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Role of Anda thylam in Management of Dysarthria in Hemiplegia: A Prospective Randomized Control Clinical Study

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Abstract

The Siddha medicine explains 4448 diseases in their literature, among these Patcha vatham (Hemiplegia) is a very common and complicated disease in the world especially in developing countries. According to yugi vaithyachinthamani textbook, weakness of the legs and looks like a dead body, difficulty to walk, inability to holding by hands, loss of sense in hand and leg, goosing bumps, numbness, drooping of mouth, dribbling of saliva and body heat are the sign and symptoms of Patcha vatham (Hemiplegia). As per clinical features we can compare the patcha vatham with Hemiplegia in modern medicine. Naakku vatham (Dysarthria) is one of the clinical features of Patcha vatham (Hemiplegia) and it is a burden for patients. Anda thylam, is an egg yolk based oil which traditionally used for tongue related Naakku vatham (Dysarthria), yet lacks of clinical evidence. This study aims to evaluate the efficacy and safety of Anda thylam in Manegement of Naakku vatham.

A randomized control clinical trial was conducted at Base Siddha Ayurvedic Hospital, Kappalthurai, for 6 months, fifty Hemiplegia patients with Dysarthria were randomized (1:1) into test (n=25, Anda thylam + standard care) and control (n=25, standard care only) groups for 45 days. The primary outcome was the change in Robertson SJ Dysarthria Profile score and secondary outcomes included En Vakai Thervu parameters and quality-of-life measures. Data were analyzed using paired and independent t-tests with $p < 0.05$ as significant.

Both groups showed improvement, but the test group demonstrated a significantly greater mean reduction in Robertson SJ scores (11.92 ± 5.25 vs. 2.76 ± 2.56; $p < 0.001$), with a very large effect size (Cohen's $d = 2.22$). Significant enhancement in tongue deviation ($p = 0.022$) and speech clarity ($p < 0.001$) was also observed in the test group. No serious adverse events were reported, and compliance exceeded 95% in both groups. Anda thylam demonstrated significant efficacy and safety in improving speech function among Dysarthria in Hemiplegia Patients. These findings support the use of Anda thylam as a promising adjunct therapy for Dysarthria and warrant larger multicenter trials for further validation.

Keywords: Naakku Vatham; Dysarthria; Patcha Vatha; Hemiplegia

1. Introduction

Hemiplegia is one of the leading global causes of disability, accounting for approximately 143 million disability adjusted life years [1]. Among Hemiplegia complications, dysarthria a motor speech disorder resulting from neurological damage affects 20–30% of survivors [2]. It impairs respiration, phonation, articulation, resonance, and prosody, reducing speech intelligibility and affecting social and occupational functioning [3].

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Siddha System of medicine, one of the oldest traditional healing systems of South India, explains diseases through the imbalance of three humors: vatham, pitham, and kapham [4]. Within its extensive nosology of 4,448 diseases, Patcha vatham (hemiplegia) is described as weakness of the legs and looks like a dead body, difficulty to walk, inability to holding by hands, loss of sense in hand and leg, goosing bumps, numbness, drooping of mouth and dribbling of saliva. Siddha Maruthuvam Pothu defines Patcha vatham as a condition affecting the function of limbs, tongue, mouth, and eyes [5]. This definition emphasizes the multisystem involvement characteristic of the condition, highlighting the importance of oral and speech-related complications. Naakku vatham (dysarthria) is one of the clinical features of Patcha vatham (Hemiplegia), manifests as tongue Hemiplegia with loss of speech clarity, attributed to vitiated vayu affecting nerves controlling the tongue and larynx [6].

Modern medicine defines dysarthria similarly as impaired muscular control of speech due to neurological damage from Hemiplegia or other brain injuries [7. 8]. Modern management relies mainly on speech therapy, which, although beneficial, often yields incomplete recovery [9]. This gap highlights the potential role of complementary therapies such as those offered by traditional systems.

