RESEARCH PAPER

Clinical Evaluation of Individualized Homoeopathic Medicines in Smokeless Tobacco Dependence: A Prospective, Single-Blind Interventional Cohort Study

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Running Title: Individualized Homoeopathy in Smokeless Tobacco Dependence

Abstract

Background: Smokeless tobacco (SLT) dependence is a pervasive public health burden across South Asia, driving high rates of oral potentially malignant disorders and cardiovascular morbidity. Conventional nicotine replacement and pharmacotherapeutic regimens show modest long-term abstinence rates in SLT chewers. Although classical homoeopathic literature describes several remedies for the constitutional and toxicological effects of tobacco, prospective clinical data evaluating individualized prescriptions remain sparse.

Objectives: To evaluate the clinical effectiveness of individualized homoeopathic medicines in reducing physical nicotine dependence, subjective craving intensity, oral-health-related quality of life impairment, and daily chewing frequency among chronic smokeless tobacco users over a 6-month follow-up period.

Methods: A prospective, single-blind, interventional clinical study was conducted on 100 adult smokeless tobacco users (aged 20–60 years; baseline FTND-ST score ≥ 4) at the outpatient department of Prayas Nasha-Mukti Evam Manochikitsa Kendra, Bhopal, India. Following detailed case-taking and repertorization using the Complete Repertory in CARA software, patients received one of eleven individualized homoeopathic remedies, with interspersed *Sacchrum lactis (Rubrum*) placebo phases to preserve single-blinding. Prescriptions distributed in descending order of clinical frequency were *Arsenicum album* (n = 16), *Cinchona officinalis [China]* (n = 14), *Nux vomica* (n = 13), *Tabacum* (n = 11), *Ignatia amara* (n = 10), *Staphysagria* (n = 9), *Natrum carbonicum* (n = 8), *Caladium seguinum* (n = 7), *Erythroxylum coca* (n = 5), *Phosphorus* (n = 4), and *Spigelia anthelmia* (n = 3). Outcomes were assessed at baseline and 6 months using the Fagerström Test for Nicotine Dependence–Smokeless Tobacco (FTND-ST), Oral Health Impact Profile (OHIP-18), Daily Tobacco Consumption Frequency (sessions/day), and a 0–10 Subjective Craving Visual Analogue Scale.

Results: At the 6-month endpoint, statistically significant reductions were observed across the cohort (N = 100) in FTND-ST scores (6.01 ± 1.99 to 4.38 ± 2.68; mean reduction: 1.63 ± 2.07; Wilcoxon $p < 0.001$; $d = 0.79$, $r = 0.45$), OHIP-18 scores (baseline: 25.14 ± 8.77 vs. 6 months: 20.45 ± 9.99; mean reduction: 4.69 ± 4.17; $t = 11.24$, $p < 0.001$; Cohen's $d = 1.12$), and subjective craving intensity (7.35 ± 1.84 to 5.89 ± 2.95; mean reduction: 1.46 ± 2.58; Wilcoxon $p < 0.001$; $d = 0.57$, $r = 0.35$). Daily chewing frequency declined from 15.10 ± 5.07 to 14.17 ± 7.09 sessions/day (mean difference: 0.93 ± 4.99; paired t-test $p = 0.065$; $d = 0.19$). Subgroup analysis demonstrated distinct clinical profiles: *Ignatia amara* (Δ = 6.00 ± 4.19, $p = 0.001$), *China* (Δ = 5.79 ± 4.58, $p = 0.004$), *Staphysagria* (Δ = 5.78 ± 4.66, $p = 0.006$), and *Arsenicum album* (Δ = 5.25 ± 3.04, $p < 0.001$) produced pronounced improvements in oral quality of life and dependence, whereas *Tabacum* (n = 11) achieved the most marked reduction in daily chewing sessions (Δ = 3.73 ± 4.38, $p = 0.008$, $d = 0.85$).

Conclusion: Individualized homoeopathic therapy significantly attenuates physical nicotine dependence, subjective craving, and oral health impairment in chronic smokeless tobacco users. Pairing constitutional prescribing with structured behavioral habit-reversal counseling is warranted to accelerate the extinction of residual motor chewing habits.

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Keywords: *Smokeless tobacco dependence; Individualized homoeopathy; FTND-ST; Oral Health Impact Profile (OHIP-18); Repertorization; Single-blind clinical trial, Tobacco, Homoeopathy.*

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1. Introduction

Commercial cultivation and ceremonial consumption of Nicotiana tabacum date back several millennia in the Americas, where indigenous communities employed the leaf as an analgesic, poultice, and ritual intoxicant[1]. Over the past century, however, industrial processing has transformed tobacco into the single largest preventable cause of premature mortality worldwide, accounting for nearly 8 million deaths annually—approximately 17.8% of global adult mortality[2]. While public health campaigns in Western nations have focused predominantly on combustible cigarettes, the epidemiological landscape across South and South-East Asia is dominated by smokeless tobacco (SLT)[2,3]. According to the Global Adult Tobacco Survey (GATS-2), India is the world's second-largest producer and consumer of tobacco, with 267 million adult users (28.6% of the adult population)[3]. Crucially, smokeless tobacco products—including khaini (slaked lime and sun-dried tobacco), gutkha (crushed areca nut, catechu, lime, flavorings, and tobacco), zarda, and betel quid—represent the primary mode of consumption, used by 21.4% of Indian adults (199.4 million individuals) and contributing to more than 1.35 million deaths every year.[3,4]

Unlike inhaled cigarette smoke, which delivers a rapid arterial bolus of nicotine to the cerebral circulation within ten seconds, oral smokeless tobacco is held in the mandibular or labial sulcus for extended periods, resulting in sustained transmucosal absorption and prolonged systemic nicotine exposure. Nicotine acts as a potent agonist at neuronal α4β2 nicotinic acetylcholine receptors (nAChRs) in the ventral tegmental area, triggering dopaminergic release within the nucleus accumbens and reinforcing conditioned reward pathways.[5] Chronic mucosal contact with unburned tobacco nitrosamines (such as N-nitrosonornicotine [NNN] and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone [NNK]), compounded by the mechanical abrasion and alkaloid toxicity of areca nut in gutkha preparations, inflicts severe local tissue damage.[6] Clinical sequelae include gingival recession, chronic periodontitis, leukoplakia, oral submucous fibrosis (OSMF), and squamous cell carcinoma of the buccal mucosa—the most common malignancy among Indian men.[4,6]

