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Effect Of Herbal Formulation On Motor Functions In Pediatric Spastic Cerebral Palsy-An Open Randomised Controlled Trial

Dr. Preetham Pai[1*], Dr Leena Srivastava[2], Dr Parag Gaikwad[3], Dr Roopesh Jadhav[4]

[*1]Professor, Department of Kaumarabhritya, Bharati Vidyapeeth (deemed to be university) College of Ayurved, Pune-411043, India.

[2]Developmental Pediatrician, Bharati Vidyapeeth (deemed to be university) Medical College & Hospital, Pune-411043, India.

[3]Honorary Pediatrician, Department of Kaumarabhritya, Bharati Vidyapeeth (deemed to be university) College of Ayurved, Pune-411043, India.

[4]Junior research fellow,research project on cerebral palsy funded by Ayurgyan scheme , ministry of AYUSH,GOI.

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ABSTRACT

Spastic cerebral palsy (CP), majorly characterised by muscle stiffness and motor dysfunction, significantly impacts the quality of life of affected individuals and also the relatives of the sufferer. Modern management of cerebral palsy (CP) has significantly improved symptom control and quality of life, but it has several limitations. One of the significant drawbacks is the lack of curative treatment, as current medical approaches focus primarily on managing symptoms rather than reversing brain damage.

Seeing challenges, alternative and integrative approaches, including traditional medicine like Ayurveda, may provide a more holistic, accessible, and sustainable solution for managing CP.

Ayurvedic medicine offers potential effectiveness for managing such neurological conditions. This study investigates the efficacy of Kalyanak Ghritam (KG), a classical Ayurvedic formulation, in improving motor function and reducing spasticity in children with spastic cerebral palsy. The study was conducted as a randomised, controlled clinical trial with participants in the age group 2–7 years diagnosed with spastic CP. The treatment group received oral administration of KG along with standard physiotherapy, while the control group was treated with physiotherapy alone. The outcomes were assessed using validated tools like the Gross motor milestones, GMFM and Modified Ashworth Scale.

The results demonstrated a statistically significant improvement in motor milestones turning over, head holding, crawling and standing and muscle power in the treatment group compared to the control group. KG showed good neuroprotective and muscle-strengthening effects, suggesting its potential as an adjunct therapy in spastic CP management. The study concludes that integrating Ayurvedic herbal formulation like KG with conventional rehabilitation strategies may enhance treatment outcomes in spastic cerebral palsy, finally improving the quality of life of sufferers.

Keywords: *Kalyanaka Ghritam, Spastic Cerebral Palsy,herbal formulation,motor functions*

1. INTRODUCTION

Cerebral palsy (CP) is a group of neurological conditions that affect movement, muscle tone, and motor skills, resulting from damage to the developing brain before, during, or shortly after birth. This brain damage impacts the ability to control muscles and coordinate movement, leading to varying levels of physical disability. The severity of CP differs widely; some individuals experience mild motor impairments, while others may have severe disabilities requiring lifelong care. Common symptoms include spasticity (muscle stiffness), ataxia (lack of muscle coordination), and dyskinesia (involuntary movements). Additionally, CP may be linked to other complications such as intellectual disabilities, seizures, and difficulties with vision, hearing, or speech.

CP is also a leading cause of childhood disability, affecting a child's ability to move, maintain posture, and balance. The incidence of cerebral palsy in India is approximately 3 per 1,000 live births, which is higher than the global average of about 2 per 1,000 live births[1]. Both children with CP and their caregivers often experience lower health-related quality of life due

to the physical and emotional challenges posed by the condition. Among the four main types of CP, spastic cerebral palsy is the most common, affecting 70-80% of individuals with the disorder[2]. It is characterized by increased muscle tone, resulting in stiff muscles and awkward, difficult movements, and may lead to joint deformities over time.

Although there is no cure for cerebral palsy, treatments focus on managing symptoms and improving quality of life. These interventions, tailored to the specific needs of each person, often involve a multidisciplinary approach, combining medical care, therapy, and assistive devices. The therapies are often expensive, and patients do not continue the treatment for a longer duration. However, traditional medicine, particularly Ayurveda, offers alternative therapies for improving motor functions and reducing spasticity. Kalyanaka Ghritam is a classical Ayurvedic formulation primarily used for neurological and psychological disorders. It contains ghee (clarified butter) infused with herbs and is believed to have neuroprotective, rejuvenating, and calming effects. It is traditionally recommended for improving brain function, reducing spasticity, and enhancing the quality of life in neurodegenerative conditions. Pre-clinical studies have proven the safety of Kalyanaka Ghritam on the liver and the kidneys. Clarified butter-based formulations are said to penetrate deeply into tissues, which may help reduce muscle stiffness and promote relaxation[3,4]. The herbal components of Kalyanak Ghritam are believed to enhance nerve function and protect against further damage[5]. Thus providing improvements in speech, cognitive functions, and overall motor coordination[6].

Hence a study was conducted to analyse the effect of oral administration of Kalyanaka ghritam on motor functions in pediatric spastic cerebral palsy.

2. METHODOLOGY

CTRI Registration: The study is registered under the CTRI. The registration number is CTRI/2019/07/020410

Ethics certificate: The trial is registered under the Institutional Ethics Committee.

Project no. BVDUCOA/EC/Project/KBB/2023-24

Date – 28/12/2023

Study design: An open-label randomized controlled trial was conducted at Ayurvedic Pediatric OPD, Bharati Vidyapeeth (deemed to be) University College of Ayurved and Hospital, Pune.

Study population: Children suffering spastic cerebral palsy in the age group of 2- 7 years were enrolled for the study. Total 30 subjects suffering from spastic cerebral palsy were enrolled for the study.The GMFCS scoring was noted in all 30 enrolled subjects. The distribution of patients across different levels of GMFCS was as follows: 10% of the patients were classified at level 1, indicating the least impairment. Level 2 had 13.33% of the patients, while 26.66% were categorized under level 3. Level 4 accounted for 10% of the cases, and the highest proportion, 46.66%, was found at level 5, representing the most severe motor limitations. This distribution highlights the varying degrees of functional mobility among the patients, with a significant number experiencing severe impairment.

Cerebral palsy subjects suffering from seizures;multiple contractures; who have undergone selective dorsal rhizotomy ;presenting with Hydrocephalus requiring surgical intervention;suffering from acute infections, infectious diseases; presenting with grade 5 spasticity were excluded from the study.

Sample size determination:

The sample, i.e. n, was calculated using the prevalence rate of cerebral palsy, which is 2-3/1000 live births.

