs of conventional medication was also reported in three of the articles.^{4–6}

The five studies each conclude in favour of the clinical effectiveness of homeopathy. They illustrate:

- post-treatment improvement in quality of life scores in patients with headache;³
- better clinical improvement from acute otitis media after homeopathy compared with subsequent conventional medicine;⁴
- swifter resolution of hyperactivity in children compared with historical placebo controls;⁵
- homeopathy at least as clinically effective as conventional medication in a primary care setting;⁶
- improved sperm count in men with infertility problems.⁷

Comment

Outcomes research progresses beyond mere unstructured observation and yet still represents clinical findings in the 'real world' setting of homeopathic medical care. The results summarised above are a useful contribution to a growing homeopathic research

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literature, illustrating positive clinical outcome as well as the value of this form of research. It is important to note, however, that such observational studies do not in themselves offer evidence of an effect that can be causally attributed to the homeopathic intervention. Because of the absence of a concurrent (randomised) control group, these kinds of studies can merely point to a possible *association* between treatment and outcome.

An important feature of outcomes research in homeopathy is that it can inform new RCTs aimed to examine clinically relevant hypotheses in a more rigorous manner. In fact, favourable clinical evidence for homeopathy from RCTs is already available for some of the conditions highlighted in this article: otitis media,^{8,9} ADHD,¹⁰ upper respiratory tract infections,^{11,12} and allergic rhinitis.^{13,14}

Work on clinical outcomes studies can thus be seen as a valuable evidence-seeking activity with which homeopathic practitioners can (and should) pursue research. It would be a practical contribution that many could make towards an evidence base, without undertaking the rigorous demands of experimental trials. Such creative activity would contribute importantly to a culture of critical enquiry that would help to inform consideration of the relative value of RCTs, clinical outcomes and other forms of research in homeopathy across a wide diversity of specific medical conditions and less specific clinical problems.

References

- 1 Walach H, Jonas WB, Lewith GT. The role of outcomes research in evaluating complementary and alternative medicine. *Altern Ther Health Med* 2002; **8**: 88–95.
- 2 Linde K, Clausius N, Ramirez G, *et al.* Are the clinical effects of homeopathy placebo effects? A meta-analysis of placebo-controlled trials. *Lancet* 1997; **350**: 834–843.
- 3 Muscari-Tomaioli G, Allegri F, Miali E, *et al.* Observational study of quality of life in patients with headache, receiving homeopathic treatment. *Br Hom J* 2001; **90**: 189–197.
- 4 Frei H, Thurneysen A. Homeopathy in acute otitis media in children: treatment effect or spontaneous resolution? *Br Hom J* 2001; **90**: 180–182.
- 5 Frei H, Thurneysen A. Treatment for hyperactive children: homeopathy and methylphenidate compared in a family setting. *Br Hom J* 2001; **90**: 183–188.
- 6 Riley D, Fischer M, Singh B, *et al.* Homeopathy and conventional medicine: an outcomes study comparing effectiveness in a primary care setting. *J Altern Complement Med* 2001; **7**: 149–159.
- 7 Gerhard I, Wallis E. Individualized homeopathic therapy for male infertility. *Homeopathy* 2002; **91**: 133–144.
- 8 Harrison H, Fixsen A, Vickers A. A randomized comparison of homeopathic and standard care for the treatment of glue ear in children. *Complement Ther Med* 1999; **7**: 132–135.
- 9 Jacobs J, Springer DA, Crothers D. Homeopathic treatment of acute otitis media in children: a preliminary randomized placebo-controlled trial. *Pediatr Infect Dis J* 2001; **20**: 177–183.
- 10 Lamont J. Homeopathic treatment of attention deficit hyperactivity disorder. A controlled study. *Br Hom J* 1997; **86**: 196–200.
- 11 Weiser M, Clasen BPE. Controlled double-blind study of a homeopathic sinusitis medication. *Biol Ther* 1995; **13**: 4–11.
- 12 de Lange de Klerk ES, Blommers J, Kuik DJ, *et al.* Effect of homeopathic medicines on daily burden of symptoms in children with recurrent upper respiratory tract infections. *Br Med J* 1994; **309**: 1329–1332.
- 13 Reilly DT, Taylor MA, McSharry C, Aitchison T. Is homeopathy a placebo response? Controlled trial of homeopathic potency, with pollen in hayfever as model. *Lancet* 1986; **ii**: 881–886.
- 14 Taylor MA, Reilly D, Llewellyn-Jones RH, *et al.* Randomised controlled trial of homeopathy versus placebo in perennial allergic rhinitis with overview of four trial series. *Br Med J* 2000; **321**: 471–476.