Standard clinical guidelines for tobacco cessation combine behavioral counseling with first-line pharmacotherapies, including *Nicotine Replacement Therapy* (NRT; gums, lozenges, transdermal patches), the α4β2 partial agonist *varenicline,* and the *norepinephrine-dopamine* reuptake inhibitor *bupropion*.[7,8] In everyday clinical practice across India, however, these interventions face substantial barriers. Cochrane meta-analyses and clinical reviews indicate that pharmacotherapies designed for cigarette smokers yield lower sustained abstinence rates among smokeless tobacco chewers, where the tactile ritual of holding a quid in the cheek pouch is deeply ingrained in occupational routines.[7,8] Furthermore, adverse effects—such as nausea, vivid dreams, insomnia, and neuropsychiatric agitation with *Varenicline* or *Bupropion*—along with prohibitive recurring costs, frequently lead to premature treatment discontinuation and relapse.[7]

Homoeopathy, founded by Samuel Hahnemann on the therapeutic law similia similibus curentur ("let likes be cured by likes"), approaches substance dependence not merely as an isolated chemical receptor disorder, but as a dynamic disturbance involving the patient's mental constitution, physical generals, and underlying miasmatic predisposition.[9] Classical materia medica texts document specific clinical indications for managing both the acute withdrawal syndrome and the chronic systemic sequelae of tobacco abuse.[10,11,12] In *Hahnemann's Materia Medica Pura* and *Hering's Guiding Symptoms*, *Tabacum* is characterized by profound vagal and autonomic symptoms—deathly nausea, cold clammy perspiration, vertigo on opening the eyes, and precordial sinking—mirroring acute nicotinism.[10,11] *Nux vomica* is classically indicated for driven, sedentary individuals suffering from gastric irritability, morning retching, and nervous sleeplessness following prolonged stimulant excess.[11,12] *Arsenicum album* addresses patients marked by intense psychomotor restlessness, burning mucosal pains ameliorated by warmth, and deep-seated health anxiety, whereas *Cinchona officinalis (China)* corresponds to chronic nervous exhaustion, digestive flatulence, and neuralgic hyperesthesia secondary to prolonged vital depletion.[11,12] Similarly, *Ignatia amara* and *Staphysagria* correspond to tobacco habituation maintained by unresolved grief, emotional volatility, or suppressed indignation, while *Caladium seguinum, Natrum carbonicum, Erythroxylum coca, Phosphorus,* and *Spigelia anthelmia* cover distinct organopathic and sensory modalities in chronic chewers.[12,14]

Recent clinical investigations have provided encouraging preliminary data regarding homoeopathic management of tobacco use disorder. Narrative reviews and controlled clinical studies evaluating either individualized prescriptions or targeted remedies (such as *Caladium seguinum* and *Staphysagria*) have reported significant reductions in Fagerström dependence scores and improvements in general well-being.[15-18] Nevertheless, well-structured prospective studies examining how an individualized spectrum of homoeopathic remedies influences both validated oral-health quality of life metrics and domain-specific dependence parameters remain scarce. The present prospective, single-blind clinical study was therefore undertaken to evaluate the clinical effectiveness of eleven individualized homoeopathic medicines—prescribed strictly according to symptom totality and repertorization—on oral health impact, physical nicotine dependence, subjective craving intensity, and daily chewing frequency over a 6-month observation period.

2. Materials and Methods

2.1 Study Design and Clinical Setting

This study was designed as a prospective, single-blind, interventional clinical cohort trial conducted at the Outpatient Department (OPD) of Prayas Nasha-Mukti Evam Manochikitsa Kendra (De-addiction and Psychiatric Rehabilitation Centre), Bhopal, Madhya Pradesh, India, under the academic aegis of Janardan Rai Nagar Rajasthan Vidyapeeth (Deemed to be University), Udaipur. Patient recruitment and follow-up were carried out between April 2024 and August 2025, comprising a 12-month enrollment window and a mandatory 6-month active follow-up period for each participant. The study design and clinical reporting adhere to the REDHOT (Reporting Data on Homeopathic Treatments) supplement to the CONSORT guidelines.[19]

2.2 Ethical Approval and Informed Consent

The study protocol, case recording proforma, and bilingual patient information sheets were reviewed and approved by the Institutional Ethical Committee (IEC) of Janardan Rai Nagar Rajasthan Vidyapeeth (Deemed to be University), Udaipur, prior to trial initiation. The study was conducted in full accordance with the ethical principles of the Declaration of Helsinki and the Indian Council of Medical Research (ICMR) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. Every prospective participant received a comprehensive verbal and written explanation of the study objectives and follow-up schedule in Hindi or English, and written informed consent was obtained prior to baseline assessment.

2.3 Participant Eligibility Criteria

A total of 119 consecutive adult patients presenting to the de-addiction OPD with a primary complaint of smokeless tobacco habit were screened for eligibility. Nineteen patients were excluded or lost to follow-up due to relocation or non-compliance with scheduled visits, resulting in a final analyzed cohort of 100 participants who completed the full 6-month protocol.

Inclusion Criteria: (1) Adult males and females aged between 20 and 60 years; (2) Chronic daily consumption of smokeless tobacco products (gutkha, khaini, zarda, or betel quid with tobacco) with a minimum frequency of at least two chewing sessions per day for ≥ 1 year; (3) Baseline Fagerström Test for Nicotine Dependence–Smokeless Tobacco (FTND-ST) score ≥ 4, indicating moderate-to-severe physical dependence; (4) Expressed self-motivation to quit or reduce tobacco use; and (5) Willingness to provide written informed consent and attend scheduled follow-up consultations.

Exclusion Criteria: (1) Individuals aged < 20 years or > 60 years; (2) Patients with severe, unstable psychiatric disorders (e.g., acute psychosis, bipolar mania, or active suicidal ideation) or decompensated cardiovascular, hepatic, or renal disease; (3) Concurrent use of conventional pharmacotherapies for tobacco cessation (nicotine gums/patches, bupropion, varenicline, or cytisine) within 4 weeks prior to enrollment; (4) Pregnant or lactating women; and (5) Presence of frank ulcero-proliferative oral mucosal lesions suspicious for invasive squamous cell carcinoma requiring immediate oncological referral.

2.4 Homoeopathic Intervention, Repertorization, and Blinding Protocol

At the baseline visit, each enrolled participant underwent an in-depth Hahnemannian case-taking interview (lasting 45–60 minutes) conducted by a qualified homoeopathic physician using a standardized Case Recording Proforma. Case analysis encompassed the presenting complaints of tobacco craving and withdrawal, oral mucosal symptoms (burning, salivation, aphthae, restricted mouth opening), physical generals (thermal reaction, appetite, thirst, sleep, bowel habits), and characteristic mental and emotional traits (anxiety, irritability, grief, occupational stress, and emotional suppression)[9,13].

