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Role of Mashadi Yoga in the Management of Balashosha with Special Reference to Protein-Energy Malnutrition in Children: A Randomized Controlled Trial

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Abstract

Introduction: In India, childhood undernutrition accounts for 45% of under-5 mortality alone and remains a key public health problem. The management of undernutrition depends upon the nutritional status, degree of hyper-metabolism, expected duration of illness and associated complications. It can be managed in three ways 1) by *Nidan Parivarjan* (Causative factors), 2) by *Shodhan* (bio-cleansing therapy) and shaman (palliative therapy) 3) by *Rasayan* (rejuvenation) utilization. The study aimed to assess the efficacy of *Mashadi* Yoga A & B in the management of *Balashosha* (Protein-energy Malnutrition-PEM) in children.

Methodology: It was an open-labeled, randomized, controlled clinical study conducted on 40 children suffering from the symptoms of *Balashosha*. Both drugs *Mashadi Yoga* A and *Mashadi Yoga* B were given in a dose of 20g twice a day for 60 days in the morning before breakfast and in the evening at snack time with one glass of Luke warm milk.

Results: the efficacy of both drugs was assessed on anthropometric parameters and subjective parameters along with laboratory parameters. On statistical analysis, individually both drugs had shown significant improvement in clinical, anthropometric as well as in laboratory parameters. However, on the inter-group comparison, *Mashadi Yoga* A exhibited significant results in all parameters although both groups showed statistically non-significant results.

Conclusion: *Mashadi Yoga* A and *Mashadi Yoga* B both are effective in the management of *Balashosha* in children.

Keywords: *Balashosha,* Protein-energy malnutrition, PEM, *Mashadi Yoga*

Introduction

Childhood malnutrition, a consequence of inadequate nutrition, persists as a pressing concern in developing nations like India due to poverty, illiteracy, and insufficient social awareness. UNICEF's report in 2019 revealed malnutrition as the primary cause of death among children, with India accounting for a substantial portion of undernourished and low birth-weight infants globally [1]. Factors like repeated morbidity, decreased appetite, and increased susceptibility to infections [2] exacerbate malnutrition, aggravated by poor socio-economic conditions and inadequate childcare practices. Multiple causative factors contribute to Protein-Energy Malnutrition (PEM), including poor nutrition, malabsorption, recurrent infections, and socio-environmental elements. Ayurvedic approaches described by *Acharya* Vagbhata [3] focus on balancing digestive fire (Agni) and eradicating causative factors to treat *Balashosha* (PEM). These methods involve dietary regulation, mild bio-cleansing therapies, digestive enhancement, and nourishing procedures with specific herbs and formulations, such as those emphasizing bitter and pungent tastes and promoting rejuvenation (*Rasayana*) properties. Maharishi Charak's recommendations advocate medications for health promotion and immunity enhancement, including the use of modified *Mashadi Yoga* formulations, tailored for children's palatability, outlined in ancient Ayurvedic texts.

Aim

To assess the efficacy of both the *Mashadi Yoga* in *Balashosha*.

Objective

- To assess the change in the weight.
- To provide an effective, safe, and economical remedy for managing Malnutrition in children.

Materials and Methods

The study involved a randomized, open-labeled clinical trial,

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allocating eligible malnutrition subjects using computer-generated randomization. Upon understanding the trial, patients gave assent, and guardians provided consent in the local language during screening. Malnourished children meeting the criteria were chosen from the Kaumarbhritya department's outpatient facility. Both trial drugs, Mashadi Yoga A [4] (Table 1) and Mashadi Yoga B [5] (Table 2) were precisely prepared and packaged as cookies at a nearby bakery, maintaining strict hygiene and standard operating procedures. (Figure 1 SOP).

Table 1: Ingredients of *Mashadi Yoga* A

S. N.	Name of drug	Latin name	Family	Useful part	Composition in 1Kg
1.	*Godhuma*	Triticum aestivum	Poaceae	Seed	160g
2.	*Shali-tandoola*	Oryza sativa	Poaceae	Seed	85g
3.	*Masha*	Phaseolus mungo	Fabaceae	Seed	85g
4.	*Yava*	Hordeum vulgare	Poaceae	Seed	90g
5.	*Pippali*	Piper Longum	Piperaceae	Fruit	15g
6.	Sugar	Saccharum officinarum	Poaceae		190g
7.	Ghrit	Clearified Butter			375g

Table 2: Ingredients of *Mashadi Yoga B*

S. N.	Name of drug	Latin name	Family	Useful part	Composition in 1Kg
1.	*Godhuma*	Triticum aestivum	Poaceae	Seed	150g
2.	*Shali-tandoola*	Oryza sativa	Poaceae	Seed	75g
3.	*Masha*	Phaseolus mungo	Fabaceae	Seed	75g
4.	*Mudga*	Phaseolus Trilobus	Fabaceae	Seed	30g
5.	*Tila*	Sesamum Indicum	Pedaliaceae	Seed	30g
6.	*Ashwagandha*	Withania somnifera	Solanaceae	Root	50g
7.	*Sugar (Bura)*	Saccharum officinarum	Poaceae		250g
8.	*Ghrit*				340g

