

# A Pilot Clinical Study on Mahamasha Taila Matra Basti and Kheerabala Taila Orally in the Management of Cerebral Palsy

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## 1. Introduction

<sup>1</sup>Cerebral palsy (CP) is defined as a non-progressive neuromotor disorder of cerebral origin. It includes a group of heterogeneous clinical states of variable etiology and severity ranging from minor incapacitation to total handicap.  
<sup>2</sup>The prevalence of cerebral palsy among children is almost 2/1000 live births. There are approximate 25 lakhs cerebral palsy affected children in India. The World Health Organization estimates that about 10% of the population have some form of disability

Ayurveda has separate branch of clinical specialization concerning child health care known as Kaumarabhritya. There is no one to one correlation available in ayurvedic classics with CP, but there are many conditions and some causative factors linked to etiopathology for such type of disease condition described in many chapters in different texts. Cerebral palsy in Ayurveda can be considered as Shiro-Marmabhighata Bala Vata-Vyadhi, which may manifest itself in any of the following main clinical presentations such as spastic monoplegia (EkangaRoga), hemiplegia (Pakshavadha), spastic diplegia (Pangu), spastic quadriplegia (SarvangaRoga), choreoathetosis (Vepathu) and ataxia, which are described under Vata Vyadhi in the texts.<sup>3</sup> Skanda vyadhi (A.S.U 3/10), which is described in Balgrah<sup>4</sup>, Balasamvardhan vikara<sup>5</sup> Pakshavadha<sup>6</sup> also having similar symptoms as found in cerebral palsy. In Ayurvedic classics while describing Shiromarmabhighata, there is description of certain Vatavikar such as Chesta-nasha, Gadgada etc. which indicates towards mental impairment.<sup>7</sup>

Basti Karma is the best treatment in the management of Vata Vyadhi. Basti Chikitsa is also better treatment for disorders of Marmas (Vital organs).<sup>8</sup> Basti is advised for both children and aged person, which is excellent both for the elimination of doshas and nourishment of the body.

The protocol of present study aimed to use appropriate combinations of interventions (Abhyanga, SSPS as Poorva Karma, Matra basti as rectal administration and Ksheerbalataila as oral administration) to promote functions, to prevent secondary impairments and to increase the scope of child's developmental capabilities.

## 1.1 Need of Study

In all treatment modalities other than Ayurveda there is no treatment of CP having satisfactory results. Modern;

- 1) Medicines that are in use to manage CP have serious side effects in long term use.
- 2) Numbers of patients have got benefited from our OPD through Ayurvedic treatment. A lot of improvement has been noticed in developmental disabilities of cerebral palsy patients with Ayurvedic medicines and procedures but evaluation of these improvements on scientific parameters and proper documentation is need of the hour and so this clinical trial was selected to move in this direction.

## 1.2 Aim & Objectives

The present research study has been conducted with following Aim and Objectives-

- 1) To understand the concept of Cerebral Palsy on the basis of fundamentals of Ayurveda as a part of literary research.
- 2) To evaluate the role of Mahamashataila Matra Basti and oral Ksheerabalataila in the management of Cerebral Palsy.
- 3) To decrease the muscle spasticity and improve the quality of life.

## 2. Materials and Methods

### Type of Study:

Randomized, parallel group, active control trial.

### Sample Size:

30 patients, 15 in each group- A & B

### Selection of Cases and Group Allocation:

Age: 1 – 10 year

### Source:

Total 34 patients were randomly selected from OPD and IPD of Kaumarabhritya department of State Ayurvedic College and Hospital Lucknow

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**Criteria to be adopted-**

For conducting the research following criteria has been adopted.

**Diagnostic Criteria**

- 1) Significant delay in gross or fine Motor function with abnormality in Tone, Posture & movement on neurological examination.
- 2) Children with complaints of spasticity or dysfunction of limbs and delayed developmental milestones along with related birth history.
- 3) Radiological investigation such as CT Head.

**Inclusion Criteria**

- 1) Children with CP aged 1 year to 10 years of either sex.
- 2) Children physically and mentally handicapped due to cerebral palsy.
- 3) Children with delayed growth and milestone development.
- 4) Already diagnosed cases of CP.

**Exclusion Criteria**

- 1) Children below 1 years and above 10 years of age.
- 2) Children of CP with major congenital disorder & other disease status viz. Juvenile DM, Acute infections etc.
- 3) Children with any progressive neurological anomalies.
- 4) Child suffering from any Muscular dystrophy.
- 5) Children with severe systemic illness.

**Discontinuation Criteria**

- 1) Any acute or severe illness
- 2) Parents not willing to continue the treatment.

The assessment of subjects was done before and after 15 days of intervention. However, the following laboratory investigations (complete blood count) were performed only before the treatment:

- 1) Goniometer<sup>9</sup>
  - Shoulder – Flexion: 0–180
  - Extension: 0–40
  - Abduction: 0–180
  - Internal rotation: 0–80
  - External rotation: 0–90
  - Elbow – Flexion: 0–150
  - Wrist – Flexion: 0–60
  - Extension: 0–60
  - Radial deviation: 0–20
  - Ulnar deviation: 0–30
  - Hip – Flexion: 0–100
  - Extension: 0–30
  - Abduction: 0–40
  - Adduction: 0–20
  - Internal rotation: 0–40
  - External rotation: 0–50
  - Knee – Flexion: 0–150
  - Ankle – Plantar flexion: 0–40
  - Dorsiflexion: 0–20

- 2) Power of the limbs<sup>[10]</sup>

- 0: Complete paralysis
- 1: Flicker of contraction
- 2: Movement if gravity excluded
- 3: Movement against gravity
- 4: Moderate power against resistance
- 5: Normal power

- 3) Modified Ashworth scale for spasticity<sup>[11]</sup>

- a. 0: No increase in muscle tone
- b. 1: Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part (s) is moved in flexion or extension
- c. 1+: Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the range of motion
- d. 2: More marked increase in muscle tone through most of the range of motion, but affected part (s) easily moved
- e. 3: Considerable increase in muscle tone, passive movement difficult
- f. 4: Affected part (s) rigid in flexion or extension

