RESEARCH PAPER

Study Protocol Of Randomised Controlled Clinical Trial On Add On Effect Of Mashabaladi Kashaya Along With Panchakarma Therapy In The Management Of Spastic Cerebral Palsy In Children

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ABSTRACT

Background: Spastic cerebral palsy (SCP) is the most common form of cerebral palsy, characterized by increased muscle tone and impaired motor function. Integrative therapies such as Panchakarma may improve outcomes, and Mashabaladi Kashaya may enhance therapeutic effects.

Objective: To evaluate the add-on effect of Mashabaladi Kashaya along with Panchakarma therapy in children with spastic cerebral palsy.

Methods: A randomized controlled clinical trial with two parallel groups was conducted over 48 days, followed by a 3-month follow-up. Children aged 1–10 years with SCP were randomly assigned to the trial group (Panchakarma with Mashabaladi Kashaya) or control group (Panchakarma only). Outcome measures included Modified Ashworth Scale, Goniometry, GMFM, MRC Scale, and Barthels Index.

Trial Status: Recruitment and intervention have been completed.

Outcome: The study is expected to demonstrate improvements in spasticity, mobility, and functional outcomes with combined therapy.

Keywords: NA

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1. Introduction

Cerebral palsy (CP) is the leading cause of childhood disability affecting function and development with a prevalence of 2 to 2.5 per 1000 live births affecting about 3-8% of the population with 15-20% of physically disabled children and incidence of 3/1000 (WHO).[1] CP is defined as a non-progressive neuro-motor disorder of cerebral origin. Motor disorders of CP are often accompanied by disturbances of sensation, perception, cognition, communication, and behaviour. CP is classified into four types viz., spastic, ataxic, dyskinetic, and mixed. [2] Spastic CP (ICD-10 under the category G80) accounts for a major portion of CP with incidence between 70% and 80%.[3]It is characterized by (i) exaggerated tendon jerks (hyper reflexia) and (ii) increased muscle response to applied stretch, positively correlated with the lengthening rate (velocity-dependent hypertonia)[4]

Cerebral palsy is an umbrella term encompassing a group of non-progressive, noncontagious condition that causes motor impairment by abnormalities in movement, posture, and tone. It cannot be correlated with any single condition mentioned in Ayurveda, as it is a multifactorial disease. However, considering the classification and the respective features of the types, it can be considered as *Janma Bala Pravritta Vyadhi* (congenital disorder). It can also be caused due to Doshas (bodily humors). It can be considered as *Shiro Marmabhighata Vata Vyadhi* (diseases caused due to injury to head). Where *Marmaghata* occurs due to various causes which are *Garbhapurvaka* (before conception), *Prasava Purvaka* (before delivery), *Prasavakaleena* (during delivery), *Prasavottara* (After delivery)i. The therapeutic management is done considering that it is *Vata Pradhana vyadhi*, where *Vatahara* internal medicines along with *Snehana, Swedana* and *Basti* are the main line of treatment.[5]

This study focuses on the management of children of spastic cerebral palsy with the administration of certain Ayurvedic internal and external treatment modalities. Previous study on effect of *Bala taila Matra Basti* on spastic cerebral palsy showed significant reduction in spasticity hence *Bala taila Matra Basti* is taken as control in this study.[6]

Mashabaladi Kashaya is one of the formulation indicated in Pakshaghat which is selected for internal medication in this study, it contains *Masha (Phaseolus mungo), Bala (Sida cordifolia) Kapikacchu (Mucuna pruriens), Kritrina (Cymbopogon schoenanthus), Rasna (Pluchea lanceolata), Ashwagandha (Withania somnifera), Erandmool (Ricinus communis) Kashaya* with the prakshep of *Hingu (Ferula foetida)* and *Saindhav Lavana (Sodium chloride).* (Most of the above content are *Vatahara, Balya* and *Brimhana*).[7] Along with internal medication *Bala taila Matra Basti* will be given to the patients of spastic cerebral palsy

Many studies have been conducted to evaluate effect of *Panchakarma* therapy in cerebral palsy and have proven to be beneficial but studies on add on effect of internal medication along with Panchakarma therapy are limited.

Contents of selected internal drug "*Mashabaladi Kashaya*" are *Vatahara, Balya* and *Brimhana* and easily available everywhere in the Country, hence if found effective it can be added in general Ayurveda treatment protocol for Cerebral palsy for further multi centric trials.