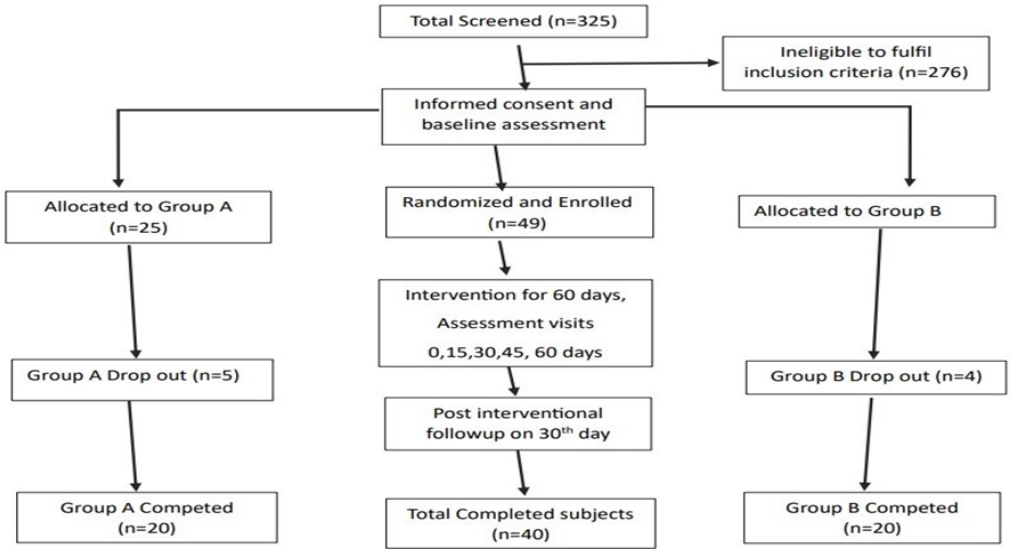

Fig 1: Consort Flow chart

Eligible Criteria

Children between the age of 5 to 10 years of either sex, irrespective of religion, socioeconomic status and food habits. Subjects evaluated with Grade 1 and 2 of Malnutrition (I.A.P Grading of Malnutrition [6]). Children whose parents are willing to give consent for clinical trial. Children with symptoms of Balashosha [7] like *Arochaka* (uninterested), *Jwara* (fever), *Pratishyaya* (catarrh), *Kasa* (cough), *Mukha-Snigdhata* (glossy face), *Mukh-Shwetata* (paleness of face), *Netra-Snigdhata* (glossy eyes), *Netra-Shwetata* (paleness of eyes), *Shwasa* (dyspnea), *Shotha* (inflammation) and *Kesha-Shushkata* (dryness of hair) were included for the trial.

Exclusion Criteria

Systemic diseases Children suffering from known major systemic illness necessitating hospitalization-Tuberculosis, Diabetes, or any other infectious illness requiring active management. Children with Gross congenital problems, evidence of malignancy, genetic anomaly, Mal-absorption syndrome or inborn errors of metabolism. Children evaluated with other grades of PEM, i.e., normal, grade-3 and grade-4 of IAP classification.

Data Collection

Source: In the present study children coming to O.P.D. of Balaroga Department, National institute of Ayurveda, Jaipur are included.

Age Group: Children between 5 to 10 years were selected after clinical evaluation.
Study Design: Open randomized control trial study.
Intervention: Subjects between 5 to 10 years fulfilling the inclusion criteria for malnutrition were selected randomly and divided into two groups, Group A (*Mashadi Yoga* A) and (*Mashadi Yoga* B) Group B. For each group's subjects, both medicaments were given in a dose of 20gm twice a day with cow milk before breakfast and evening snack time for 60 days and had a post-intervention follow-up period of 30th days.
Diet and Lifestyle: Counseling was given to each patient and parents in both groups. Each patient had been instructed to use their daily home food, Play both indoor and outdoor games and exercise. Food and daily activity patterns were assessed based on the 24-hour recall method during the follow-up visits and appropriate advice was given to all children and their guardians from time to time.

Criteria for Assessment

a) **Subjective Parameters:** Assessment of clinical features (*Arochaka, Jwara, Pratishyaya, Kasa, Mukha Snigdhata, Mukha Shwetata, Netra Snigdhata, Netra Shwetata, Shwasa, Shotha* and *Kesha Shushkata*) of *Balashosha* depending on the severity was done on a four-point scale. Nil-G0, Mild-G1, Moderate-G2, Severe-G3
b) **Anthropometric Parameters:** Following anthropometric measurements, were assessed before and after the 60 days of intervention: Weight in kg; Height in cm; BMI in kg/m^2; Mid-Upper Arm Circumference (MUAC) at left hand in mm; Mid-thigh circumference (MTC) in mm; Skin fold thickness–Triceps in mm, Mild Calf circumference in mm.
c) **Laboratory Parameters:** Here, the present study used laboratory parameters like Total Serum Protein, Serum Albumin, Serum Globulin, and the Albumin/Globulin ratio to check how the protein levels change or grow.

Overall Assessment of Therapy
Overall assessment of therapy was assessed based on objective parameters like anthropometric measurements, especially weight and subjective parameters addressing the symptoms of *Balashosha.*

Outcomes
Primary Outcome
- To assess the efficacy of trial drug "Mashadi Yoga" in the management of Balshosha.

Secondary Outcome
- Improvement in weight,
- Improvement in Body Mass Index (B.M.I),
- Improvement in skin fold thickness.

Sample Size-40 (20 in each group)

Randomization
Computer-based online system for randomization via randomization.com, 72 subjects randomized into 2 blocks, to reproduce this plan, use the seed 29088, Randomization plan created on 29/9/2022, 3:07:59 PM.
Randomization Allocation Concealment Mechanism: The SNOSE method is used for concealment.
Binding: Single-blind

Statistical Methods
The data generated in the interventional study were analyzed using Graph Pad Instant 3.10 version, 32 bits, created on 10 July 2009.
For non-parametric data, the 'Wilcoxon matched pairs test' was applied. For statistical improvement analysis in the clinical features of Balashosha, in both groups and for intergroup comparison, the 'unpaired Mann-Whitney Test' was applied to determine statistical differences in clinical features. Later, the results were interpreted.
For parametric data analysis, the paired 't' test was applied in single groups BT and AT, while for intergroup data analysis, the unpaired 't' test was used.