- N= z2 p(1-p)/(d2)
- N=1.96x0.03 (1-0.03)/0.05x0.05
- N=3. Since the number was small, a sample size of 30 was decided
- Z=1.96, P =Prevalence rate.

Intervention: 42 Subjects were screened for spastic cerebral palsy. Out of them 30 diagnosed cases of spastic cerebral palsy were enrolled for the study. Informed consent was collected from the parent after explaining the details of the trial. A detailed case consisting of main complaints present history, past history, family history, treatment history,developmental history etc was taken in a specialized CRF designed for the study. Subjects who fit the inclusion criteria and given informed consent were randomly allotted to either the study group or the control group. The subjects in the study group received herbal ghee(kalyanaka ghritam) orally and physiotherapy for 5 and 6 months, respectively. The control group received only physiotherapy for 6 months.

The subjects were followed up every month to assess any improvement in the gross motor milestones ,muscle power and reduction in the spasticity. The gross motor mile stones were assessed using the standard CDC grading . Muscle power in upper and lower limbs were assessed using the MRC grading and spasticity was noted while enrolling the patient using the Modified Ashworth Scale.The table below provides Details of physiotherapy and dose of herbal ghee.

Dose of the trial drug:

Trial drug	Age group	dose	vehicle	Duration
Kalyanaka Ghritam	2-5 years	2.5 gms bid after lunch and dinner	nil	5 months
	5-7 years	5 gms bid, after lunchand dinner.		

Details of Online Physiotherapy Sessions:

S. no	Days	Timing	Online mode	Documentation
1.	Monday Tuesday Wednesday Thursday Friday Saturday	2 pm-5 pm 2 pm-5 pm 2 pm-5 pm 2 pm-5 pm 2 pm-5 pm 2 pm-5 pm	1. Online sessions were conducted on a one-to-one basis using WhatsApp video call 2. The physiotherapist demonstrated the exercises to the mother and then the mother did the exercise to her child. 3. The exercises were advised based on the affected muscle groups	A separate register was maintained in which details of the physiotherapy sessions were maintained. The patient's name, age, date, and details of physiotherapy given were entered in the register.

SOP of preparation of Trial drug- Kalyanaka Ghritam

The trial drug was prepared by AYUSH Ayurved, a GMP-certified pharmacy. The individual drugs were authenticated according to the API parameters (Ayurveda pharmacoepia of India), and then the drug was prepared traditionally as mentioned in sharanghadhara Samhita. The standardization of Kalyanaka Ghritam was also done according to the API parameters. The authentication and standardization certificates are attached in Annexures I and II.

Safety parameters of KG: Diddi Sneha Latha, Arulmozhi et al. have conducted toxicity studies of KG on male Wistar rats. They studied the safety pharmacology of the KG in oral and Nasal route in Wistar rats for 28 days.

CNS, CVS and respiratory profile were evaluated on days 0,14 and 28 days

No harmful events were seen in CNS, CVS, and the respiratory safety profile of KG.

Ingredients of Kalyanaka Ghritam:

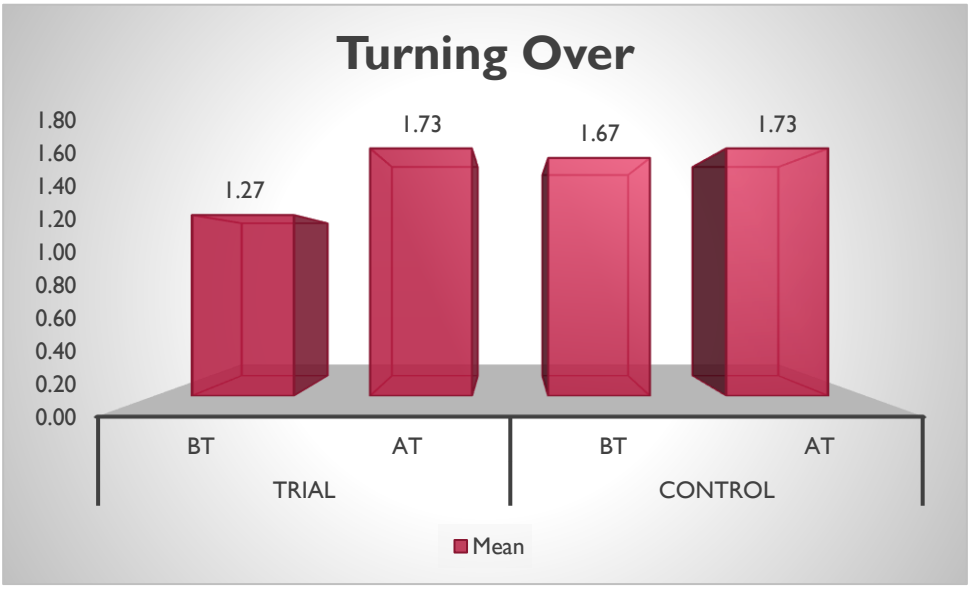
S. No	Drug (Sanskrit name)	Botanical name	Part used	Chemical constituents	Action
1	*Dadima*	Punica Granatum Linn	pericarp	Punicalin, punicalagine	Cytotoxic, anti inflammatory
2	*Devadaru*	Cedrus deodara	heartwood	Wikstromol, matairesamol	Anti convulsant, anti sarcoptic
3	*Brihati*	Solanum indicum	Whole plant	Quercitin,solanidine,solasodine	mollusascidal,immunomodulatory
4	*Kusta*	Saussurea leppa	root	Saussureamine, quercin	cardiotonic, immunomodulatory
5	*Manjista*	Rubia cordifolia linn	stem	Anthraquinone, alizarin	Anti microbial, anti oxidant

6	*Vella*	Embelia ribes	seed	Embelin,cinnamic acid	Contraceptive, anti oxidant
7	*Talisapatra*	Abies webbiana	leaf	Abiesin, azirdin	Anti inflammatory, hypnotic
8	*Utpala*	Nymphoea stellate	flower	Nymphayol, gallic acid	Tumor inhibition, immunogenic
9	*Bhadrela*	Amomum subulatum	seed	eucalyptol	Anti ulcer, cardio-adaptogen
10	*Vishaala*	Cirullus colocynthis	fruit	Colocynthin, pectin gum,colocynthetin,isorintin, isovitixin	Analgesic, mosquito-larvicidal
11	*Krishna sariva*	Idnocarpus frutescens	root	Cryptocin, cryptolepain	Anti oxidant hepato protective
12	*Swetha sariva*	Cryptolepis buchanana	root	Descine, hemidescine, emidine,hemisine	Anti oxidant ,neuro protective
13	*Haridra*	Curcuma longa	rhizome	Curcumin, curcuminiods, curcumene	Ani diabetic, anti oxidant
14	*Daruharidra*	Berberis aristata	stem	Berbamine,berberin, palmatine, dihydrocaroline	Anti PAF(platelet activation factor), hepato protective
15	*Shaliparni*	Desmodium gangeticum	root	Chlorogenin,diosgenin,dioscin, ruskogenin, rhamnose, campasterol	Anti-oxidant, tranquillizer, CNS depressant
16	*Prshniparni*	Uraria picta	root	4-methylenedioxyisoflevanone,5-dihydroxy-2	Anti inflammatory, anti dote for snake bite
17	*Priyangu*	Callicarpa macrophylla	inflorescence	Ursolic acid, betulinic acid, daucosterol	Anti arthritic, anti fungal
18	*Kamal pushpa*	Nymphea stellata	flower	Nymphayol (25,26-dinorcholest-5-en-3b-ol) corilagin, gallic acid, gallic acid methyl ester, isokaempferide, kaempferol, quercetin-3-methyl ether, quercetin	Analgesic and anti inflammatory action