Thus, in the present trial an attempt will be made to study the add on effect of *Mashabaladi Kashaya* along with *Panchakarma* therapy in the management of spastic cerebral palsy in children of age group 1-10 years

2. OBJECTIVES:

PRIMARY OBJECTIVE

- To evaluate the effect of treatment on spasticity and range of motion

SECONDARY OBJECTIVE

- To evaluate effect on improvement in gross motor function.
- To evaluate effect on improvement in muscle strength.
- To evaluate effect on improvement in daily activities of life

Trial design: It is a Randomized Controlled Clinical Trial of 48 days with two parallel groups, each group will be subjected to 2 courses of *Panchakarma* therapy, with an interval of 14 days between each course, One course of *Panchakarma* therapy will be for 17 days and the post treatment follow-up will be after 3 months after completion of intervention

Study Setting: Diagnosed patients of spastic cerebral palsy fulfilling the Inclusion criteria between age group 1-10 years will be selected after clinical evaluation at department of Kaumarbhritya, All India Institute of Ayurveda, Sarita Vihar, New Delhi..

Eligibility Criteria:

Patients attending OPD, Department of Kaumarabhritya, AIIA with Spastic Cerebral Palsy will be screened and will be included in the study after consent procedure and randomization. Structured questionnaire will be used for data collection from the patient. A special Case Record Format (CRF) will be prepared and shall be maintained for all registered patients in the study.

INCLUSION CRITERIA

- Diagnosed Case of Cerebral palsy
- Age group of 1 to 10 years of either gender
- Parents submitting written consent to participate in the study.

EXCLUSION CRITERIA

- Children more than 10 years of age and less than 1 years age
- Progressive neurological disorder,
- Children suffering from any systemic illness,
- Children with severe intractable epilepsy as co-morbidity,
- Acute illness that would interfere with carrying out the interventions,
- Recent orthopaedic surgery/casting/splint,
- Children had received botox (last 1yr) or had undergone phenol block injection or intrathecal baclofen medication, Fixed contractures,
- Congenital disorders like Down's syndrome, Fragile -X syndrome or any congenital anomalies,
- Children with any major congenital malformations such as Congenital Heart Disease (CHD)
- Caregiver not willing to sign the informed consent form.

Intervention:

Group	Course 1	*Parihar kala*	Course 2
A	• *Udvartana* 3 days, • *Sarvanga Abhanga* by *Bala taila& Nadi Swedana* by *Dashamool kashaya* (for 14 days) and • *Bala tailaMatra basti* for 7 days (From 11th day to 17th day) + • Internally *Mashabaladi kashaya* throughout the process	• 14 days + • *Internally Mashabaladi Kashaya*	• *Udvartana* 3 days, • *Sarvanga Abhanga* by *Bala taila& Nadi Swedana* by *Dashamool kashaya* (for 14 days) and • *Bala tailaMatra basti* for 7 days (From 42nd day to 48th day) + • Internally *Mashabaladi kashaya* throughout the process
B	• *Udvartana* 3 days, • *Sarvanga Abhanga by Bala taila& Nadi Swedana by Dashamool kashaya* (for 14 days) and • *Bala tailaMatra basti* for 7 days (From 11th day to 17th day • No Internal Medication	• 14 days • No Internal Medication	• *Udvartana* 3 days, • *Sarvanga Abhanga by Bala taila& Nadi Swedana by Dashamool kashaya* (for 14 days) and • *Bala tailaMatra basti* for 7 days (From 42nd day to 48th day • No Internal Medication

3. **Research Methodology**:

Sample Size:

The statistically significant sample size is determined following the existing available data records generated in the previous research work in the study on children with spastic cerebral palsy at KLE,Belgaum,where in the mean Modified Ashworth Scale score at beginning was 2.5 with standard deviation of 0.97,the Modified Ashworth scale score declined by 0.6 at 30 days .It is assumed that the pooled standard deviation = 0.9 and difference at 30 days would be as 0.6 gives us

effect size $= \frac{0.6}{0.9} = 0.667$

Assuming 95% Level of Confidence , for declaring that the test drug is superior to the active control drug , 80% power and 2 sided test gives us minimum sample size in each group as **35** (i.e. a total sample size of 70, assuming equal group sizes),.

Considering 10% discontinuation or drop out , total sample size is **77**.

Formula for 2 Groups –

$$\text{Sample size} : (N) = \frac{2\, s_p^2\, (Z_{1-a/2} + Z_{1-b})^2}{U_d^2}$$

where,

$$s_p^2 = \frac{s_1^2 + s_2^2}{2}$$

N = Sample Size

$Z_{1-a/2}$= Significance level,

Z_{1-b} = Power,

s_1^2 = Standard deviation of first group ,

s_2^2 = Standard deviation of second group

Recruitment:

Randomization will be assigned after screening. It will be done by computer generated random table.

ALLOCATION

Allocation assignment ratio 1:1.

