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Research Article

EFFECT OF *VACHALASUNADI TAILAM* AS *MUKHABHYANGA* AND *SHIROABHYANGA* IN SIALORRHEA OF CHILDREN WITH CEREBRAL PALSY AGED 4-12 YEARS

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ABSTRACT

Sialorrhea in children with cerebral palsy arises from oro-facial neuromuscular dysfunction. In Ayurveda, this presentation is understood as *Lalasrava* (salivation) or *Praseka* (excessive salivation), driven by *Kapha* (phlegm) *Avarana* (occlusion) obstructing *Prana* and *Vyana Vayu* (types of bodily air) within the oral cavity (*Mukha Sthana*). This single-arm, prospective, pre-post clinical trial enrolled 24 pediatric participants aged 4–12 years with a confirmed diagnosis of cerebral palsy and frequent anterior drooling (CTRI/2023/11/059985) to evaluate the clinical efficacy of *Vachalasunadi Tailam* (medicated herbal oil) administered via combined *Mukhabhyanga* (facial oil massage) and *Shiroabhyanga* (head oil massage). *Vachalasunadi Tailam* was administered once daily at home by trained parents for 21 consecutive days (5ml for *Mukhabhyanga* with orofacial stimulation; 2.5ml for *Shiroabhyanga*). Primary outcomes were evaluated at baseline (day 0), post-intervention (day 22), and follow-up (day 53) using the Drooling Quotient-Five Minutes and the Drooling Questionnaire for Indian children with cerebral palsy. Pairwise comparisons of both assessment tools showed a highly significant reduction in drooling frequency and severity from baseline to day 22 ($p<0.01$). This therapeutic effect was sustained at the day 53 follow-up ($p<0.01$) with zero reported adverse drug reactions. Combined *Mukhabhyanga* and *Shiroabhyanga* with *Vachalasunadi Tailam* is a safe, effective home intervention that achieves *Vata Anulomana* (regularization of nervous impulses), systematically clears *Kapha Avarana*, improves oro-motor coordination, and enhances quality of life.

INTRODUCTION

Cerebral Palsy (CP) remains the leading cause of permanent childhood motor disability, affecting 1 to 5 per 1,000 live births globally[1]. Characterized as a non-progressive neurological disorder originating from an insult to the developing fetal or infant brain, CP manifests through a spectrum of clinical severities, ranging from mild motor coordination deficits to profound physical disability. While spasticity stands as the predominant motor abnormality, other clinical phenotypes include dyskinetic, ataxic, and mixed forms. Beyond primary motor impairments, CP is complicated by a constellation of comorbid challenges, including disturbances in sensory perception, cognitive deficits, communication barriers, behavioral disorders, secondary musculoskeletal deformities, and epilepsy[2]. Among these secondary manifestations, oral-motor and sensory dysfunctions are common, causing severe feeding difficulties, compromised somatic growth, impaired speech development, and an inability to manage oral secretions.

Sialorrhea, or pathological drooling, is a debilitating manifestation that impacts 10% to 58% of children diagnosed with CP. Rather than arising from an overproduction of saliva, sialorrhea in this population is primarily driven by an underlying deficit in the neuromuscular and sensory systems that govern oral mechanisms and postural control[3]. The involuntary, persistent loss of saliva is caused by reduced automatic swallowing frequency, poor oral-motor coordination, inadequate lip closure, and

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decreased sensory awareness within the orofacial musculature.

The clinical and psychosocial consequences of untreated sialorrhea are profound. Physically, continuous exposure to salivary enzymes causes chronic perioral skin maceration, tissue breakdown, halitosis, and recurrent local infections. Psychosocially, it induces social isolation, peer marginalization, and a severe reduction in self-esteem[4]. Furthermore, managing severe drooling elevates caregiver burden, requiring continuous clothing changes and constant skin care, which places families under immense emotional and economic stress. Effective management of sialorrhea is recognized as a vital determinant in improving the global quality of life and social integration for both the affected children and their caregivers[5].

Conventional management strategies encompass surgical salivary duct rerouting, behavioral interventions, intraoral appliances, localized botulinum toxin injections, and systemic pharmacological therapies, such as anticholinergic agents. While these interventions reduce salivary flow, they are frequently limited by undesirable adverse effects, including severe xerostomia, diarrhoea, blurred vision, urinary retention, loss of taste, vomiting, and paradoxical insomnia. Due to these chronic side effects and the invasive nature of surgical options, families express dissatisfaction with conventional treatments[5]. This underscores an urgent clinical need for tolerable, effective, non-invasive, and sustainable strategies, driving research interest toward validated traditional, complementary, and integrative medical frameworks.

