



Individualization versus Standardization: Designing Randomized Controlled Trials that Respect Homoeopathic Principles

¹Dr Ritesh Raychura, ²Dr Vivek Rajput, ³Dr Hari Sharanam Pandey, ⁴Dr Ram Naresh Yadav, ⁵Dr Dilip Thakor

¹Professor, Dept of Human Physiology and Biochemistry, Nootan Homoeopathic Medical College and Hospital, Visnagar, India

² Professor, Dept of Human Physiology and Biochemistry, Nootan Homoeopathic Medical College and Hospital, Visnagar, India

³ Professor, Dept of Human Homoeopathic Pharmacy, Nootan Homoeopathic Medical College and Hospital, Visnagar, India

⁴ Professor, Dept of Organon of Medicine, Nootan Homoeopathic Medical College and Hospital, Visnagar, India

⁵Assistant Professor, Dept of Human Anatomy, Nootan Homoeopathic Medical College and Hospital, Visnagar, India

ABSTRACT

Homoeopathy is built on individualized prescribing, while the randomized controlled trial (RCT) is built on standardized interventions. This tension is often blamed for inconsistent or inconclusive trial results. This article argues that the conflict is mostly one of design. It reviews how homoeopathic RCTs have handled individualization, introduces the concept of model validity, and proposes a framework that standardizes the process of prescribing rather than the remedy. It outlines blinding, comparator, outcome, analysis and reporting strategies, and recommends a pragmatic, process-standardized design as the most defensible route to credible evidence.

Keywords: homoeopathy; individualization; randomized controlled trial; model validity; pragmatic trial; research methodology

1. Introduction

Hahnemann's *Organon* holds that the remedy must match the whole patient, not the disease label alone [1]. Two patients with the same diagnosis may receive different medicines, and one patient may need different medicines over time. A conventional parallel-group RCT, by contrast, usually tests one fixed intervention against a comparator. Applying that template unchanged to individualized homoeopathy risks testing something that is not homoeopathy at all.

The evidence base shows the consequences. Meta-analyses of placebo-controlled trials have reached divergent conclusions, and those conclusions depend heavily on which trials are included and how quality is judged [2–4]. Two systematic reviews by Mathie and colleagues found small pooled effects favouring homoeopathy in both individualized and non-individualized trials. They also concluded that the reliable evidence was limited by risk of bias and that firm conclusions were not possible [5,6]. The Australian NHMRC review took a more sceptical position [7]. Whatever one's view, the shared lesson is that better-designed trials are needed.

2. Two kinds of validity

Internal validity asks whether a trial's result is free from bias. Model validity asks whether the trial tests the intervention as it is actually practised. A trial can score well on the first and poorly on the second, for example by giving a single fixed remedy for a diagnosis to every participant. Mathie and colleagues assessed homoeopathic RCTs on both dimensions and found that few were strong on both [8]. Individualization is therefore not an obstacle to be engineered away. It is part of what a valid trial must preserve.

3. Design options and their trade-offs

3.1 Fixed-remedy (standardized) trials.

Every participant receives the same medicine for the same condition. This is simple to blind and analyse, and it suits some acute, well-defined conditions. Its weakness is low model validity for classical homoeopathy, so a negative result says little about individualized care.

3.2 Individualized prescription, then randomization.

The practitioner takes the case and selects the remedy, and only then is the patient randomized to active remedy or identical placebo. This is the most common compromise. Examples include trials in childhood diarrhoea, fibromyalgia and ADHD [9–11]. It preserves the prescribing decision and still permits double blinding.

3.3 Semi-standardized or restricted-list designs.

Practitioners choose from a pre-specified list of remedies for the condition, often with a decision algorithm. This reduces variability but narrows individualization, and the limit should be stated openly.

3.4 Pragmatic comparative-effectiveness designs.

Patients are randomized to a homeopathic care pathway versus usual care or another strategy, with no placebo. These answer a real-world question, whether the whole care package helps, but they cannot separate remedy effects from consultation and context effects. The PRECIS-2 tool helps authors place a design on the explanatory–pragmatic spectrum and justify the choice [12,13].

3.5 Alternative structures.

N-of-1 and crossover trials let each patient act as their own control and suit chronic, stable conditions. The cohort multiple RCT design can help where recruitment is difficult [14].

4. Standardizing the process, not the remedy

The central proposal is to standardize *how* individualization is done so that it becomes reproducible and auditable:

- **Structured case-taking.** Use a common template covering chief complaint, modalities, generals, mentals and past history.
- **Defined prescribing procedure.** Specify the repertory or software, the method of analysis and the potency and repetition rules in advance.
- **Prescription review.** An independent senior panel can review each prescription for adherence to the protocol. This also gives a measure of prescribing consistency.
- **Follow-up and change rules.** Pre-specify when a remedy may be repeated, changed or stopped, and how a second prescription is handled in the blinded phase.
- **Practitioner qualification and training.** Define the minimum experience and calibrate the team before recruitment starts.
- **Record the reasoning.** Log the remedy rationale for every participant, so the analysis can later test whether concordance with protocol predicts outcome.

5. Blinding and comparators

Identical placebo globules or liquids should be prepared and coded by an independent pharmacy. The same practitioner should give every participant the same length and quality of consultation in both arms. Otherwise the non-specific effects of the consultation confound the comparison. A trial of rheumatoid arthritis illustrates why: its authors attributed benefit to the consultation process rather than the remedy [15]. A blinding-integrity check, in which participants and assessors guess their allocation at the end, should be included.

6. Outcomes

Combine a validated condition-specific measure with a patient-centred measure of the kind used in individualized care, such as MYMOP, and a global change rating. Pre-specify one primary outcome and the time point at which it is assessed. Adverse events and aggravations should be recorded with a defined protocol, so that safety data are as rigorous as efficacy data.