19	*Nagakesar*	Mesua fernea	stamen	Mesuaferrol,mesual, mesuagin, messuaferrone	Anti convulsant, anti venom action
20	*Malati*	Jasminum officinale	flower	Ursolic acid, eugenol,oleuropein, oleacein	Analgesic, anti cholinesterenase
21	*Danti*	Baliospermum montanum		Montanin, baliospermin,axillarininc acid	Anti cancerous and immunomodulator
22	*Padmaka*	Prunus cerasoides		Quercitin,prunetin, carasinone, carasidin	Anti tumor action and anti oxidant
23	*Amalaki*	Emblica officinalis	pericarp	Phylleblim, emblecol, gallic acid, ellagic acid, vit c, phyllemblin	Neuroprotective action and anti oxidant
24	*Haritaki*	Terminalia chebula	pericarp	Chebulic acid, gallic acid,chebulagic acid, mannitol	Hepatoprotective action and , anticancerous
25	*Vibhitaki*	Terminalia bellirica	pericarp	Gallic acid, chebulic acid,ellagic acid, punicalagin, neochebulinic acid	Anti hypertensive action, analgesic
26	*Tagara*	Vallariana jatamamsi	root	Valerene,actinidine, chatinine	Carminative, antispasmodidc and anti scorpion poison
27	*Rakta chandan*	Pterocarpus santalinus	Heart wood	Santalin,lupeol, pterocarpan, santal	Anti helminthic action and aphrodisiac
28	*Elavaluka*	Prunus avium	Stem bark	Catechin ,epicatechin, quercitin, quercitin 3 rutinoside	Neuroprotective, anti cancerous action
29	Clarified butter.				

	Trial group	**Control group**
Intervention	Kalyanaka Ghritam and Physiotherapy physiotherapy	Physiotherapy
Duration	6 months	6 months
Patients recruited	15	15
Assessment parameters	Gross motor milestones,muscle power, Modified Ashworth scale	Gross motor milestones, Muscle power. Modified Ashworth scale
Follow ups taken	D0,D30,D60,D90,D120,D120,D150,D180	D0,D30,D60,D90,D120,D120,D150,D180

3. OBSERVATIONS AND RESULTS

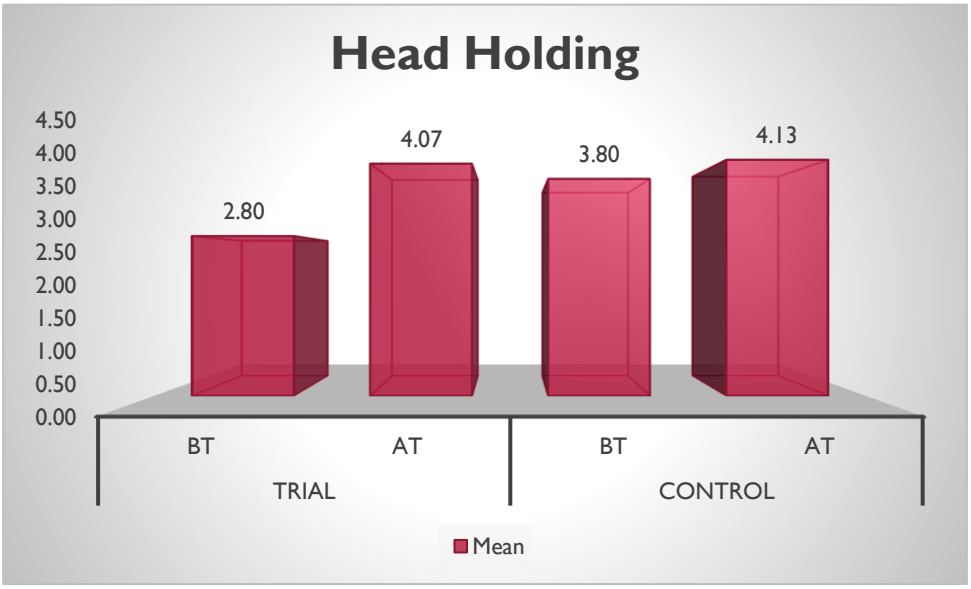


Headholding motor mile stone:

Head Holding		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Trial	BT	2.80	4.00	2.34	0.60	-2.263[b]	0.0237	45.24	Sig
	AT	4.07	5.00	1.62	0.42				
Control	BT	3.80	5.00	1.82	0.47	-1.633[b]	0.1025	8.77	NS
	AT	4.13	5.00	1.81	0.47				

Since observations are on ordinal scales (gradations), we have used the Wilcoxon Signed Rank Test to test efficacy in the Trial Group and Control Group. From the above table, we can observe that the P-value for the Trial Group is less than 0.05, While the P-value for the Control Group is greater than 0.05.