Symptom totality was erected and systematically repertorized using the *Complete Repertory* module within *CARA Professional Repertory Software*[13,14]. Final remedy differentiation was confirmed by cross-referencing the repertorial panel against standard Materia Medica authorities (*Hahnemann, Hering, Clarke*, and *Boericke*)[10,11,12]. Because prescriptions were strictly individualized to each patient's constitutional and symptomatic totality rather than randomized to fixed arms, the resulting subgroup sizes naturally followed a descending clinical frequency

distribution across eleven remedies: *Arsenicum album* (n = 16), *Cinchona officinalis* [*China*] (n = 14), *Nux vomica* (n = 13), *Tabacum* (n = 11), *Ignatia amara* (n = 10), *Staphysagria* (n = 9), *Natrum carbonicum* (n = 8), *Caladium seguinum* (n = 7), E*rythroxylum coca [Coca]* (n = 5), *Phosphorus* (n = 4), and *Spigelia anthelmia* (n = 3).

All homoeopathic medicines were procured from a Good Manufacturing Practice (GMP)-certified homoeopathic pharmaceutical manufacturer prepared strictly in accordance with the Homoeopathic Pharmacopoeia of India (HPI). Active treatment was initiated in the 30C centesimal potency, dispensed as four medicated cane-sugar globules (size 40) administered orally twice daily on a clean tongue, 30 minutes before meals. To maintain single-blinding, patients were kept unaware of the identity of the prescribed remedy and potency throughout the 6-month trial. Indistinguishable unmedicated sucrose globules (Rubrum / Sacchrum lactis) packaged in identical amber glass vials were dispensed during phases of steady clinical improvement to prevent unnecessary repetition of the dynamic remedy and to control for expectation bias.[9] Follow-up assessments were conducted weekly during Weeks 1 and 2 to monitor acute withdrawal symptoms and remedy reaction, fortnightly at Month 1, and monthly from Months 2 through 6 (with fortnightly interim reviews if craving scores fluctuated). Where clinically indicated by a plateau in symptom resolution, potency was stepped up to 200C or 1M according to classical posological principles.

2.5 Outcome Measures

Four standardized clinical outcome parameters were recorded at baseline (pre-intervention) and at the completion of the 6-month follow-up (post-intervention):

1. Oral Health Impact Profile (OHIP-18): An 18-item validated short-form psychometric instrument derived from Slade's Oral Health Impact Profile [20,21], assessing the impact of oral mucosal and dental conditions across seven domains: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. Items are rated on a 5-point Likert scale (0 = never to 4 = very often; total score range: 0–72), where higher scores indicate greater oral health impairment and lower quality of life.

2. Fagerström Test for Nicotine Dependence – Smokeless Tobacco (FTND-ST): A validated 6-item instrument adapted specifically for smokeless tobacco users by Ebbert et al. [22,23], quantifying physical nicotine dependence based on time to first morning chew, difficulty refraining in restricted places, unwillingness to give up the first morning quid, number of pouches/tins consumed, frequency of chewing in the first hours after waking, and chewing during physical illness. Total scores range from 0 to 10, with scores ≥ 4 denoting moderate-to-high physical dependence.

3. Daily Smokeless Tobacco Consumption Frequency: Quantitative self-reported count of individual smokeless tobacco chewing sessions (pouches, quids, or pinches placed in the buccal sulcus) per day, averaged over the preceding 7 days.

4. Subjective Craving Intensity Scale: A 10-centimeter horizontal Visual Analogue Scale (VAS) anchored from 0 ("complete absence of desire or urge to chew tobacco") to 10 ("overwhelming, irresistible craving for tobacco"), capturing the patient's perceived urge over the preceding week.

2.6 Statistical Analysis

Data curation and statistical computations were performed using Python 3.14 (utilizing NumPy 2.x, Pandas, and SciPy.stats libraries). Continuous variables are expressed as mean ± standard deviation (SD), and categorical demographic variables as frequency counts and percentages (n, %). For each outcome variable, paired individual change scores were calculated as Δ = Score baseline − Score 6-month, such that positive difference values represent clinical improvement (reduction in impairment, dependence, chewing frequency, or craving). Prior to hypothesis testing, the distributional normality of the paired difference scores (Δ) was formally evaluated using the Shapiro–Wilk test ($\alpha = 0.05$). Where difference scores satisfied the assumption of normality (Shapiro–Wilk $p \geq 0.05$), parametric two-tailed paired Student's t-tests were applied; where distributions deviated significantly from normality (Shapiro–Wilk $p < 0.05$, as observed in bounded ordinal scales), the non-parametric Wilcoxon signed-rank test was utilized. To quantify the magnitude of clinical effect independent of sample size, standardized effect sizes were computed as Cohen's d ($d = \text{Mean_diff} / \text{SD_diff}$, classified per Cohen's conventions as negligible [< 0.20], small [0.20–0.49], medium [0.50–0.79], and large [≥ 0.80]), supplemented by the Wilcoxon effect size $r = |Z| / \sqrt{N}$ for non-parametric comparisons. All statistical tests were two-tailed, with $p < 0.05$ considered statistically significant.

3. Results

3.1 Baseline Demographic Profile and Remedy Allocation

Of the 119 smokeless tobacco users screened during the recruitment period, 100 participants completed the 6-month interventional protocol and were included in the final intention-to-treat analysis. The mean age of the study cohort was 42.06 ± 9.24 years (range: 24–58

years), reflecting a predominance of working-age adults in their third to fifth decades of life. Males constituted 67.0% (n = 67) of the cohort and females accounted for 33.0% (n = 33), consistent with regional epidemiological patterns in Madhya Pradesh where gutkha and zarda chewing is prevalent among male transport, construction, and clerical workers, while khaini and tobacco tooth-powder/betel quid usage is substantial among women.