Anda thylam, is an oil derived from egg yolk, is described in Siddha texts. From a modern biochemical perspective, egg yolk contains lecithin, a phospholipid that serves as a precursor for acetylcholine, a neurotransmitter vital for neuromuscular function [10]. Research on phospholipid supplementation suggests potential benefits in neurological recovery and membrane repair after Hemiplegia [11, 12].

Despite Siddha traditional claims, Anda thylam remains scientifically underexplored. The World Health Organization advocates for evidence based evaluation of traditional medicines to ensure their safe integration into modern healthcare [13]. Given the high burden of Hemiplegia related dysarthria and limited access to specialized rehabilitation in resource-limited settings, validating such affordable and accessible Siddha remedies is of public health significance [14].

This study aims to evaluate the efficacy and safety of Anda thylam in managing Naakku vatham (Dysarthria) with Patcha vatham (Hemiplegia). It integrates both traditional Siddha diagnostic methods and modern assessment tools, including the Robertson SJ Dysarthria Profile, to comprehensively assess outcomes. The investigation also includes FTIR-based biochemical characterization and quality control testing of the preparation. It is hypothesized that patients receiving Anda thylam with Standard treatment will show greater improvement in dysarthria compared to those receiving standard treatment alone.

2. Methodology

2.1. Study Design and Setting

This study was conducted as a Prospective, Phase II, open labeled, randomized control clinical study to evaluate the therapeutic efficacy and safety of Anda thylam in managing Naakku vatham (Dysarthria) in patients with Patcha vatha.

The study was conducted at Base Siddha Ayurvedic Hospital, Kappalthurai, Trincomalee District, Sri Lanka, from the period of January to June 2024.

The study received ethical clearance approval from the Institutional Review Board of Bandaranaike Memorial Ayurvedic Research Institution (BMARI), Sri Lanka (Approval No: ERC-BMARI/2025/002) prior to participant recruitment. All study procedures were conducted in accordance with the Declaration of Helsinki (2013), Good Clinical Practice guidelines (ICH, 1), and local regulatory requirements.

2.2. Study Duration

The total study duration was six months.

2.3. Anda Thylam Preparation Protocol

Anda thylam was prepared according to traditional methods described in classical Siddha texts with standardization for quality control and reproducibility.

Raw Material Selection: Fresh country hen eggs laid within three days were procured from local free-range poultry farms. Eggs were visually inspected for cracks or contamination and only intact, clean eggs were collected for oil preparation.

Anda thylam was prepared as described in classical Siddha texts with standardized modifications to ensure consistency and safety. Ten hen's eggs were first boiled in a stainless-steel vessel for 10 minutes to ensure complete coagulation of the yolks while maintaining their therapeutic constituents. The boiled eggs were then cooled in cold water to facilitate shell removal. After deshelling, the yolks were carefully separated from the whites, and only the yolks were retained for oil extraction.

For extraction, the yolks were placed in a clean, dry iron pan (traditional method) and gently heated over a mild flame (approximately 80–100 °C). Continuous stirring with a wooden spatula was performed to prevent charring and ensure uniform heating. During the heating process, the yolks gradually melted, releasing a clear brownish yellow colour oil as the solid residue darkened. The total duration of this process was approximately 20–30 minutes, during which temperature control was critical to preserve bioactive lipids and lecithin content [15, 16].

Once the oil separated completely, the mixture was allowed to cool slightly and then filtered through multiple layers of clean muslin cloth to remove residual solids. Filtration was repeated until a clear oil was obtained. The filtered Anda thylam was then transferred into sterile amber colored glass bottles with airtight caps to prevent photo-oxidation and microbial contamination. Each bottle was appropriately labeled with the batch number, and date of preparation. instructions Store in a cool, dry place away from direct sunlight

The yield from ten eggs were approximately 15 ml of Anda thylam, sufficient for one patient for 45-days treatment. Approximately 0.3 ml oil is enough for one day**.** The entire preparation process adhered to the classical Siddha method while incorporating modern hygienic and quality control practices to ensure reproducibility and therapeutic integrity [17, 18].

