

Efficacy of Kalyanavalehachornam with Panchabhoutikaghritapratimarshanasya in Vaakvikara, Primary Developmental Speech Delay in Children- Study Protocol for a Randomized Controlled Trial

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Roles and responsibilities

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Date of Submission: 20-09-2025

Date of Acceptance: 30-09-2025

I. BACKGROUND AND RATIONALE

Speech is a manifestation of language that uses decodable vocal sounds as the medium of exchange. It is created by a series of complex and coordinated movements of the respiratory, laryngeal, oropharyngeal, and oral systems. Speech skills have a pivotal role in learning and social relationship. Speech disorders are persistent delays and deficits in the development of speech skills and voice quality. It includes problems in the production of speech sounds, disruptions in the flow or rhythm of speech, problems with voice pitch, volume, or quality, and poor intelligibility. Generally, children will develop speech fundamentals during toddler and preschool period. Thus developmental maturation delay in speech and language is often noticed in this period. When these delays persist and affect communication, they are termed as disorders.¹

Speech delay is often overlooked as parents believe that it could be familial trait and follow wait and watch policy.² It is found predominantly in 3 to 5 years age group than younger ones. Previous study exclaims boys are 2.6 times more likely to develop speech-language disorders than girls.³ Studies done by Nair et al who have developed the LEST scale amongst 3-6 years stated 5% prevalence.⁴ National Sample Survey Organization (NNSO), Government of India, reported 5.06% speech disability with 5.5% in urban area and 4.90% in a rural area of India.⁵ However, the prevalence rate of speech delay might vary in Karnataka and yet to be established.

Vaak pravruithi (speech production) is the function of udanavayu. Paaniniyashikshastates thatatma (soul) in association with buddhi (intellect) decides speech production and later in turn stimulates the manas (mind). Thus, the manas (mind) under the influence of Buddhi (intellect) stimulate the jataragni (digestive fire). The jataragni (digestive fire) further stimulates the udanavata, which in contact with talwadi structures (organs of speech) produces different shabda (sounds). As per Ayurveda, receptive language develops as a result of indriyarthasannikarsha (Sequential interaction between the sensory organ with object), on which the buddhi and manas acts, thereby leading to jnanotpatti (acquisition of knowledge). This jnana (knowledge) is processed by the brain and later the buddhi acts on vakindriya (motor organ of speech) -Jihva (tongue) and the jnana is expressed as speech together with the help of prana and udanavayu. Language is the faculty of buddhi while speech is produced by the sense organ.^{6,7} Ayurveda denotes speech disorders asvaakvikara (speech disorder) which is a broad umbrella term. Mukatva (dumbness), minmina (nasal twang), gadgadatwa (stuttering), vaaksanga (Lalling speech) are to be included under this category. Sushruta has explained the manifestation of speech disorders asvata gets avarana (blocks) by kapha in shabdahavahadhamani (sense of hearing) and produces Mooka, Minmina, and Gadgada.⁸

Recent studies on Vaakvikara (speech disorder) like vakshuddhikarachurna, kalyanavalehachornam, samvardhanaghrita, swarnamritaprshana, saraswatarista show significant results, but yet no controlled trial has

been done to establish its efficacy. Kalyanavalehachornam has been already proven effective in speech impairment with only moderate improvement. There is more scope for improvement with addition of other therapy along with kalyanavalehachornam. Thus, Pratimarshanasya (nasal instillation) with Panchabhoutikaghrita explained by kashyapawhich is indicated for mukhata, jada (dullness), vakvidwamsa (cessation of speech) is taken in this study. Pratimarshanasya (nasal instillation) by the virtue of its action at neuropsychological and neurovascular level is claimed to improve speech in children. However, Combination of these two therapeutic approaches could yield better improvement rather than a single formulation administration in speech disorders.

OBJECTIVES

- Primary objective is to evaluate the efficacy of oral administration of kalyanavalehachornam with panchabhouthikaghritapratimarshanasya on vaakvikara, primary developmental speech delay in children based upon REELS⁹. And to assess the improvement in speech in children

with vaakvikara, primary developmental speech delay based on SLDC speech language development chart¹⁰.

- Secondary objectives isto compare the effect of oral administration of kalyanavalehachornam with panchabhouthikaghritapratimarshanasya and kalyanavalehachornam alone in control group on vaakvikara, primary developmental speech delay in children based on REELS, SLDC.