Individualized case repertorization resulted in a strictly unequal, descending distribution across 11 homoeopathic remedies (Table 1 and Figure 1). Constitutional polychrests addressing combined neuro-affective restlessness, gastrointestinal irritation, and chronic vital depletion accounted for the largest share of prescriptions: *Arsenicum album* was prescribed to 16 patients (16.0%), *Cinchona officinalis (China)* to 14 patients (14.0%), and *Nux vomica* to 13 patients (13.0%). The toxicological simillimum *Tabacum* was indicated in 11 patients (11.0%), followed by remedies addressing psychogenic and emotional etiologies—*Ignatia amara* in 10 patients (10.0%) and *Staphysagria* in 9 patients (9.0%). The remaining 27% of the cohort required remedies matching more specific constitutional or organopathic symptom pictures: *Natrum carbonicum* (n = 8, 8.0%), *Caladium seguinum* (n = 7, 7.0%), *Erythroxylum coca* (n = 5, 5.0%), *Phosphorus* (n = 4, 4.0%), and *Spigelia anthelmia* (n = 3, 3.0%).

Table 1: Baseline Demographic Characteristics, Prescribed Homoeopathic Remedies, and Primary Constitutional/Clinical Indications (N = 100)

Category / Remedy Prescribed	Subgroup / Potency	n (%) / Value	Dominant Constitutional & Clinical Guiding Indications
Age (Years)	Mean ± SD (Range)	**42.06 ± 9.24 (24–58)**	Predominantly working-age adults (30–50 years) with chronic SLT habit
Sex Distribution	Male / Female	**67 (67.0%) / 33 (33.0%)**	Male predominance (gutkha/khaini); significant Female (betel-quid/zarda) cohort
1. Arsenicum album	30C / 200C	**16 (16.0%)**	Marked psychomotor restlessness, health anxiety, burning buccal mucosa > warm drinks
2. Cinchona officinalis (China)	30C / 200C	**14 (14.0%)**	Chronic vital exhaustion, anemia, flatulent dyspepsia, neuralgic hyperesthesia
3. Nux vomica	30C / 200C	**13 (13.0%)**	Occupational stress, irritability, insomnia, morning gastric retching, stimulant excess
4. Tabacum	30C / 200C	**11 (11.0%)**	Toxicological simillimum; deathly nausea, vertigo, cold sweat, vagal sinking on abstinence
5. Ignatia amara	30C / 200C	**10 (10.0%)**	Emotional triggers (grief, worry), mood lability, globus hystericus, frequent sighing
6. Staphysagria	30C / 200C	**9 (9.0%)**	Habit maintained by suppressed anger/indignation, spongy bleeding gums, early caries
7. Natrum carbonicum	30C / 200C	**8 (8.0%)**	Mental exhaustion from exertion, chronic gastric catarrh, aphthae, sun aggravation
8. Caladium seguinum	30C / 200C	**7 (7.0%)**	Intense craving with dry burning

			mouth, forgetfulness, tobacco-induced sexual neurasthenia
9. Erythroxylum coca (Coca)	30C	**5 (5.0%)**	Nervous timidity, exertional dyspnea, habitual craving for stimulants to sustain labor
10. Phosphorus	30C / 200C	**4 (4.0%)**	Tall, sensitive constitution; burning sensations, hemorrhagic gingivitis, craving cold drinks
11. Spigelia anthelmia	30C	**3 (3.0%)**	Left-sided trigeminal/facial neuralgia, cardiac palpitations, offensive breath in chewers

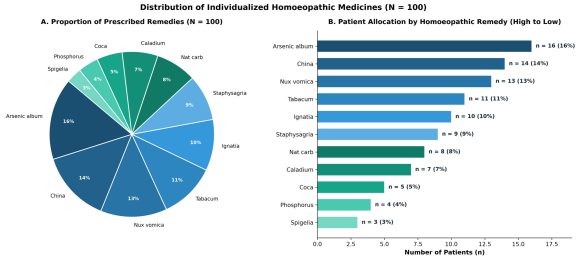


Figure 1: Distribution of individualized homoeopathic medicines across the study cohort (N = 100). (A) Proportional representation of the eleven prescribed remedies. (B) Descending rank-order frequency from Arsenicum album (n = 16) to Spigelia anthelmia (n = 3).

3.2 Overall Cohort Treatment Outcomes (N = 100)

Across the complete cohort of 100 smokeless tobacco users, 6 months of individualized homoeopathic management produced highly statistically significant improvements in three of the four primary outcome domains: oral-health-related quality of life (OHIP-18), physical nicotine dependence (FTND-ST), and subjective craving intensity (Table 2 and Figure 2).

Specifically, the mean baseline OHIP-18 score decreased from 25.14 ± 8.77 to 20.45 ± 9.99 at 6 months, yielding a mean reduction of 4.69 ± 4.17 points (95% CI: 3.86–5.52). Because the paired OHIP-18 difference scores conformed to a normal distribution (Shapiro–Wilk W = 0.978, p = 0.081), parametric analysis was applied, confirming a highly significant treatment effect (paired t = 11.24, p < 0.001) with a large standardized effect size (Cohen's d = 1.12). Clinically, patients reported substantial relief from buccal mucosal burning, recurrent aphthous ulceration, dental sensitivity, and mealtime discomfort.

Physical nicotine dependence, measured via FTND-ST, declined from a baseline mean of 6.01 ± 1.99 to 4.38 ± 2.68 at the 6-month endpoint, representing a mean reduction of 1.63 ± 2.07 points (95% CI: 1.22–2.04). Due to moderate skewness in the discrete difference scores (Shapiro–Wilk p = 0.016), the non-parametric Wilcoxon signed-rank test was performed alongside the paired t-test; both confirmed a highly significant reduction in physical dependence (p < 0.001; Cohen's d = 0.79, Wilcoxon r = 0.45, medium-to-large effect). Similarly, subjective craving intensity dropped significantly from 7.35 ± 1.84 at baseline to 5.89 ± 2.95 at 6 months (mean reduction: 1.46 ± 2.58 points; Shapiro–Wilk p = 0.014; Wilcoxon p < 0.001; Cohen's d = 0.57, r = 0.35).

In contrast, the overall daily frequency of smokeless tobacco chewing sessions showed only a modest reduction over the 6-month period, shifting from 15.10 ± 5.07 sessions/day at baseline to 14.17 ± 7.09 sessions/day at endpoint (mean reduction: 0.93 ± 4.99 sessions/day; Shapiro–Wilk p = 0.320). On parametric testing, this difference did not reach the conventional threshold for statistical significance (paired t = 1.86, p = 0.065; Cohen's d = 0.19, negligible effect), pointing to an important behavioral dissociation between reduced neurobiological craving/dependence and the persistence of habitual motor chewing routines.