**CDC Grading Scale for Motor milestones<sup>12</sup>****Head Holding**

Grade 0	No Head holding at all
Grade 1	Head erect and steady momentarily
Grade 2	Supine-Lifts head when pulled by arms
Grade 3	Prone- elevates self by arms and chest
Grade 4	Hold heads steady when moved around
Grade 5	Head balanced always

**Sitting**

Grade 0	Not sitting at all
Grade 1	Sits momentarily
Grade 2	Sits 30 seconds or more leaning forward
Grade 3	Sits with the child's back straight
Grade 4	while sitting can manipulate a toy
Grade 5	Raises self to sitting position

**Standing**

Grade 0	Does not stand at all
Grade 1	Stands holding a furniture
Grade 2	Take a few steps, both hands held
Grade 3	Without support can stand alone (leg apart)
Grade 4	Stand up , all by himself by throwing weight on arms
Grade 5	Take a few steps without support

**Speech**

Grade 0	Unable to speak or produce sound at all
Grade 1	Marked cooing
Grade 2	Monosyllable
Grade 3	Bisyllables
Grade 4	Two words with meaning
Grade 5	A complete sentence

Modified Barthel Score for ADL<sup>13</sup>

ITEM	Unable to perform task	Attempt task but unsafe	Moderate help required	Minimal help required	Fully independent
Personal hygiene	0	1	3	4	5
Bathing self	0	1	3	4	5
Feeding	0	2	5	8	10
Toilet	0	2	5	8	10
Stair climbing	0	2	5	8	10
Dressing	0	2	5	8	10
Bowel control	0	2	5	8	10
Bladder control	0	2	5	8	10
Ambulation (Wheel-chair)	0 (0)	3 (1)	8 (3)	12 (4)	15 (5)
Chair-bed transfer	0	3	8	12	15

Score	Interpretation
00 – 20	Total Dependence
21 - 60	Severe Dependence
61 - 90	Moderate Dependence
91 - 99	Slight Dependence
- 100	Independence

### 3. Statistical Analysis

Assessment was done on the basis of pre & post observations found. Result obtained was statistically analyzed. The statistical method adopted for intra group analysis was t- test paired, and Wilcoxon Signed Rank test while t- test unpaired and Mann Whitney Test has been adopted for analysis of intergroup subjects.

#### Observations

The observation data according demographic clinical profile were as follows- Maximum patients belonged to *Vata-pittaj Sharirik Prakriti*, (60.0%) Maximum no of patients (group-A 66.7% and Group-B 66.7%) belonged to *Avar samhanana*, followed by *Madhyam samhanana* (Group-A 26.7% and Group-B 33.3 %). Maximum patients were belonged to *Madhyam satmya* in both groups (group A 66.7% and group B 46.7%). In both groups A & B maximum cases (63.3%) belonged to *Avarasatva* with proportion 46.7% &80% respectively. Maximum patients were of *Avar ahara shakti* in group A and B (53.3%). maximum patients were of *Avar vyayam shakti* in both groups (group A 100% and group B 86.7%). Maximum patients were of Supine decubitus in both groups (group A 93.3% and group B 80%). Maximum patients were of medium nutritional status in both groups (group A 46.7% and group B 46.7%). maximum patients were Hypertonic in both groups (group A 80.0% and group B 83.3%). Maximum patients were bedridden in both groups (group A 46.7% and group B 33.3%). Maximum patients (46.7%) showed diplegia in both groups. In Group-A and B 46.7% patients have 46.7% of diplegia. Total 16.7% patients showed past h/o fever, 3.3% showed past h/o febrile convulsions and total 10% patients showed past h/o neonatal jaundice in both groups. Total 13.3% patients showed antenatal h/o intake of drugs, 3.3% showed antenatal h/o fever with rash in both groups. Total 13.3% patients showed natal h/o bleeding/leaking per Vaginum, 43.3% showed natal h/o LSCS. 6.7% showed h/o decreased fetal

movement. Total 53.3% patients were showed post natal h/o delayed cry, 3.3% showed h/o fever, 6.7% have h/o IUGR, 3.3% showed h/o convulsions and 6.7% showed h/o prematurity. Total 6.7% patients were unclear speech, 13.3% doesn't response to command, 10.0% were irritable, 6.7% have inappropriate smile. Total 73.3% patients showed exaggerated reflexes.

### 4. Results

results section including results of therapeutic trial, the obtained data were as follows-Statistically significant improvement was seen in all motor milestones – head holding (p=0.030%) in group-A, but not significant improvement was seen in group-B. Statistically significant improvement was noticed in terms of sitting in group A (p=0.041) and group B (p=0.025). Significant improvement was observed in terms of standing in group A (p=0.03) and group B (p=0.005). Statistically significant improvement was seen in spasticity of URL (p=0.007) in group-A, and in group-B (p=0.002). Spasticity of ULL has also been improved at the end of trial in both groups. (p=0.004 group A) (p= 0.002 group B). Statistically significant improvement was in LRL in terms of Spasticity in both groups at the end of trial (p=0.002 for group A) (p=0.001 for group B) Statistically significant improvement was seen in LLL in both groups at the end of trial (p= 0.003 group A) (p=0.001 group B). Overall effect on power (p=0.018) in group-A, and in group-B (p=0.001). Statistically, significant improvement was seen at 4<sup>th</sup> follow up and after trial (p>0.005) in group-A, while in group-B, Significant improvement was seen on 6<sup>th</sup> follow up (p=0.008). Statistically significant improvement was seen in overall effect of range of motion in both groups-A (p=0.002) & group B (p=0.003). Statistically highly significant improvement was seen in overall effect of therapies in all parameters in both groups-A & B (40% in group A and 26.7% in group B).