STUDY DESIGN AND CLINICAL SOURCE

The study is a single centered, double arm, open labelled, randomized prospective interventional trial designed to evaluate the efficacy of panchabhouthikaghrita along with kalyanavalehachornamin vaakvikara, primary developmental speech delay. The clinical participants for trial and control group will comprise children aged 3-6 years, of either gender, presenting with developmental speech delay.They will be recruited from the Outpatient department and Inpatient department of Kaumarabhritya at Shri Dharmasthala Manjunatheswara Institute of Ayurveda and Hospital, Bengaluru.

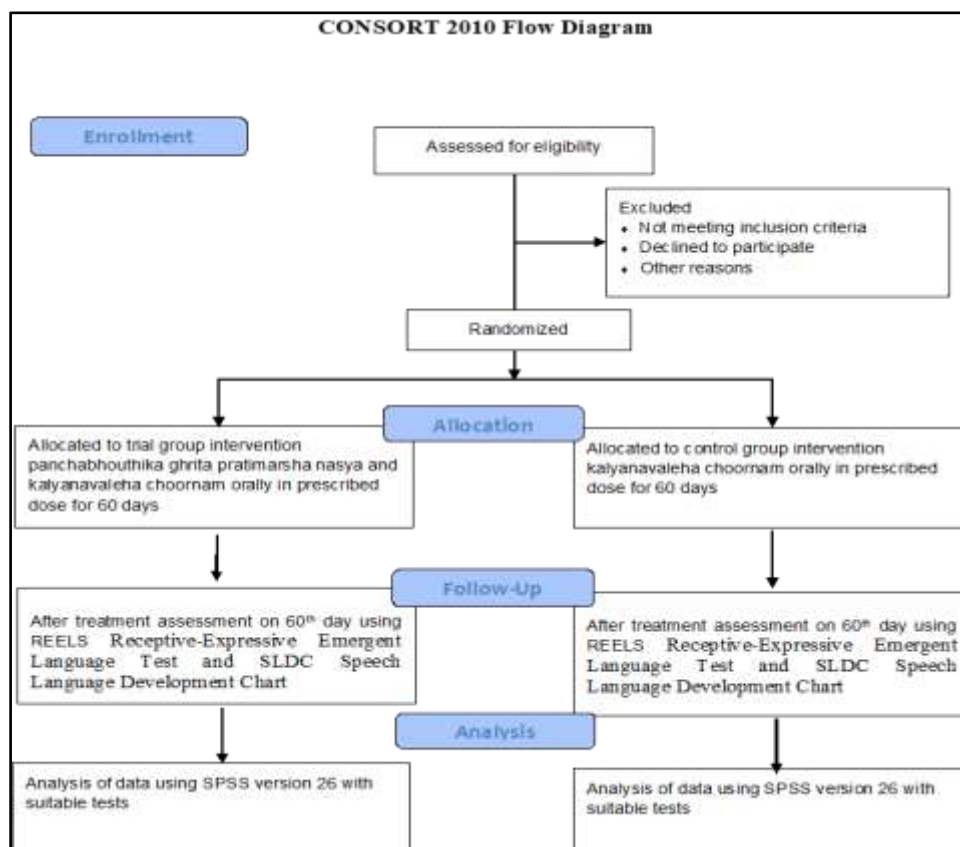


Figure No 1: Consort flow diagram of the study

ELIGIBILITY CRITERIA

ICD-10 CODE: F80.4

STUDY SETTING AND PARTICIPANTS

Minimum 30 children attending outpatient department and inpatient department of Kaumarabhritya of Shri Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital (SDMIAH), Bengaluru who are fulfilling the inclusion criteria and willing to participate in the study under the parental assent or consent will be recruited for study for a period of 60 days. 30 children will be randomly divided into 2 groups namely Group A (15 children) and Group B (15 children). Group A (Study group) will be administered with Panchabhouthikaghritaprathimarshanasya in a dose of 2 drops through nasal route along with kalyanavalehachoorname in a dose of 1500gm twice daily. Group B (Control group) will be administered with kalyanavalehachoorname in a dose of 1500gm twice daily. Assessment will be done for the data obtained using REELS (Receptive- Expressive Emergent Language test and SLDC (Speech language Development Chart).

Statistical analysis will be done by considering the data of day-1 (BT), day-60 (AT) by using suitable test.