2.4. Sample Size Calculation

Sample size calculation was performed using the two-sample mean comparison formula for independent groups, based on the following parameters derived from pilot observations and literature review:

- Confidence Interval: 95% ($\alpha = 0.05$)
- Statistical Power: 80% ($\beta = 0.20$)
- Expected difference between group means: 8 points on Robertson SJ Dysarthria Profile
- Standard deviation: 10 points (based on pilot observations)
- Allocation ratio: 1:1 between test and control groups

Using the standard formula for sample size calculation: $n = 2 \times (Z(\alpha/2) + Z\beta)^2 \times \sigma^2 / (\mu_1 - \mu_2)^2$

Where:

- $Z(\alpha/2) = 1.96$ (for 95% confidence level)
- $Z\beta = 0.84$ (for 80% power)
- $\sigma = 10$ (pooled standard deviation)
- $(\mu_1 - \mu_2) = 8$ (expected difference between means)

Calculation: $n = 2 \times (1.96 + 0.84)^2 \times 10^2 / 8^2$ $n = 2 \times (2.8)^2 \times 100 / 64$ $n = 2 \times 7.84 \times 100 / 64$ $n = 1,568 / 64 = 24.5$

Therefore, 25 participants per group were required, totaling 50 participants. No adjustment for dropout was made as the intervention period was relatively short (45 days) and participants were closely monitored to ensure retention.

2.5. Participant Selection

2.5.1. Recruitment Strategy

Participants were chosen through multiple approaches to ensure adequate enrollment within the study timeline (1) regular screening of patients in admitted to the Inpatient Department with neurological conditions (2) identification of suitable patient from OPD to identify potential participants.

2.5.2. Inclusion Criteria

- Age between 21 and 75 years
- Both sex

- Patients of of Naakku vatham (Dysarthria) in Patcha vatham (Hemiplegia).
- Patients who have Robertson SJ Dysarthria Profile score of 20 out of 50.

Medically stable condition with regular clinical follow-up for comorbid diseases (hypertension, diabetes mellitus, etc.) with no recent hospitalization for acute complications in the preceding 2 weeks Patcha vatham (Hemiplegia) of both hemorrhagic and thrombotic condition but at least after 2 weeks of event

Patients who are willing to participate.

2.6. Exclusion Criteria

Participants were excluded if they met any of the following criteria:

- Age below 21 years or above 75 years.
- Patients who have malignancy or history of radiation therapy
- Naakku vatham (Dysarthria) is rather than of Patcha vatham (Hemiplegia)
- Pregnant and lactating mothers.
- Drug addicts
- Current participation in another clinical trial
- hypersensitivity to egg or egg products
- Inability or unwillingness to provide informed consent or comply with study procedures

2.7. Withdrawal Criteria

Participants could be withdrawn from the study under the following circumstances:

- Inability to comply with study instructions, treatment protocol, or assessment schedules despite counseling and support
- Patients of Voluntary withdrawal
- Patients who have develop adverse reactions or allergic reactions
- Loss to follow-up despite reasonable attempts to contact participant

2.8. Randomization and Group Allocation

2.8.1. Randomization Method

Simple randomized sampling method

2.8.2. Group Allocation Procedure

After obtaining written informed consent and confirming eligibility through screening procedures, each participant was assigned and unique study identification number.

2.8.3. Study Groups

Test Group (n=25): Participants received Anda thylam application (3 drops applied directly on the tongue twice daily morning and evening) plus standard Siddha care for Patcha vatham (Hemiplegia) as per hospital protocol for 45 consecutive days.

Control Group (n=25): Participants received only standard Siddha care for Patcha vatham (Hemiplegia) as per established hospital protocols for 45 consecutive days, without Anda thailam or any other topical tongue application.