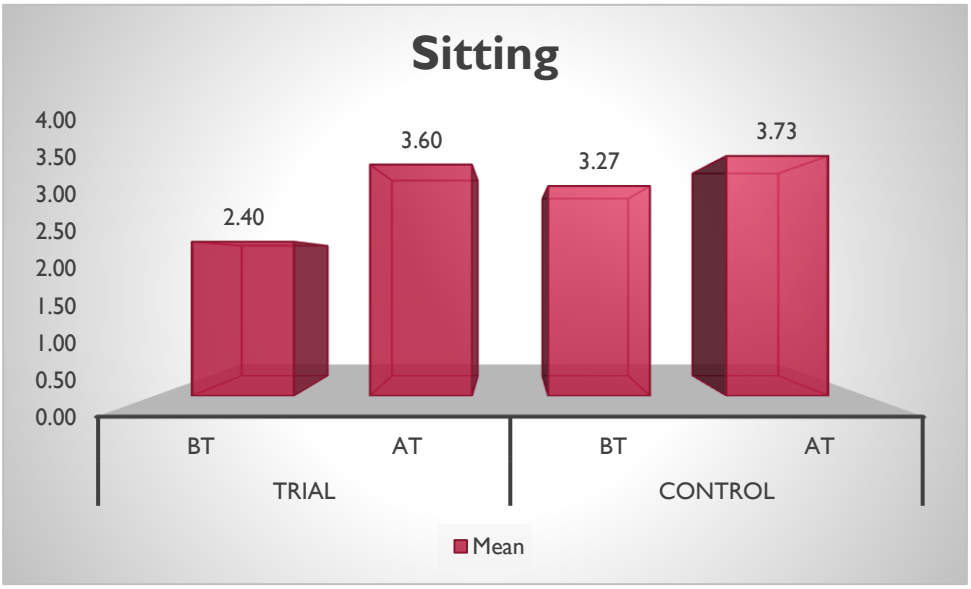
Hence, we can conclude that the effect observed in the Trial Group is significant while the Control Group is not significant.



Sitting mile stone:

Sitting		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Trial	BT	2.40	4.00	2.35	0.61	-2.388[b]	0.0169	50.00	Sig
	AT	3.60	4.00	1.35	0.35				
Control	BT	3.27	4.00	2.02	0.52	-2.121[b]	0.0339	14.29	Sig
	AT	3.73	5.00	1.75	0.45				

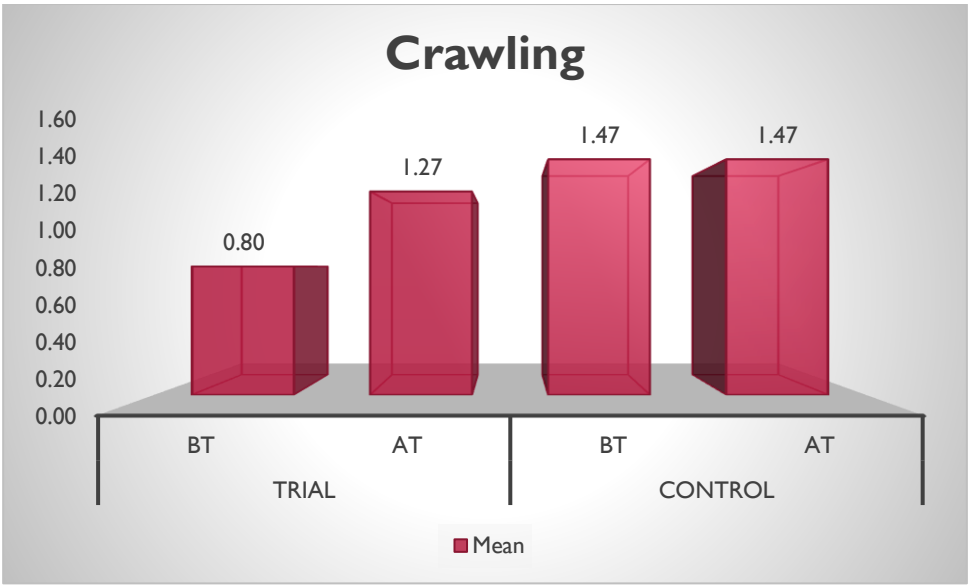
Since observations are on ordinal scales (gradations), we have used the Wilcoxon Signed Rank Test to test efficacy in the Trial Group and Control Group. From the above table, we can observe that the P-value for the Trial Group and Control Group is less than 0.05. Hence, we can conclude that the effect observed in the Trial Group and Control Group is significant.



Crawling mile stone:

Crawling		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Trial	BT	0.80	0.00	1.01	0.26	-2.070[b]	0.0384	58.33	Sig
	AT	1.27	2.00	0.88	0.23				
Control	BT	1.47	2.00	0.74	0.19	.000[d]	1.0000	0.00	NS
	AT	1.47	2.00	0.74	0.19				

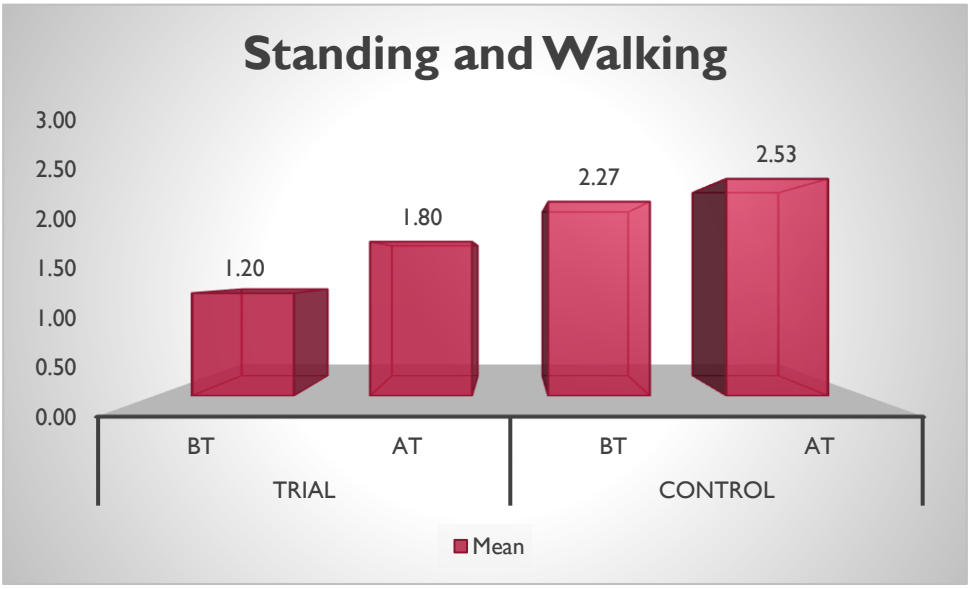
Since observations are on an ordinal scale (gradations), we have used the Wilcoxon Signed Rank Test to test efficacy in the Trial Group and Control Group. From the above table, we can observe that the P-value for the Trial Group is less than 0.05, While the P-value for the Control Group is greater than 0.05. Hence, we can conclude that the effect observed in the Trial Group is significant while the Control Group is not significant.



Standing and walking mile stone:

Standing and Walking		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Trial	BT	1.20	0.00	1.74	0.45	-2.041[b]	0.0412	50.00	Sig
	AT	1.80	2.00	1.86	0.48				
Control	BT	2.27	2.00	2.22	0.57	-1.342[b]	0.1797	11.76	NS
	AT	2.53	4.00	2.36	0.61				

Since observations are on ordinal scales (gradations), we have used the Wilcoxon Signed Rank Test to test efficacy in the Trial Group and Control Group. From the above table, we can observe that the P-value for the Trial Group is less than 0.05, While the P-value for the Control Group is greater than 0.05. Hence, we can conclude that the effect observed in the Trial Group is significant while the Control Group is not significant.