Observational Results
40 subjects had completed the trial [Figure 2 Consort flow diagram]. Maximum number of subjects 95% were suffering from Grade 1 malnutrition in Group A while 80% were suffering from Grade 1 in Group B. Most affected age groups were found between 5-6 years, 7-8 years and 9-10 years of age, each having 22.5% and male children are more 22 (55%) affected. Maximum affected children were from the lower middle class 17 (42.5%) and urban habitat i.e., 37 (92.7%).

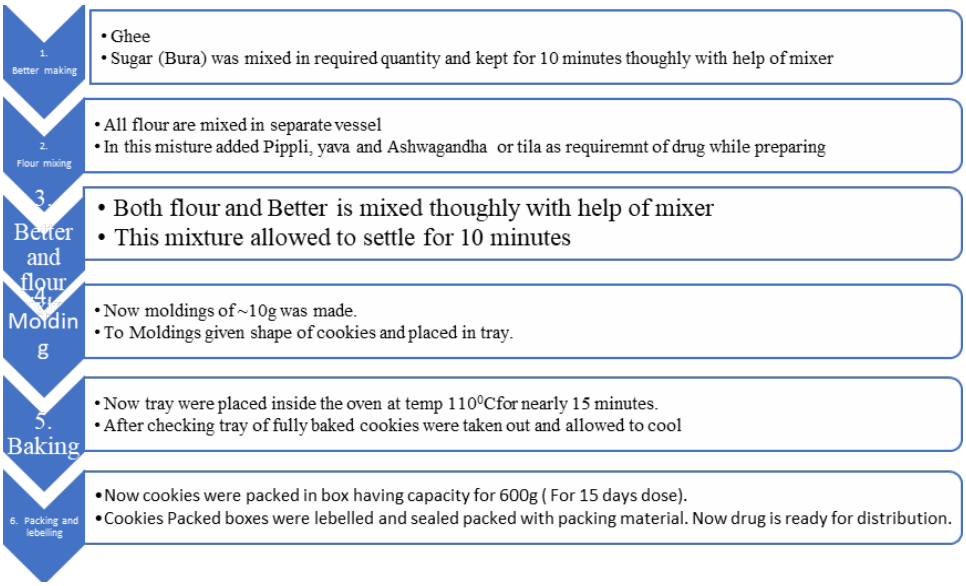

Fig 2: Standard operating procedure used for cookies formation

Interventional Results

Effect of therapy on outcome measures

- Improvement in subjective parameters can be seen in Table-3.
- Improvement in Anthropometric Parameters can be seen in Table-4.
- Improvement in Laboratory Parameters can be seen in [Table 5]

Table 3: Effect of therapy on Subjective parameters in both group

S. No	Parameter	Group	Mean		Diff.	Improve. %	SD ±	SE ±	W	P	Result
			BT	AT							
1.	*Arochaka*	A	2.050	0.300	1.750	85.37%	0.5501	0.1230	210.0	<0.0001	ES
		B	1.850	0.200	1.650	89.19%	0.5871	0.1313	210.0	<0.0001	ES
2.	*Mukha Snigdhata*	A	1.750	0.300	1.450	82.85%	0.5104	0.1141	210.0	<0.0001	ES
		B	2.100	0.550	1.550	73.80%	0.6048	0.1352	190.0	<0.0001	ES
3.	*Mukha Swetata*	A	1.300	0.050	1.250	96.15%	0.4443	0.0993	210.0	<0.0001	ES
		B	1.450	0.250	1.200	82.76%	0.5231	0.1170	190.0	<0.0001	ES
4.	*Netra Swetata*	A	1.150	0.5263	1.105	96.09s	0.4588	0.1053	171.0	<0.0001	ES
		B	1.300	0.200	1.1000	84.61%	0.3078	0.0688	210.0	<0.0001	ES
5.	*Netra Snigdhata*	A	1.150	0.150	1.000	86.96%	0.4588	0.1026	171.0	<0.0001	ES
		B	0.950	0.100	0.850	89.47%	0.3663	0.0819	153.0	<0.0001	ES
6.	*Kesha Shushkata*	A	0.6500	0.200	0.4500	69.23%	0.6863	0.1535	28.00	<0.0001	ES
		B	0.8947	0.421	0.4737	70.00%	0.5130	0.1177	49.00	0.0039	ES
7.	*Pratishyaya*	A	1.850	0.6000	1.250	67.57%	0.5982	0.1338	190.0	<0.0001	ES
		B	1.900	0.3000	1.600	84.21%	0.7539	0.1686	171.0	<0.0001	ES
8.	*Jwara*	A	1.850	0.6000	1.250	67.57%	0.5982	0.1338	190.0	<0.0001	ES
		B	1.900	0.3000	1.600	84.21%	0.7539	0.1686	171.0	<0.0001	ES
9.	*Kasa*	A	1.850	0.6000	1.250	67.57%	0.5982	0.1338	190.0	<0.0001	ES
		B	1.900	0.3000	1.600	84.21%	0.7539	0.1686	171.0	<0.0001	ES
10.	*Shwasa*	A	0.100	0.0500	0.0500	50.0%	0.2236	0.0500	1.00	>0.9999	N S
		B	1.700	0.3000	1.400	82.35%	0.3000	0.6806	3.00	0.5000	N S