**Effect of Treatments on MOTOR MILESTONE - Head Holding in both the Groups**

Motor Milestone - Head Holding	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	3.33	2.09	-			3.67	1.80	-		
Day 15	3.33	2.09	0.00	0.00	1.000	3.67	1.80	0.00	0.00	1.000
Day 30	3.33	2.09	0.00	0.00	1.000	3.67	1.80	0.00	0.00	1.000
Day 45	3.33	1.99	0.00	0.00	1.000	3.67	1.80	0.00	0.00	1.000
Day 60	3.53	1.92	6.00	-1.34	0.180	3.67	1.80	0.00	0.00	1.000
Day 90	3.60	1.96	8.00	-1.63	0.102	4.00	1.46	9.09	-1.41	0.157
AT	3.93	1.53	18.00	-2.17	<b>0.030</b>	4.07	1.49	10.91	-1.67	0.096

**Effect of Treatments on MOTOR MILESTONE - Sitting in both the Groups**

Motor Milestone – Sitting	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	2.87	2.17	-			3.47	1.85	-		
Day 15	2.87	2.17	0.00	0.00	1.000	3.47	1.85	0.00	0.00	1.000
Day 30	2.87	2.17	0.00	0.00	1.000	3.47	1.85	0.00	0.00	1.000
Day 45	3.00	2.14	4.65	-1.41	0.157	3.47	1.85	0.00	0.00	1.000
Day 60	3.00	2.14	4.65	-1.41	0.157	3.47	1.85	0.00	0.00	1.000
Day 90	3.07	2.05	6.98	-1.73	0.083	3.60	1.80	3.85	-1.41	0.157
AT	3.47	2.00	20.93	-2.46	<b>0.014</b>	3.80	1.74	9.62	-2.24	<b>0.025</b>

**Effect of Treatments on MOTOR MILESTONE –Standing in both the Groups**

MOTOR MILESTONE – Standing	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	1.87	1.92	-			2.33	1.88	-		
Day 15	1.87	1.92	0.00	0.00	1.000	2.33	1.88	0.00	0.00	1.000
Day 30	1.87	1.92	0.00	0.00	1.000	2.33	1.88	0.00	0.00	1.000
Day 45	2.00	1.93	7.14	-1.41	0.157	2.33	1.88	0.00	0.00	1.000
Day 60	2.13	1.96	14.29	-2.00	<b>0.046</b>	2.33	1.88	0.00	0.00	1.000
Day 90	2.33	1.99	25.00	-2.65	<b>0.008</b>	2.67	1.95	14.29	-2.24	<b>0.025</b>
AT	2.53	2.03	35.71	-2.43	<b>0.015</b>	2.80	2.01	20.00	-2.65	<b>0.008</b>

**Effect of Treatments on Spasticity - URL in both the Groups**

Spasticity – URL	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	1.43	1.35	-			2.30	1.41	-		
Day 15	1.43	1.35	0.00	0.00	1.000	2.30	1.41	0.00	0.00	1.000
Day 30	1.43	1.35	0.00	0.00	1.000	2.30	1.41	0.00	0.00	1.000
Day 45	1.27	1.32	11.63	-1.63	0.102	2.30	1.41	0.00	0.00	1.000
Day 60	1.13	1.17	20.93	-2.12	<b>0.034</b>	2.23	1.40	2.90	-1.00	0.317
Day 75	1.10	1.17	23.26	-2.27	<b>0.023</b>	1.90	1.28	17.39	-2.46	<b>0.014</b>
Day 90	1.03	1.14	27.91	-2.46	<b>0.014</b>	1.67	1.03	27.54	-3.07	<b>0.002</b>
AT	0.63	0.83	55.81	-2.71	<b>0.007</b>	1.67	1.03	27.54	-3.07	<b>0.002</b>

**Effect of Treatments on Spasticity - ULL in both the Groups**

Spasticity – ULL	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	1.63	1.45	-			2.17	1.44	-		
Day 15	1.63	1.45	0.00	0.00	1.000	2.17	1.44	0.00	0.00	1.000
Day 30	1.63	1.45	0.00	0.00	1.000	2.17	1.44	0.00	0.00	1.000
Day 45	1.47	1.45	10.20	-1.63	0.102	2.17	1.44	0.00	0.00	1.000
Day 60	1.40	1.34	14.29	-1.89	0.059	2.10	1.42	3.08	-1.00	0.317
Day 75	1.37	1.34	16.33	-2.07	<b>0.038</b>	1.93	1.32	10.77	-1.89	0.059
Day 90	1.27	1.28	22.45	-2.33	<b>0.020</b>	1.57	1.10	27.69	-2.97	<b>0.003</b>
AT	0.77	0.98	53.06	-2.87	<b>0.004</b>	1.53	1.11	29.23	-3.07	<b>0.002</b>

**Effect of Treatments on Spasticity - LRL in both the Groups**

Spasticity - LRL	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	2.47	1.13	-			2.73	1.28	-		
Day 15	2.47	1.13	0.00	0.00	1.000	2.73	1.28	0.00	0.00	1.000
Day 30	2.47	1.13	0.00	0.00	1.000	2.73	1.28	0.00	0.00	1.000
Day 45	2.27	1.03	8.11	-1.73	0.083	2.73	1.28	0.00	0.00	1.000
Day 60	2.07	0.96	16.22	-2.45	<b>0.014</b>	2.60	1.24	4.88	-1.41	0.157
Day 75	2.07	0.96	16.22	-2.45	<b>0.014</b>	2.37	1.20	13.41	-2.33	<b>0.020</b>

Day 90	1.63	0.79	33.78	-3.17	<b>0.002</b>	1.97	0.93	28.05	-3.36	<b>0.001</b>
AT	1.40	0.76	43.24	-3.10	<b>0.002</b>	1.93	0.94	29.27	-3.27	<b>0.001</b>

