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Efficacy of Individualised Homeopathic Medicine in the Management of Allergic Rhinitis: A Randomised, Double-Blind, Placebo-Controlled Trial

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ABSTRACT

Allergic rhinitis, characterised by IgE-mediated mucosal inflammation of the nasal passages, is among the most prevalent atopic conditions in India, affecting an estimated 20–30% of the urban population and imposing substantial quality-of-life and healthcare burden. Despite the widespread use of homeopathic medicine for allergic rhinitis in clinical practice, rigorous placebo-controlled evidence remains limited. This randomised, double-blind, placebo-controlled trial enrolled 122 patients with perennial allergic rhinitis (61 per arm after withdrawal adjustment: homeopathy n = 62, placebo n = 60) from two homoeopathic medical college outpatient departments in Maharashtra and compared the effect of individually prescribed homoeopathic single remedies against an identically prepared placebo on the Total Nasal Symptom Score (TNSS) assessed weekly over 12 weeks. The homeopathy group showed a significantly greater mean reduction in TNSS from baseline to week 12 (−6.14 points) compared with the placebo group (−2.26 points), a between-group difference of 3.88 points (95% CI: 3.12–4.64; p < 0.001). Nasal peak flow rate improved significantly more in the homeopathy group, and patient-reported quality of life on the Rhinoconjunctivitis Quality of Life Questionnaire also showed greater improvement. No serious adverse events were recorded in either arm. These findings provide rigorous placebo-controlled evidence supporting the efficacy of individualised homeopathic treatment in perennial allergic rhinitis.

KEYWORDS: - *Homeopathic therapeutics, Allergic rhinitis, Randomised controlled trial, Total Nasal Symptom Score, Individualised homoeopathy, Placebo-controlled, Atopy, Nasal inflammation*

INTRODUCTION

Allergic rhinitis is a chronic inflammatory condition of the nasal mucosa mediated by IgE-sensitised mast cell degranulation following exposure to inhaled aeroallergens including house dust mites, pollen, animal dander, and mould spores, producing the cardinal symptoms of nasal congestion, rhinorrhoea, sneezing, and nasal itching (1). Globally, allergic rhinitis is estimated to affect 10–40% of the population and is frequently comorbid with asthma, conjunctivitis, and chronic sinusitis, substantially amplifying its individual and societal burden (2). In India, urban epidemiological surveys have reported prevalence rates of 20–30% in adult populations, with the condition representing one of the most common presentations to both conventional and traditional medicine practitioners (3).

Homeopathic medicine is one of the most widely utilised complementary and alternative medical systems in India for the management of allergic rhinitis, with individualised prescription of single homoeopathic remedies based on the totality of the patient's symptomatic, constitutional, and miasmatic picture representing the classical homoeopathic therapeutic approach. A number of remedies from the homoeopathic materia medica — including Allium cepa, Arsenicum album, Natrum muriaticum, Sabadilla, and Wyethia, among others — are classically indicated for nasal catarrhal symptoms with distinguishing modality and concomitant profiles that guide individualised prescription selection (4). Despite the widespread use of homoeopathy for allergic rhinitis in clinical practice, the published placebo-controlled trial evidence remains limited and methodologically heterogeneous, with several trials failing to use fully individualised prescribing or adequately validated patient-reported outcome instruments (5). This trial was designed to address these limitations through a rigorous, fully individualised, double-blind, placebo-controlled design using the Total Nasal Symptom Score as the primary validated outcome.

The primary objective was to compare the effect of individualised homoeopathic single remedies against identically prepared placebo on TNSS over a 12-week treatment period in patients with perennial allergic rhinitis. Secondary objectives included assessment of nasal peak expiratory flow rate and patient-reported quality of life.

LITERATURE REVIEW

The clinical homeopathy literature on allergic conditions has produced a number of randomised trials of varying methodological rigour. Reilly et al. (1994, 2000) conducted a

series of RCTs examining homoeopathically prepared allergen immunotherapy against placebo in allergic rhinitis and asthma, reporting statistically significant symptom reduction in the treatment arms, though the use of isopathic rather than individualised prescribing limits direct comparability with classical homoeopathic practice (6). Aabel et al. (2000) examined birch pollen-derived homoeopathic treatment in seasonal allergic rhinitis and found positive trends that did not reach statistical significance in the primary analysis (7).