- Random allocation sequence generated by Guide
- Participants enrolled and assigned to intervention by college PhD scholar

Data collection methods:

Data collected will be entered in the Case record proforma specially designed for the study by the researcher and will be later transferred to MS office excel and SPSS version 25.

Statistical methods:

Descriptive Statistics: Frequency, mean, standard deviation and standard error; median and percentile

Inferential Statistics: Inferential statistics will be done by fixing level of significance at $P<0.05$.

Non-parametric test: Wilcoxon-signed rank test- Subjective data will be assessed before and after treatment differences within group

Mann Whitney U test –will be assessed between the trial and control group.

Freidman test –for multiple comparisons of more than 2 sets within the same group

Parametric test: Unpaired t – test for objective data, assessed between groups Paired t – test will be assessed within group before and after treatment. Categorical data would be assessed with Chi-square test. Effect size will be assessed.

Data monitoring:

The researcher and guide will oversee data to ensure adherence to intervention protocols, any adverse effects, and enrolment of the participants. Data will be submitted periodically to the research and data monitoring committee of the department. This committee will review the progress, data integrity, and compliance of this trial at regular meetings. The committee will further have the power to run data audits and interim analysis when appropriate. The Ethical Review Board will be timely informed by the principal investigator any changes regarding study methods or treatment. Ragi stimulation activities conducted at home will be consistently monitored via electronic media.

Safety measures and managing adverse effects Although serious side effects are not anticipated from the protocol, any unexpected events that arise during or after the intervention will be recorded and will promptly inform the appropriate specialists. The therapist will document any adverse reactions related to therapy in their records and subsequently report these to the lead investigator. Prior to the intervention, parents will be asked about any known food allergies and briefed on possible side effects from oral medications and therapies so they can inform the principal investigator as soon as possible if any issues occur. Any notable adverse effects will be thoroughly documented and included in the final trial report

Ethical issues and informed consent:

On 05 January 2023, the Institutional Ethics Committee of the All India Institute of Ayurveda, New Delhi (AIIA), granted ethical approval for the trial (IEC-302/19.12.2022/PhD-12/2022). The study has been prospectively registered with the Clinical Trial Registry India (CTRI/2023/06/053447). The researcher is committed to upholding the ethical principles outlined in the Helsinki statement. All trial participants will provide written informed consent or assent prior to enrolment. Participation in the trial is entirely voluntary, and individuals may withdraw at any time without affecting their treatment. Upon completion of the trial, data will be accessible to the primary investigator, data auditors, and authors. If any adverse effects occur, post-trial care will be provided to participants. Research findings will be disseminated through publication in open access, peer-reviewed journals and presentations at conferences.

Trial status : The Trial is completed.

4. Discussion:

Spastic cerebral palsy constitutes the most prevalent subtype and is associated with increased muscle tone, exaggerated reflexes, delayed motor milestones, and reduced functional independence.[2] Conventional management of spastic cerebral palsy primarily focuses on elimination of externally exacerbating causes and rehabilitation strategies, including physiotherapy, occupational therapy, and speech therapy, along with pharmacological agents aimed at reducing spasticity. While these interventions play an important role in symptomatic management, their long-term effectiveness is often limited, and pharmacological therapies may be associated with adverse effects such as sedation, muscle weakness, and reduced compliance.[8] Consequently, there is growing interest in complementary and integrative therapeutic approaches that can provide sustained functional improvement with better tolerability.

From an Ayurvedic perspective, the clinical manifestations of spastic cerebral palsy closely

resemble conditions described under *Pakshaghata, Ekanga Vata, and Janma Bala Pravritta Vyadhi,* wherein derangement of Vata Dosha results in impairment of movement and neuromuscular coordination. *Panchakarma* therapies, particularly *Basti*, being the primary line of treatment for *Vata Vyadhi* due to their systemic action and capacity to nourish the nervous system. Basti is described as *Ardha Chikitsa* for *Vata* disorders and is considered effective in restoring normal physiological functions of *Vata Dosha.[*9]

Previous clinical studies have demonstrated the beneficial role of *Panchakarma* procedures such as *Abhyanga, Swedana,* and *Matra Basti* in children with cerebral palsy. These therapies have been shown to reduce muscle spasticity, improve joint mobility, and enhance gross motor function.[10] However, Panchakarma therapies are episodic in nature, and sustained clinical improvement may require continuous internal support through oral medications.