DIAGNOSTIC CRITERIA:

DSM V criteria for Speech sound disorder¹¹

- A. Persistent difficulty with speech sound production that interferes with speech intelligibility or prevents verbal communication of messages.
- B. The disturbance causes limitations in effective communication that interfere with social participation, academic achievement, or occupational performance, individually or in any combination.
- C. Onset of symptoms is in the early developmental period.
- D. The difficulties are not attributable to congenital or acquired conditions, such as cerebral palsy, cleft palate, deafness or hearing loss, traumatic brain injury, or other medical or neurological conditions

INTERVENTIONS

Upon enrollment, children will receive either the intervention medicine or control group medicine based on allocation.

Table no. 1 Plan of study

Group	Name Of Medicine	Dose	Dosage form	ROA	TOA	Anupana	Duration
Trial group	Panchabhout ikaghrita	2 drops each nostrils BD.	Drops	Prathimarsha nasya (Nasal instillation)	After getting up in morning , evening	-	60 days
	Kalyanavale hachoorname	1500mg BD dose	Choorna	Oral	AF	2 mlGhrita 1 ml honey	60 days
Control group	Kalyanavale hachoorname	1500mg BD dose	Choorna	Oral	AF	2 mlGhrita 1 ml honey	60 days

*TOA-Time of Administration

*ROA- Route of Administration

*BF-before food

*AF-After food

WITHDRAWAL CRITERIA

Subjects may be withdrawn from the study at any point if they experience adverse events, fail to adhere to the study protocol, develop new or worsening medical conditions and are lost to follow up, as determined by the researcher.

OUTCOMES

Primary outcome measure

Improvements and difference in expressive and receptive language ability based on the pre-posttest assessment scores using REELS.

Improvements and difference in Phonology, Semantics, Syntax-morphology, Pragmatics development chart using SLDC.

Secondary outcome measure

To compare the effect of oral administration of kalyanavalehachooram with panchabhouthikaghritapratimarshanasya and kalyanavalehachooram in control group on vaakvikara, primary developmental speech delay in children based on REELS, SLDC.

PARTICIPANT TIMELINE: The schedule of clinical assessment performed at each visit is exhibited in figure no.2.

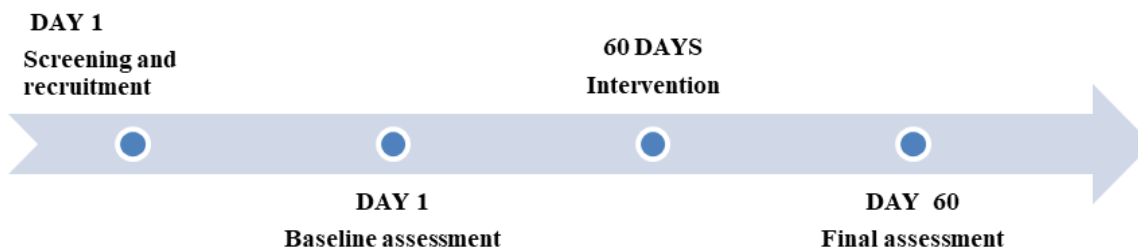


Figure no: 2

SAMPLE SIZE

The sample size was calculated based on the standard deviation and percentage improvement observed in a previous trial, ensuring adequate power to detect statistically significant differences. The sample size for the current study was derived using below formula and was determined to be 30. The sample size was calculated using Standard

Deviation from previous study using formula $N = 2 (SD)^2 \times (Z(1-\alpha) + Z\beta)^2 / d^2$

This generates the minimum sample of 15 children in each arm.

Considering 10% dropout rate, sample size is taken as 15 in each arm.

Accounting total of 30 participants for study.

Sample size for current study will be 15.

Table no:2 sample size

Trial group	Group A- Panchabhouthikaghritapratimarshanasya and kalyanavalehachooram orally	15 children
Control group	Group B –kalyanavalehachooram orally	15 children

RECRUITMENT

The study will recruit children between 3-6 years of age, of either gender, presenting with signs and symptoms of vaakvikara(Primary developmental speech delay). Participants will be selected from the outpatient department and inpatient department of Kaumarabhritya department at Shri Dharmasthala Manjunatheswara Institute of Ayurveda and Hospital, Bengaluru.Both the trial group and control group will be recruited from the same population using the same inclusion and exclusion criteria.

participants to either the trial group or control group

Allocation concealment mechanism: Random allocation using computer generated random tickets which will be kept labeled in a sealed cover

Implementation:The sealed covers containing the random tickets will be opened in front of guide at the start of the intervention.