Table 4: Effect of therapy on Anthropometric parameters in both Groups

S. No	Parameter	Group	Mean		Diff.	% of Relief	SD	SE	"t" value	P	Result
			BT	AT							
1.	Weight	A	16.290	17.440	1.15	7.06%	0.566	0.1266	9.084	<0.0001	H S
		B	16.950	18.080	1.13	6.67%	0.437	0.09763	11.57	<0.0001	H S
2.	Height	A	114.41	114.84	0.43	0.38%	0.269	0.05943	7.236	<0.0001	H S
		B	114.97	115.41	0.43	0.38%	0.317	0.07081	6.143	<0.0001	H S
3.	MUAC	A	149.30	151.60	2.30	1.54%	1.261	0.2819	8.159	<0.0001	H S
		B	114.97	115.41	0.43	2.54%	0.317	0.07081	6.399	<0.0001	H S
4.	MTC	A	271.10	273.20	2.10	0.77%	1.373	0.3069	6.842	<0.0001	H S
		B	272.35	275.40	3.05	1.12%	1.791	0.4005	7.616	<0.0001	H S
5.	Mid-calf circum.	A	173.40	175.60	2.20	1.26%	1.196	0.2675	8.223	<0.0001	H S
		B	175.60	178.73	3.15	1.78%	1.959	0.4381	7.133	<0.0001	H S
6.	Skin-fold thickness	A	2.390	2.550	0.16	6.69%	0.127	0.02847	5.620	<0.0001	H S
		B	2.210	3.340	1.13	51.13%	3.862	0.8637	1.308	<0.0001	H S
7.	BMI	A	12.419	13.310	0.89	7.17%	0.436	0.09746	9.143	<0.0001	H S
		B	12.892	13.649	0.76	05.87%	0.404	0.09022	8.391	<0.0001	H S
MUAC = Mid Upper arm Circumference, MTC= Mid-thigh circumference, circum.= Circumference, BMI=Body mass index											

Table 5: Effect of therapy on Laboratory parameters in both group

S. No	Parameter	Group	Mean		Diff.	% of Relief	SD	SE	"t" value	P	Result
			BT	AT							
1.	T. Serum Protein	A	7.265	7.564	0.298	4.11%	0.5702	0.1275	2.341	0.0303	S
		B	7.299	7.325	0.026	0.36%	0.7704	0.1723	0.1509	0.8816	N S
2.	Serum Albumin	A	4.545	4.788	0.243	5.35%	0.3163	0.0707	3.435	0.0028	H S
		B	4.578	4.760	0.182	4.07%	0.4173	0.0933	1.950	0.0660	N S
3.	Serum Globulin	A	2.718	2.776	0.058	2.14%	0.5317	0.1189	0.4878	0.6313	N S
		B	2.686	2.636	0.050	1.86%	0.5627	0.1258	0.3974	0.6955	N S
4.	A/G ratio	A	1.584	1.749	0.165	10.42%	0.7153	0.1600	1.032	0.3152	N S
		B	1.680	1.905	0.225	13.42%	0.4690	0.1049	2.150	0.0446	S

Comparison of the Effect of Therapy on Subjective, Anthropometric and Laboratory Parameters

Intergroup comparison of all subjective parameters, anthropometric parameters and laboratory parameters of *Balashosha* exhibited non-significance outcomes and had $p>0.05$. [Table 6] [Table 7] [Table 8] It can be considered that both drugs have equal effects nor more or less than each other.

Table 6: Inter-group comparison of Subjective parameters (n=20)

S. No	Parameter	Group	Mean AT	SD ±	SE ±	U	P*	Result
1.	*Arochaka*	A	0.3000	0.5712	0.1277	188	0.6682	N S
		B	0.2000	0.4104	0.09177			
2.	*Mukha Snigdhata*	A	0.3000	0.4702	0.1051	200	0.9864	N S
		B	0.3000	0.4702	0.1051			
3.	*Mukha Swetata*	A	0.0500	0.2236	0.0500	160	0.0842	N S
		B	0.2500	0.4443	0.0993			
4.	*Netra Swetata*	A	0.0500	0.2236	0.0500	170	0.1638	N S
		B	0.2000	0.4104	0.0918			
5.	*Netra snigdhata,*	A	0.1000	0.3078	0.0688	200	0.9792	N S
		B	0.1000	0.3078	0.0688			
6.	*Kesh Shushkata,*	A	0.2000	0.4104	0.0917	160	0.1784	N S
		B	0.4000	0.5026	0.1124			
7.	*Pratishyaya,*	A	0.4000	0.5026	0.1124	190	0.7593	N S
		B	0.3500	0.4834	0.1094			
8.	*Jwara,*	A	0.6000	0.5026	0.1124	140	0.0619	N S
		B	0.3000	0.4702	0.1051			
9.	*Kasa*	A	0.4000	0.5026	0.1124	180	0.5233	N S
		B	0.3000	0.4702	0.1051			
10.	*Swas*	A	0.0500	.2236	0.0500	200	0.9714	NS
		B	0.0500	.2236	0.0500			
U= Mann Whitney U Statistical value,								

