Commentary Article

Clinical Research Models in Homeopathy: Theoretical and Epidemiological Reflections

Renata Lemonica[1], Fernanda Maria Simões da Costa Fujino[2], Andrea Lucia Bastos Carneiro[3], Ana Amélia Campos Claro Olandim[2]

Affiliation addresses are listed at the end of the article.

ABSTRACT

Homeopathic practice is founded on individualisation and the totality of symptoms, seeking correspondence between a patient's clinical manifestations and the effects observed in drug provings. This conceptual basis demands research strategies that uphold contemporary standards of clinical science while ensuring model validity, faithfully representing the therapeutic rationale of homeopathy. The choice of an appropriate methodological design is essential to ensure both reliability and consistency with homeopathic principles. Conventional frameworks such as randomised controlled trials must be adapted to preserve model validity, particularly through the use of individualised prescriptions. In other contexts, research may employ standardised remedies (including the *genus epidemicus*), N-of-1 trials, non-randomised interventional studies or observational designs. The suitability of each model depends on clinical characteristics (chronic, acute or epidemic conditions), the purpose of the study (exploratory or confirmatory), epidemiological factors such as symptom homogeneity, morbidity and mortality, as well as statistical considerations. This article thus examines the theoretical, clinical, and epidemiological criteria guiding the selection of research designs in homeopathy. By emphasising model validity as a central criterion, and by analysing the conceptual foundations, practical challenges and limitations of each approach, it aims to promote the methodological and clinical relevance of homeopathy research.

Keywords homeopathy, clinical trial, research design, evidence-based medicine

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Correspondence Renata Lemonica, MD, MSc, PhD, Medical School of São Paulo State University 'Julio de Mesquita Filho'—UNESP, Rua Damião Pinheiro Machado, 658 Centro, Botucatu, SP 18603-560, Brazil, Email: renatalemonica@gmail.com

Introduction

Homeopathy is based on an individualised therapeutic approach that evaluates the totality of a patient's symptoms, encompassing physical, emotional and cognitive dimensions. Its practice relies on the principle of *similia similibus curentur* ('likes should be treated by likes'), whereby substances capable of inducing specific symptoms in healthy individuals are employed to relieve comparable patterns of symptoms in patients. Knowledge of these effects is obtained through systematic provings of medicines, in which healthy volunteers record the symptoms elicited by controlled exposure to homeopathic preparations—potentised substances—that is, substances subjected to successive dilutions (or triturations and dilutions), each followed by succussions (vigorous shaking).[1,2]

Accordingly, homeopathic practice is guided by a set of clinical and methodological principles that underpin the individualised prescription of potentised substances. Remedy selection is based on the most peculiar, intense and characteristic signs and symptoms of the individual (§153 of the *Organon*),[1] hierarchically organised into general, mental, local, modal and concomitant categories.

Repertorisation techniques, together with a detailed understanding of the homeopathic *Materia Medica*, are employed to identify the most appropriate remedy, which acts by stimulating the organism's intrinsic self-regulatory mechanisms. As part of the individualised therapeutic process, dosage, frequency of administration and clinical follow-up are carefully determined. This methodological structure provides the foundation for clinical decision-making in homeopathy and shapes its distinctive approach to patient care.[3]

Homeopathic therapeutic success—encompassing the restoration of overall functional balance and improvement in physical, emotional and adaptive well-being—has long been recognised, with observed benefits in various conditions such as depression, anxiety, sleep disorders, fibromyalgia, respiratory allergies, rheumatoid arthritis, childhood diarrhea and epidemic situations.[4–11] Nevertheless, research in homeopathy faces methodological challenges distinct from those of conventional biomedical interventions, primarily due to the issue of individuality. Whilst the principles of randomisation, blinding and statistical validity are indispensable to biomedical research, their isolated application is insufficient to faithfully represent the therapeutic paradigm of homeopathy. The challenge lies in balancing the standardisation required by conventional clinical models with the inherent individualisation of homeopathic practice, in which each patient

requires a unique prescription. Consequently, the choice of methodological model becomes crucial, as it determines not only the statistical robustness of the results but also their scientific legitimacy and relevance to real-world clinical practice.[3,12,13]

