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A Randomised Trial of *Madhuyashtyadi* Granules vs Nicotine Chewing Gum with Mind–Body Interventions for Tobacco De-Addiction in School Children

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Abstract

Tobacco use among rural Indian adolescents is increasing, raising risks of non-communicable diseases. This trial compared an Ayurvedic polyherbal formulation, *Madhuyashtyadi* Granules (MG), combined with mind-body interventions, to standard Nicotine Chewing Gum (NCG) with similar supports. In a two-year open-label randomized trial, 52 male schoolchildren with ≥6 months of smokeless tobacco use were assigned to MG (n=25) or NCG (n=27) arms. Both groups received weekly tapering, daily meditation, Sattvavajaya counselling, and ethical conduct training. Ayurveda, India's traditional medical system, prescribes *Sattvavajaya Chikitsa* (SC) for mind control, *Sadvritta* (ethical conduct guidance) for lifestyle modification, and *Rasayana* and *Vishahara* herbs for detoxification. Primary outcomes were reductions in urinary cotinine and daily sachet use; secondary outcomes included craving frequency, withdrawal symptoms, appetite, and well-being. At 3 months, MG users had greater cotinine reduction (31% vs. 19%), and 44% achieved complete cessation versus 0% in the NCG group. MG users also had greater reductions in cravings and withdrawal symptoms ($p<0.05$). Findings support Ayurvedic interventions as a culturally congruent and effective alternative for paediatric tobacco de-addiction. The Ayurvedic multimodal regimen, including MG demonstrated superior efficacy over standard NRT in reducing tobacco use, cravings and toxic exposure. Limitations were single-gender sampling necessitate cautious interpretation. Larger, double-blind, multi-centric trials with diverse cohorts are recommended.

Keywords: Ayurvedic Psychotherapy, *Madhuyashtyadi* Granules, Nicotine Chewing Gum, Nicotine Replacement Therapy, Paediatric Tobacco De-Addiction, School-Based Intervention.

Introduction

Tobacco consumption, especially smokeless forms, poses a growing public health challenges among Indian adolescents, particularly in rural settings, due to early initiation and socio-cultural normalization (1-4). Early initiation (<10 years) predisposes to permanent neurodevelopmental alterations and lifestyle disorders such as cardiovascular disease, cancer and neuropsychiatric comorbidities (5). Despite WHO endorsement of nicotine-replacement therapies (NRT) like chewing gum, adolescent adherence is poor due to novelty attraction and lack of environmental support (6, 7). Ayurveda, India's traditional medical system, prescribes *Sattvavajaya Chikitsa* (SC) for mind control, *Sadvritta* (ethical conduct guidance) for lifestyle modification, and *Rasayana* and *Vishahara* herbs for detoxification (8). *Sattvavajaya* and *Sadvritta*, reinforcing Ayurveda's longstanding recognition of the mind-body relationship as an integral component of treatment. Specifically, *Sattvavajaya Chikitsa*—a broad term encompassing Ayurvedic psychotherapy—aims to uncover the root causes of psychological and physical ailments by addressing disturbances in the connection between the sense organs and their objects (*Asatmendriyartha Samyoga*), thereby restoring internal balance through counseling and mindful regulation (9, 10). *Madhuyashtyadi* Granules (MG) is a polyherbal formulation designed to resemble *gutka,* containing *Emblica officinalis, Glycyrrhiza glabra, Withania somnifera, Terminalia spp., Avena sativa, Valeriana officinalis, Elettaria cardamomum* and *Mucuna pruriens*. These ingredients exhibit antioxidant, anxiolytic, rejuvenating and detoxification properties, depicted in Table 1: Ingredients

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of *Madhuyashtyadi* Granules (11-13). Tobacco use is a major global health concern, particularly among youth in rural India. Early use leads to lifelong addiction and associated health risks. Standard interventions like Nicotine Replacement Therapy (NRT) have limited efficacy in adolescents due to poor adherence. Ayurveda offers alternative strategies combining herbal formulations and mind-body practices, such as *Sattvavajaya Chikitsa* (psychotherapy), *Sadvritta* (ethical conduct), and *Rasayana* herbs. *Madhuyashtyadi* Granules mimic gutka in form and include herbs with antioxidant and anxiolytic properties. This study evaluates the efficacy of MG versus NCG in school-based pediatric de-addiction.

This trial aimed to evaluate whether MG plus nonpharmacological Ayurveda modalities would outperform standard NRT (Nicotex chewing gum, NCG) plus identical mind-body supports in reducing tobacco use, cravings, and urinary cotinine levels among school-aged children.