7. Sample size, analysis and bias

Individualized trials add variance because treatments differ between patients. Plan the sample size conservatively and pre-specify an intention-to-treat analysis. Mixed models can account for clustering by practitioner, and sensitivity analyses can explore the effect of remedy changes. Register the protocol before recruitment. In India, registration with the Clinical Trials Registry–India (CTRI) is expected, and publishing the protocol following SPIRIT guidance strengthens credibility [16].

8. Reporting

Transparent reporting is how individualized trials earn trust. CONSORT, with its pragmatic-trial extension, provides the core structure [17,18]. The RedHot supplement adds items specific to homeopathic interventions [19]. TIDieR supports a full description of the intervention [20], and HOM-CASE and CARE guide case reports [21,22]. Authors should state plainly how individualization was operationalized, what was standardized and what was left to clinical judgement.

9. Limitations and honest framing

No design will answer every question. A process-standardized trial still tests a defined version of individualization, and its results should be generalized with care. Plausibility debates continue [23,24], and readers will expect authors to engage with them rather than avoid them. Reviewers are more persuaded by candid reporting of null or small effects than by selective emphasis, and the field's credibility depends on that discipline.

10. Conclusion

Individualization and rigour are compatible. Trials that preserve the homeopathic prescribing model, standardize the process, protect blinding, and report transparently can produce evidence that is both clinically meaningful and scientifically defensible. Such trials are the most useful contribution the research community can now make.

References

1. Hahnemann S. *Organon of Medicine*. 6th ed. Translated by Boericke W. New Delhi: B. Jain Publishers.
2. Shang A, Huwiler-Müntener K, Nartey L, et al. Are the clinical effects of homeopathy placebo effects? Comparative study of placebo-controlled trials of homeopathy and allopathy. *Lancet*. 2005;366(9487):726–732.
3. 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(9081):834–843.
4. Lüdtke R, Rutten ALB. The conclusions on the effectiveness of homeopathy highly depend on the set of analyzed trials. *J Clin Epidemiol*. 2008;61(12):1197–1204.
5. Mathie RT, Lloyd SM, Legg LA, et al. Randomised placebo-controlled trials of individualised homeopathic treatment: systematic review and meta-analysis. *Syst Rev*. 2014;3:142.
6. Mathie RT, Ramparsad N, Legg LA, et al. Randomised, double-blind, placebo-controlled trials of non-individualised homeopathic treatment: systematic review and meta-analysis. *Syst Rev*. 2017;6:63.
7. National Health and Medical Research Council. *Evidence on the Effectiveness of Homeopathy for Treating Health Conditions*. Canberra: NHMRC; 2015.
8. Mathie RT, Van Wassenhoven M, Jacobs J, et al. Model validity and risk of bias in randomised placebo-controlled trials of individualised homeopathic treatment. *Complement Ther Med*. 2016;25:120–125.
9. Jacobs J, Jiménez LM, Gloyd SS, Gale JL, Crothers D. Treatment of acute childhood diarrhea with homeopathic medicine: a randomized clinical trial in Nicaragua. *Pediatrics*. 1994;93(5):719–725.
10. Bell IR, Lewis DA, Brooks AJ, et al. Improved clinical status in fibromyalgia patients treated with individualized homeopathic remedies versus placebo. *Rheumatology (Oxford)*. 2004;43(5):577–582.
11. Frei H, Everts R, von Ammon K, et al. Homeopathic treatment of children with attention deficit hyperactivity disorder: a randomised, double blind, placebo controlled crossover trial. *Eur J Pediatr*. 2005;164:758–767.
12. Thorpe KE, Zwarenstein M, Oxman AD, et al. A pragmatic–explanatory continuum indicator summary (PRECIS): a tool to help trial designers. *J Clin Epidemiol*. 2009;62(5):464–475.
13. Loudon K, Treweek S, Sullivan F, et al. The PRECIS-2 tool: designing trials that are fit for purpose. *BMJ*. 2015;350:h2147.
14. Relton C, Torgerson D, O'Cathain A, Nicholl J. Rethinking pragmatic randomised controlled trials: introducing the "cohort multiple randomised controlled trial" design. *BMJ*. 2010;340:c1066.
15. Brien S, Lachance L, Prescott P, McDermott C, Lewith G. Homeopathy has clinical benefits in rheumatoid arthritis patients that are attributable to the consultation process but not the homeopathic remedy: a randomized controlled clinical trial. *Rheumatology (Oxford)*. 2011;50(6):1070–1082.

16. Chan AW, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200–207.
17. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ.* 2010;340:c332.
18. Zwarenstein M, Treweek S, Gagnier JJ, et al. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. *BMJ.* 2008;337:a2390.
19. Dean ME, Coulter MK, Fisher P, Jobst K, Walach H. Reporting data on homeopathic treatments (RedHot): a supplement to CONSORT. *J Altern Complement Med.* 2007;13(1):19–23.
20. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ.* 2014;348:g1687.
21. Gagnier JJ, Kienle G, Altman DG, et al. The CARE guidelines: consensus-based clinical case reporting guideline development. *J Clin Epidemiol.* 2014;67(1):46–51.
22. Van Haselen RA. Homeopathic clinical case reports: development of a supplement (HOM-CASE) to the CARE clinical case reporting guideline. *Complement Ther Med.* 2016;25:78–85.
23. Rutten L, Mathie RT, Fisher P, Goossens M, van Wassenhoven M. Plausibility and evidence: the case of homeopathy. *Med Health Care Philos.* 2013;16(3):525–532.
24. Jonas WB, Kaptchuk TJ, Linde K. A critical overview of homeopathy. *Ann Intern Med.* 2003;138(5):393–399.