

methodology proved especially effective for these children. It was found that remedies often needed repeating to retain effectiveness. This suggested obstacles to cure. CEASE proved effective at removing obstacles after which constitutional remedies needed repeating less often, and their effectiveness was enhanced. Despite the small sample size, this study suggests that homeopathic treatment is an effective intervention for children with ADHD. However limitations such as lack of randomisation, blinding and unequal sample sizes mean results have limited generalisability.

A Pragmatic Randomised Controlled Clinical Trial is being designed to enhance and develop the findings of the above Case Series and provide more powerful and robust evidence. The aim of the trial is to evaluate the comparative clinical and cost effectiveness of adjunctive treatment provided by homeopaths for children with a diagnosis of ADHD, in comparison to standard care alone.

Key elements of the design include the retention of the totality of homeopathic treatment; a control group receiving standard care; equal sample sizes of adequate power; random distribution of groups; groups representative of the ADHD population; homeopathic treatment undertaken by several homeopaths in several locations; evaluation of clinical and cost effectiveness using appropriate outcome measurements reflecting the requirements of stakeholders; and allowance of sufficient trial time to detect results. These studies into homeopathic effectiveness for ADHD are the first pragmatic studies comparing the totality of the homeopathic intervention with usual care. They build on the work of Frei (2005) and Lamont (1997) who demonstrated the effectiveness of Homeopathic remedies for children with ADHD; Jacobs (2005) who demonstrated the effectiveness of remedies and the clinical intervention. A systematic review recommended studies of 'homeopathy as it is practised by homeopaths ie pragmatic trials.

## Cutting edge to clinical effectiveness: the implications of recent theoretical and research findings in homeopathy

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Much recent progress in research in homeopathy has been at polar ends of the spectrum: in theory and basic science and clinical effectiveness studies. I will review the implications for research in homeopathy.

'Weak quantum theory' hypotheses for homeopathy have been proposed by Walach and Milgrom. These hypothesise nonlocal action and 'entanglement' so that treatment effects occur in both treatment and control groups in randomised

controlled trials (RCTs). These hypotheses have been criticised for not suggesting an experimental test. Beauvais has applied a quantum-like statistical model to RCTs of homeopathy. This gives rise to a remarkable prediction: that the difference between placebo and homeopathy groups vanishes in centralized blind trials due to 'smearing' (effects of homeopathy occurring in the placebo group). This could be overcome by in situ randomization/unblinding: the observables are measured and all operations from randomization to unblinding are performed locally in a defined order, without central supervision. Similarly Almirantis notes that if non-local factors are involved, there will be resistance to reproducibility, so effect sizes will be larger if control treatments were randomly selected homeopathic medicines, rather than blank, since this introduces uncertainty. These theories are testable and have important practical implications if verified.

Recent empirical findings in basic science include evidence on the role of nanoparticles of original substances, silica and gas. Bell's NPCAS model hypothesises that homeopathic medicines consist of nanoparticles, low level stressors cross-adapted to allostatic overload (allostasis is the physiological process of restoring homeostasis, allostatic overload occurs when these mechanisms are overwhelmed). Implications for research include that outcomes should be multivariate and measured over time. These predictions are congruent with those made by nonlocal theories.

Nonlocal theories have not been tested, let alone verified. There are alternative explanations for the alleged lack of positive findings in RCTs of homeopathy. These include that there is nothing to explain. The results of meta-analyses are disputed and, as Mathie et al.'s recent bibliometric study showed, the literature has not been adequately searched: 30 eligible RCTs not listed by previous meta-analyses were found. Another possible explanation for false-negative results is the quality of homeopathy. Mathie has led the development of a method to evaluate the model validity of homeopathy in clinical trials.

There is a growing number of veterinary RCTs and animal experiments of relatively simple design with positive results. These include replication of the effects of highly dilute thyroxine on amphibian metamorphosis, nosodes for diarrhoea in piglets and an homeopathic complex in fish farming. These seem not to be in line with nonlocal hypotheses.

EPI-3 is a large scale comparative effectiveness study comparing GPs using homeopathy, mixed practice and conventional medicine in France. Upper respiratory tract infections, sleep disorders, anxiety and depression and musculoskeletal disorders were studied in terms of clinical benefit, medical care and medication consumption, adverse effects and loss of therapeutic opportunity. Patients seeking treatment from homeopathic GPs were similar to those attending conventional physicians. Homeopathy had advantages in at least one domain for each disease category.