Table 2: Overall Cohort Pre- vs. Post-Intervention Clinical Outcomes at 6 Months (N = 100)

Outcome Parameter	Baseline (Mean ± SD)	6-Month Endpoint (Mean ± SD)	Mean Diff (Δ) (Mean ± SD)	Shapiro–Wilk (p-value)	Statistical Test Applied	p-value	Effect Size (Interpretation)

OHIP-18 Score (0–72)	25.14 ± 8.77	20.45 ± 9.99	4.69 ± 4.17	0.081 (Normal)	Paired t-test	**< 0.001***	d = 1.12 (Large)
FTND-ST Score (0–10)	6.01 ± 1.99	4.38 ± 2.68	1.63 ± 2.07	0.016 (Non-normal)	Wilcoxon Signed-Rank	**< 0.001***	d = 0.79 / r = 0.45 (Medium)
Daily Tobacco (Sessions/Day)	15.10 ± 5.07	14.17 ± 7.09	0.93 ± 4.99	0.320 (Normal)	Paired t-test	0.065 (NS)	d = 0.19 (Negligible)
Craving Intensity (VAS 0–10)	7.35 ± 1.84	5.89 ± 2.95	1.46 ± 2.58	0.014 (Non-normal)	Wilcoxon Signed-Rank	**< 0.001***	d = 0.57 / r = 0.35 (Medium)

**Statistically significant at p < 0.001 (two-tailed). NS: Not statistically significant (p ≥ 0.05). OHIP-18: 18-item Oral Health Impact Profile; FTND-ST: Fagerström Test for Nicotine Dependence–Smokeless Tobacco.*

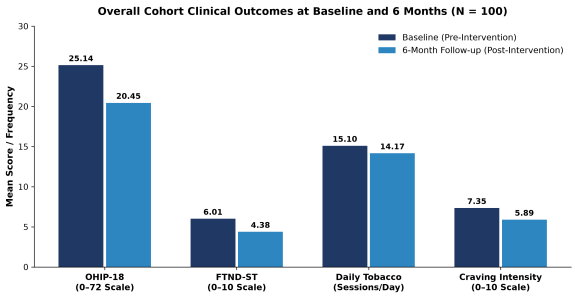


Figure 2: Overall cohort comparison of pre-intervention (baseline) and post-intervention (6-month) mean scores across all four clinical outcome measures (N = 100). Highly significant reductions (p < 0.001) were achieved in OHIP-18, FTND-ST, and Craving Intensity.

3.3 Subgroup Analysis Across the Eleven Homoeopathic Remedies

To evaluate how clinical response varied across individual constitutional and symptomatic prescriptions, subgroup analyses were performed for all eleven remedy groups across oral health and dependence parameters (Table 3 and Figure 3) as well as daily consumption and craving parameters (Table 4 and Figure 4).

In the assessment of Oral Health Impact Profile (OHIP-18), nine of the eleven remedy subgroups demonstrated statistically significant within-group reductions ($p < 0.05$) with medium-to-large standardized effect sizes (Table 3). The largest absolute mean reduction in oral health impairment was recorded in the *Ignatia amara* subgroup (n = 10; baseline: 30.10 ± 11.59 to 24.10 ± 12.85; Δ = 6.00 ± 4.19; p = 0.001; d = 1.43), closely followed by *Cinchona officinalis [China]* (n = 14; Δ = 5.79 ± 4.58; Wilcoxon p = 0.004; d = 1.26) and *Staphysagria* (n = 9; Δ = 5.78 ± 4.66; p = 0.006; d = 1.24). Highly consistent oral quality-of-life gains were likewise observed in the largest subgroup, *Arsenicum album* (n = 16; baseline: 24.88 ± 8.23 to 19.62 ± 8.98; Δ = 5.25 ± 3.04; p < 0.001; d = 1.73), as well as *Caladium seguinum* (n = 7; Δ = 5.43 ± 3.69; p = 0.008; d = 1.47) and *Erythroxylum coca* (n = 5; Δ = 5.40 ± 3.05; p = 0.017; d = 1.77). Only the two smallest tail subgroups - *Phosphorus* (n = 4; Δ = 2.00 ± 4.40; p = 0.430) and *Spigelia anthelmia* (n = 3; Δ = 3.00 ± 3.61; p = 0.286)—did not reach statistical significance due to limited statistical power at n ≤ 4.

For physical nicotine dependence (FTND-ST), statistically significant reductions were achieved in the top five most frequently prescribed remedies as well as *Natrum carbonicum* (Table 3). *Ignatia amara* (n = 10; Δ = 2.30 ± 2.83; p = 0.030; d = 0.81) and *Arsenicum album* (n = 16; baseline: 6.75 ± 1.48 to 4.56 ± 1.82; Δ = 2.19 ± 1.60; p < 0.001; d = 1.37) exhibited the most pronounced attenuation of physical nicotine dependence. Strong, statistically significant FTND-ST improvements were also documented in *Tabacum* (n = 11; Δ = 1.82 ± 1.99; p = 0.013; d = 0.91), *Nux vomica* (n = 13; Δ = 1.62 ± 2.26; p = 0.024; d = 0.72), *Natrum carbonicum* (n = 8; Δ = 1.62 ± 1.69; p = 0.029; d = 0.96), and *China* (n = 14; Δ = 1.07 ± 1.86; p = 0.050; d = 0.58).

Table 3: Remedy-Specific Subgroup Analysis for Oral Health Impact Profile (OHIP-18) and Nicotine Dependence (FTND-ST) Across Eleven Homoeopathic Medicines (N = 100)

Prescribed Remedy	n	OHIP Pre (Mean±	OHIP Post (Mean±	OHIP Δ (Mean±	OHIP p-val	FTND Pre (Mea	FTND Post (Mea	FTND Δ (Mean±	FTND p-val