Since observations are on an ordinal scale (gradations), we have used the Wilcoxon Signed Rank Test to test efficacy in the

Trial Group and Control Group. From the above table, we can observe that the P-value for the Trial Group and Control Group is less than 0.05. Hence, we can conclude that the effect observed in the Trial Group and Control Group is significant.

Variable	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value	Result
Turning Over	Trial	15	17.57	263.50	81.500	0.065	NS
	Control	15	13.43	201.50			
	Total	30					
Head Holding	Trial	15	18.30	274.50	70.500	0.043	Sig
	Control	15	12.70	190.50			
	Total	30					
Sitting	Trial	15	17.20	258.00	87.000	0.231	NS
	Control	15	13.80	207.00			
	Total	30					
Crawling	Trial	15	18.00	270.00	75.000	0.016	Sig
	Control	15	13.00	195.00			
	Total	30					
Standing and Walking	Trial	15	16.97	254.50	90.500	0.218	NS
	Control	15	14.03	210.50			
	Total	30					

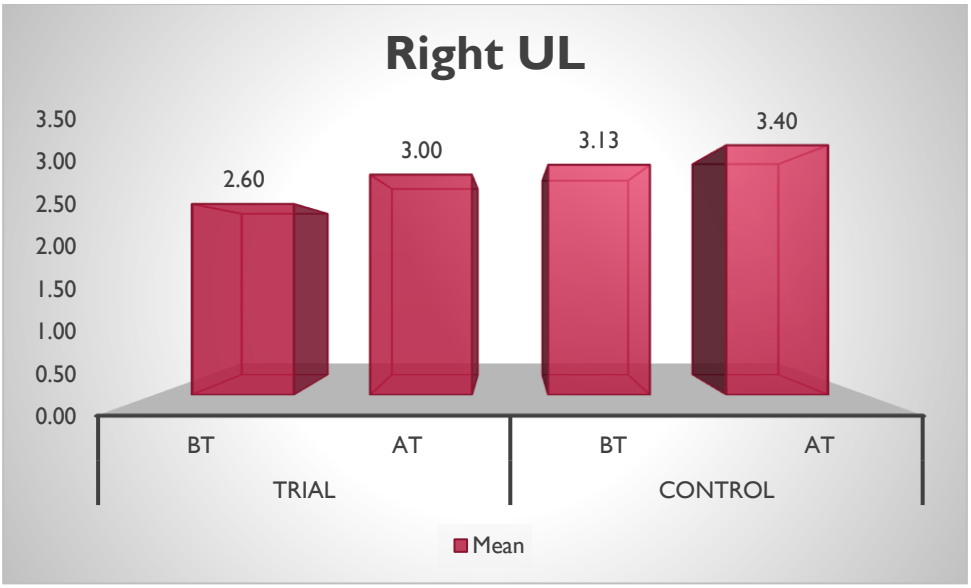
Mann Whitney U Test is carried out to compare the Trial Group and the Control Group. From the above table, we can observe that the P-value is <.05 for head holding and crawling. Hence, there is a significant difference between the treatment given in the trial group and the control group. For the milestones turning over, sitting, standing and walking, p>0.05. Hence, we can conclude that there is no significant difference between the Trial Group and Control Group for these milestones.

4. MUSCLE POWER

Right Upper limb (Rt UL)

Rt UL		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Trial	BT	2.60	3.00	1.18	0.31	-1.387[b]	0.1653	15.38	NS
	AT	3.00	3.00	1.13	0.29				
Control	BT	3.13	4.00	1.25	0.32	-1.414[b]	0.1573	8.51	NS
	AT	3.40	4.00	1.12	0.29				

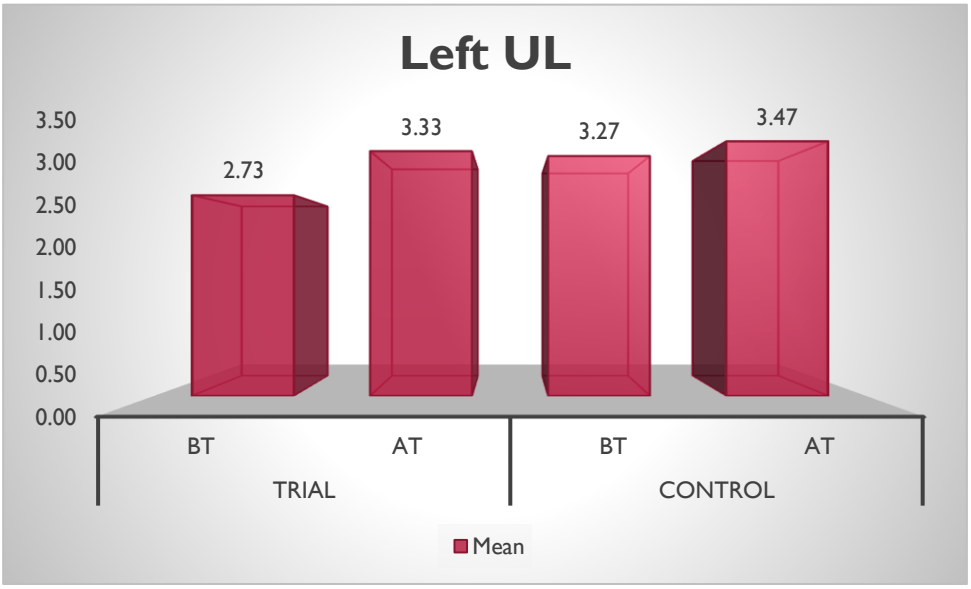
Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy in Trial Group and Control Group. From above table, we can observe that, P-Value for Trial Group and Control is greater than 0.05. Hence, we can conclude that effect observed in Trial Group and Control Group is not significant for muscle power.