Blinding:This study will employ an Open label design, where both the researcher and participant will be aware of the group assignments.

ASSIGNMENT OF INTERVENTIONS

ALLOCATION:

Sequence generation: Computer generated random allocation will be used to assign

DATA COLLECTION

Data will be collected using a specially designed Case Report Form (CRF) that incorporates assessment scales. The researcher will enter the collected data into the CRF, which will

then be transferred to MS office excel and SPSS version 26 for statistical analysis.

STATISTICAL ANALYSIS

Both descriptive and inferential statistics will be used to analyze the collected data. Descriptive Statistics will be used to summarize the demographic data and other relevant information, expressed in frequency (f), percentile (%), range and Median. Ordinal data will be expressed in mean, standard deviation and standard error. The Shapiro Wilk test will be used to assess normality, and based on the results, either parametric test or non-parametric test will be employed. For inferential statistics, the study will analyze both qualitative and quantitative data. A significance level of $p < 0.05$ will be used. Non-parametric tests, including Friedman's test and post-hoc Wilcoxon signed rank test, will be used for within-group comparisons, while the Mann-Whitney U test will be used for between-group comparisons. Parametric tests, such as paired t-tests and unpaired t-tests, will also be employed, along with repeated measures Data monitoring

ANOVA. The magnitude of the tests will be evaluated using Cohen's D effect size. All statistical analyses will be performed using SPSS version 26.

DATA MANAGEMENT

The researcher and guide will closely monitor the study data, ensuring the adherence to the intervention protocol, tracking adverse effects and overseeing participant enrolment. They will also conduct audits, perform interim analysis and report any ADR or changes in study protocol to the Ethical Review Board via principal investigator. The investigator may terminate the participant from the study if their continued participation poses a risk to their safety or wellbeing.

Specifically, withdrawal may occur if adverse effects require immediate attention or if the investigator determines that remaining in the study could cause harm to the participant.

SAFETY MEASURES AND MANAGING ADVERSE EFFECTS

Although the study protocol is expected to be safe for children, the monitoring team will closely track any unexpected occurrences during the intervention period. In the event of an adverse reaction, the relevant authority will be promptly informed. Parents / guardians will record any issues in their log and notify the principal investigator. All

significant adverse events will be documented and published in final record.

ETHICS AND DISSEMINATION

Research ethics approval

On May 16 2024, the Institutional Ethics Committee of Shri Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital (SDMIAH) granted the trial ethical approval (SDMIAH/IEC/55/2024). On 18/03/2025, the trial has been registered prospectively with the Clinical Trial Registry India (CTRI) (CTRI/2025/03/082548). Confidentiality and anonymity will be maintained throughout the study. Upon completion of the trial, the anonymized data will be made accessible to the primary investigator, data auditors ensuring transparency and accountability.

Protocol amendments

Any modifications to the study protocol will be communicated to relevant authority inclusive of investigator, guide, Institutional ethics committee (IEC), participant and their family and trial registry (CTRI). All changes will be documented, justified and will be as approved by IEC prior to implementation.

Study Recruitment status

Recruitment for the study is currently open and underway. As of now, 18 subjects have successfully enrolled in the study.

Informed consent, Confidentiality and Access to data

Prior to enrolment, written informed consent/assent will be obtained from parents by designated investigator. The consent will be taken abiding the protocol and will ensure participant understanding of the study purpose, procedures, risk and benefits. Personal and medical information gathered during the study will be strictly confidential. Access to the information will be limited to authorised personnel, who may review records for specific purpose, including result analysis, ensuring study integrity by IEC members and rare court proceedings. Identity of child will remain anonymous and name will not be disclosed.

Declaration of interests: The author declares no conflict of interest.

Ancillary and post-trial care

In the event of any adverse event resulted from the trial participation, the researcher will

ensure appropriate treatment or referral to guarantee necessary care. After study completion, participants were advised to follow dietary recommendations. However, no formal post-trial care was advised.

Dissemination policy

The study data will be published in indexed scientific journal and if feasible, may be presented at seminars / conference.

Funding: The intervention, statistical analysis and all other components of the study is Self-funded trial Registered under RGUHS

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