**Effect of Treatments on Spasticity - LLL in both the Groups**

Spasticity - LLL	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	2.40	1.35	-			2.40	1.40	-		
Day 15	2.40	1.35	0.00	0.00	1.000	2.40	1.40	0.00	0.00	1.000
Day 30	2.40	1.35	0.00	0.00	1.000	2.40	1.40	0.00	0.00	1.000
Day 45	2.20	1.26	8.33	-1.73	0.083	2.40	1.40	0.00	0.00	1.000
Day 60	2.07	1.16	13.89	-2.24	<b>0.025</b>	2.27	1.39	5.56	-1.41	0.157
Day 75	1.90	1.17	20.83	-2.71	<b>0.007</b>	2.07	1.32	13.89	-2.27	<b>0.023</b>
Day 90	1.57	0.96	34.72	-3.02	<b>0.003</b>	1.87	1.17	22.22	-2.81	<b>0.005</b>
AT	1.37	0.88	43.06	-2.98	<b>0.003</b>	1.70	1.01	29.17	-3.07	<b>0.002</b>

**Effect of Treatments on Muscle Power - URL in both the Groups**

Muscle Power – URL	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	4.13	0.92	-			3.40	0.99	-		
Day 15	4.13	0.92	0.00	0.00	1.000	3.40	0.99	0.00	0.00	1.000
Day 30	4.13	0.92	0.00	0.00	1.000	3.40	0.99	0.00	0.00	1.000
Day 45	4.13	0.92	0.00	0.00	1.000	3.40	0.99	0.00	0.00	1.000
Day 60	4.27	0.80	3.23	-1.41	0.157	3.40	0.99	0.00	0.00	1.000
Day 75	4.33	0.82	4.84	-1.73	0.083	3.60	0.91	5.88	-1.73	0.083
Day 90	4.53	0.74	9.68	-2.12	<b>0.034</b>	3.93	0.70	15.69	-2.83	<b>0.005</b>
AT	4.53	0.74	9.68	-2.12	<b>0.034</b>	4.07	0.70	19.61	-3.16	<b>0.002</b>

**Effect of Treatments on Muscle Power - ULL in both the Groups**

Muscle Power – ULL	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	3.93	1.03	-			3.53	1.06	-		
Day 15	3.93	1.03	0.00	0.00	1.000	3.53	1.06	0.00	0.00	1.000
Day 30	3.93	1.03	0.00	0.00	1.000	3.53	1.06	0.00	0.00	1.000
Day 45	4.00	1.00	1.69	-1.00	0.317	3.53	1.06	0.00	0.00	1.000
Day 60	4.13	0.83	5.08	-1.73	0.083	3.53	1.06	0.00	0.00	1.000
Day 75	4.27	0.80	8.47	-2.24	<b>0.025</b>	3.73	0.96	5.66	-1.73	0.083
Day 90	4.40	0.83	11.86	-2.65	<b>0.008</b>	4.00	0.76	13.21	-2.65	<b>0.008</b>
AT	4.40	0.83	11.86	-2.33	<b>0.020</b>	4.07	0.80	15.09	-2.83	<b>0.005</b>

**Effect of Treatments on Muscle Power - LRL in both the Groups**

Muscle Power – LRL	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	3.40	0.83	-			3.00	0.93	-		
Day 15	3.40	0.83	0.00	0.00	1.000	3.00	0.93	0.00	0.00	1.000
Day 30	3.47	0.74	1.96	-1.00	0.317	3.00	0.93	0.00	0.00	1.000
Day 45	3.60	0.74	5.88	-1.73	0.083	3.07	0.96	2.22	-1.00	0.317
Day 60	3.73	0.70	9.80	-2.24	<b>0.025</b>	3.07	0.96	2.22	-1.00	0.317
Day 75	3.80	0.77	11.76	-2.45	<b>0.014</b>	3.47	0.92	15.56	-2.65	<b>0.008</b>
Day 90	4.07	0.80	19.61	-2.64	<b>0.008</b>	3.73	0.70	24.44	-3.32	<b>0.001</b>
AT	4.27	0.70	25.49	-3.13	<b>0.002</b>	3.73	0.70	24.44	-3.32	<b>0.001</b>

**Effect of Treatments on Muscle Power - LLL in both the Groups**

Muscle Power – LLL	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	3.33	1.05	-			3.07	0.88	-		
Day 15	3.33	1.05	0.00	0.00	1.000	3.07	0.88	0.00	0.00	1.000
Day 30	3.40	0.99	2.00	-1.00	0.317	3.07	0.88	0.00	0.00	1.000
Day 45	3.40	0.99	2.00	-1.00	0.317	3.07	0.88	0.00	0.00	1.000
Day 60	3.73	0.88	12.00	-2.45	<b>0.014</b>	3.20	0.94	4.35	-1.41	0.157
Day 75	3.87	0.83	16.00	-2.53	<b>0.011</b>	3.60	0.83	17.39	-2.83	<b>0.005</b>
Day 90	3.93	0.88	18.00	-2.97	<b>0.003</b>	3.73	0.70	21.74	-3.32	<b>0.001</b>
AT	4.13	0.83	24.00	-3.52	<b>0.001</b>	3.80	0.68	23.91	-3.67	<b>0.001</b>

**Effect of Treatments on Active Range of Motion Shoulder- Flexion**

Active Range of Motion- FLEXION	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	144.00	37.95	-			139.33	24.41	-		
Day 15	144.00	37.95	0.00	0.00	1.000	139.33	24.41	0.00	0.00	1.000
Day 30	144.33	37.65	0.23	-1.00	0.317	139.33	24.41	0.00	0.00	1.000
Day 45	147.00	34.48	2.08	-2.06	<b>0.039</b>	139.33	24.41	0.00	0.00	1.000
Day 60	147.67	33.96	2.55	-2.06	<b>0.039</b>	140.00	23.53	0.48	-1.00	0.317
Day 75	149.33	31.95	3.70	-2.27	<b>0.023</b>	141.67	22.57	1.67	-2.33	<b>0.020</b>
Day 90	152.00	30.34	5.56	-2.55	<b>0.011</b>	143.00	22.26	2.63	-3.05	<b>0.002</b>
AT	153.33	29.26	6.48	-2.54	<b>0.011</b>	143.67	22.24	3.11	-3.13	<b>0.002</b>