Beyond the classical notions of internal validity—the degree to which a study is methodologically rigorous and free from bias—and external validity—the extent to which its findings can be generalised beyond the study population—homeopathy requires an additional evaluative dimension: model validity. This concept, developed by Mathie and colleagues,[14,15] refers to the extent to which a clinical trial framework is conceptually consistent with the therapeutic system it seeks to assess. A study may be methodologically rigorous by conventional standards, yet if it disregards the central principle of individualisation, it may fail to represent homeopathy in any meaningful sense. From this perspective arises the need to re-examine research approaches not only in terms of bias reduction but also in their fidelity to the therapeutic logic of homeopathy.

Previous publications have discussed methodological aspects of homeopathy trials, but the field continues to face interpretive challenges when studies lack model validity or when heterogeneous approaches are pooled in meta-analyses.[16] Practical issues such as reproducibility, standardisation and patient acceptability have fueled ongoing debate about which methodological models are most consistent with the theoretical structure of homeopathy. Beyond technical solutions, conceptual clarity regarding model validity is essential to ensure that study designs accurately represent the therapeutic paradigm they aim to evaluate—an aspect crucial for advancing the quality and credibility of research.[17,18]

Therefore, this article aims to review the main methodological models employed in clinical research on homeopathy, highlighting their conceptual foundations and practical limitations, and to explore the key clinical, epidemiological and statistical considerations necessary for their appropriate selection and implementation.

Classifications of Clinical Presentations

Homeopathy classifies clinical presentations according to their evolutionary characteristics, duration, periodicity and either collective or individual context.[19] These distinctions are essential for selecting strategies that are methodologically coherent with the condition under study, since the choice of research approach must align with the clinical profile of the illness, taking into account its nature, duration and variability.

Individual chronic diseases are characterised by persistent, progressive or recurrent symptoms reflecting long-standing functional disturbances. These often-complex conditions exhibit significant inter-individual variability, requiring research approaches that can accommodate such diversity, such as studies based on individualised homeopathic medicines (IHMs).

Chronic conditions with acute exacerbations or alternating manifestations show intermittent worsening or remission phases, requiring longitudinal case assessments and research schemes capable of capturing dynamic clinical evolution over time. In these situations, study designs that rely on rigid crossover structures or standardised remedies risk misclassifying natural variations as treatment effects or failures.[14]

Individual acute diseases arise from external or circumstantial causes, such as infections, trauma or climatic influences. They typically present with well-defined onset, course and resolution, allowing for short-term follow-up and objective outcome measures.[1,20]

Homeopathy defines epidemic conditions as acute manifestations of the same disease affecting numerous individuals with similar symptoms. In such cases, a single remedy—the *genus epidemicus*—may be prescribed to the affected population, based on the collective symptomatology, as described in the *Organon of the Healing Art* (§100–§103).[1] The clinical homogeneity typically observed in epidemics supports the use of standardised intervention models. However, when an epidemic presents with considerable individual variability in symptom expression, the use of IHMs becomes necessary, rather than applying a single epidemic remedy. This distinction has been illustrated in recent applications, such as the management of coronavirus disease 2019 (COVID-19) and dengue.[21–24]

Research frameworks that disregard symptomatic heterogeneity compromise both sensitivity and model validity. Conversely, when methodological choices are tailored to the clinical context—chronic, acute or epidemic—homeopathy research achieves not only statistical robustness but also conceptual adequacy through enhanced model validity.[25]

Epidemiological and Methodological Criteria for Model Selection

The selection of the most appropriate methodological framework for clinical trials in homeopathy depends on the integrated analysis of clinical, epidemiological, ethical and operational factors. Key considerations include the severity of the clinical condition (morbidity and mortality), the degree of symptomatic homogeneity or heterogeneity among patients, the study's purpose (exploratory or confirmatory) and the logistical and ethical feasibility of the proposed scheme.[12]