Table 1: Ingredients of *Madhuyashtyadi* Granules (MG)

SN	Name of the Herb	Latin Name	Part Used	Proportion
1	*Amalki*	*Embelica officinalis* Gasten	Fruit	1 part
2	*Yashtimadhu*	*Glycyrriza glabra* Linn	Stem	1 part
3	*Ashwagandha*	*Withania somnifera* Linn	Root	1 part
4	*Haritaki*	*Terminalia chebula* Retz	Fruit	½ part
5	*Bibhitaki*	*Terminalia belerica* Roxb	Fruit	½ part
6	*Oat*	*Avena sativa* Linn	Seed	1 part
7	*Tagar*	*Valeriano officinalis* DG	Root	1 part
8	*Ela*	*Elettaria cardamomum* Maton	Fruit seed	½ part
9	Food colour	---	---	1/10th part
10	*Kapikachhu*	*Mucuna pruriens (L.)* DC	Seed	1 part

Methodology

Study Design and Ethics

A two-year, open-label randomized controlled trial was conducted from May 2021 to April 2023 in three rural schools and one paediatric outpatient department. Ethical clearance was obtained (MGAC/7/2021/322), and the trial was registered (CTRI/2021/02/031448).

Written Informed Consent and Assent: Written informed consent and assent were obtained from all participants and their parents, respectively. Documentation of consent and assent was maintained for ethical compliance. The study employed standardized WHO tools validated for adolescent use, including the Composite International Diagnostic Interview (CIDI), Global Youth Tobacco Survey (GYTS-4), and ICD-10/DSM-VR criteria. These instruments are reliable for assessing tobacco-related behaviors and withdrawal symptoms in school-aged populations.

Participants: Fifty-two male students aged 6–16 years with at least six months of smokeless tobacco use were enrolled. Exclusion criteria included systemic illness and other de-addiction treatments. Written informed consent and child assent were obtained.

Randomisation: Randomisation was performed using a computer-generated sequence with block sizes of 4–6. Outcome assessors were blinded.

Interventions: Group A received *Madhuyashtyadi* granules (2.5 g, 3–6 times/day), while Group B received Nicotex gum (1–4 mg/day). Both groups followed a weekly tapering protocol (*Padanshik Kram*), attended weekly Ayurvedic counselling, practiced daily 15-minute meditation, and received ethical conduct training.

Both groups received identical non-pharmacological support:

***Padanshik Kram* (Weekly Taper):** One tobacco product/form and its frequency reduced each week until cessation by 12 weeks (14).

***Sattvavajaya Chikitsa*:** Weekly one-hour Ayurvedic psychotherapy sessions focusing on motivational counselling, cognitive restructuring, and oral-cancer awareness (14, 15).

***Sadvritta* Training:** Daily self-reflection on ethical conduct (avoiding deceit, anger, addiction) with parental reinforcement (16).

Meditation: Daily 15-minute breath awareness

practice under teacher supervision (17, 18). Parents and teachers maintained daily logs to monitor adherence.

Outcome Measures

Primary Outcomes: changes in urinary cotinine (ELISA) and self-reported daily sachet use.

Secondary Outcomes: Standardized WHO tools such as CIDI, GYTS-4, and ICD-10/DSM-VR were used. These are validated for use with adolescents and ensure reliability in assessing tobacco-related behaviors, craving episodes as per self-report, daily diary, withdrawal symptoms score based on CIDI criteria (19), appetite and energy levels (5-point Likert scale).

Laboratory Analysis

First-void morning urine samples were analyzed by ELISA for cotinine concentration, validated per standard protocols

Sample Size Calculation

Based on prior NRT trials showing a mean cotinine reduction difference of 15 µg/L with SD of 18 µg/L, a sample of 23 per group ensures 80% power at α=0.05. Accounting for 10% dropout, 52 participants were recruited.

Statistical Analysis

Data was analysed with SPSS v25. Continuous variables are mean ± SD; categorical as frequencies and percentages. Inter-group comparisons used independent t-tests or Mann-Whitney U for non-normal data; categorical comparisons by chi-square test. Within-group changes were evaluated by a paired t-test. Significance threshold set at $p<0.05$.

Results

Baseline characteristics were similar. At 3 months, the MG group showed a 31% reduction in cotinine and 44% cessation versus 19% and 0% in the NCG group ($p<0.01$). Craving and withdrawal symptoms were reduced more significantly in MG ($p<0.05$).