Table 7: Intergroup Comparison of Anthropometric Parameters

S. No	Parameter	Group	Mean AT	SD	SE	W	P	S
1.	Weight	A	17.440	2.540	0.5680	0.8893	0.3799	N S
		B	18.080	1.977	0.4420			
2.	Height	A	114.84	6.714	1.501	0.2648	0.7927	N S
		B	115.41	6.900	1.543			
3.	MUAC	A	151.60	12.758	7.572	0.3090	0.7595	N S
		B	152.63	7.572	1.693			
4.	Mid-Thigh Circumference,	A	273.20	16.305	3.646	0.4441	0.6595	N S
		B	275.40	14.996	3.353			
5.	Mid-Calf Circum.	A	175.60	14.809	3.311	0.7547	0.4555	N S
		B	178.73	11.116	2.486			
6.	Skin fold thickness	A	2.550	0.5605	0.1253	0.9425	0.3578	N S
		B	3.340	3.707	0.8288			
7.	Body Mass Index	A	13.310	1.047	0.2340	1.208	0.2361	N S
		B	13.649	0.6935	0.1551			

Table 8: Intergroup Comparison of Laboratory Parameters

S. No	Parameter	Group	Mean AT	SD	SE	t-value	P	S
1.	Total Serum Protein	A	7.564	0.4348	0.09722	1.493	0.1436	N S
		B	7.325	0.5686	0.1271			
2.	Serum Albumin	A	4.788	0.2593	0.05799	0.2948	0.7698	N S
		B	4.760	0.3268	0.07308			
3.	Serum Globulin	A	2.776	0.2780	0.06215	1.029	0.3100	N S
		B	2.636	0.5437	0.1216			
4.	Albumin/Globulin ration	A	1.749	0.1742	0.03895	1.648	0.1076	N S
		B	1.905	0.3858	0.08626			

Overall Assessment of Percentage Improvement in Subjective, Anthropometric and Laboratory Parameters

- In terms of subjective parameters, in Group B, out of 10 subjective/clinical symptoms, 8 subjective (*Arochaka, Mukha-Swetata, Netra Swetata, Netra Snigdhata, Pratishyaya, Jawara, Kasa, Swasa*) parameters exhibited Very Good improvement (more than 75%), while 2 subjective parameters (*Mukha-Snigdhata, Kesha Shushkata*) has exhibited good improvement (between 50-75%).
- In terms of subjective parameters, in Group A, out of 10 subjective/clinical symptoms, 5 subjective parameters (*Arochaka, Mukha-snigdhata, Mukha-swetata, Netra Swetata, Netra Snigdhata,*) had exhibited Very Good improvement (more than 75%), 4 subjective parameters (*Kesha shushkata, Pratishyaya, Jawara, Kasa,*) had exhibited Good improvement (between 50-75%) and 1 subjective parameter *Swasa* has exhibited Poor improvement (less than 25%).
- In terms of subjective parameters, none had been found to place in no Improvement zone.
- In terms of anthropometry and laboratory parameters, both Group A and B exhibited poor improvement (less than 25%) on parameters.
- Although it became apparent that both drugs improved subjective measures, for the assessment of anthropometry and objective parameters, the sample size and length of the study were too short, and they should be extended.

Follow-up Observation

After the intervention, a follow-up study has shown that subjects in both groups had further improvement in subjective [Table 9] and anthropometric parameters. [Table 10]

Table 9: Follow-up comparison of Subjective parameters

S. No	Parameter	Group A			Group B		
		BT	After 60 days	After 90 days	BT	After 60 days	After 90 days
1.	*Arochaka*	20	5	2	20	4	1
2.	*Mukha Snigdhata*	20	6	0	19	6	3
3.	*Mukha Swetata*	20	1	0	20	5	3
4.	*Netra Swetata*	19	1	0	20	4	1
5.	*Netra snigdhata,*	18	3	1	18	2	1
6.	*Kesh Shushkata,*	10	4	3	16	8	4
7.	*Pratishyaya,*	17	8	0	18	7	0
8.	*Jwara,*	19	12	1	20	6	0
9.	*Kasa*	19	8	0	19	6	1
10.	*Swas*	2	1	0	2	1	1

Table 10: Follow-up comparison of Anthropometric parameters (n=20)

S. No	Parameter	Group	Mean AT	SD	SE	W	P	S
1.	Weight	A	17.440	2.540	0.5680	0.8893	0.3799	N S
		B	18.080	1.977	0.4420			
2.	Height	A	114.84	6.714	1.501	0.2648	0.7926	N S
		B	115.41	6.900	1.543			
3.	MUAC	A	151.60	12.758	2.853	0.3167	0.7537	N S
		B	152.65	7.555	1.689			
4.	Mid-Thigh Circumference,	A	273.20	16.305	3.646	0.4441	0.6595	N S
		B	275.40	14.996	3.353			
5.	Mid-Calf Circumference,	A	175.60	14.809	3.311	0.4591	0.7479	N S
		B	178.70	11.150	2.493			
6.	Skin fold thickness	A	2.550	0.5605	0.1253	0.4174	0.6787	N S
		B	2.485	0.4133	0.0924			
7.	Body Mass index	A	13.310	1.047	0.2340	1.208	0.2347	N S
		B	13.649	0.6935	0.1551			

Discussion

The current RCT aimed to compare the effectiveness of both *Mashadi Yoga* A and B in conjugation with a normal home-based diet. As a whole, the *Mashadi yoga* formulation contains *Katu, tikta* and *Madhur Rasa* which aided in restoring *Jatharagni* along with *Dhatawagni* and also had *Rasayana* properties. Due to the *Yogavahi* property of *Pippli* [8] in *Mashadi Yog* A had worked on microcirculation and improved digestion, hence got relief in terms of laboratory parameters as compared to *Mashadi Yoga* B and opened channels after improving the *Dhatwagni.* [Table 11] While *Mashadi Yoga* B of Group B having Ashwagandha [9] worked as an anabolic catalyst resulting in growth in anthropometric parameters.