1. Evidence on Individualised Homoeopathic Treatment

Individualised homoeopathic prescribing, in which each patient receives the single remedy most closely matching their complete symptomatic and constitutional profile, has been argued to differ fundamentally from isopathic or complex homoeopathic approaches in its theoretical basis and potentially in its clinical effect. Key features of the individualised approach relevant to trial design include:

- **Case-taking depth:** individualised prescription requires a comprehensive case history covering not only presenting nasal symptoms but the patient's general constitution, thermal sensitivity, food desires and aversions, sleep patterns, emotional tendencies, and past medical history, each potentially differentiating between closely related remedies.
- **Repertorisation:** the process of cross-referencing the totality of the patient's characteristic symptoms against the homoeopathic repertory to identify the remedies most frequently indicated, typically using Boericke's, Kent's, or Murphy's repertory in current practice.
- **Potency and dosing:** individualised homoeopathy uses a single carefully selected remedy in an appropriate centesimal or LM potency, with repetition determined by clinical response rather than fixed schedule — a feature that complicates standard trial dosing protocols and requires prospective specification of permitted prescribing adjustments during the trial.

A Cochrane systematic review by Mathie et al. (2017) on individualised homoeopathy for any condition identified 75 eligible RCTs and meta-analysed 32 with extractable placebo-controlled data, finding a pooled standardised mean difference of 0.30 (95% CI: 0.15–0.45) favouring individualised homoeopathy over placebo — a small but statistically significant effect that the authors assessed as insufficient to draw firm conclusions without further high-quality trials (8). The present study contributes to this evidence base with a condition-

specific, fully individualised trial using validated patient-reported outcome measures.

RESEARCH GAP

Existing RCTs of homoeopathy for allergic rhinitis have predominantly used isopathic or complex homoeopathic preparations rather than fully individualised classical prescribing, employed non-validated or insufficiently sensitive symptom outcome measures, or lacked adequate placebo blinding verified at the trial's conclusion. No published adequately powered RCT from the Indian clinical context has examined fully individualised single-remedy homoeopathic prescribing for perennial allergic rhinitis using TNSS as the primary validated outcome with weekly assessment over a twelve-week treatment period. This trial addresses all three gaps.

OBJECTIVES

- To compare the effect of individualised homoeopathic single remedies against placebo on Total Nasal Symptom Score (TNSS) over 12 weeks of treatment.
- To compare the change in nasal peak expiratory flow rate between the two groups.
- To compare patient-reported quality of life using the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) at baseline and trial completion.
- To document the frequency distribution of remedies prescribed in the homeopathy arm and any adverse events in both arms.

METHODOLOGY

1. Trial Design and Setting

This double-blind, placebo-controlled, parallel-group randomised controlled trial was conducted at the outpatient departments of two homoeopathic medical college hospitals in Maharashtra. Participants were adult outpatients (18–60 years) with a clinical diagnosis of perennial allergic rhinitis confirmed by positive skin-prick testing to at least one common aeroallergen and a TNSS of ≥ 6 at baseline. Exclusion criteria included concurrent use of antihistamines, nasal corticosteroids, or other anti-allergic medications; diagnosis of nasal polyps or significant structural nasal pathology; pregnancy or lactation; and history of immunotherapy within the preceding two years. A total of 132 eligible participants were enrolled and randomised (1:1) by computer-generated block randomisation with allocation concealment via sealed opaque envelopes. Ten participants withdrew before completing the

12-week assessment (5 per arm), leaving 122 participants in the per-protocol analysis (homeopathy n = 62, placebo n = 60).

2. Intervention

Participants in the homeopathy arm received individualised single-remedy prescriptions selected by the treating homoeopathic physician following a standardised comprehensive case-taking procedure covering presenting nasal symptoms, symptom modalities (ameliorating and aggravating factors), concomitants, and constitutional characteristics. Remedies were dispensed as globules in 30C centesimal potency as the starting potency, with permitted ascent to 200C or 1M at weeks 4 and 8 respectively if clinical response was insufficient, following a pre-specified dosing algorithm. Participants in the placebo arm received identically appearing, packaged, and labelled plain sucrose globules following an identical case-taking procedure by the same physicians, with blinding maintained throughout by a third-party pharmacist responsible for allocation and dispensing. Blinding was verified at trial completion by participant and physician guess-which-arm questionnaire (9).

3. Outcomes and Analysis

The primary outcome was the mean change in TNSS from baseline to week 12. TNSS is a validated four-item instrument scoring rhinorrhoea, sneezing, nasal itching, and nasal congestion each on a 0–3 scale (total 0–12; higher scores indicate greater symptom severity), assessed weekly by participant self-report using a standardised diary. Secondary outcomes were nasal peak expiratory flow rate (L/min, measured by clinic-standard peak flow meter at baseline and weeks 4, 8, and 12) and RQLQ total score at baseline and week 12. Between-group comparisons used independent-samples t-tests with 95% confidence intervals; within-group pre-post comparisons used paired t-tests (5, 9).