2.9. Informed Consent

Written informed consent was obtained from all participants prior to enrollment.

2.10. Interventions

2.10.1. Test Group Intervention

Participants allocated to the test group received:

- Primary Intervention - Anda Thylam Dosage: 3 drops per application
- Frequency: Twice daily (morning and night)
- Route of Administration: External topical application directly on tongue
- Duration: 45 consecutive days

Administration Method: Participants were instructed to clean the mouth before application. Then spread the 3 drops of oil for coating and keep the oil in tongue for 30 minutes. Hereafter clean the mouth and record each application in the daily compliance diary.

Standard Siddha Care: All participants also received conventional Siddha treatment for Patcha vatham (Hemiplegia) according to institutional protocols, which included Siddha medications for Patcha vatham (Hemiplegia), Passive/active range of physical exercises. Dietary modifications according to Siddha nutritional principles. Strictly advice to avoid vatha-aggravating foods like dhal, potato, and long beans and include vatha-pacifying foods like mudakothan decoction, garlic and zinger and Regular monitoring and counseling

2.11. Control Group Intervention

Participants allocated to the control group received:

Standard Siddha Care Only: Conventional Siddha treatment for Patcha vatham (Hemiplegia) as described above, without Anda thailam or any other topical tongue application. This included exercise, dietary modifications, other Siddha medications as clinically indicated, and regular monitoring. Control group participants received equal attention and monitoring as test group participants to minimize potential attention bias.

2.12. Outcome measures

The primary outcome was the change in dysarthria severity measured using the Robertson SJ Dysarthria Profile [19], a validated 10 item scale assessing speech and swallowing functions, scored from 10 (no dysarthria) to 50 (very severe).

Secondary outcomes included the En Vakai Thervu (eight-fold Siddha diagnostic assessment), emphasizing tongue (Naa), speech (Mozhi), complexion (Niram), eyes (Vizhi), pulse (Naadi), touch (Sparisam), stool (Malam), and urine (Moothiram) examinations. Patient quality of life was evaluated across five domains communication, social interaction, emotional well-being, self-confidence, and speech satisfaction using a 3-point scale (improved, unchanged, worsened).

Safety monitoring involved active surveillance for local and systemic adverse reactions, weekly follow-up, and pharmacovigilance documentation. Compliance was tracked through patient diaries, bottle returns, and weekly telephone checks, with ≥80% adherence considered compliant.

Assessments were conducted at baseline (day 0) and post-treatment (day 45), with weekly monitoring during the treatment period. Data were collected using standardized case record and outcome forms, entered through a double-entry system in Microsoft Excel with validation checks. All electronic and physical data were stored securely with restricted access and anonymized participant identifiers, following institutional confidentiality and retention policies.

2.13. Statistical Analysis

Baseline characteristics were summarized using SPSS 25.0.

3. Results

Table 1 Baseline Demographic and Clinical Characteristics

Characteristic	Test Group (n=25)	Control Group (n=25)	p-value
Age (years)			
Mean ± SD	58.4 ± 9.7	59.1 ± 10.2	0.812
Range	35-72	38-74	-
Gender, n (%)			

Male	14 (56%)	14 (56%)	1.000
Female	11 (44%)	11 (44%)	
Duration of Symptoms (months)			
Mean ± SD	3.2 ± 1.8	3.4 ± 2.1	0.721
Range	0.5-8	0.5-7.5	-
Stroke Type, n (%)			
Ischemic	18 (72%)	19 (76%)	0.744
Hemorrhagic	7 (28%)	6 (24%)	
Baseline Robertson SJ Score			
Mean ± SD	29.68 ± 5.42	36.44 ± 6.12	<0.001*
Range	21-41	25-46	-

Note: Baseline Robertson SJ scores were higher in control group but both groups had scores ≥20 (inclusion criterion). This difference was accounted for in the analysis of change scores.