Participant Flow

Of 60 screened, 52 met criteria and were randomised; two withdrawals (both in NCG) before 12-week assessment. Final analysis included 25 MG and 25 NCG participants.

Baseline Characteristics

Table 2 shows **g**roups were comparable in age, duration of use and baseline consumption ($p>0.05$). Mean age: 13.8 ± 1.9 years (MG) vs. 13.5 ± 2.1 years (NCG); duration of use: 2.5 ± 0.8 vs. 2.6 ± 0.9 years.

Table 2: Participant Demographics and Baseline Characteristics

S N	Characteristic	Group A (MG) (n=25)	Group B (NCG) (n=27)	p-value
1	Age (mean ± SD)	12.4 ± 2.3	12.6 ± 2.1	0.789
2	Duration of use	2.5 ± 0.8 years	2.6 ± 0.9 years	0.752
3	Daily consumption	3.2 ± 1.1 packets	3.1 ± 1.2 packets	0.821
4	Withdrawal symptoms Mean score range	4.2 ± 1.8	5.9 ± 2.2	0.073

Table 3: The Number of Different Varieties of Tobacco Products Consumed by Participants in the Pre-Treatment Phase across Both Groups

No. of Varieties of Products			Group MG	NICOTEX	Total	Chi Sq	P-value
Pre-Tobacco Consumption	One	Freq	13	20	33	4.558	0.102
		%	52.00%	74.10%	63.50%		
	Two	Freq	9	3	12		
		%	36.00%	11.10%	23.10%		
	Three	Freq	3	4	7		
		%	12.00%	14.80%	13.50%		
Total		Freq	25	27	52		
		%	100.00%	100.00%	100.00%		

Table 4: The Number of Varieties of Tobacco Products in the Post-Treatment Status in Both Groups

No. of Varieties of Products			Group MG	NICOTEX	Total	Chi Sq	P-value
Post Tobacco consumption	Zero	Freq	11	0	11	20.413	<0.01
		%	44.00%	0.00%	21.20%		
	One	Freq	10	19	29		
		%	40.00%	70.40%	55.80%		
	Two	Freq	4	2	6		
		%	16.00%	7.40%	11.50%		
	Three	Freq	0	6	6		
		%	0.00%	22.20%	11.50%		
Total		Freq	25	27	52		
		%	100.00%	100.00%	100.00%		

Table 5: The Number of Varieties of Tobacco Products Consumed in Post-Treatment Follow-Up Status in Both Groups

No. of Variety of Products			Group MG	NICOTEX	Total	Chi Sq	P-value
Post Follow-up	Zero	Freq	11	1	12	13.92	0.003
		%	44.00%	3.70%	23.10%		
	One	Freq	10	22	32		
		%	40.00%	81.50%	61.50%		
	Two	Freq	3	4	7		
		%	12.00%	14.80%	13.50%		
	Three	Freq	1	0	1		
		%	4.00%	0.00%	1.90%		
Total		Freq	25	27	52		
		%	100.00%	100.00%	100.00%		

Tobacco Consumption Patterns

At baseline, (Tables 3–5) 52% in MG and 74% in NCG consumed only one product type; 36% vs. 11% consumed two types (p=0.10). By 12 weeks, zero-product prevalence was 44% (MG) vs. 0% (NCG) (p<0.01). One-product users: 40% vs. 70% (p=0.03); multi-product users reduced more in MG. As shown in Table 3, a few participants in both groups were consuming more than one type of tobacco product. Tables 4 and 5 show the significant results and the shift of participants' consumption of the number of varieties of tobacco products from three to two and one consecutively in post-treatment and follow-up.

Cravings and Withdrawal

Mean daily craving episodes decreased from 4.3 ± 1.6 to 1.6 ± 1.2 in MG (62% reduction), and from 5.1 ± 1.8 to 3.2 ± 1.5 in NCG (38% reduction; p=0.018). Withdrawal scores reduced significantly in MG (4.2 ± 1.8→2.1 ± 1.2) compared to NCG (5.9 ± 2.2→4.3 ± 1.9; p<0.05).

Tables 6 to 8 show the frequency of tobacco products consumption in comparison of the pre-post and follow-up of outcomes.