		SD)	**SD)**	**SD)**	**ue (d)**	**n± SD)**	**n± SD)**	**SD)**	**ue (d)**
Arsenicum album	**16**	24.88 ±8.23	19.62 ±8.98	5.25± 3.04	<0.001a (1.73)	6.75± 1.48	4.56± 1.82	2.19± 1.60	<0.001a (1.37)
Cinchona officinalis (China)	**14**	26.36 ±10.85	20.57 ±11.93	5.79± 4.58	0.004b (1.26)	6.07± 2.06	5.00± 3.16	1.07± 1.86	0.050a (0.58)
Nux vomica	**13**	25.23 ±8.92	21.62 ±9.89	3.62± 5.27	0.029a (0.69)	5.85± 2.48	4.23± 2.89	1.62± 2.26	0.024a (0.72)
Tabacum	**11**	19.64 ±7.46	16.00 ±11.17	3.64± 4.76	0.030a (0.7	5.64± 1.57	3.82± 2.75	1.82± 1.99	0.013a (0.9
Ignatia amara	**10**	30.10 ±11.59	24.10 ±12.85	6.00± 4.19	0.001a (1.43)	6.20± 1.93	3.90± 2.42	2.30± 2.83	0.030a (0.81)
Staphysagria	**9**	24.33 ±6.78	18.56 ±9.03	5.78± 4.66	0.006a (1.24)	6.11± 1.45	4.89± 2.26	1.22± 2.33	0.155a (0.52)
Natrum carbonicum	**8**	29.12 ±7.24	26.25 ±9.02	2.88± 3.14	0.036a (0.92)	5.12± 1.46	3.50± 2.33	1.62± 1.69	0.029a (0.96)
Caladium seguinum	**7**	23.29 ±6.10	17.86 ±6.44	5.43± 3.69	0.008a (1.47)	6.57± 3.05	5.43± 4.12	1.14± 1.95	0.172a (0.58)
Erythr	**5**	24.40	19.00	5.40±	0.	7.20±	5.20±	2.00±	0.

Erythroxylum coca (Coca)		±7.77	±9.92	3.05	0.17a (1.77)	1.48	3.27	3.16	2.30a (0.63)
Phosphorus	**4**	22.25 ±8.10	20.25 ±7.80	2.00± 4.40	0.430a (0.45)	5.00± 2.16	4.00± 3.46	1.00± 2.16	0.423a (0.46)
Spigelia anthelmia	**3**	25.33 ±8.74	22.33 ±7.57	3.00± 3.61	0.286a (0.83)	3.33± 2.31	2.33± 0.58	1.00± 1.73	0.423a (0.58)

Note: Δ = Baseline score minus 6-month score (positive values denote reduction in impairment/dependence). Superscripts indicate statistical test based on Shapiro–Wilk normality: (a) Paired Student's t-test; (b) Wilcoxon signed-rank test. Values in parentheses next to p-values denote Cohen's d.

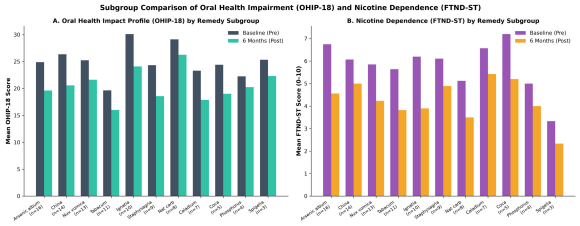


Figure 3: Subgroup comparison of baseline (pre-treatment) and 6-month (post-treatment) mean scores across all eleven homoeopathic remedies for (A) Oral Health Impact Profile (OHIP-18) and (B) Fagerström Test for Nicotine Dependence–Smokeless Tobacco (FTND-ST).

Subgroup patterns for Daily Tobacco Consumption Frequency and Subjective Craving Intensity (Table 4 and Figure 4) revealed a striking pharmacological divergence between toxicological and constitutional remedies. Specifically, *Tabacum* (n = 11) produced the largest and most statistically robust reduction in daily chewing frequency across the entire cohort, cutting intake from 15.55 ± 6.07 to 11.82 ± 5.60 sessions/day (Δ = 3.73 ± 4.38 sessions/day; Wilcoxon p = 0.008; d = 0.85), yet registered the smallest change in subjective craving intensity (7.55 ± 2.30 to 7.36 ± 3.07; Δ = 0.18 ± 1.78; p = 0.742). Meaningful reductions in daily chewing frequency were also seen in *Spigelia anthelmia* (n = 3; Δ = 3.33 ± 0.58; p = 0.010), China (n = 14; Δ = 2.14 ± 5.11; p = 0.220), and *Nux vomica* (n = 13; Δ = 2.00 ± 4.76; p = 0.156).

Conversely, in the Subjective Craving domain, significant reductions were driven by constitutional and neuro-emotional remedies: *Ignatia amara* (n = 10; Δ = 2.20 ± 2.20; p = 0.012; d = 1.00), *China* (n = 14; Δ = 1.86 ± 2.91; p = 0.033; d = 0.64), and *Arsenicum album* (n = 16; Δ = 1.50 ± 2.37; p = 0.023; d = 0.63), with borderline trends in *Nux vomica* (Δ = 1.54 ± 2.73; p = 0.065) and *Staphysagria* (Δ = 1.44 ± 2.24; p = 0.089). Notably, in subgroups such as *Arsenicum album* (Δ = −0.88 ± 5.33 sessions/day, p = 0.521) and *Erythroxylum coca* (Δ = −2.60 ± 6.88, p = 0.446), even though physical dependence (FTND-ST) and peak cravings declined, the raw daily count of chewing episodes remained statistically unchanged or fluctuated slightly as patients substituted smaller, briefer pinches to pacify residual oral fixation.

Table 4: Remedy-Specific Subgroup Analysis for Daily Smokeless Tobacco Consumption Frequency and Subjective Craving Intensity Across Eleven Homoeopathic Medicines (N = 100)

Prescribed Remedy	n	Tobacco Pre (Mean± SD)	Tobacco Post (Mean± SD)	Tobacco Δ (Mean± SD)	Tobacco p-value (d)	Craving Pre (Mean± SD)	Craving Post (Mean± SD)	Craving Δ (Mean± SD)	Craving p-value (d)
Arsen	**16**	11.6	12.5	-0.	0.5	7.62	6.12	1.50	0.0