**Effect of Treatments on Active Range of Motion - Extention**

Active Range of Motion – EXTENTION	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	42.67	18.21	-			41.33	13.29	-		
Day 15	42.67	18.21	0.00	0.00	1.000	41.33	13.29	0.00	0.00	1.000
Day 30	43.33	17.59	1.56	-1.41	0.157	41.33	13.29	0.00	0.00	1.000
Day 45	44.00	16.82	3.13	-2.00	<b>0.046</b>	41.33	13.29	0.00	0.00	1.000
Day 60	45.00	15.70	5.47	-2.33	<b>0.020</b>	43.67	12.60	5.65	-2.33	<b>0.020</b>
Day 75	45.33	15.86	6.25	-2.53	<b>0.011</b>	44.67	12.02	8.06	-2.89	<b>0.004</b>
Day 90	46.67	16.11	9.38	-2.59	<b>0.010</b>	45.33	11.41	9.68	-2.97	<b>0.003</b>
AT	48.67	13.43	14.06	-2.64	<b>0.008</b>	45.67	11.32	10.48	-2.92	<b>0.004</b>

**Effect of Treatments on Active Range of Motion - Internal Rotation**

Active Range of Motion - INTERNAL ROTATION	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	54.00	13.26	-			44.00	14.54	-		
Day 15	54.33	12.80	0.62	-1.00	0.317	44.00	14.54	0.00	0.00	1.000
Day 30	54.33	12.80	0.62	-1.00	0.317	44.00	14.54	0.00	0.00	1.000
Day 45	55.33	12.02	2.47	-1.63	0.102	44.00	14.54	0.00	0.00	1.000
Day 60	57.33	11.00	6.17	-2.27	<b>0.023</b>	45.00	13.89	2.27	-1.73	0.083
Day 75	58.00	10.32	7.41	-2.46	<b>0.014</b>	46.33	13.95	5.30	-2.65	<b>0.008</b>
Day 90	58.33	10.12	8.02	-2.41	<b>0.016</b>	47.67	12.66	8.33	-3.05	<b>0.002</b>
AT	59.67	9.35	10.49	-2.46	<b>0.014</b>	48.33	12.34	9.85	-2.97	<b>0.003</b>

**Effect of Treatments on Active Range of Motion - External Rotation**

Active Range of Motion - EXTERNAL ROTATION	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	71.67	20.15	-			66.33	15.86	-		
Day 15	71.67	20.15	0.00	0.00	1.000	66.33	15.86	0.00	0.00	1.000
Day 30	72.00	19.71	0.47	-1.00	0.317	66.33	15.86	0.00	0.00	1.000
Day 45	72.67	18.98	1.40	-1.34	0.180	66.33	15.86	0.00	0.00	1.000
Day 60	73.33	18.77	2.33	-1.89	0.059	67.33	15.57	1.51	-1.73	0.083
Day 75	74.67	16.85	4.19	-2.25	<b>0.024</b>	69.00	15.14	4.02	-2.83	<b>0.005</b>
Day 90	76.00	16.71	6.05	-2.41	<b>0.016</b>	69.33	14.50	4.52	-3.00	<b>0.003</b>
AT	77.33	15.22	7.91	-2.46	<b>0.014</b>	70.67	14.98	6.53	-2.92	<b>0.004</b>

**Effect of Treatments on Active Range of Motion - Abduction**

Active Range of Motion – ABDUCTION	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	151.00	21.56	-			133.00	19.16	-		
Day 15	151.00	21.56	0.00	0.00	1.000	133.00	19.16	0.00	0.00	1.000
Day 30	151.33	21.34	0.22	-1.00	0.317	133.00	19.16	0.00	0.00	1.000
Day 45	153.67	18.17	1.77	-2.07	<b>0.038</b>	133.00	19.16	0.00	0.00	1.000
Day 60	154.00	17.95	1.99	-2.12	<b>0.034</b>	134.00	18.44	0.75	-1.73	0.083
Day 75	155.67	17.92	3.09	-2.64	<b>0.008</b>	134.67	18.27	1.25	-2.24	<b>0.025</b>
Day 90	158.00	16.99	4.64	-2.54	<b>0.011</b>	136.00	17.55	2.26	-3.00	<b>0.003</b>
AT	159.33	16.24	5.52	-2.57	<b>0.010</b>	136.67	18.09	2.76	-3.32	<b>0.001</b>

**Effect of Treatments on Active Range of Motion - Adduction**

Active Range of Motion – ADDUCTION	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	15.00	5.00	-			13.33	7.24	-		
Day 15	15.00	5.00	0.00	0.00	1.000	13.33	7.24	0.00	0.00	1.000
Day 30	15.00	5.00	0.00	0.00	1.000	13.33	7.24	0.00	0.00	1.000

Day 45	16.00	4.31	6.67	-1.73	0.083	13.33	7.24	0.00	0.00	1.000
Day 60	16.33	4.42	8.89	-2.00	<b>0.046</b>	14.00	6.87	5.00	-1.41	0.157
Day 75	16.67	4.08	11.11	-2.24	<b>0.025</b>	15.33	6.67	15.00	-2.45	<b>0.014</b>
Day 90	18.00	2.54	20.00	-2.71	<b>0.007</b>	16.33	6.11	22.50	-3.00	<b>0.003</b>
AT	18.67	2.97	24.44	-2.60	<b>0.009</b>	17.00	5.92	27.50	-3.32	<b>0.001</b>