Table 11: Inter-group Comparison of therapy effect on laboratory parameters

S. No	Parameter	Group	Mean AT	SD	SE	t-value	P	S
1.	Total Serum Protein	A	7.564	0.4348	0.0972	1.493	0.1436	N S
		B	7.325	0.5686	0.1271			
2.	Serum Albumin	A	4.788	0.2593	0.0579	2.689	0.0107	N S
		B	4.578	0.2327	0.0520			
3.	Serum Globulin	A	2.776	0.2780	0.0621	1.029	0.3123	N S
		B	2.636	0.5437	0.1216			
4.	A/G ratio	A	1.749	0.1742	0.0389	1.648	0.1113	N S
		B	1.905	0.3858	0.0862			

In the *Balashosha* subjects, *Arochaka* was recognized as the most common and initial symptom, possibly arising from *Mandagni* and *Srotovarodha*. This led to the formation of improper *(Vikrita*) *Rasa Dhatu,* resulting in *Aruchi/Arochaka,* characterized by a lack of interest in consuming food.

Upon administering the trial drugs, *Mashadi Yoga* A (*Yava, Pippali)* and *Mashadi Yoga* B (*Tila* [10], *Mudga* [11], *Ashwagandha* [12],) with sugar and G*hrita* [13, 14], along with other drugs possessing *Aruchi Nashaka* properties, all components exhibited *Deepana, Pachana, Brimhana, Balya,* and *Rasayana* properties. These actions corrected *Agni* and opened *Srotovarodha* (microchannels), leading to the production of *Avikrita Rasa Dhatu*. Consequently, the symptoms of *Arochaka* in *Balashosha* were alleviated.

Although the symptoms *Mukha Shwetata* and *Netra Shwetata* appear in *Pandu Roga* [15], like disorders these also present in the pathogenesis of *Balashosha.* In the *Balashosha* these may be due to insufficient intake of desired nutrient contents in the diet and result of mandagni, production, and accumulation of *Aam*, *Srotorodha,* and improper work of *Dhatvagni* on tissue level. All these factors contribute to insufficient formation of hemoglobin, thus the *Mukha Shwetata* and *Netra Shwetata* appear in the subject of *Balashosha.*

The trial drugs, *Mashadi Yoga A (Yava, Pippali) and Mashadi Yoga B* (*Tila, Mudga, Ashwagandha*) have sugar and *Ghrita* along with other drugs having *Ushana Viryata, Rukshata, Agnivardhak* and *Aam Nashaka* properties, was administered, all the drug components also had *Deepana, Pachana*, *Brimhana, Balya* and *Rasayana* properties that corrected *Agni* and opened *Srotovarodha* (microchannels), leading to the production of *Avikrita Rasa Dhatu*. Consequently, the symptom of *Mukh Snigdhata and Netra Snigdhata* disappears.

Regular intake of *Madhur Ahar* and aggravated *Kapha Dosha* causes *Agnimandya*. *Srotorodha* and improper work of *Dhatvagni* on tissue level resulting in progressive *Dhatu Kshaya*. along with *Aam* formation, result in unctuousness of face, unctuousness of eyes, paleness of face paleness of eyes constipation, *Kasa and Swasa,* nearly symptoms of *Pandu* (Pallor).

This feature exhibits the chronicity of disease, as a result of *Dhatu Kshaya*, this condition develops slowly. *Keshya* effect of *Shali-shashtika, Rasayana* effect of *Ghrita* & *Ksheer* are well described in the Ayurveda classics if they are used and practiced in daily routine life.

In the pathogenesis of Balshosha, the formation of succeeding Dhatus was hampered or in little amount, therefore, Kesh Shushkata features can be seen in subjects with chronic malnutrition.

In *Balashosha* subjects, *Jwara* was the most commonly observed symptom. It might have been caused by *Kaphadhikya + Mandagni →Srotovarodha* which led to the formation of improper (*Vikrita*) *Rasa Dhatu* and resulted in the Accumulation of improper *Kapha* in *Aamashaya* which later caused the expulsion of *Pitta* to *Vimarga Gaman* result in raised body temperature i.e.*Jwara.*

These trial drugs, *Mashadi Yoga* A (*Yava, Pippali*) and *Mashadi Yoga* B (*Tila, Masha, Mudga, Ashwagandha*) have components like *Godhoom, Shashtika shali, Ghrita* and *Sugar,* which have *Deepana, Pachana, Kapha-piita shamak,*

Brimhana, Balya and *Rasayana* properties that corrected *Agni* and Clear *Srotovarodha* (microchannels), leading to the production of *Avikrita Rasa Dhatu,* antipyretic and analgesic effects resulting relief from *Jwara.*

In *Balashosha* subjects, *Pratishyaya* was the most commonly observed symptom. It might have been caused by *Kaphadhikya + Mandagni → Srotovarodha* which led to the formation of improper (*Vikrita) Rasa Dhatu* and resulted in the Accumulation of improper *Kapha* which was later associated with *Vimarga Gamit Vata* and *Pitta*, thereafter start running out through nostrils.

When the trial drugs, *Mashadi Yoga A (Yava, Pippali) and Mashadi Yoga B* (*Tila, Masha, Mudga, Ashwagandha*) having sugar and *ghrita* along with other drugs having *Agnivardhark* properties, was administered, all the drug components also had *Deepana, Pachana*, *Brimhana, Balya* and *Rasayana* properties that corrected *Agni* and opened *Srotovarodha* (microchannels), leading to the production of *Avikrita Rasa Dhatu*. Consequently, the symptoms of *Pratishyaya* were reduced.