Cerebral palsy can be comprehensively understood in Ayurveda by combining the mechanics of *Vata vyadhi* (disease caused by vitiated *Vata*) with the developmental timelines of *Phakka roga* (delayed milestone disease)[6]. The neuromuscular features of spastic, hemiplegic, and diplegic CP align with *Vata prakopa lakshanas* (symptoms of *Vata* aggravation) like *Sankocha* (spasticity)[7] or *Vatavyadhis* like *Pakshaghata* (hemiplegia)[8], *Sarvangaroga* (generalized neurological illness), or *Akshepaka* (convulsive spasms)[9]. Meanwhile, *Vyadhija phakka*[10] addresses the chronic, systemic developmental delays where a child fails to walk by one year of age. Management focuses on correcting *Agni* (digestive fire), followed by *Snehana* (oleation), *Swedana* (sudation), and *Vasti* (medicated enema) to relieve rigidity, prevent muscle wasting, and enhance motor function.

Although classical Ayurveda lacks a direct equivalent for sialorrhea, its clinical presentation mirrors *Lalasrava* or *Praseka*. Pathological drooling in CP stems from neurological deficits that cause oro-facial motor dysfunction, resulting in poor lip closure and impaired swallowing reflexes. Patho-physiologically, motor initiation and muscular movements (*Chesta*) are governed by *Vata dosha*. Specifically, failure of lip closure involves *Vyana vayu dushti* (dysfunction of pervading nervous energy), while impaired swallowing reflex implicates *Prana vayu dushti* (dysfunction of vital inward nervous energy). However, because the oral cavity (*Mukha*) is a primary site of *Kapha* (*Kapha sthana*), this dysfunction is driven by *Kapha avarana*, where vitiated *Kapha* occludes the natural pathways of *Vata*.

Therapeutic intervention must simultaneously clear *Kapha avarana* and pacify *Vata*. The protocol relies on sequential *Snehana* and *Swedana*. *Mukhabhyanga* combined with specialized *mardana* (therapeutic massage) provides local mobilization. Crucially, because the underlying pathology originates in the brain (*Mastulunga majja*), targeting the *Siras* (head) is mandatory. Centrally acting external therapies collectively termed *Murdhataila*[11], including *Shiroabhyanga*, *Shirodhara*, *Shiropichu*, and *Shirovasti*, directly pacify *Vata kopa* in *Siras*, thereby enhancing neuromuscular coordination and reducing sialorrhea. While *Shirovasti* is the most effective, *Shiroabhyanga* offers a viable alternative for outpatient settings due to its affordability and ease of administration.

Vachalasunadi Tailam[12], described in the *Taila prakaranam* of *Sahasrayogam*, was selected as the trial drug. This formulation comprises four ingredients: *Vacha* (*Acorus calamus*)[13], *Lashuna* (*Allium sativum*)[14], *Haridra* (*Curcuma longa*)[15], and *Bilvapatra* (*Aegle marmelos*)[16]. These herbs possess *Vata-kapha samana* properties, making the formulation highly effective in mitigating *Vata kopa* by removing *Kapha avarana*. The precise aim of this clinical study is to evaluate the efficacy of *Vachalasunadi Tailam*, administered via *Mukhabhyanga* and *Shiroabhyanga*, in managing sialorrhea in children with cerebral palsy aged 4 to 12 years.

MATERIALS AND METHODS

Study design and settings

This study was designed as a single-arm, interventional, prospective, pre-post clinical trial. Pediatric participants were recruited from the Outpatient Department (OPD) of Kaumarabhritya, Government Ayurveda College Hospital for Women and Children, Poojapura, Thiruvananthapuram.

Ethical considerations and trial registration

The clinical protocol was approved by the Institutional Ethics Committee (IEC No. 631-31/08/2022) and prospectively registered with the Clinical Trials Registry-India (CTRI Reference No. CTRI/2023/11/059985). Informed objectives and

procedures were explained, and written informed consent was obtained from parents alongside child assent forms translated into Malayalam.

Inclusion criteria

- Children aged 4 to 12 years of either sex.
- A confirmed clinical diagnosis of cerebral palsy.
- Presence of frequent anterior drooling significantly impacting hygiene or social well-being.