Mashabaladi Kashaya is a classical formulation indicated in *Pakshaghata* and other *Vata*-dominant neurological disorders.[7] The formulation contains drugs possessing *Vatahara, Balya, Brimhana,* and *Rasayana* properties, which are essential for strengthening neuromuscular function and improving motor coordination. Ingredients such as *Bala* (*Sida cordifolia*) and *Ashwagandha* (*Withania somnifera*) are known for their nervine tonic and muscle-strengthening effects, while *Kapikacchu* (*Mucuna pruriens*) has been reported to support neuromuscular transmission and coordination.[11] *Rasna* (*Pluchea lanceolata*) alleviates stiffness and pain, and *Erandamoola* (*Ricinus communis*) aids in pacification of aggravated *Vata Dosha.[*12]When administered alongside Panchakarma, Mashabaladi Kashaya is expected to act synergistically by supporting neuromuscular strength, improving mobility, and preventing deterioration of motor function.

The present study protocol is designed to systematically evaluate the add-on effect of Mashabaladi Kashaya with Panchakarma therapy in children with spastic cerebral palsy. By adopting a structured clinical methodology and standardized assessment parameters, the study aims to generate evidence-based data regarding the safety and efficacy of this combined Ayurvedic intervention. Such evidence is essential for bridging the gap between classical Ayurvedic principles and contemporary clinical practice.

If found effective, the outcomes of this study may contribute to the development of standardized Ayurvedic treatment protocols for spastic cerebral palsy. Furthermore, the study may provide a scientific basis for integrating Ayurvedic therapies into multidisciplinary rehabilitation programs, thereby offering a holistic and sustainable approach to the management of cerebral palsy.

5. **Ethics and Registration**: Approved by the Institutional Ethics Committee (IEC Approval Number: (IEC-302/19.12.2022/PhD-12/2022).) and registered with the Clinical Trials Registry of India (CTRI Registration Number: (CTRI/2023/06/053447).

REFERENCES

1. Rosenbaum P, Paneth N, Leviton A, Goldstein M, Bax M, Damiano D, et al. A report: the definition and classification of cerebral palsy. *Developmental Medicine & Child Neurology Supplement*. 2007;109:8–14. doi:10.1111/j.1469-8749.2007.tb12610.x
2. Bax M, Goldstein M, Rosenbaum P, Leviton A, Paneth N, Dan B, et al. Proposed definition and classification of cerebral palsy. *Developmental Medicine & Child Neurology*. 2005;47(8):571–576. doi:10.1017/S001216220500112X
3. ICD-10-CM diagnosis code G80.0: Spastic quadriplegic cerebral palsy. Available from: https://www.icd10data.com/ICD10CM/Codes/G00-G99/G80-G83/G80-/G80.0 [cited 2026 Jan 23].
4. Bax M. Terminology and classification of cerebral palsy. *Lancet*. 1964;2:1330–5. **https://doi.org/10.1111/j.1469-8749.1964.tb10791.x**
5. National workshop on standard treatment protocol guidelines for the management of cerebral palsy NIA, Jaipur, 17-18 Jan 2019 general description and concept of cerebral palsy definition. Available from https://www.nia.nic.in/pdf/BaseDraft.pdf /
6. Kurubar A Deepti, B.T.Munnoli,Vijaykumar,Arbar Aziz, Patil Amol. Role of Matra Basti (Enema) over Abhyanga (Massage) and Sweda (Sudation) in Reducing Spasticity in Cerebral Palsy with Suddha Bala Taila-A Randomized Comparative Clinical Study. International Journal of Ayurveda and Pharma Research 2014; 2(2): 47-5
7. Shastri Ambikadatta, Bhashajya Ratnavali, Vatarog Chikitsa, Chaukhamba Sanskrit

Sansthan, Varanasi, 5th edition , 2005, Vatavyadhi chikitsa, 26/71-72, Page- 543.

8. Delgado MR, Tilton A, Russman B. Management of spasticity in cerebral palsy. *Pediatric Drugs*. 2010;12(2):91–101.
9. Agnivesha. *Charaka Samhita*. Sharma RK, Dash B, editors. Varanasi: Chaukhambha Sanskrit Series; 2013. Sutra Sthana, Chapter 20 (Maharoga Adhyaya).
10. Patil VC, Baghel MS. Clinical evaluation of Panchakarma therapy in cerebral palsy. *AYU (An International Quarterly Journal of Research in Ayurveda)*. 2010;31(4):447–452. doi:10.4103/0974-8520.82043
11. Thatte UM, Rege NN. Neuropharmacology of Ayurvedic drugs. *Indian Journal of Experimental Biology*. 2011;49(11):807–815.
12. Vagbhata. *Ashtanga Hridaya*. Tripathi B, editor. Varanasi: Chaukhambha Sanskrit Pratishthan; 2012. Sutra Sthana, Chapter 1.