Here in this study, two different drugs were used which have different modes of action. *Mashadi Yoga* A contains *Pippali and Yava* along with *Godhoom, Shali Tandoola, Masha, Ghrita, and Sugar.* Those mainly work as *Deepan, Pachan, Balya*, *Brimhana, Srotorodha-nashak, Rechaka, Agnivardhaka, Anabhishyandi, Rucya,* and *Yogavahi.*

Whereas, *Mashadi Yoga* B had *Ashwagandha, Mugda* along with *Godhoom, Shali Tandoola, Masha, Tila, Ghrita, and Sugar.* Those having properties like *Ruchiprada* [16], *Shairyakar* [17], *Kasaghna, Mamsakshaya Nashak, Santarpan, Vedana Nashak, Agnivardhaka, Anabhishyandi, Rucya and Dahahar.*

Above said properties and actions of the drug components help improve the digestion, assimilation, and absorption of the food material in the body, i.e., known as strengthening the *Jathragni* and *Dhatwagni*. When all the *Agnies* are functioning properly with optimal availability of nutrients and food articles, it results in the formation of a better quality of *Rasa* and other further *Dhatu*. An optimal level of all seven *Dhatus* is known as good health of the person. The *Balya, Brimhana,* and *Rasayana* properties of both *Mashadi Yoga* A and *Mashadi Yoga* B are responsible for the weight gain and change in other parameters of the anthropometric in the malnourished subjects.

In the pathogenesis/*Smaprapti* of *Balashosha,* the presence of *Agnimandhya, Srotorodha*, and *Dhatu Kshaya*, poor nourishment, etc. are the key players. The poor nourishment of all seven *Dhatus* (mainly the first one *Rasa Dhatu*) also involves and contributes as *Dushya* for the disease *Balashosha* and for other diseases that may present as a symptom of *Balashosha*. *Mandagni* leads to disruption in *Dhatu Poshana* by producing the *Aam* and inadequate *Rasa*. This *Aam* may create blockage of *Rasavaha Srotasa*, it disrupts the process of the next *Dhatu* production hence leading to *Balashosha*/Malnutrition.

As the production of inadequate *Rasa Dhatu* may disrupt the essential nutrient supply in the form of the production of less potent next six *Dhatus*, this ultimately impacts' subsequent tissues. This disturbance can lead to malnutrition, macronutrients, and micronutrient deficiencies and ultimately affect the health, and immune system [18] (*Bala* and *Ojas*). Additionally, inadequate *Rasa Dhatu* and deficient micronutrients may influence the synthesis of plasma proteins, immunological substances, etc. which are essential for immune support. Thus, for managing malnutrition/*Balashosha* along with nutritional supplements, keeping the person in a disease-free condition is also essential. Thus, the medicine or diet indicated or being used in the treatment of *Balashosha* should contain properties like *Agnidipana, Brahan, Rasayan, Jivaniya* etc.

In Both *Mashadi Yoga* A and *Mashadi Yoga* B, *Godhoom, Shali tandoola, Masha, Ghritam,* and Sugar were common; *Godhuma* having properties such as *Brihmana, Vrishya, Sandhankar, Balya, Varnya, Hridya, Sulaprashaman, Shashtika Shali* having properties such as *Tridhoghna, Daurbalyahar Mutrakrichchhahar, Masha* having properties such as *Jivaniya, Vedasthpana, Purishajana, Yakraduttejaka, Mutrala, Santarpaka*, *Ghritam* [19] having properties such as *Agnidipana, Cakashushya, Aayushya, Hrudya, Kantiprada, Medhya, Rasayana, Snehanakar, Tejobalavardhaka, Vrishya,* Sugar having properties such as *Cakshushya, Dhatuvardhaka, Hridya, Pittahara, Vrishya, Vata-Pittahara, Mutrala, Santarpana,* and *Balya Saraka.*

In the *Mashadi Yoga* A, *Pippali* and *Yava* were different but *Godhoom, Shali Tandoola, Masha, Ghrita,* and *Sugar* were common in both the *Mashadi Yoga* A & B. *Pippali* [20] has properties such as *Rasa-Katu, Madhura* [21], *Guna-Laghu, Snigdha, Tikshana, Virya-Ushna, Anushnsita, sita* [22], *Vipaka-Madhura, Karma-Kapha Vata shamak, Dipan, Pachan, Vrushya, Rasayan, Rechaka, Yoagvahi,* Chemcal composition [23]-Alkaloid piperine, Piperlogumine, Pipernanaline, Piperundecalidine, piperlongum (piplartine), piperlonguminine and also methyl 1-3, 4, 5-trimethoxycinnamate Sesamin, a lignan dihydrostigmastral. The presence of L-tyrosine, L-cysteine hydrochloride, DL-serine and L-aspartic acid, Pharmacological activity-Digestive, Febrifuge, Haematinic, Cholagogue, Emmengogue, Abortifacient, Antitubercular, Antibacterial, Anti-inflammatory, Hepatoprotective, Anti-oxidant.

Yava [24] has the properties such as *Rasa-Kashaya, Madhur, Katu, Guna-Sheet, Ruksha, Ishat guru, Laghu* [25], *Virya-Sheet, Vipaka-Madhur, Dosha-Kaphapittahara,* Therapeutic uses-*Vranaropana, Dipan, Medya, Kanthya, Varnasthairyakar, Meda, Peenasa, Swas, Kasa, Urusthambha, Raktavikar, Trishnanashak,* Chemcal composition-Strach, Protein insoluble, Protein Soluble, Fibre, Ash, Fat, Pharmacological activity-Useful in Obesity, Diabetes, anaemia, Cough, Asthma, Coryza, colic, erysipelas, Vomiting, Ulcers, Dysuria, Hyperacidity, Rheumatism.