Muscle power of Left Upper Limb(UL)

Left UL		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Trial	BT	2.73	3.00	1.10	0.28	-2.460[b]	0.0139	21.95	Sig
	AT	3.33	3.00	1.05	0.27				
Control	BT	3.27	4.00	1.10	0.28	-1.134[b]	0.2568	6.12	NS
	AT	3.47	4.00	1.06	0.27				

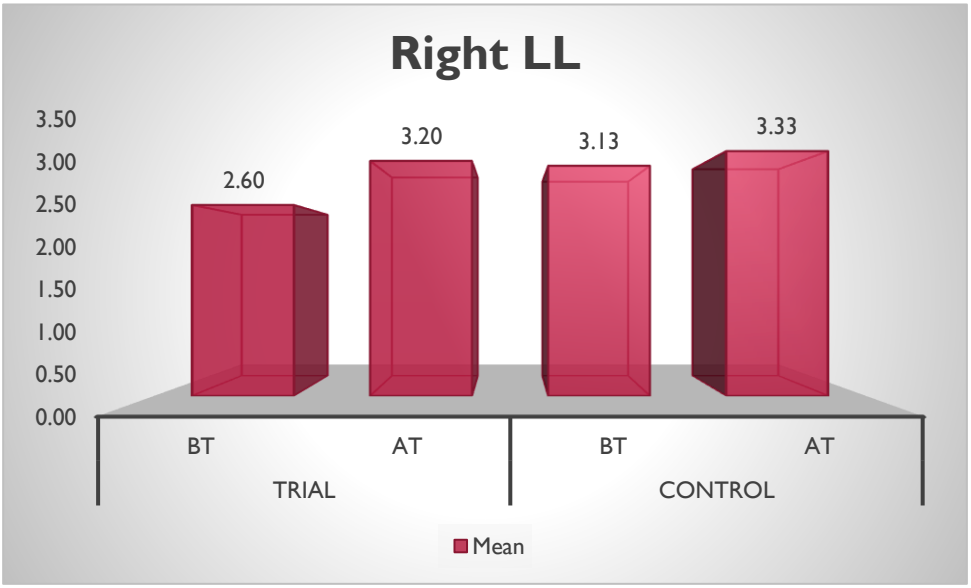
Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy in Trial Group and Control Group. From above table, we can observe that, P-Value for Trial Group is less than 0.05 While P-Value for Control Group is greater than 0.05. Hence, we can conclude that effect observed in Trial Group is significant while Control Group is not significant.



Muscle power of Right Lower Limb(Rt LL)

Rt LL		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Trial	BT	2.60	3.00	1.12	0.29	-2.460[b]	0.0139	23.08	Sig
	AT	3.20	3.00	1.01	0.26				
Control	BT	3.13	3.00	1.06	0.27	-1.134[b]	0.2568	6.38	NS
	AT	3.33	3.00	1.05	0.27				

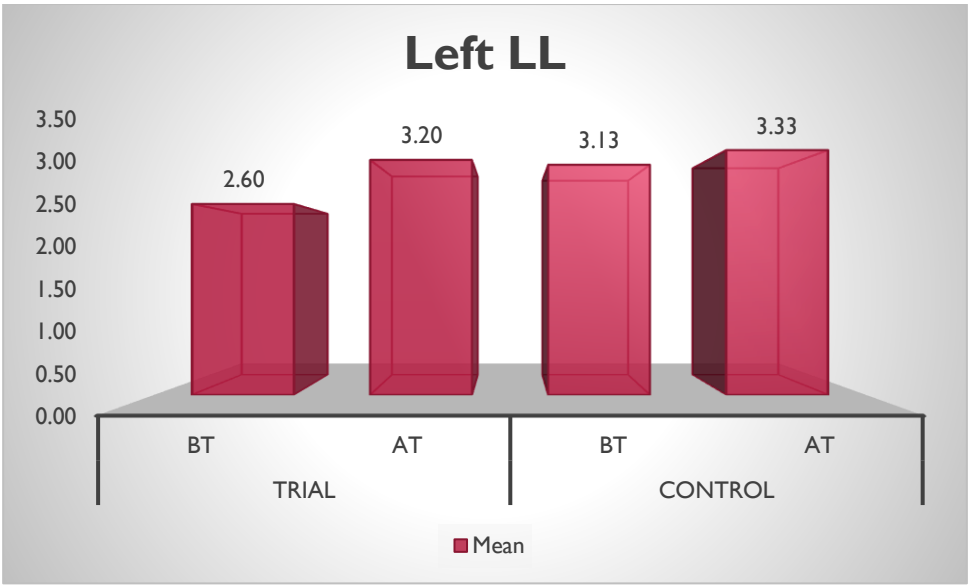
Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy in Trial Group and Control Group. From above table, we can observe that, P-Value for Trial Group is less than 0.05 While P-Value for Control Group is greater than 0.05. Hence, we can conclude that effect observed in Trial Group is significant while Control Group is not significant.



Muscle power of Lt LL:

Lt LL		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Trial	BT	2.60	3.00	1.12	0.29	-2.460[b]	0.0139	23.08	Sig
	AT	3.20	3.00	1.01	0.26				
Control	BT	3.13	3.00	1.06	0.27	-1.134[b]	0.2568	6.38	NS
	AT	3.33	3.00	1.05	0.27				

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy in Trial Group and Control Group. From above table, we can observe that, P-Value for Trial Group is less than 0.05 While P-Value for Control Group is greater than 0.05. Hence, we can conclude that effect observed in Trial Group is significant while Control Group is not significant.



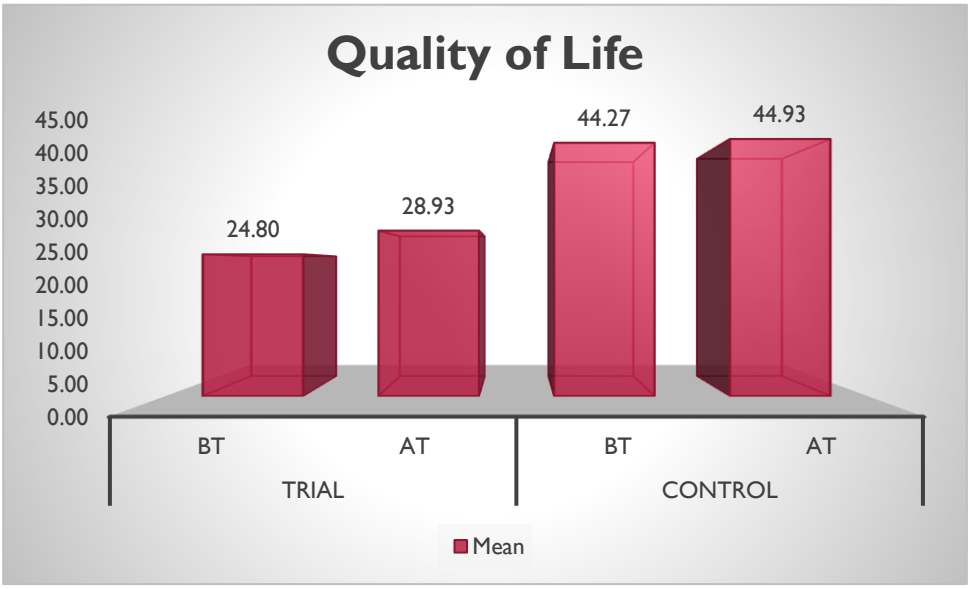
Variable	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value	Result
Rt UL	Trial	15	16.77	251.50	93.500	0.367	NS
	Control	15	14.23	213.50			
	Total	30					
Left UL	Trial	15	17.03	255.50	89.500	0.263	NS
	Control	15	13.97	209.50			
	Total	30					
Rt LL	Trial	15	17.03	255.50	89.500	0.263	NS
	Control	15	13.97	209.50			
	Total	30					
Lt LL	Trial	15	17.03	255.50	89.500	0.263	NS
	Control	15	13.97	209.50			
	Total	30					