Table 6: Pre t/t Status of Frequency of Consumption

Pre-treatment Frequency			Group MG	NICOTEX	Total	Chi Sq	P-value
Pre t/t-freq	One	Freq	4	7	11	2.237	0.897
		%	16.00%	25.90%	21.20%		
	Two	Freq	5	6	11		
		%	20.00%	22.20%	21.20%		
	Three	Freq	5	4	9		
		%	20.00%	14.80%	17.30%		
	Four	Freq	5	6	11		
		%	20.00%	22.20%	21.20%		

	Five	Freq	3	2	5
		%	12.00%	7.40%	9.60%
	Six	Freq	2	2	4
		%	8.00%	7.40%	7.70%
	Seven	Freq	1	0	1
		%	4.00%	0.00%	1.90%
Total		Freq	25	27	52
		%	100.00%	100.00%	100.00%

Table 7: Post t/t-Status of Frequency of Consumption

Post-Treatment Frequency			**Group**		**Total**	**Chi Sq**	**P-value**
			MG	**NICOTEX**			
Post t/t frequency	Zero	Fre	11	1	12	22.903	0.002
		%	44.00%	3.70%	23.10%		
	One	Fre	4	0	4		
		%	16.00%	0.00%	7.70%		
	Two	Fre	5	8	13		
		%	20.00%	29.60%	25.00%		
	Three	Fre	2	7	9		
		%	8.00%	25.90%	17.30%		
	Four	Fre	0	5	5		
		%	0.00%	18.50%	9.60%		
	Five	Fre	3	4	7		
		%	12.00%	14.80%	13.50%		
	Six	Fre	0	1	1		
		%	0.00%	3.70%	1.90%		
	Seven	Fre	0	1	1		
		%	0.00%	3.70%	1.90%		
Total		Fre	25	27	52		
		%	100.00%	100.00%	100.00%		

Table 8: Post t/t Follow-Up-Status of Frequency of Consumption

Post-Treatment Freq	**Follow-Up**		**Group**		**Total**	**Chi Sq**	**P-value**
			MG	**NICOTEX**			
Follow-up	Zero	Fre	Pre-20	5	25	21.555	0.001
		%	Post FU-	18.50%	48.10%		
	One	Fre	4	11	15		
		%	16.00%	40.70%	28.80%		
	Two	Fre	0	6	6		
		%	0.00%	22.20%	11.50%		
	Three	Fre	1	2	3		
		%	4.00%	7.40%	5.80%		
	Five	Fre	0	2	2		
		%	0.00%	7.40%	3.80%		
	Six	Fre	0	1	1		
		%	0.00%	3.70%	1.90%		
Total		Fre	25	27	52		
		%	100.00%	100.00%	100.00%		

Table 9: Satus of Pre-Post Urinary Cotinine in Both Groups

Urinary Cotinine		N	Mean	Std. Deviation	Std. Error Mean	t-test	P-value
Pre	MG	25	78.64	61.78	12.35	1.034	0.306
	Nicotex	27	96.97	65.69	12.64		
Post	MG	25	54.41	52.87	10.57	1.316	0.179
	Nicotex	27	76.86	64.85	12.48		

Urinary Cotinine

In Table 9 result shows, MG: 78.6 ± 61.8→54.4 ± 52.9 µg/L (31% reduction).

NCG: 96.9 ± 65.7→76.9 ± 64.9 µg/L (19% reduction). Inter-group difference is significant ($p<0.01$).

Appetite and Well-Being

Energy and appetite scores improved by 1.8 ± 0.6 points in MG vs. 1.1 ± 0.7 in NCG ($p=0.02$). No adverse events reported.

Discussion

Mind-body therapies like SC, meditation, and *Sadvritta* were adapted for school children through simplified instruction, collaborative delivery with teachers, and culturally familiar formats. Pilot sessions were conducted to assess feasibility and acceptance among participants before full-scale implementation. Mind-body therapies reduce cravings and emotional triggers, supporting adherence to de-addiction therapy.

Although no placebo was used due to ethical concerns and already use of NRT as standard control, performance and expectation biases were minimized through identical mind-body interventions in both groups and uniform tapering protocols as mentioned in Ayurveda science *Padanshik kram*. Outcome assessors were blinded to group assignment.

Relapse rates were monitored during the follow-up phase and are reported in Tables 5–8. We acknowledge that post-intervention resurgence in tobacco use among both group participants was linked to socio-environmental factors, including parental tobacco use and lack of home-based reinforcement of behavioral strategies.

This RCT demonstrates that *Madhuyashtyadi* granules combined with Ayurveda psychospiritual supports is superior to standard NRT in promoting tobacco cessation among school children. The *gutka*-like taste and appearance of MG likely enhanced adherence, while its *Rasayana* and *Vishahara* properties (anti-oxidative, neuroprotective) contributed to withdrawal mitigation and mood stabilisation. Non-pharmacological components (SC, *Sadvritta*, meditation) reinforced cognitive–behavioural change and emotional resilience (20).