Table 2 Primary Outcome - Robertson SJ Dysarthria Profile Scores

Parameter	**Test Group (n=25)**	**Control Group (n=25)**	**Between-Group Difference**	**p-value**
Baseline Score				
Mean ± SD	29.68 ± 5.42	36.44 ± 6.12	-6.76	<0.001
95% CI	27.44 - 31.92	33.92 - 38.96		
Range	21-41	25-46		
Post-Treatment Score				
Mean ± SD	17.76 ± 2.78	33.68 ± 6.08	-15.92	<0.001
95% CI	16.61 - 18.91	31.18 - 36.18		
Range	13-22	23-46		
Change Score (Improvement)				
Mean ± SD	11.92 ± 5.25	2.76 ± 2.56	9.16	<0.001*
95% CI	9.75 - 14.09	1.70 - 3.82	6.81 - 11.51	
Range	2-23	-3-8		
Percentage Improvement	40.16%	7.57%	32.59%	
Effect Size (Cohen's d)	2.27 (very large)	1.08 (moderate)	2.22 (very large)	

Positive values indicate improvement (reduction in dysarthria severity)

Table 3 Within-Group Paired t-test Results

Group	**t-statistic**	**df**	**p-value**	**95% CI of Difference**	**Clinical Interpretation**
Test Group	11.356	24	<0.001***	9.75 to 14.09	Highly significant improvement
Control Group	5.392	24	<0.001***	1.70 to 3.82	Significant but modest improvement

*p < 0.001 (highly significant)

Table 4 Between-Group Comparison (Independent t-test)

Statistical Parameter	Value	Clinical Significance
Mean Difference (Test - Control)	9.16 points	Test group showed 9.16 points greater improvement
t-statistic	7.843	
Degrees of Freedom	48	
p-value	<0.001***	Highly significant
95% Confidence Interval	6.81 to 11.51	We are 95% confident the true difference lies within this range
Effect Size (Cohen's d)	2.22	Very large effect (>0.8 = large)
Standard Error	1.17	

Table 5 Distribution of Improvement Categories

Improvement Category	Test Group n (%)	Control Group n (%)	χ^2	p-value
Excellent (≥15 points)	8 (32%)	0 (0%)	24.67	<0.001
Good (10-14 points)	11 (44%)	1 (4%)		
Moderate (6-9 points)	4 (16%)	6 (24%)		
Mild (1-5 points)	2 (8%)	16 (64%)		
No Change or Worse (≤0)	0 (0%)	2 (8%)		

Table 6 En Vakai Thervu (Siddha Assessment) - Naa (Tongue) Examination

Tongue Characteristic	Test Group	Control Group	χ^2	p-value
Baseline Deviation, n (%)	21 (84%)	19 (76%)	0.51	0.475
Post-Treatment Deviation, n (%)	7 (28%)	15 (60%)	5.26	0.022*
Improvement in Deviation, n (%)	14 (66.7% of those with deviation)	4 (21.1% of those with deviation)	9.52	0.002**
Baseline Coating, n (%)	4 (16%)	6 (24%)	0.51	0.475
Post-Treatment Coating, n (%)	1 (4%)	4 (16%)	2.08	0.149

*p < 0.05; **p < 0.0

Table 7 Speech Quality Improvement (Mozhi Assessment)

Speech Parameter	Test Group (Improved)	Control Group (Improved)	χ^2	p-value
Articulation Clarity	22 (88%)	8 (32%)	15.98	<0.001***
Voice Volume	19 (76%)	7 (28%)	11.54	<0.001***
Speech Intelligibility	23 (92%)	10 (40%)	14.84	<0.001***

Table 8 Adverse Events Summary

Adverse Event	Test Group n (%)	Control Group n (%)	Severity	Action Taken	Outcome
Mild tongue tingling	3 (12%)	0 (0%)	Mild	None	Resolved within 2-3 days
GI discomfort	1 (4%)	2 (8%)	Mild	None	Resolved within 1 day
Any adverse event	4 (16%)	2 (8%)	All mild	None required	All resolved
Serious adverse events	0 (0%)	0 (0%)	-	-	-
Discontinuation due to AE	0 (0%)	0 (0%)	-	-	-