Exclusion criteria

- Neurodegenerative conditions associated with congenital or genetic disorders.
- Acute or chronic respiratory diseases.
- Co-existing vocal pathologies, such as vocal nodules.
- Concurrent medical interventions for sialorrhea, or anti-epileptic and anti-convulsant drug regimens.

Sample size and sampling strategy

A target sample size of 24 pediatric participants was achieved using a consecutive sampling strategy, recruiting consecutive cases presenting to the outpatient clinic who met all definitive inclusion criteria.

Clinical interventions

The trial drug, *Vachalasunadi Tailam*, was prepared strictly in accordance with classical pharmaceutical standards. Caregivers were trained in application methods. The protocol was administered once daily at home for 21 consecutive days, consisting of two synchronous external therapies:

Mukhabhyanga

A volume of 5ml of lukewarm *Vachalasunadi Tailam* was applied uniformly over the patient's cheeks, jaws, and anterior cervical region. The parent performed a 20-minute localized massage incorporating four specialized techniques adapted from standard rehabilitation protocols [3]:

- Pressure (5 minutes): Firm digital pressure applied bilaterally across cheeks moving toward the lips (10 repetitions), followed by firm pressure along the lower jaw (10 repetitions).
- Tapping (5 minutes): Slow, rhythmic percussion/tapping applied uniformly over both cheeks (10 repetitions).
- Stroking (5 minutes): Firm downward bilateral strokes originating from the zygomatic arch toward the commissures of the lips (10 repetitions).
- **Stretching (5 minutes):** Gentle manual outward stretching of the cheeks and lateral corners of the mouth.

Following stimulation, the oil was retained on the skin for 10 minutes to facilitate local absorption before washing with lukewarm water.

Shiroabhyanga

Concurrently, a volume of 2ml of *Vachalasunadi Tailam* was applied daily to the scalp with a gentle, rhythmic massage. The oil remained on the scalp for 45 minutes to facilitate therapeutic action on the central nervous system framework before being washed off with lukewarm water.

Outcome measures and Timeline

Primary outcome variables evaluated were pre- and post-intervention scores of the Drooling Quotient-Five Minutes (DQ5)[17] and the Drooling Questionnaire for Indian children with CP[18]. Evaluations were structured across three intervals: Baseline (T0/Day 0), Post-Intervention (T1/Day 22), and Follow-Up (T2/Day 53).

Statistical analysis

Quantitative data were statistically analysed using SPSS software (Version 26.0). Changes between baseline and post-intervention/follow-up scores were evaluated using the paired t-test assuming a normal distribution of data, with significance set a priori at $p<0.05$.

OBSERVATION AND RESULTS

A total of 24 patients were recruited and analysed; there were no dropouts.

Socio-demographic observations

The baseline analysis revealed that the majority of participants belonged to the 4–6 years age bracket (45.83%), followed by 7–8 years (33.33%), and 9–12 years (20.83%). Males comprised 66.67% and females 33.33%. Geographically, 54.17% resided in rural areas and 45.83% in urban sectors. Socioeconomic stratification indicated 41.67% middle class, 33.33% lower class, and 25.00% upper class. Ayurvedic *Desha* (habitat) distribution showed 54.17% in *Sadharana desha* (mixed land), 41.67% in *Janghala desha* (arid land), and 25.00% in *Anoopa desha* (marshy land).

Table 1: Baseline Socio-Demographic Characteristics of the Cohort

Baseline Characteristic	Sub-category	Patient Count (n=24)	Percentage (%)
Age Group	4-6 Years	11	45.83%
	7-8 Years	8	33.33%
	9-12 Years	5	20.83%
Gender	Male	16	66.67%
	Female	8	33.33%

Socio-economic status	Lower	8	33.33%
	Middle	10	41.67%
	Upper	6	25.00%
Domicile	Rural	13	54.17%
	Urban	11	45.83%
Desha	*Sadharana*	13	54.17%
	Janghala	5	41.67%
	Anoopa	6	25.00%

Clinical observations

The cohort distribution showed spastic diplegic CP in 45.83%, spastic quadriplegic CP in 41.67%, mixed CP in 8.33%, and ataxic CP in 4.17%. Preterm birth was documented in 62.50%. Antenatal histories included hyperemesis gravidarum (29.17%), multiple gestations (16.67%), gestational hypertension (12.50%), maternal infections (12.50%), antenatal pyrexia (8.33%), and maternal trauma (4.17%). Consanguineous marriage was present in 20.83%.