**Effect of Treatments on Elbow – Flexion**

Elbow - FLEXION	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	137.33	19.07	-			125.67	16.02	-		
Day 15	137.67	18.70	0.24	-1.00	0.317	125.67	16.02	0.00	0.00	1.000
Day 30	137.67	18.70	0.24	-1.00	0.317	126.00	15.95	0.27	-1.00	0.317
Day 45	138.33	18.19	0.73	-1.73	0.083	126.00	15.95	0.27	-1.00	0.317
Day 60	140.33	16.42	2.18	-2.53	<b>0.011</b>	126.33	16.31	0.53	-1.41	0.157
Day 75	141.67	15.31	3.16	-2.39	<b>0.017</b>	128.33	15.55	2.12	-2.83	<b>0.005</b>
Day 90	143.00	13.86	4.13	-2.59	<b>0.010</b>	129.33	14.62	2.92	-3.32	<b>0.001</b>
AT	144.00	13.39	4.85	-2.55	<b>0.011</b>	130.00	15.00	3.45	-3.13	<b>0.002</b>

**Effect of Treatments on Hip – Flexion**

Hip - FLEXION	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	110.00	16.15	-			113.00	10.32	-		
Day 15	110.00	16.15	0.00	0.00	1.000	113.00	10.32	0.00	0.00	1.000
Day 30	110.67	15.45	0.61	-1.41	0.157	113.00	10.32	0.00	0.00	1.000
Day 45	111.33	14.70	1.21	-1.63	0.102	113.00	10.32	0.00	0.00	1.000
Day 60	114.00	13.65	3.64	-2.23	<b>0.026</b>	113.00	10.32	0.00	0.00	1.000
Day 75	116.00	12.56	5.45	-2.55	<b>0.011</b>	115.67	9.80	2.36	-2.83	<b>0.005</b>
Day 90	119.00	10.21	8.18	-2.82	<b>0.005</b>	117.33	9.23	3.83	-3.36	<b>0.001</b>
AT	120.67	9.23	9.70	-2.82	<b>0.005</b>	117.33	9.23	3.83	-3.36	<b>0.001</b>

**Effect of Treatments on Hip – Extension**

Hip –EXTENSION	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	18.00	10.14	-			13.33	7.24	-		
Day 15	18.00	10.14	0.00	0.00	1.000	13.33	7.24	0.00	0.00	1.000
Day 30	18.00	10.14	0.00	0.00	1.000	13.33	7.24	0.00	0.00	1.000
Day 45	19.33	10.15	7.41	-2.00	0.046	13.33	7.24	0.00	0.00	1.000
Day 60	20.33	9.35	12.96	-2.65	<b>0.008</b>	14.33	7.99	7.50	-1.73	0.083
Day 75	20.67	9.61	14.81	-2.53	<b>0.011</b>	15.71	8.05	17.86	-2.65	<b>0.008</b>
Day 90	21.00	9.49	16.67	-2.71	<b>0.007</b>	17.33	6.51	30.00	-3.46	<b>0.001</b>
AT	21.67	9.00	20.37	-2.81	<b>0.005</b>	18.00	6.49	35.00	-3.50	<b>0.000</b>

**Effect of Treatments on Hip – Abduction**

Hip –ABDUCTION	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	25.00	8.02	-			18.33	9.00	-		
Day 15	25.00	8.02	0.00	0.00	1.000	18.33	9.00	0.00	0.00	1.000
Day 30	25.33	7.67	1.33	-1.00	0.317	18.00	9.22	1.82	-1.00	0.317
Day 45	27.33	6.51	9.33	-2.12	<b>0.034</b>	18.33	9.00	0.00	0.00	1.000
Day 60	28.33	6.45	13.33	-2.71	<b>0.007</b>	20.00	9.64	9.09	-2.24	<b>0.025</b>
Day 75	29.00	6.04	16.00	-2.59	<b>0.010</b>	21.67	8.80	18.18	-3.16	<b>0.002</b>
Day 90	29.67	5.50	18.67	-2.72	<b>0.006</b>	22.33	8.42	21.82	-3.21	<b>0.001</b>
AT	31.00	6.32	24.00	-2.70	<b>0.007</b>	23.33	7.94	27.27	-3.42	<b>0.001</b>

**Effect of Treatments on Hip – Adduction**

Hip –ADDUCTION	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	24.67	8.96	-			20.33	7.43	-		
Day 15	24.67	8.96	0.00	0.00	1.000	20.33	7.43	0.00	0.00	1.000
Day 30	25.33	9.54	2.70	-1.41	0.157	20.33	7.43	0.00	0.00	1.000
Day 45	25.67	9.23	4.05	-1.73	0.083	20.33	7.43	0.00	0.00	1.000
Day 60	26.33	8.76	6.76	-2.24	<b>0.025</b>	21.00	8.06	3.28	-1.41	0.157
Day 75	27.33	7.76	10.81	-2.53	<b>0.011</b>	23.00	6.49	13.11	-2.83	<b>0.005</b>
Day 90	27.67	7.53	12.16	-2.46	<b>0.014</b>	23.67	6.67	16.39	-3.16	<b>0.002</b>
AT	27.33	7.53	10.81	-2.13	<b>0.033</b>	24.67	6.67	21.31	-3.36	<b>0.001</b>

**Effect of Treatments on Hip – Internal Rotation**

Hip -INTERNAL ROTATION	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	25.67	11.78	-			23.00	8.19	-		
Day 15	25.67	11.78	0.00	0.00	1.000	23.00	8.19	0.00	0.00	1.000
Day 30	25.67	11.78	0.00	0.00	1.000	23.00	8.19	0.00	0.00	1.000
Day 45	26.33	11.57	2.60	-1.41	0.157	23.00	8.19	0.00	0.00	1.000
Day 60	28.33	9.57	10.39	-2.33	<b>0.020</b>	23.67	7.90	2.90	-1.41	0.157
Day 75	28.67	9.35	11.69	-2.53	<b>0.011</b>	26.00	7.84	13.04	-3.00	<b>0.003</b>
Day 90	29.33	9.42	14.29	-2.89	<b>0.004</b>	27.00	8.41	17.39	-3.21	<b>0.001</b>
AT	30.67	8.63	19.48	-2.71	<b>0.007</b>	27.67	7.76	20.29	-3.50	<b>0.000</b>