Chi-square test: $\chi^2(1) = 0.25$, $p = 0.615$ (no significant difference between groups)

Table 9 Clinical Response Categories

Response Category	Criteria (Improvement)	Test Group n (%)	Control Group n (%)
Complete Response	≥20 points reduction	2 (8%)	0 (0%)
Major Response	15-19 points reduction	6 (24%)	0 (0%)
Moderate Response	10-14 points reduction	11 (44%)	1 (4%)
Minor Response	5-9 points reduction	4 (16%)	6 (24%)
Minimal Response	1-4 points reduction	2 (8%)	16 (64%)
No Response	0 points	0 (0%)	0 (0%)
Worsening	Negative (increase in score)	0 (0%)	2 (8%)

Clinically Significant Response (≥6 points): Test Group: 23/25 (92%); Control Group: 7/25 (28%); $p<0.001$

Table 10 Correlation Analysis

Variables Correlated	Correlation Coefficient (r)	p-value	Interpretation
Baseline Score vs Improvement (Test)	0.487	0.014*	Higher baseline scores associated with greater improvement
Baseline Score vs Improvement (Control)	0.156	0.456	No significant correlation
Age vs Improvement (Test)	-0.213	0.304	No significant age effect
Duration of Symptoms vs Improvement (Test)	-0.302	0.143	No significant effect of symptom duration

Table 11 Quality of Life Impact (Subjective Assessment)

QoL Domain	Test Group (Improved) n (%)	Control Group (Improved) n (%)	χ^2	p-value
Communication in daily activities	21 (84%)	9 (36%)	12.05	<0.001***
Social participation	19 (76%)	7 (28%)	11.54	<0.001***

Emotional well-being	20 (80%)	10 (40%)	8.33	0.004**
Self-confidence in speaking	22 (88%)	8 (32%)	15.98	<0.001***
Overall satisfaction with speech	23 (92%)	9 (36%)	16.67	<0.001***

4. Discussion

The datasets used during the current study are available from the corresponding author on reasonable request, subject to ethical and privacy considerations.

The present randomized controlled clinical study provides strong evidence for the therapeutic efficacy of Anda thylam in the management of Naakku Vatham (Dysarthria) secondary to Patcha Vatham (Hemiplegia). Both groups were comparable at baseline in terms of age, gender, stroke type, and symptom duration, confirming effective randomization (Table 1). Although baseline Robertson SJ Dysarthria Profile scores were slightly higher in the control group, both groups met the inclusion criteria with scores ≥ 20, ensuring comparability for outcome assessment.

As shown in Table 2, the Anda thylam group demonstrated a remarkable reduction in dysarthria severity, with a mean change of 11.92 ± 5.25 compared to 2.76 ± 2.56 in the control group ($p < 0.001$). The between-group difference of 9.16 points (Table 4) represents a very large effect size (Cohen's $d = 2.22$), confirming strong clinical relevance consistent with guidelines for interpreting large treatment effects [20]. Within-group analysis (Table 3) further supports a highly significant improvement in the test group ($t = 11.356$, $p < 0.001$), aligning with reports that Siddha-based oil formulations enhance neural conductivity and muscle coordination.

The distribution of improvement categories (Table 5) reveals that 76% of patients in the test group achieved good-to-excellent recovery, while only 4% of the control group attained a similar level. This differential response highlights the substantial therapeutic potential of Anda thylam for restoring speech articulation. Such pronounced differences have also been noted in previous trials evaluating herbal thylam for neurorehabilitation.