High-severity conditions (e.g., acute epidemics with high morbidity and mortality) justify the use of standardised remedies, such as the *genus epidemicus*.[21,26,27]

Low-mortality conditions, especially chronic and functional diseases with extensive variability (fibromyalgia, asthma, insomnia, depression, rheumatoid arthritis), require individualisation to preserve fidelity to homeopathic principles. Using a single remedy in these contexts risks generating false negatives. Preserving model validity is therefore essential, and for this purpose, randomised controlled trials with IHMs (IHM-RCTs)—although complex—align more strongly with homeopathic principles and enable more accurate efficacy and effectiveness assessment.[11,17]

Symptomatic heterogeneity also has direct statistical implications. Populations with wide clinical variability may require very large sample sizes to detect effects with standardised remedies, whereas IHM-based frameworks, though operationally demanding, achieve stronger theoretical coherence and greater sensitivity to therapeutic effects.[14]

Ethical and logistical factors are equally decisive. Placebo use in severe conditions or among vulnerable groups may be ethically questionable, strengthening the case for observational rather than interventional designs in these contexts.[21,28] Recruitment

can also be limited by patient preference, as many individuals are reluctant to risk allocation to placebo.[29]

Beyond these considerations, reproducibility remains one of the main challenges in homeopathy research. Although well-established methods of repertorisation and consistent criteria for remedy selection are available, homeopathic prescribing is inherently individualised and depends on the clinician's interpretation. Since different conceptual schools co-exist within homeopathy, each practitioner may prioritise a distinct symptom core when formulating the case, thereby introducing potential observational bias. This variability may compromise comparability across centres and make the standardisation of multicentre studies more difficult. Therefore, it is essential that researchers transparently describe the homeopathic approach adopted, including its theoretical basis, the repertorisation process, the number and timing of consultations and the criteria used to evaluate clinical improvement. Reproducibility becomes feasible when these elements are clearly documented and when therapeutic management rigorously and consistently adheres to the homeopathic principles defined in the study protocol.[15,30]

These barriers highlight the need for adaptive strategies and pragmatic solutions that safeguard model validity while respecting practical constraints. Ensuring clarity in outcome definitions, using sensitive measurement tools and adopting person-centred endpoints—such as quality of life, functionality and time to recovery—are essential for enhancing both interpretability and clinical relevance in homeopathy research.[3,30] Only the integration of methodological rigour and fidelity to the homeopathic paradigm—with respect for patient individuality and transparency in the description of the practices adopted—can ensure that scientific findings are simultaneously valid, reproducible and representative of clinical reality.

Model Validity in Homeopathic Clinical Research

As proposed by Mathie and colleagues,[14,31] model validity in clinical research on homeopathy includes the extent to which a trial authentically incorporates the principles of individualisation and symptom totality, thereby determining whether the study truly evaluates homeopathy as it is practiced and ensuring that its scientific conclusions are both methodologically robust and clinically meaningful.

Randomised placebo-controlled trials of IHMs generally achieve higher model validity, since they preserve the defining element of homeopathic practice: the prescription tailored to the patient's totality of symptoms. In contrast, trials using non-individualised homeopathic medicines (NIHMs)—where a standardised remedy is given irrespective of individual variation—may possess internal validity, ensuring methodological rigour, but show low model validity in heterogeneous chronic conditions, thus risking false-negative outcomes. In epidemic or clinically homogeneous contexts, however, NIHM designs may achieve acceptable levels of model validity when aligned with the concept of the *genus epidemicus*.[14,21,31]

Other research frameworks may further enhance model validity by more closely mirroring routine clinical settings and respecting the dynamic process of individualisation. Their strength lies not merely in bias control, but in their ability to capture the clinical complexity, longitudinal variability and therapeutic reasoning that define homeopathic care.[14,32]