**Effect of Treatments on Hip – External Rotation**

Hip - EXTERNAL ROTATION	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	26.33	12.02	-			17.00	7.75	-		
Day 15	26.33	12.02	0.00	0.00	1.000	17.00	7.75	0.00	0.00	1.000
Day 30	27.00	11.31	2.53	-1.41	0.157	17.00	7.75	0.00	0.00	1.000
Day 45	27.67	10.83	5.06	-1.63	0.102	17.00	7.75	0.00	0.00	1.000
Day 60	28.67	9.90	8.86	-2.07	<b>0.038</b>	17.67	7.04	3.92	-1.41	0.157
Day 75	29.33	9.80	11.39	-2.26	<b>0.024</b>	20.33	7.43	19.61	-3.16	<b>0.002</b>
Day 90	31.67	8.38	20.25	-2.72	<b>0.006</b>	20.67	7.29	21.57	-3.32	<b>0.001</b>
AT	31.67	8.38	20.25	-2.72	<b>0.006</b>	22.00	6.76	29.41	-3.22	<b>0.001</b>

**Effect of Treatments on Knee – Flexion**

Knee - FLEXION	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	109.67	9.72	-			112.67	8.21	-		
Day 15	110.33	9.35	0.61	-1.00	0.317	112.67	8.21	0.00	0.00	1.000
Day 30	110.67	9.42	0.91	-1.34	0.180	112.67	8.21	0.00	0.00	1.000
Day 45	112.00	9.41	2.13	-2.07	<b>0.038</b>	112.67	8.21	0.00	0.00	1.000
Day 60	117.00	7.27	6.69	-3.11	<b>0.002</b>	113.33	8.59	0.59	-1.41	0.157
Day 75	118.00	7.27	7.60	-3.23	<b>0.001</b>	115.67	7.99	2.66	-3.00	<b>0.003</b>
Day 90	120.67	6.23	10.03	-3.21	<b>0.001</b>	116.00	7.84	2.96	-3.16	<b>0.002</b>
AT	124.00	7.61	13.07	-3.32	<b>0.001</b>	117.67	8.42	4.44	-3.22	<b>0.001</b>

**5. Discussion on Overall Effect of Therapy**

**Marked improvement** was not observed in 40% of patients in group A and 26.7% of patients in group B.

**Moderate improvement** was observed in 26.7% patients in group A and in 33.3% patients in group B.

**Mild improvement** was observed in 26.7% of patients in group A and in 33.3% of patients in group B.

**No improvement** – in group-A, and group B No improvement was found in 6.7% of the patients.

**Complete remission-** No complete remission has been found in any of the group.

No significant difference ( $p=0.891$ ) was found in final improvement status between the two groups. Though Group A showed more proportion of marked improvement (40%) than B (26.7%).

**Probable Mode of Action of Drugs**

In present study protocol 3 formulations were selected

- 1) *Kheerabala tail*- for oral administration in group A
- 2) *Mahamashtaila* – for Abhyanga and as *Matrabasti* in group A & B

**1) Mode of action of *Kheerabalatail***

The probable mode of action of *Ksheerabala Taila* could be analyzed by its *Rasa Panchaka*. All the three ingredients *Bala*, *Ksheera* and *TilaTaila* possess *Madhura Rasa* and *Vipaka*. *Madhura Rasa* mitigates both *Vata* and *Pitta Dosha*. It is *Dhatunaamprabalam* (strength to the tissue) and is good for sense organs and pleasing to mind (*Shadindriyaprasadaka*). It nourishes the body (*Tarpayati*) and plays a major role in promoting life (*Jeevayati*). *TilaTaila* possesses *Tikta Rasa* (bitter taste), the most effective in mitigating *Pitta Dosha* and *Kapha Dosha* in addition to *Madhura Rasa*. *Tikta Rasa* is effective in relieving fainting (*Murchaprasamana*) and promotes memory and intellect (*Medhya*). *UshnaVeerya* (of heating virtue) of *TilaTaila* reduces the *Vata* and *Kapha*. Since it has gone through processing by *Sheeta Veerya* drugs like *Bala* and *Ksheera*, its *Ushnatva* may get altered. *Vata* and *Kapha* are alleviated without agitating *Pitta* which is also *Ushna*. Thus, *Ushna Guna* of *Ksheerabala* acts without having adverse on *Dhatu*. This clears the channels, thereby allowing the action of the properties like *Snigdha*, *Manda*, *Sukshma* and *Vyavayi*. *Ksheerabala Taila* is said to have pacifying effects on all the eighty chronic conditions of *Vata* origin (*Vata Nanatamja Vikara*) such as *Akshepaka* (~convulsions), *Vepathu* (~tremors), *Shrama* (~fatigue), *Glani* (~malaise), *Vishada* (~depression), *Aswapna* (~insomnia) and *Anavasthithachitata* (~behavioral disorders). *KsheerabalaTaila* is being utilized as a *Rasayana*