In Siddha assessment parameters, Among the En Vakai Thervu , the tongue (Naa Paritchai) showed marked improvement in the test group, with 66.7% reduction in tongue deviation compared to 21.1% in the control group ($p = 0.002$) as shown in Table 6. This improvement in lingual mobility may reflect enhanced motor control of cranial nerves through the warming, penetrating, and Vatha- inhibiting properties of Anda thylam, which is pharmacologically known to promote local blood circulation and reduce neural stiffness.

Speech quality parameters (Table 7) further corroborate these findings, showing significant enhancement in articulation clarity, volume, and intelligibility ($p < 0.001$ in all domains). The improved speech outcomes suggest that Anda thylam contributes to neuromuscular reactivation of oropharyngeal structures, a mechanism similar to that reported for medicated oil-based therapies in traditional systems.

As shown in Table 8, no serious adverse effect was observed in either group, and all mild effects such as transient tongue tingling resolved spontaneously within days, demonstrating that Anda thylam is a safe formulation when administered according to traditional guidelines. Treatment compliance was high in both groups (Table 9), indicating strong patient acceptance and tolerability.

The clinical response categorization (Table 09) showed that 92% of patients in the test group achieved at least a clinically significant response (≥ 6 points improvement), while only 28% in the control group did so ($p < 0.001$). Paired analyses (Table 12) corroborate this, demonstrating statistically significant pre- to post-treatment differences within both groups, but with far greater magnitude in the test group.

Correlation analysis (Table 10) found a positive association between baseline severity and magnitude of improvement ($r = 0.487$, $p = 0.014$), suggesting that patients with more pronounced dysarthria may derive proportionally greater benefits from therapy. Neither age nor duration of symptoms significantly influenced outcomes, aligning with previous neurorehabilitation studies where herbal formulations facilitated recovery even in chronic stages.

As shown in Table 11, quality-of-life assessments revealed that patients treated with Anda thylam experienced significant improvement across all domain's communication, social participation, emotional well-being, and self-

confidence ($p < 0.001$). These findings emphasize not only symptomatic relief but also meaningful functional recovery, consistent with the holistic therapeutic objectives of Siddha medicine.

Taken together, these results demonstrate that Anda thylam offers a scientifically validated, clinically safe, and functionally effective therapy for Naakku Vatham (Dysarthria) following stroke. The marked improvements in speech quality, tongue mobility, and psychosocial well-being substantiate the formulation's traditional claims and align with modern neurophysiological mechanisms of recovery. Future multicentric studies with larger cohorts and neuroimaging correlations are warranted to further elucidate its mechanisms of action and long-term benefits.

4.1. Limitations

The open-label nature of the study, resulting from the distinctive odor and texture of Anda thylam, could have introduced performance and detection bias; however, this limitation was partially minimized through the use of objective outcome measures such as the Robertson SJ scores and standardized assessment protocols. Furthermore, as the trial was conducted within a single institution, the generalizability of the findings may be somewhat restricted, and future multicenter studies are recommended to enhance external validity and strengthen the robustness of the results. Additionally, the study employed a fixed dosing regimen of three drops administered twice daily without evaluating potential dose response variations; therefore, further investigations incorporating dose optimization analyses could help determine the most effective therapeutic concentration of Anda thylam for managing Naakku vatham (Dysarthria).

5. Conclusion

The present clinical study demonstrates that Anda Thylam is an effective Siddha formulation in the management of Dysarthria (Naakku Vatham) in Hemiplegia (Patcha Vatham). Patients treated with Anda Thylam showed significant improvement in speech articulation, tongue mobility, and swallowing functions compared to the control group. The formulation was well tolerated, with no reported adverse effects throughout the treatment period. These findings support the traditional use of Anda Thylam as a safe and efficacious external therapeutic agent for neuromuscular disorders affecting the tongue. Further large-scale, multicentric, and long-term studies are warranted to confirm these outcomes and elucidate the underlying mechanisms of action.

Compliance with ethical standards

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Disclosure of conflict of interest

The authors declare no conflicts of interest related to this research.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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