Clinical Research Models in Homeopathy

1. Two-arm RCTs

Two-arm RCTs are experimental studies designed to assess the safety and the efficacy or effectiveness of a health intervention. Participants are randomly assigned to one of two treatment groups: the experimental arm (receiving the test intervention) and the control arm (receiving either a placebo or the standard treatment). This design enables comparison of homeopathic interventions with placebo or conventional treatments. Such studies remain the gold standard in clinical research because they minimise bias by ensuring that groups are comparable in both known and unknown characteristics that could influence outcomes. Researchers observe the results of both groups over time to determine whether there are statistically and clinically significant differences.[32,33]

It is important to emphasise that this type of study requires significant adaptations for homeopathy. It may be implemented through the use of IHMs, or standardised medicines administered to all participants regardless of their individual symptomatology. This latter approach is particularly relevant in high-mortality contexts requiring rapid intervention, such as epidemics with clinically homogeneous cases, fitting appropriately into standardised designs of *genus epidemicus* versus placebo. Conversely, when standardised medicines are applied to clinically heterogeneous populations, methodological failure becomes more likely, leading to statistically negative results that reflect inadequacies in study design rather than true therapeutic inefficacy.[32,33]

Although IHM-RCTs provide the most robust framework available for assessing causal efficacy and effectiveness in homeopathy, their implementation requires pragmatic adaptation and methodological innovation to remain both feasible and faithful to homeopathic therapeutic principles.

2. Non-Randomised Interventional Studies

Non-randomised interventional studies may include either a single cohort (uncontrolled) or two cohorts (controlled). These designs retain the experimental nature of intervention assessment but without random allocation. In single-cohort studies, all participants receive the same individualised homeopathic treatment, and their clinical status is compared before and after the intervention. This approach is particularly useful when including a control group is ethically or logistically unfeasible, or when closer observation of therapeutic response is desirable.

Such studies can enhance model validity by reflecting the individualised and longitudinal dynamics of real-world homeopathic care. They allow flexible adjustments during follow-up and facilitate prompt management of any aggravations or adverse events. However, the absence of randomisation—and, in some cases, of a control group—introduces potential biases and limits internal validity, requiring careful interpretation of outcomes.

When explanatory trials—placebo-controlled studies testing efficacy under homogeneous and tightly controlled conditions—

demonstrate significant effects beyond placebo, this does not necessarily imply that the treatment will be equally effective in real-world settings. Missing information, such as direct comparisons between therapeutic strategies, may restrict clinical decision-making.

In such contexts, pragmatic clinical trials—controlled by another active or standard treatment, including participants representative of the general population (often with co-morbidities), and assessing real-world effectiveness and cost-effectiveness—gain particular relevance. Pragmatic designs share several features with non-randomised interventional studies: both prioritise external validity, evaluating interventions in naturalistic settings, whilst explanatory randomised trials mainly emphasise internal validity.[29,34–36]

Together, these frameworks broaden the methodological scope of homeopathy research. Explanatory RCTs determine causal efficacy under ideal conditions, whereas pragmatic and non-randomised interventional studies assess the applicability, safety and effectiveness of homeopathy in everyday clinical practice.

3. Observational Studies

Observational studies play an important role in assessing homeopathic practice under routine treatment conditions. They can be considered a research tool to describe 'real-world' care scenarios, since data are obtained from patients in actual medical practice. Observational studies do not involve researcher intervention; they simply observe and record events or exposures as they naturally occur. These may be prospective or retrospective data collection studies, involving one group of participants or comparing groups that exist naturally (e.g., patients treated with homeopathy vs. those who are not). Such studies can reveal associations but cannot establish causality as experimental studies do. However, they allow for more generalisable and robust estimates of effects in clinical practice.[29,34–36]

The results of observational studies—such as prospective or retrospective data collection designs, cross-sectional analyses and case series—cannot prove homeopathy's efficacy, as other factors may explain the effects: the natural course of disease (e.g., spontaneous resolution in self-limited conditions like childhood diarrhoea or viral infections; fluctuating disorders such as migraines, asthma or autoimmune diseases), placebo effects amplified by patient expectations or the therapeutic encounter, regression to the mean (especially relevant in homeopathy research, since patients often seek care at symptom peaks), and unreported concurrent treatments. However, these studies can inform future research on treatment or medicine efficacy.[5,29,36]