Deha Prakriti analysis showed *Vata-pitta prakriti* in 37.50%, *Kapha-pitta* in 25.00%, *Vata-kapha* in 20.83%, *Pitta-vata* in 12.50%, and *Pitta-kapha* in 4.17%. Local examination showed complete inability to close lips in 54.17%, partial lip closure in 45.83%, halitosis in 58.33%, and perioral ulceration in 25.00%. Baseline feeding difficulties were present in 62.50%, chronic constipation in 58.33%, and appetite status was moderate in 41.67%, good in 33.33%, and poor in 25.00%.

Table 2: Clinical Status and Phenotypic Spectrum of the Enrolled Cohort

Diagnostic Category	Observed Parameter	Patient Count (n=24)	Cohort Percentage (%)
Cerebral palsy type	Spastic diplegic CP	11	45.83%
	Spastic quadriplegic CP	10	41.67%
	Mixed CP	2	8.33%
	Ataxic CP	1	4.17%
Gestational Maturity	Preterm birth	15	62.50%
	Full-term birth	9	37.50%
Parental & maternal history	Recurrent spontaneous abortions	6	25.00%
	Consanguineous marriage	5	20.83%
	Multiparous pregnancy	4	16.67%
Antenatal complications	Hyperemesis gravidarum	7	29.17%
	Multiple gestations	4	16.67%
	Gestational hypertension	3	12.50%
	Maternal antenatal infections	3	12.50%
	Antenatal Pyrexia (Fever)	2	8.33%
	Antepartum vaginal bleeding	1	4.17%
	Gestational maternal trauma	1	4.17%
Deha prakriti	*Vata-Pitha*	9	37.50%
	Kapha-Pitha	6	25.00%
	Vata-Kapha	5	20.83%

	Pitha-Vata	3	12.50%
	Pitha-Kapha	1	4.17%
Oro-facial examination	Complete inability to close lips	13	54.17%
	Partial lip closure	11	45.83%
Secondary oral signs	Halitosis	14	58.33%
	Perioral ulceration	6	25.00%
Gastrointestinal presentation	Feeding difficulties	15	62.50%
	Chronic constipation	14	58.33%
Baseline appetite status	Moderate appetite	10	41.67%
	Good appetite	8	33.33%
	Poor appetite	6	25.00%

Therapeutic observations

Visual representations tracking mean scores are designated on separate detached sheets (Supplementary Figures 1–3).

Effect of intervention in Drooling Quotient - 5 minutes

Table 3: Measured Mean Differences for Drooling Quotient - 5 Minutes

Treatment	N	Mean	SD
BT (Before Treatment)	24	45.10	7.28
AT (After Treatment)	24	36.04	6.91
AF (After Follow-Up)	24	35.52	7.63

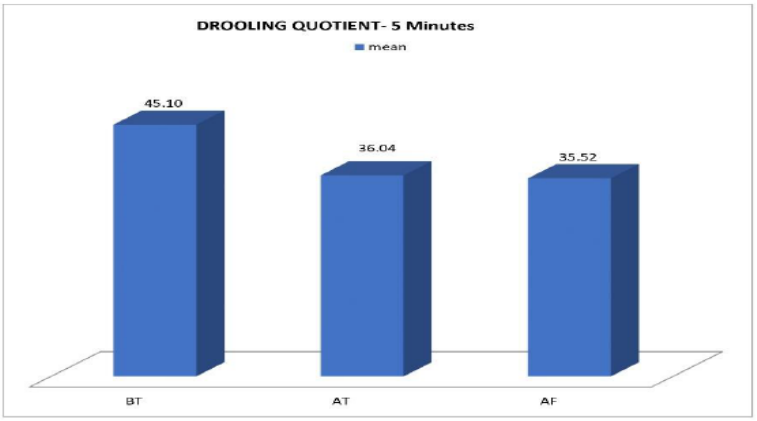

Figure 1: Vertical bar chart mapping dynamic changes in mean DQ5 scores across BT, AT, and AF periods.