icum album		2±4.57	0±7.39	88±5.33	21a (-0.17)	±2.16	±3.61	±2.37	23a (0.63)
Cinchona officinalis (China)	**14**	14.93±5.84	12.79±7.59	2.14±5.11	0.220b (0.42)	6.57±2.03	4.71±2.55	1.86±2.91	0.033a (0.64)
Nux vomica	**13**	12.85±4.04	10.85±6.23	2.00±4.76	0.156a (0.42)	6.92±1.66	5.38±2.99	1.54±2.73	0.065a (0.56)
Tabacum	**11**	15.55±6.07	11.82±5.60	3.73±4.38	0.008b (0.85)	7.55±2.30	7.36±3.07	0.18±1.78	0.742a (0.10)
Ignatia amara	**10**	16.70±3.33	16.80±6.21	-0.10±3.67	0.933a (-0.03)	7.40±1.90	5.20±2.39	2.20±2.20	0.012a (1.00)
Staphysagria	**9**	14.22±4.60	13.00±7.11	1.22±5.14	0.496a (0.24)	7.33±1.50	5.89±2.52	1.44±2.24	0.089a (0.64)
Natrum carbonicum	**8**	19.75±4.43	19.25±6.34	0.50±4.84	0.779a (0.10)	7.88±1.89	6.50±3.51	1.38±3.20	0.264a (0.43)
Caladium seguinum	**7**	16.86±3.48	17.29±6.65	-0.43±5.71	0.849a (-0.08)	7.14±1.21	5.14±3.53	2.00±3.96	0.230a (0.51)
Erythroxylum coca (Coca)	**5**	18.20±4.49	20.80±7.50	-2.60±6.88	0.446a (-0.38)	7.20±1.48	6.60±1.34	0.60±2.19	0.573a (0.27)
Phosphorus	**4**	14.75±4.43	14.25±8.54	0.50±5.00	0.854a (0.10)	8.50±1.73	7.50±3.11	1.00±3.46	0.604a (0.29)
Spigelia anthelmia	**3**	18.67±3.51	15.33±3.51	3.33±0.58	0.010a (5.74)	8.33±0.58	6.00±1.73	2.33±1.53	0.118a (1.52)

Note: Δ = Baseline score minus 6-month score. Superscripts denote statistical test applied: (a) Paired Student's t-test; (b) Wilcoxon signed-rank test. Values in parentheses next to p-values denote Cohen's d.

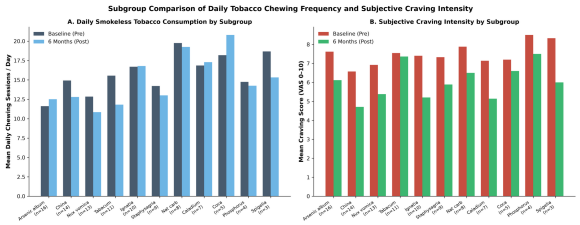


Figure 4: Subgroup comparison of baseline and 6-month mean scores across all eleven homoeopathic remedies for (A) Daily Smokeless Tobacco Consumption Frequency (sessions/day) and (B) Subjective Craving Intensity (VAS 0–10).

4. Discussion

The present prospective, single-blind clinical study evaluated the real-world effectiveness of individualized homoeopathic therapy in 100 chronic smokeless tobacco users over a 6-month period. The findings demonstrate that remedies selected strictly via Repertorial totality and Materia Medica differentiation produce highly significant improvements in oral-health-related quality of life (OHIP-18 reduction of 4.69 ± 4.17 points, $p < 0.001$, $d = 1.12$), physical nicotine dependence (FTND-ST reduction of 1.63 ± 2.07 points, $p < 0.001$, $d = 0.79$), and subjective craving intensity (VAS reduction of 1.46 ± 2.58 points, $p < 0.001$, $d = 0.57$). These results corroborate earlier clinical observations by Shah et al.[16] and Deepak[17], who reported substantial declines in Fagerström dependence scores under individualized Homoeopathic care, while extending the evidence base to encompass validated Oral-health quality of life metrics and a broader eleven-remedy clinical spectrum.

A particularly instructive finding of our study is the divergence between the marked attenuation of physical dependence and craving (both $p < 0.001$) and the comparatively modest, statistically non-significant decline in overall daily chewing frequency (15.10 ± 5.07 to 14.17 ± 7.09 sessions/day; Δ = 0.93 ± 4.99, $p = 0.065$). In clinical tobacco research, this phenomenon is well recognized among chronic gutkha and khaini chewers.[5,22] Unlike cigarette smoking—where each unit is discrete and requires lighting—smokeless tobacco chewing involves a continuous, low-threshold motor habit linked to workplace vigilance, driving, post-prandial digestion, and bowel evacuation. On FTND-ST item analysis and clinical follow-up, patients reported that they no longer woke up with an urgent compulsion to chew within the first 30 minutes of the morning, retained the quid for much shorter durations, and reduced the quantity of tobacco per pinch. However, when experiencing reduced peak cravings and healed oral mucosa, several participants continued the conditioned tactile gesture of placing tiny pinches in the buccal sulcus during work shifts. This highlights a critical clinical distinction: while homoeopathic simillimum therapy effectively downregulates neurobiological withdrawal and mucosal distress, extinguishing deeply automatized motor rituals requires concurrent behavioral habit-reversal training.

Unlike fixed-protocol trials that assign equal numbers of patients to pre-selected remedies, the unequal descending distribution observed in our cohort—ranging from *Arsenicum album* (n = 16) and *China* (n = 14) down to *Phosphorus* (n = 4) and *Spigelia* (n = 3)—reflects the epidemiological reality of constitutional prescribing in an Indian de-addiction clinic. *Arsenicum album* emerged as the single most frequently indicated remedy (16.0%), achieving highly significant reductions across OHIP-18 (Δ = 5.25 ± 3.04, $p < 0.001$, $d = 1.73$), FTND-ST (Δ = 2.19 ± 1.60, $p < 0.001$, $d = 1.37$), and subjective craving (Δ = 1.50 ± 2.37, $p = 0.023$). In chronic gutkha chewers, prolonged exposure to slaked lime and areca alkaloids produces burning stomatitis, xerostomia with unquenchable thirst for small sips, gastric epigastric burning, and profound nocturnal restlessness accompanied by fear of developing oral cancer—a clinical picture that corresponds directly to the pathogenetic totality of *Arsenicum album*[10,12].

Cinchona officinalis [China] (n = 14, 14.0%) and *Nux vomica* (n = 13, 13.0%) represented the second and third most frequent prescriptions. *China* proved remarkably effective in improving oral health quality of life (OHIP-18 Δ = 5.79 ± 4.58, $p = 0.004$) and curbing craving (Δ = 1.86 ± 2.91, $p = 0.033$), while reducing daily intake by 2.14 sessions/day. Clinically, *China* suited chronic chewers presenting with sallow pallor, chronic sialorrhea (excessive loss of salivary fluids from constant spitting), flatulent dyspepsia, and hyperesthetic gingivae sensitive to the slightest touch.[11] *Nux vomica* demonstrated balanced efficacy in reducing physical dependence (FTND-ST Δ = 1.62 ± 2.26, $p = 0.024$), improving OHIP-18 (Δ = 3.62 ± 5.27, $p = 0.029$), and lowering daily chewing frequency by 2.00 sessions/day, matching its classic indication in overworked, irritable individuals who rely on tobacco and tea to overcome mental fatigue and chronic constipation.[10,12]