Data collection studies, a type of observational design, follow a group of individuals sharing a specific exposure (e.g., homeopathic treatment) over a defined period, measuring outcomes of interest without experimental intervention. They may be prospective (the most common) or retrospective (using existing records). Large data collection studies can reduce effect size overestimation, allowing for safety assessments.[29]

Despite these limitations, observational studies have recorded meaningful effects, including improvements in sleep quality, stress, anxiety and depression—even without control groups.[5,9,36] When interpreted carefully, such findings may indicate safety, feasibility and potential therapeutic benefits. Their value increases when complemented by broader observational datasets, public health indicators and, where possible, comparative analyses and experimental studies, contributing to a more comprehensive picture of homeopathic interventions.[34,35]

Moreover, incorporating qualitative research methods—such as patient narratives, interviews or thematic analyses—adds depth to these frameworks, capturing subjective experiences, therapeutic relationships and contextual influences often invisible to quantitative endpoints. Integrating qualitative and quantitative findings strengthens model validity.[37]

Thus, observational studies hold an important, though defined, place in homeopathy research. They are especially suitable for exploratory investigations, service evaluations, or emergency contexts where controlled trials are impractical. Their capacity to reflect the clinical reality of homeopathy gives them conceptual value; however, they cannot replace controlled designs when the goal is to establish causal efficacy. When properly structured, they provide essential insights into applicability and patient-centred outcomes, complementing rather than substituting more rigorous trial methods.[29,34,35]

4. N-of-1 Trials

The N-of-1 trial is an individualised clinical design in which a single patient is randomly and blindedly exposed to alternating periods of active treatment and placebo. Incorporating a crossover structure allows the same individual to serve as their own control, offering a highly personalised evaluation of clinical response.

Conceptually, this design aligns with homeopathy's individualised focus and the uniqueness of symptom presentation. Its advantages include reduced inter-subject heterogeneity, feasibility with small samples, and compatibility with personalised medicine trends. It is also ethically attractive in equipoise situations, as patients serve as their own controls.[38]

However, significant challenges arise. In fluctuating conditions—such as chronic asthma, recurrent migraines or autoimmune diseases with unpredictable courses—it becomes difficult to distinguish treatment effects from spontaneous remissions or natural oscillations. These limitations are particularly critical in chronic, low-mortality contexts, where symptom variability can easily confound interpretation.[38,39]

The evolution of a homeopathy case may involve temporary aggravations, delayed responses or intercurrent events (e.g., infections, trauma, emotional stress), all of which complicate crossover assumptions and washout requirements. Furthermore, the inherent therapeutic flexibility of homeopathic prescribing often conflicts with the stability required in N-of-1 designs. These structural constraints reduce model validity, as the framework no longer reflects the dynamic and adaptive nature of real clinical practice.[39]

To mitigate these issues, several adaptations have been proposed: detailed clinical recording, flexible timelines anchored to clinical milestones rather than fixed epochs, pre-defined adaptive rules for potency adjustments, and aggregation of multiple N-of-1 studies combined with mixed-methods analysis. Such strategies may enhance interpretability while preserving some fidelity to the homeopathic model. Nevertheless, even with refinements, N-of-1 trials should be regarded primarily as exploratory tools for

hypothesis generation and methodological development. They offer valuable insights, but they cannot be considered the definitive research model for homeopathy as their limited model validity constrains their ability to fully represent the therapeutic paradigm.[38,39]

Discussion

The selection of a methodological framework for clinical research in homeopathy must balance scientific rigour with fidelity to its therapeutic principles. This balance directly impacts not only the validity of the findings but also the accurate representation of the therapeutic paradigm. The critical criterion for appraising homeopathic research is therefore not merely statistical validity, but model validity—the degree to which a study design remains faithful to the conceptual foundations of homeopathy while retaining methodological robustness.[14,31]

The choice of study design must be guided by the clinical context. In epidemic situations—where affected individuals present highly similar symptom patterns and where rapid intervention is required—the use of a single remedy based on the collective symptom totality (*genus epidemicus*) may be both clinically appropriate and methodologically coherent.[26,27] In such settings, RCTs with standardised remedies can achieve acceptable model validity.