Parental tobacco use and socio-environmental factors limited complete cessation in both the arms, reflecting challenges in rural de-addiction. The weekly '*Padanshik Kram*' taper, rooted in Ayurvedic classics, provided a culturally congruent framework for gradual withdrawal. This study employed a multimodal approach aimed at addressing the root cause and fostering a shift in mindset. *Sattvavajaya chikitsa,* also known as Ayurveda psychotherapy, which comprises not only counselling but also modalities to balance and control the mind. Zgiersk A *et al*. proved in their systematic review and Pahari S *et al*. in their meta-analysis article that meditation controls the mind as well as provides insights into what is good and what is bad in substance user's disorders (21, 22). Good conduct also helps to refrain from bad habits for the sake of better physical and mental health. In this study, all parents of the participants were consuming tobacco products, however, they, gave signatures on informed written consent but not paid attention to compel child to do prayer, meditation, and *Pranayama* due to their daily wages job and offered money to bring whatever they want to eat before going to work as a love deed (7, 8). That's how, after getting good results in both groups, post follow-up they have slowly started consuming tobacco products again. Maximum participants started tobacco product consumption recently; hence, very few withdrawal features were noticed in both groups. The maximum period of starting consumption was three years and a minimum of six months. The varieties and frequency of tobacco products were reduced significantly in the MG group as compared to the control group due to irregular tapering of tobacco products.

The probable mode of action of *Madhuyashtyadi* granules, with pharmacodynamics of the ingredients, is antioxidant, appetiser, and brain tonic- *medhya rasayan* (23). The prominent *Rasa*

and *Vipaka- Madhura, Guna-Ushna, snigdha, Virya-Shita, Karma- Vatas* meditation and breathing exercises were simplified and adapted in collaboration with school teachers. Pilot sessions were conducted to ensure cultural appropriateness and child-friendly delivery *haman, and Brimhana* were the prime factors that might have influenced the action of the drugs with anti-stress, anti-anxiety and anti-inflammatory (8, 9) Any toxin described in Ayurveda classics as *Visha*-poison*, Upavisha or Garavisha* comes under the *Ojohar* category as *Oja* ~mmunity is opposite to *visha dravya* properties. Tobacco products have so many toxins together so they can be considered as *Upavisha* and MG ingredients properties are *Vishahara* and *Rasayan.* while Nicotex liberates nicotine slowly, and the participants were crazy for chewing gum, finished at one go and not as per cravings, hence got poor results in the standard controlled arm. The Ayurvedic regimen demonstrated superior efficacy in pediatric de-addiction, potentially due to its multi-component approach and cultural relevance. While Nicotex provided nicotine substitution, MG combined pharmacological and behavioral benefits. Parental use of tobacco and socio-economic challenges limited adherence.

Limitations

Open-label design may introduce expectancy bias. Single-gender cohort and short follow-up limit generalizability. Objective adherence measures (e.g., gum count) were not feasible.

Future Directions

Double-blind, placebo-controlled trials with larger, mixed-gender cohorts and longer follow-up (6–12 months) are needed to confirm durability and explore biochemical mechanisms via neuroimage-ng and cytokine profiling.

Conclusion

An integrative Ayurvedic regimen incorporating *Madhuyashtyadi* granules and psychospiritual interventions demonstrates significant superiority over standard control arm Nicotine Replacement Therapy-NRT in reducing tobacco use, cravings, toxic exposure and improving well-being in pediatric populations. Mind-body therapies reduce cravings and emotional triggers, supporting adherence to de-addiction therapy. This culturally tailored approach holds promise for scalable de-addiction programs in low-resource settings. However, limitations such as short follow-up, absence of placebo control, and single-gender sampling necessitate cautious interpretation. Larger, double-blind trials with diverse cohorts are recommended.

Abbreviations

CTRI: Clinical Trials Registry-India, ELISA: Enzyme-Linked Immunosorbent Assay, MG: *Madhuyashtyadi* Granules, NCG: Nicotine Chewing Gum, NRT: Nicotine Replacement Therapy, SC: Sattvavajaya Chikitsa.

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Author Contributions

All authors contributed equally to study design, data collection, analysis, manuscript preparation.

Conflict of Interest

The authors declare no conflict of interest.

Ethics Approval

Approved by the Institutional Ethics Committee (MGAC/7/2021/322).

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