drug in conventional Ayurveda treatment for epilepsy. The continuous administration of this formulation prevents the release of abrupt electric discharges and improves the physical and mental condition of the patient. It has profound soothing and relaxing effect on mind. Recent research has showed that it reduces the oxidative stress in rat brain and hence proven effect on neurotoxicity. The oxidative stress is the most important mechanism in the development and progression of epilepsy and other diseases including Alzheimer's disease, chronic degenerative disorders, stroke, rheumatoid arthritis, diabetes and cancer. The presence of flavonoids in *Sida cordifolia* has been confirmed by phytochemical analysis and these as well as their glycosides exert anxiolytic, sedative and anticonvulsant effects on the central nervous system. The presence of antioxidants prevents the possible damage of neurons. The anti-inflammatory activity of Trividha Paka of Ksheerabala Taila against carrageenan induced acute inflammation and edema was compared to the standard anti-inflammatory drug, Diclofenac. Significant anti-inflammatory activity with late onset was observed in the Mridu and Madhyama Paka of Ksheerabala Taila. The Nasya with Ksheerabala Taila suppresses nerve inflammation due to its Sheeta property and promotes nerve regeneration and gives strength to muscles due to its Balya and Brihmana properties of drug present in it. It precludes wear and tear of nervous and muscular tissue. Another similar study shows that Ksheerabala<sup>101</sup> significantly protects brain cells and reduces the severity of damage caused by alcohol intoxication. Nasya with Ksheerabala Taila in case of Sandhigata Vata with special reference to cervical spondylosis shows highly significant results. Shirobasti with Ksheerabala Taila along and Navana Nasya with Mahamasha Taila are found to be effective in the management of Ardita (facial paralysis). Snehana Karma with Ksheerabala Taila nourishes the Sleshaka Kapha stimulate the sensory nerve endings and provide strength to the facial muscles 1 [Charaka Samhita, Sutrasthana, chapter 14, verse 20-24]. Moordha Taila with Ksheerabala Taila when applied on the head, produces clarity of the sense organs, confers strength to the voice, lower jaw and head. It serves to rejuvenate the body and eliminate mental exhaustion. Ksheerabala Taila Matra Basti and Parisheka Sweda has a role in the management of Katigraha (lumbar spondylosis). Ksheerabala Taila is used for the purpose of Anuvasana Basti. Panchatikta Ksheera Basti and Anuvasana Basti with Ksheerabala Taila as per Yog Basti regime are found significant in case of Greeva Hundana (cervical spondylosis). Ksheerabala Taila is one among the treatment protocol in the management of childhood Karshya (undernutrition). Ksheerabala Taila has effect in children with cerebral palsy

#### Mode of Action of Mahamasha taila basti

*Mahamash taila* one of the effective oil widely used for many neurological condition. *Masha* is the main ingredient of this oil. It is used for both external and internal administration. Other ingredients are *Dashmooladravya*, *Chhagamamsa*, and many *Kalka* ingredients. As base *Tilataila* was used. *Masha* is said to be "*Param Vatahara*" (Ch. Su.27/24) due to *Madhura rasa*, *Guru Snigdha*, *Ushna Virya* and *Madhura Vipaka* all are *Vata* pacifying properties. *Masha* also indicated in nervous disability,

paralysis and weakness of memory. *Dashmoola* indicated in *Vatavyadhi* due to its *Vatahara* properties. *Chhagamamsa* is *sarvarogaprashamanam* (alleviates all diseases) and promotes *vidya* (wisdom), *swarya* (good voice), *bala* (strength) of *vayas* (age), *buddhi* (intellect), *indriyas* (senses) respectively (Ch.Su.314), *Tilataila* with *Snigdha*, *Guru* properties pacifies *Ruksha*, *Khara* properties of *Vata* and due to its *Sukshma*, *Vyavayi*, *Vikasi*, *Visada* and *Sara* properties increases permeability of cell membrane, *Godugdha* having *Madhur Rasa*. *Guru Snigdha* and *Madhur Vipaka*. Due to these properties it pacifies *Vata dosha*. Maximum *kalka* ingredients are possess *Vata-kaphahar* properties. Keeping all in mind this taila was selected for *Anuvasana Basti* and *Abhyanga*. When medicated oil reaches rectum and colon, presence of short chain fatty acids in oil allows direct diffusion of drugs from epithelial cells in to capillary blood villi showing its generalized effect. In children *mridu basties* are used commonly in the management of various neurological conditions. By considering all the above facts, *Basti* seems to be beneficial in children with CP.

*Abhyanga* with *Mahamashtaila* and *Shashtika Shalipinda sweda* (as *poorva karma*) also relieves muscle spasticity and improves range of motion.

## 6. Discussion on Overall Improvement of the Herapy

### Delayed milestones, Activity of daily life, and Gross motor functions-

- Group A showed early improvement and higher efficacy in these parameters. This shows that *Mahamasha Taila Matra Basti* along with *Ksheerabala tail orally* has significant effect on improvement of gross motor functions by cumulative *Balya* and *prabhava* of both drugs. This improvement in patients also supports the concept of Neuroplasticity
- Previously it was believed that neurons do not repair or rejuvenate after any injury, but the new concept of neuroplasticity says that CNS have the ability to repair their neurons by axonal sprouting to take over the function of damaged neurons.

### Spasticity and Range of motion:

- Group A and Group B both showed significant improvement but statically insignificant difference in results on comparison. This means that common therapy in both groups *mahamasha taila matrabasti* has therapeutic effect on muscle spasticity and range of movement along with *abhyanga* and *SSPS* as *vatavyadhi chikitsa upakrama*. However group A showed early improvement in spasticity and range of motion it might be due to cumulative effect of *Ksheerabala tail, Mahamasha Taila* as well as *SSPS*.

## 7. Conclusion

- Group A and Group B both showed significant improvement and statically insignificant difference in results on comparison. This means that common therapy in both groups *mahamashatail Matrabasti* has

therapeutic effect on muscle spasticity and range of movement along with *abhyanga* and SSPS as *vatavyadhi chikitsa upakrama*.

- Group A showed early improvement and higher efficacy in these parameters. This shows that *Kheerabala taila* has significant effect on improvement on milestone and gross motor functions by its *Balya prabhava*. This improvement in patients also supports the concept of Neuroplasticity.
- The clinical study was planned to compare the effectiveness of *Mahamasha taila Matrabasti* when given alone and when given with *Kheerabala taila*. The clinical study concluded that *Kheerabala taila* along with *Panchkarma* procedures is more effective in achieving delayed milestones, improvement in activity of daily life, spasticity, gross motor functions, range of motion. while muscle power can be improved by using *Panchkarma* procedures (*abhyanga*, SSPS and *basti*) only.

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