By contrast, chronic and functional diseases—marked by inter-individual variability and typically low mortality risk—demand preservation of therapeutic individualisation. In these contexts, standardised prescriptions (NIHMs) reduce trial sensitivity and risk producing false negatives.[40] For such conditions, IHM-RCTs provide an appropriate methodological scheme. By preserving individualisation while embedding randomisation, blinding and controlled comparison, they uniquely combine high model validity with conventional scientific rigour. As highlighted in systematic reviews, IHM-RCTs tend to demonstrate larger effect sizes than standardised homeopathy trials,[33,41] underscoring the necessity of this model for generating credible evidence.

Despite their strong alignment with the theoretical framework of homeopathy, IHM-RCTs are not without challenges, one of which is reproducibility. Since prescriptions are tailored to individual symptom profiles, results may vary according to the prescriber's therapeutic approach and methodological consistency.[14,16] Moreover, the requirements of randomisation and blinding can conflict with clinical reality, as the length of consultations and the dynamic nature of prescribing complicate protocol standardisation.[12] Patient preference also represents a major barrier: many individuals decline participation in RCTs when facing the possibility of allocation to placebo, limiting recruitment and generalisability.[37] Ethical and logistical constraints—including the time-intensive process of repertorisation, the costs involved and the risk of reduced adherence—further highlight the difficulties in implementing large-scale IHM-RCTs.[15] These limitations do not undermine the central role of IHM-RCTs in assessing causal efficacy and real-world effectiveness; rather, they underline the need for methodological innovation and pragmatic adaptations that safeguard model validity while addressing the realities of clinical research practice.[12,14,15]

At the same time, alternative designs—such as N-of-1 trials, non-randomised interventional studies and observational studies—play important, albeit complementary, roles, as their inherent limitations make them insufficient on their own for definitive assessments of efficacy.[15,38,39]

Taken together, these considerations highlight that no single design is universally applicable. The most appropriate model for assessing causal efficacy in homeopathy remains the IHM-RCT, as it is the only framework capable of reconciling the principles of individualisation with the methodological safeguards of contemporary clinical science.[14,33] Around this core, other approaches—epidemic trials with standardised remedies, N-of-1 experiments, and observational and pragmatic designs—play important supporting roles, addressing specific research questions and contexts where IHM-RCTs are less feasible.

Looking forward, innovation will play an essential role in consolidating this framework. Digital technologies—including tools for real-time symptom recording, repertorisation algorithms and clinical decision support systems—can improve reproducibility and accuracy without compromising individualisation.[11,13] These advances, combined with the systematic use of patient-centred outcomes such as quality of life, functionality and time to recovery, will enhance both the validity and the clinical relevance of future studies.[30]

Advancing clinical research in homeopathy requires the integration of rigorous scientific methodological approaches with fidelity to its therapeutic principles. By prioritising frameworks that safeguard model validity, homeopathy can continue to build a robust and credible empirical foundation, strengthening its position within academic, clinical and institutional domains.

Final Considerations

Clinical research in homeopathy is grounded in the development and refinement of study designs that reflect its therapeutic principles while maintaining conceptual clarity. Individualisation is not a secondary variable, but a central component of the intervention. Research approaches that take this feature into account can generate evidence that is both scientifically sound and consistent with clinical practice. Such alignment goes beyond methodological considerations and supports the ongoing development, credibility, and integration of homeopathy within contemporary health research.

Author Affiliations

1 Acupunture and Homeopathy Service of HCFMB, Medical School of São Paulo State University 'Julio de Mesquita Filho'—UNESP, Botucatu, SP, Brazil

2 Academic Coordination of Postgraduate Program in Homeopathy, Hahnemannian George Galvão Institute, São Paulo, SP, Brazil

3 Academic Coordination of Postgraduate Program in Homeopathy, ILLAH—Institute of Health and Education, Florianópolis, SC, Brazil

Statements and Additional Information

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