Mann Whitney U Test is carried out for comparison between Trial Group and Control Group. From above table, we can observe that P-Value for almost parameters is greater than 0.05. Hence, we can conclude that there is no significant difference between Trial Group and Control Group.

5. QUALITY OF LIFE

Quality of Life		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Trial	BT	24.80	4.00	30.88	7.97	-2.524[b]	0.0116	16.67	Sig
	AT	28.93	18.00	32.52	8.40				
Control	BT	44.27	60.00	37.26	9.62	-1.342[b]	0.1797	1.51	NS
	AT	44.93	60.00	37.33	9.64				

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy in Trial Group and Control Group. From above table, we can observe that, P-Value for Trial Group is less than 0.05 While P-Value for Control Group is greater than 0.05. Hence, we can conclude that effect observed in Trial Group is significant while Control Group is not significant.



Variable	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value	Result
Quality of Life	Trial	15	18.47	277.00	68.000	0.028	Sig
	Control	15	12.53	188.00			
	Total	30					

Mann Whitney U Test is carried out for comparison between Trial Group and Control Group. From above table, we can observe that P-Value is less than 0.05. Hence, we can conclude that there is significant difference between Trial Group and Control Group.

Further, we can observe that mean rank for Trial Group is greater than Control Group. Hence, we can conclude that, effect observed in Trial Group is better than Control Group.

6. DISCUSSION FOR MANN-WHITNEY U TEST

Discussion:

Cerebral Palsy (CP) is a lifelong neurological disorder that affects movement, muscle tone, and posture. Management requires a multidisciplinary approach to improve mobility and function, enhance independence in daily activities, prevent complications (contractures, pressure ulcers, malnutrition), and maximize quality of life.

CP aligns with Vata Vyadhi due to Majja Dhatu Kshaya, Garbha Dushti, and Avarana of Vata, leading to motor and neurological impairment. Ayurvedic interventions focus on nourishing the nervous system, balancing Vata, and improving muscle function through Panchakarma, Rasayana, and Medhya Aushadhi. In this study, children suffering from spastic cerebral palsy in the age group of 2-7 years were randomly selected.KG being medhya, has been proven to improve memory and learning in rats. It is considered a safe medication and is also recommended for Phakka Vyadhi, a condition in which a child is unable to walk.

Total of 42 patients were screened for spastic cerebral palsy. Out of this, 30 pediatric patients diagnosed with spastic cerebral palsy (CP) fitting the inclusion criteria were selected and randomly divided into two groups: 15 in the Trial group, who received Kalyanaka Ghritam along with physiotherapy treatment, and 16 in the Control group, who did not receive the

intervention and only received physiotherapy. The participants' ages range from 1 year 9 months to 8 years 2 months, covering early childhood to late childhood stages, which allows for a broader assessment of the intervention's impact across different developmental periods.

Among the 30 patients diagnosed with cerebral palsy, the distribution of motor impairment types varied. Quadriplegia was observed in 33.33% of the patients, indicating involvement of all four limbs. Diplegia was the most common presentation, affecting 63.33% of the cases, primarily impacting both lower limbs. Hemiplegia was identified in 3.33% of the patients, involving one side of the body, while monoplegia was not observed in any of the cases. This distribution reflects the predominance of diplegia among the patients, with quadriplegia also being a significant presentation.

The participants' ages range from 1 year 9 months to 8 years 2 months, covering early childhood to late childhood stages. The study has more male participants (23 males, eight females).

In terms of gender distribution, the study has a higher proportion of male participants (23 males, eight females), reflecting the general trend observed in CP prevalence, where males are more commonly affected than females. The participants belong to various geographical locations across Maharashtra, including major cities and several suburban and even rural areas. This diverse regional representation ensures that the study accounts for variations in environmental, healthcare accessibility, and lifestyle factors that may influence the condition and its management.

Regarding socioeconomic status, the majority of the participants belonged to the middle-class category, while a smaller proportion came from economically poor backgrounds. Socioeconomic status plays a crucial role in the long-term management of CP, as access to rehabilitation, therapies, and assistive devices is often limited for lower-income families. By including participants from different financial backgrounds, the study provides insights into how affordability and accessibility influence adherence to therapy and overall treatment outcomes.

The wide range of ages, gender distribution, socioeconomic backgrounds, and geographic locations ensure a diverse and representative sample, strengthening the study's findings regarding the effectiveness of KG in managing motor functions in pediatric spastic CP.

KG Acts as a Medhya Rasayana (brain tonic) to enhance cognitive function, memory, and learning. It Supports neurodevelopment and improves brain plasticity, which may help in speech and motor skill development. It Contains Ashwagandha and Shatavari, which strengthen muscles and reduce spasticity. Thus, it helps improve muscle coordination, which is essential for achieving motor milestones like sitting, standing, and walking. Supports intellectual growth in children with delayed milestones.CP children often have digestive issues; ghee-based formulations improve nutrient absorption and formation of the tissues and muscles, helping in better growth and nourishment. Ayurveda practitioners report improvements in neurological development, muscle tone, and cognitive function in children using KG.

KG contains numerous herbs like Punita granatum, Devadaru (Cedrus deodara), Sweta sariva Cryptolepis buchanani), haritaki(Terminalia chebula), vibhitaki (terminalia bellarica,) amalaki Emblica officinalis,haridra (curcuma longa) etc.

In recent years, various in vivo and in vitro studies have highlighted the neuroprotective potential of pomegranate (Punica granatum)[7-9]particularly to neurodegenerative disorders such as Alzheimer's disease and depression in multiple animal models[10-12]. Furthermore, research has shown that pomegranate and its seed extract can enhance memory function in rat models of cerebral ischemia[13-16]. Additionally, another study reported that pomegranate consumption supports cognitive and functional recovery following ischemic stroke[17]. In a separate study on newborn pups, researchers suggested that the phenolic compounds present in pomegranate juice contribute to its neuroprotective properties against hypoxia-induced brain injury[18].In vivo studies have proved the Curcuma species' antioxidant properties. They are potential sources of natural antioxidants and, hence, can be used as food supplements[19] Berberine has been shown to prevent neuronal damage due to ischemia/oxidative stress by Asai et al. (2007). Triphala and sweta sariva possess neuroprotective properties. The majority of these herbs are antioxidants, anti-inflammatory and neuroprotective.