A striking pharmacological contrast was observed between *Tabacum* (n = 11) and the psychogenic remedies *Ignatia amara* (n = 10) and *Staphysagria* (n = 9). Patients prescribed *Tabacum* achieved the largest statistically significant drop in daily chewing sessions across the entire trial (Δ = 3.73 ± 4.38 sessions/day, $p = 0.008$, $d = 0.85$) alongside a solid reduction in FTND-ST (Δ = 1.82 ± 1.99, $p = 0.013$), yet exhibited virtually no reduction in self-reported cognitive craving (Δ = 0.18 ± 1.78, $p = 0.742$). Classical homoeopathic pharmacology explains this divergence:

Tabacum acts primarily on the autonomic and vagal centers to induce a state of physiological intolerance—characterized by gastric sinking, sialorrhea, and nausea at the smell or taste of tobacco—thereby compelling the patient to curtail daily chewing episodes even while the psychological desire remains active.[10,11] Conversely, *Ignatia amara* produced the highest reduction in OHIP-18 impairment ($\Delta = 6.00 \pm 4.19$, $p = 0.001$), the largest FTND-ST drop ($\Delta = 2.30 \pm 2.83$, $p = 0.030$), and a marked reduction in subjective craving ($\Delta = 2.20 \pm 2.20$, $p = 0.012$). Together with *Staphysagria* (OHIP-18 $\Delta = 5.78 \pm 4.66$, $p = 0.006$), which is classically indicated for spongy, easily bleeding gums and emotional suppression,[11,18] these findings confirm that addressing underlying affective distress directly resolves psychosomatic craving.

Among the less frequently indicated remedies (n = 3 to 8), each fulfilled a specific clinical niche within the Repertorial spectrum. *Natrum carbonicum* (n = 8) significantly reduced both OHIP-18 ($\Delta = 2.88 \pm 3.14$, $p = 0.036$) and FTND-ST ($\Delta = 1.62 \pm 1.69$, $p = 0.029$) in lethargic, heat-intolerant patients with chronic oral aphthae. *Caladium seguinum* (n = 7), long regarded by *Hering* and *Clarke* as a premier remedy for tobacco heart and burning dryness of the mouth[11,12], yielded a highly significant improvement in Oral quality of life (OHIP-18 $\Delta = 5.43 \pm 3.69$, $p = 0.008$, $d = 1.47$) and a 2.00-point mean drop in craving. *Erythroxylum coca* (n = 5) significantly improved OHIP-18 ($\Delta = 5.40 \pm 3.05$, $p = 0.017$) and lowered FTND-ST by 2.00 points in manual laborers accustomed to chewing tobacco to stave off hunger and fatigue. Finally, although *Phosphorus* (n = 4) and *Spigelia anthelmia* (n = 3) had small sample sizes reflecting their narrower clinical indications—hemorrhagic gingivitis with burning thirst in *Phosphorus*, and left-sided facial/dental neuralgia with palpitations in *Spigelia* (which nonetheless showed a significant 3.33-session/day drop in chewing, $p = 0.010$)—their inclusion underscores the necessity of preserving full Repertorial flexibility in clinical trials of Homoeopathy.

4.1 Strengths and Methodological Limitations

Key strengths of this investigation include its prospective 6-month follow-up duration, high participant retention (92.6% of screened subjects), Computerized Repertorization via CARA software to minimize prescriber arbitrariness, single-blinding with interspersed *Sacchrum lactis* (*Rubrum*) control phases, and the simultaneous evaluation of physical dependence (FTND-ST) and Oral-health quality of life (OHIP-18). Several methodological limitations must nevertheless be acknowledged. First, the study employed a single-arm interventional cohort design without a parallel, double-blind, placebo-only control group; consequently, non-specific consultation effects (the therapeutic empathy of the Homoeopathic Case-taking interview) and regression to the mean cannot be completely separated from specific remedy action. Second, daily tobacco consumption frequency was assessed via patient self-report, which is susceptible to recall bias and social desirability reporting; future trials should incorporate objective biochemical verification using urinary or salivary cotinine assays. Third, because remedies were allocated naturally by individualized symptom totality, sample sizes in the lower-frequency subgroups (*Coca, Phosphorus, and Spigelia*, n = 3–5) were underpowered for standalone parametric inference. Multi-center randomized controlled trials with larger stratified cohorts and structured cognitive-behavioral habit-reversal therapy are recommended to build upon these findings.

5. Conclusion

This prospective, single-blind clinical study demonstrates that individualized Homoeopathic medicines selected through systematic Repertorization are highly effective in reducing physical nicotine dependence (FTND-ST), subjective craving intensity, and oral-health-related quality of life impairment (OHIP-18) among chronic smokeless tobacco users over a 6-month period. The distinct clinical profiles observed across the eleven prescribed remedies—where constitutional polychrests such as *Arsenicum album, Cinchona officinalis, Nux vomica, Ignatia amara,* and *Staphysagria* excelled in resolving neuro-affective craving and oral mucosal morbidity, while *Tabacum* exerted the strongest action in curbing daily chewing frequency—validate the classical Hahnemannian principle of individualized prescribing. Integrating individualized homoeopathic care with targeted behavioral habit-reversal counseling offers a safe, cost-effective, and non-toxic therapeutic strategy for comprehensive smokeless tobacco de-addiction.

Declarations

Ethics Approval and Consent to Participate: The study protocol was approved by the Institutional Ethical Committee of Janardan Rai Nagar Rajasthan Vidyapeeth (Deemed to be University), Udaipur, Rajasthan, India. Written informed consent (in Hindi/English) was obtained from all 100 participants prior to study enrollment.

Consent for Publication: Not applicable, as no identifiable individual patient images or personal clinical identifiers are disclosed.

Availability of Data and Materials: The anonymized master chart and statistical datasets generated and analyzed during the current study are available from the corresponding author upon reasonable request.

Competing Interests: The authors declare that they have no known competing financial interests or

personal relationships that could have appeared to influence the work reported in this paper.

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Author Contributions: PT conceived the study protocol, conducted clinical case-taking, repertorization, and patient follow-ups at the Bhopal OPD, and drafted the manuscript. LJ supervised the doctoral research design, verified repertorial totality selections, and critically revised the manuscript. JNS contributed to homoeopathic posology, pharmacopoeial quality assurance, and statistical interpretation. SVR provided methodological oversight and clinical validation. MC and AC assisted in data curation, statistical verification, and literature review. All authors read and approved the final manuscript.

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