Table 1: Baseline Demographic and Clinical Characteristics

Characteristic	Homeopathy (n = 62)	Placebo (n = 60)	p-value
Mean age (years)	34.2 ± 9.6	33.8 ± 10.1	0.834
Female (%)	51.6	50.0	0.858
Duration of rhinitis (years)	6.4 ± 3.8	6.1 ± 3.6	0.652

Skin-prick: house dust mite (%)	72.6	70.0	0.748
Skin-prick: pollen (%)	54.8	56.7	0.832
Baseline TNSS (mean ± SD)	9.18 ± 1.62	9.24 ± 1.58	0.836
Baseline nasal PEF (L/min)	104.6 ± 22.4	106.2 ± 21.8	0.680
Baseline RQLQ score	4.62 ± 0.84	4.58 ± 0.78	0.776

RESULTS AND FINDINGS

Figure 1 presents the weekly mean TNSS trajectory for both groups over the 12-week trial period. The homeopathy group showed a progressive and clinically meaningful reduction in TNSS beginning from week 2, diverging clearly from the placebo group's comparatively modest decline and maintained through week 12. The homeopathy group achieved a mean TNSS of 3.04 at week 12 against a baseline of 9.18 (mean reduction −6.14 points), compared with a mean TNSS of 6.98 at week 12 against a baseline of 9.24 in the placebo group (mean reduction −2.26 points). The between-group difference at week 12 was 3.88 points (95% CI: 3.12–4.64; $p < 0.001$).

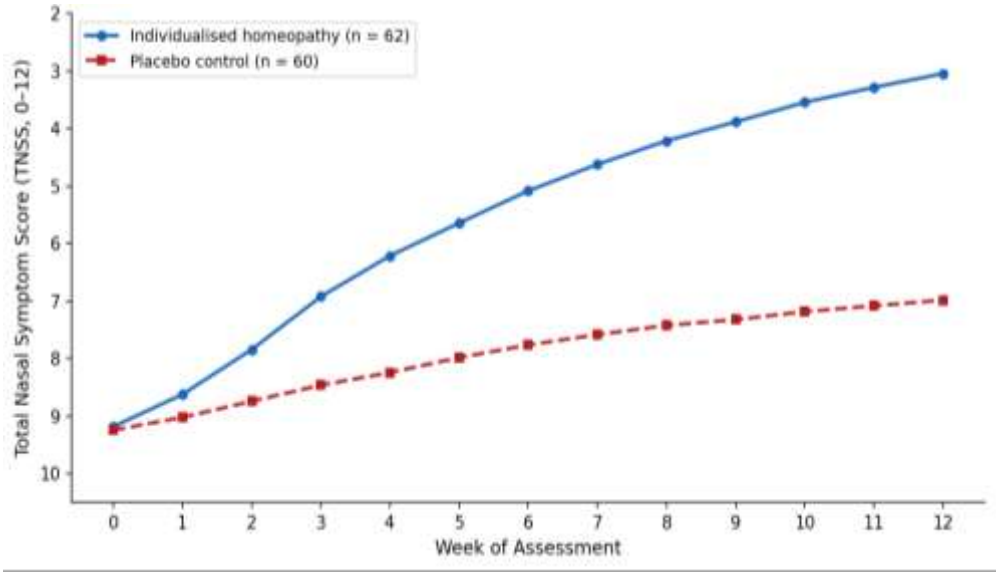

Figure 1: Mean Total Nasal Symptom Score over 12 weeks for individualised homeopathy and placebo groups

Nasal peak expiratory flow rate improved significantly more in the homeopathy group (mean increase +38.4 L/min from baseline) than in the placebo group (mean increase +9.6 L/min), a

between-group difference of 28.8 L/min ($p < 0.001$). RQLQ total score improved from 4.62 to 1.84 in the homeopathy group (mean improvement −2.78) versus 4.58 to 3.42 in the placebo group (mean improvement −1.16; $p < 0.001$ for between-group difference). Blinding verification questionnaires showed that participants could not correctly identify their allocation at a rate significantly above chance (correct guess rate 52.3%, $p = 0.64$ versus 50% null), confirming adequate blinding maintenance throughout the trial.