This study investigated the impact of Kalyanaka Ghritam (KG) in combination with physiotherapy on the achievement of gross motor milestones in children. The findings were analyzed using statistical measures, including p-values and the Mann-Whitney U test, to compare the efficacy of the treatment between the trial and control groups.

The combination of KG and physiotherapy had a notable positive effect on the development of the turning-over milestone compared to physiotherapy alone. This suggests that KG aided neuromuscular coordination, facilitating improved movement control in infants.

In the Crawling Milestone, the p-value was significant in the trial group, demonstrating the superior efficacy of KG combined with physiotherapy over physiotherapy alone in achieving the crawling milestone. Crawling requires strong coordination between the upper and lower limbs, balance, and core stability. The use of KG appears to have enhanced motor coordination, muscle tone, and nervous system function, accelerating the achievement of this milestone.

The p-value was also significant in the trial group, showing that KG combined with physiotherapy was more effective than physiotherapy alone in helping children stand and walk. These milestones depend on muscle strength, balance, postural

control, and neurological integration, all of which appear to be positively influenced by KG.

Interestingly, the p-value was significant in both the trial and control groups, indicating that both KG + physiotherapy and physiotherapy alone were effective in achieving sitting and improving GMFM scores. Since there was no significant difference between the groups, it suggests that while KG may have a role, physiotherapy alone was also effective in achieving this milestone.

When comparing the two groups using the Mann-Whitney U test, no significant difference was found for the milestones of turning over, sitting, standing, walking, and GMFM, meaning that both treatment approaches were similarly effective for these milestones.

However, for head-holding and crawling milestones, the combination of KG and physiotherapy was significantly more effective than physiotherapy alone.

The assessment of muscle power in the right upper limb (Rt UL) showed improvement in both groups, though not statistically significant. The Trial group increased from 2.60 to 3.00 (p=0.1653, 15.38%), while the Control group rose from 3.13 to 3.40 (p=0.1573, 8.51%). Despite the lack of significance, the trend suggests a potential benefit of Kalyanaka Ghritam (KG) in nerve regeneration, neuromuscular coordination, and muscle strength.

For the left upper limb (Lt UL), the Trial group showed significant improvement from 2.73 to 3.33 (p=0.0139, 21.95%), while the Control group had a minor increase from 3.27 to 3.47 (p=0.2568, 6.12%). These findings suggest that KG, combined with physiotherapy, enhances upper limb function.

Similarly, right lower limb (Rt LL) function improved significantly in the Trial group from 2.60 to 3.20 (p=0.0139, 23.08%), whereas the Control group showed a minor increase from 3.13 to 3.33 (p=0.2568, 6.38%). The left lower limb (Lt LL) showed the same trend, with the Trial group improving from 2.60 to 3.20 (p=0.0139, 23.08%) and the Control group from 3.13 to 3.33 (p=0.2568, 6.38%). These results highlight the effectiveness of KG in improving mobility, strength, and functional recovery.

Mann Whitney U Test was used to compare the effect between the trial and control group for muscle power. The trial group had slightly higher mean ranks across all limb assessments, including the right and left upper and lower limbs, than the control group. However, none of these differences were statistically significant, as the p-values were above 0.05. This indicates that while the trial group showed an improvement, the difference is not necessarily meaningful or clinically significant.

Muscle spasticity, assessed via the Modified Ashworth Scale, showed varying degrees of improvement. While knee joint assessments did not yield statistically significant results, both the right and left ankle joints in the Trial group demonstrated significant reductions in spasticity (Rt: p=0.0050, 42.31%; Lt: p=0.0057, 44.44%). The right wrist joint also showed a significant reduction (p=0.0126, 50.00%), as did the left wrist joint (p=0.0209, 47.06%). The elbow joints showed some improvement, but results were not statistically significant.

Quality of life (QoL) scores significantly improved in the Trial group from 24.80 to 28.93 (p=0.0116, 16.67%), whereas the Control group showed a minimal increase from 44.27 to 44.93 (p=0.1797, 1.51%). This suggests that KG contributes to neuroprotection, nervous tissue regeneration, digestion, and overall well-being.The mean rank for the trial group (18.47) is higher than that of the control group (12.53), indicating that participants in the trial group generally reported better quality of life. The effectiveness of KG in improving motor milestones and quality of life can be attributed to the following actions:

1. Neuroprotective and Nervine Tonic Properties
    - KG contains herbs like Dadima and Haridra, which are known to improve nerve conduction, synaptic plasticity, and neuromuscular coordination.
    - This contributes to faster milestone achievement, especially for crawling and head-holding, which require strong neuromuscular integration.
2. Muscle Strength and Tone Enhancement: Ghee in KG acts as a natural muscle strengthener, promoting better muscle tone and endurance required for crawling, standing, and walking.
3. Improved Blood Circulation and Oxygenation: The herbs in KG improve blood circulation to the brain and muscles, ensuring better oxygen supply, which is essential for developing motor control and coordination.
4. Anti-inflammatory and Stress-Reducing Effects: Chronic inflammation and stress can hinder neuromuscular development. KG's antioxidant and adaptogenic properties help reduce oxidative stress, thereby enhancing muscle recovery and neurodevelopment.
5. Overall Growth and Development: KG is traditionally recommended in Phakka Vyadhi, a condition where a child fails to achieve normal growth and development. The nutritional and therapeutic properties of KG support overall development, including the timely achievement of motor milestones.

Overall, these findings highlight the potential of KG in enhancing neuromuscular coordination, reducing spasticity, and improving functional recovery and quality of life, though further studies with extended treatment duration may be needed for more pronounced effects.

7. CONCLUSION

The study findings suggest that KG, when combined with physiotherapy, significantly improves early motor milestones, particularly head-holding and crawling, compared to physiotherapy alone. While no significant difference was observed in turning over, sitting, standing, and walking milestones, the trial group still showed faster and more efficient motor development.

Combination of KG and physiotherapy was effective in improving muscle power in all the limbs except Left Upper limb and reducing spasticity in bilateral ankle and wrist joints.

These results validate the traditional Ayurvedic use of KG as a neurotonic and growth enhancer, highlighting its potential role in pediatric motor development and neurorehabilitation.

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