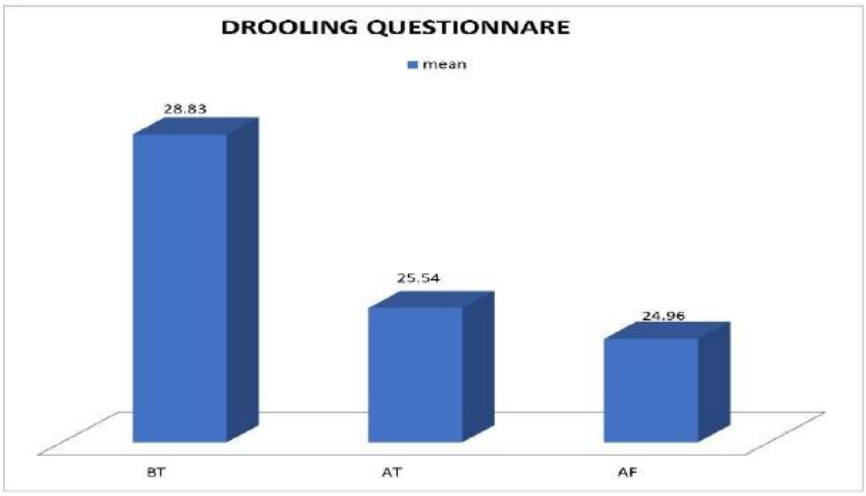

Figure 2: Comparative chart showing significant DROOLING QUESTIONNAIRE IN INDIAN CHILDREN WITH CEREBRAL PALSY score reductions tracked through the study intervals.

Table 4: Paired T-Test Variation for Drooling Quotient - 5 Minutes

Paired t	Mean	SE of Mean	df	p value
BT VS AT	9.06	0.996	23	<0.001
BT VS AF	9.58	1.100	23	<0.001
AT VS AF	0.52	0.740	23	>0.05

Since the p-value is less than 0.01 for pairs (BT, AT) and (BT, AF), the results are highly significant.

Effect of intervention in Drooling Questionnaire in Indian Children with Cerebral Palsy

Table 5: Measured Mean Differences for the Pediatric Drooling Questionnaire

Treatment	N	Mean	SD
BT (Before Treatment)	24	28.83	4.28
AT (After Treatment)	24	25.54	3.36
AF (After Follow-Up)	24	24.96	3.38

Table 6: Paired T-Test Variation for the Pediatric Drooling Questionnaire

Paired t	Mean	SE of Mean	df	p value
BT VS AT	3.292	0.547	23	<0.001
BT VS AF	3.875	0.427	23	<0.001
AT VS AF	0.583	0.329	23	>0.05

The results are highly statistically significant at 0.1% ($p < 0.01$) for pairs (BT, AT) and (BT, AF).

Comparison of effect of intervention in the severity of Drooling

Table 7: Severity Percentage Frequency Reconciliation

Drooling Severity	Baseline / BT (n=24)	Post-Treatment / AT (n=24)	Follow-Up / AF (n=24)
Severe	5 (20.83%)	0 (0.00%)	0 (0.00%)
Moderate	19 (79.17%)	18 (75.00%)	17 (70.83%)
Mild	0 (0.00%)	6 (25.00%)	7 (29.17%)

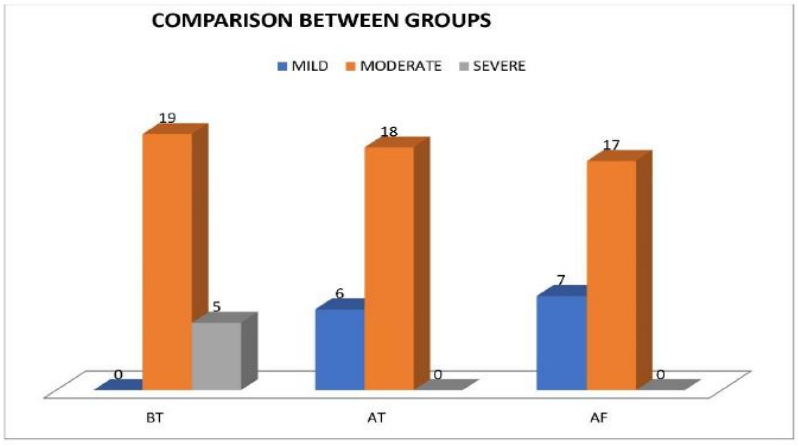

Figure 3: COMPARISON BETWEEN GROUPS ACCORDING TO SEVERITY SCALE.Severity shifts mapping the downward movement from severe to mild/moderate categories

Severe drooling was recorded in 20.83% at baseline, completely resolving to 0% both post-treatment and at follow-up. Mild cases rose from 0% to 25.00% post-treatment, and reached 29.17% at follow-up, while moderate drooling decreased progressively from 79.17% to 70.83%.