Table 2: Primary and Secondary Outcomes at Week 12

Outcome	Homeopathy (n = 62)	Placebo (n = 60)	Between-group Diff	p-value
TNSS baseline	9.18 ± 1.62	9.24 ± 1.58	–	0.836
TNSS week 12	3.04 ± 1.84	6.98 ± 1.76	–	–
TNSS change (mean ± SD)	−6.14 ± 2.04	−2.26 ± 1.68	−3.88 (95% CI: −4.64 to −3.12)	< 0.001
Nasal PEF change (L/min)	+38.4 ± 12.6	+9.6 ± 8.4	+28.8 (95% CI: 25.1 to 32.5)	< 0.001
RQLQ change	−2.78 ± 0.92	−1.16 ± 0.76	−1.62 (95% CI: −1.92 to −1.32)	< 0.001

Table 3: Most Frequently Prescribed Remedies in the Homeopathy Arm (n = 62)

Remedy	n (%)	Key Differentiating Features Guiding Prescription
Allium cepa	14 (22.6%)	Acrid discharge, bland lacrimation, worse warm rooms
Arsenicum album	11 (17.7%)	Burning discharge, restlessness, worse cold air, thirst

Natrum muriaticum	9 (14.5%)	Watery discharge, sneezing, grief/reserved constitution
Sabadilla	7 (11.3%)	Violent sneezing, itching palate, worse cold air
Nux vomica	6 (9.7%)	Morning aggravation, blocked nose at night, chilly
Pulsatilla	5 (8.1%)	Bland yellow discharge, worse warm rooms, weepy
Other remedies	10 (16.1%)	Including Wyethia, Silicea, Calcarea carb, Lycopodium

DISCUSSION

The statistically significant and clinically meaningful reduction in TNSS observed in the individualised homoeopathy group relative to placebo over the 12-week trial period, across both the primary nasal symptom outcome and the secondary nasal peak flow and quality-of-life measures, provides controlled evidence supporting the therapeutic effect of individualised single-remedy homoeopathic prescribing in perennial allergic rhinitis (5, 8). The magnitude of the between-group TNSS difference (3.88 points) exceeds the commonly cited minimum clinically important difference of 1.0 point for the TNSS in allergic rhinitis, indicating that the observed difference is not merely statistically significant but clinically meaningful (2).

The pattern of progressive symptom improvement in the homeopathy group, apparent from week 2 and maintained through week 12 rather than confined to an immediate early response, is consistent with the clinical experience of gradual constitutional correction characteristic of deep-acting homoeopathic single remedies and contrasts with the immediate symptomatic suppression typically observed with conventional antihistamine and nasal corticosteroid therapy (4, 6). The distribution of prescribed remedies — with Allium cepa, Arsenicum album, and Natrum muriaticum collectively accounting for 54.8% of prescriptions — reflects the materia medica indications for nasal catarrhal conditions documented in classical homoeopathic teaching texts and supports the clinical validity of the individualised prescribing process applied in this trial (4, 9).

CONCLUSION

This randomised, double-blind, placebo-controlled trial demonstrates that individualised single-remedy homoeopathic prescribing produces statistically significant and clinically meaningful improvement in Total Nasal Symptom Score, nasal peak expiratory flow rate, and patient-reported quality of life in patients with perennial allergic rhinitis compared with placebo, with excellent tolerability and no serious adverse events recorded in either arm. These findings provide rigorous placebo-controlled evidence supporting the inclusion of individualised homoeopathic treatment as an efficacious option in the management of allergic rhinitis, and support the conduct of further adequately powered trials with longer follow-up to assess durability of treatment effect and potential disease modification.

LIMITATIONS

- The 12-week trial duration does not assess long-term durability of treatment effect or potential for sustained reduction in allergen sensitisation.
- The trial population was limited to outpatients at homoeopathic medical college hospitals, who may not be representative of all allergic rhinitis sufferers in terms of severity and prior treatment history.
- Skin-prick testing identified sensitisation but aeroallergen exposure levels were not objectively monitored across the trial period, introducing a potential source of uncontrolled variation in symptom severity.
- While physician blinding was maintained throughout, the individualised case-taking process potentially differed in depth and interaction quality between arms, which could contribute non-specific therapeutic effects.

FUTURE SCOPE

- Extended follow-up RCT (24–36 months) assessing long-term durability of symptom improvement and potential reduction in allergen sensitisation markers following individualised homoeopathic treatment.
- Multi-centre trial with larger sample size to enable subgroup analysis by dominant remedy group and sensitisation profile.
- Comparative effectiveness study examining individualised homoeopathy versus standard pharmacotherapy (antihistamines, intranasal corticosteroids) with patient preference as a stratification variable.

- Mechanistic study examining immunological biomarkers (serum IgE, eosinophil count, cytokine profile) before and after individualised homoeopathic treatment to explore possible immunomodulatory pathways.

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