DISCUSSION

Statistical analysis and clinical significance

Pairwise comparisons of DQ5 and the Drooling Questionnaire demonstrated a highly significant reduction in post-intervention scores ($p<0.01$), establishing strong statistical significance. This quantitative decline translates to a substantial reduction in both severity and frequency of pathological drooling, directly mitigating localized hygiene challenges and caregiver burdens. Follow-up assessments conducted one-month post-treatment revealed no clinical regression, confirming excellent stability.

Bio-physical dynamics of external therapies (*Bahiparimarjana chikitsa*)

In Ayurvedic therapeutics, the efficacy of external procedures (*Bahiparimarjana Chikitsa*) relies on transdermal absorption and cellular response to the inherent attributes (*Gunas*) of the medicated oil matrix. Classical dermatology utilizes four primary somatic attributes- *Snigdha* (unctuous/oily), *Ruksha* (dry), *Sheeta* (cold), and *Ushna* (hot)- to counteract localized and systemic *Dosha* imbalances. The hyper-reactive, vitiated *Vata* driving CP demands systematic pacification (*Vata Shamana*), achieved through the combined modalities of *Snehana* and *Swedana*. *Abhyanga* fulfills both: the lipophilic nature of the oil vehicle facilitates tissue *Snehana*, while rhythmic friction (*Mardana*) combined with the *Ushna Virya* (hot potency) of the formula induces localized, mild *Swedana*.

Central and peripheral synergy: *Shiroabhyanga* and *Mukhabhyanga*

In CP, the primary site of *Vata Dosha* vitiation is located within the *Siras* (head), disrupting the *Mastulunga Majja* (brain tissue). External head therapies (*Murdhataila*), specifically prolonged *Shiroabhyanga*, are designed to stabilize intracranial *Vata*. Absorbed through the scalp, the therapeutic attributes of the oil directly address central neurological lesions within the *Mastulunga*, moderating systemic *Vata* pathology. Combined with localized *Mukhabhyanga*, it creates a synergistic approach that simultaneously addresses central coordination and peripheral muscular activation, restoring physical well-being.

Pharmacodynamics of *Vachalasunadi Tailam*

Vachalasunadi Tailam presents an ideal pharmacodynamic profile for alleviating complex *Vata-Kapha* imbalances. The liquid substrate, *Bilva Swarasa* (juice of *Aegle marmelos*), acts as a potent *Vata-hara* stabilizer. Concurrently, the processing herbs- *Vacha*, *Lashuna*, and *Haridra*- possess a dominant *Tikshna Guna* (sharp/penetrating attribute). This intensity facilitates channel purification (*Srotoshodhana*) and systematically shears through heavy, stagnant *Kapha* pooling in the oral cavity, effectively lifting the *Kapha Avarana* to restore normal *Vata* conduction. Within this formulation, *Lashuna* serves a critical dual purpose; integrated as the medicinal paste (*Kalka*), its highly penetrative properties make it the premier choice for clearing dense *Avarana* while acting as a powerful systemic *Vata-shamana* root.

Neuromuscular mechanics of resolution

The 21-day intervention protocol successfully targets both the root cause and localized symptoms of sialorrhea. Centrally, *Shiroabhyanga* pacifies deep-seated *Vata* within the central nervous system to regulate global CP pathology. Peripherally, *Mukhabhyanga* acts directly on uncoordinated oro-facial muscles: the *Tikshna Guna* clears localized *Kapha* pooling, the *Snigdha Guna* counteracts the drying, rigid nature of *Vata* to ease spasticity, and the inherent *Brimhana* (tonifying) property of the base sesame oil enhances the muscle tone of the lips and tongue, improving swallowing coordination. The combined effect achieves *Vata Anulomana*, stabilizing the swallowing reflex and significantly reducing involuntary drooling.

CONCLUSION

The findings demonstrate that *Vachalasunadi Tailam*, administered as a non-invasive external therapy, holds significant promise as an effective strategy for managing sialorrhea in pediatric CP. This study adds to the evidence supporting the integration of traditional Ayurvedic frameworks within modern pediatric neurology. Subsequent large-scale randomized controlled trials are warranted to explore long-term neuroplastic effects and expanded therapeutic applications in pediatric neuro-rehabilitation.

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