Those mainly work as *Deepan, Pachan, Balya*, *Brimhana, Srotorodha-nashak, Rechaka, Agnivardhaka, Anabhishyandi, Rucya,* and *Yogavahi.* Therefore, it boosts digestion, cleanses the body's channels, and helps to produce essential bodily fluids i.e., *Rasa Dhatu* or Plasma. It is especially useful for those with protein-energy malnutrition.

In the *Mashadi Yoga* B, *Ashwagandha, Mugda* and *Tila* were different but *Godhoom, Shali Tandoola, Masha, Ghrita,* and *Sugar* were common in both the *Mashadi Yoga* A & B.

Ashwagandha has properties such as Ras-Tikta, Kashaya, Madhura [26], *Guna-Laghu, Virya-Ushna, Vipaka-Madhura, Karma-Vatakaphapaha, Balya, Rasayana, Vajikarahvasahara, Garbhashayashothahara, Prajasthapana, Nadibalya, Mastishkashamaka, Dipana, Anulomana, Krimighna, Hrudya, Raktasodhaka, Shothahara, vedanasthapana, Mutrala, Kushthaghna, Kandughna, Kaphaghna, Shvasahara, Vatahara, Chemical properties* [27]*-Alkaoides&steroidal-Withanine, Somniferine,somnine, Pseudo-withanine, tropine, Pseudotropine, anaferine, Anahydrine*. and Pharmacological properties [28]-Sedative, Hypnotic effects, hypotensive, stimulant, immunomodulatory,

Antistress activity, Gout, Hypertension, nervine and skin diseases, prevent degenerative changes, widely used as a sex stimulant, Rejuvenator, Promotes Strength and Vigor.

Mugda [29] has properties such as *Rasa-Kasaya, Madhura, Guna-Laghu, Ruksha, Virya-Sita, Vipaka-Madhura, Doshakarma-Pittakaphaghna, Karma-Balya, Daha-santapahara, Rochana-dipana-pachana, Grahi, Caksusya, Trsnaprasamana, Chardinigrahana, Kasaghna, Pathya, Roga-Jwara, Daurbalya, Aruci-agnimandya, Therapeutic uses-tonic, febrifuge, blood purifier, expectorant, excessive thirst, digestive power.*

Tila [30] has properties such as *Rasa-Madhura, Anurasa* [31]*-Kashaya, tikta, Guna-Snigdha, Guru, Suksma, Vyavayi, Visada, Sara, Vikasi, Virya-Usna, Vipaka-Madhura, Doshakarma-Tridoshashamaka,* Karma[7]*-Balya, Cakshushya, Dipana, garbhasayasodh, aka, Keshya, Medhya, Sandhaniya, Snehana, Stanyajanana, Tvakprasadana, Vatahara, Vranaropana, Vranasodhana, Vrisya, etc.*

Those having properties like *Ruchiprada, Shairyakar, Kasaghna, Mamsakshaya Nashak, Santarpan, Vedana Nashak, Agnivardhaka, Anabhishyandi, Rucya and Dahahar.* These drugs work on the principle of *"Vrishyadinam Prabhavastu Pushnati Balamashu Hi"*[18] *Ashwagandha* and *Tila,* along with the above-described drugs commonly used in Ayurveda, offer unique benefits. *Ashwagandha* is believed to detoxify and reduce Aam, addressing toxin accumulation. It also balances *Agnimandya,* aiding digestion, but individual responses may vary. Additionally, Ashwagandha helps mitigate *Srotorodha* by promoting a balanced flow of energy. Tila, comprising Sesame seeds, is recognized for its warming and digestive support properties.

Table 12: Result in Terms of Weight Gain in Both Group

Overall Effect	Subjects	
	Group A (n=20)	Group B (n=20)
Excellent (> 2000g wt gain)	2	1
Very Good (1500-2000g wt gain)	4	1
Good (1000-1500g wt gain)	5	8
Average (500-1000g wt gain)	6	9
Poor (< 500g wt gain)	3	1

Table 13: Overall Effectiveness in Term of Weight Gain According to Age

Age	Group	Weight Gain					Total
		Excellent	Very Good	Good	Average	Poor	
5-6 years	Group A	1	0	0	2	2	5
	Group B	0	1	3	0	0	4
6-7 years	Group A	0	0	1	1	0	2
	Group B	0	0	1	1	0	2
7-8 years	Group A	0	2	1	2	0	5
	Group B	0	0	2	2	0	4
8-9 Years	Group A	0	2	0	1	1	4
	Group B	1	0	2	2	1	6
9-10 Years	Group A	1	0	2	1	0	4
	Group B	0	0	1	3	0	4
Total		3	5	13	15	4	40
Excellent (> 2000g wt gain) Average (500-1000g gain) Very Good (1500-2000g gain) Poor < 500g wt gain Good (1000-1500g gain)							

Conclusion

Both medicaments were effective in accomplishing the study's main aim of achieving weight gain [Table 12] and reduction in *Balashosha's* subjective symptoms. Following statistical analysis of evolutionary criteria, *Mashadi Yoga* B is shown to be superior to *Mashadi Yoga* A in terms of effectiveness. [Table 13] Daily Dietary habits and lifestyle modification were found to be effective in reducing symptoms along with helpful in increasing weight. In addition, it could be given to children of any age without causing any negative responses or adverse drug reactions (ADR). A further multicentric study can be used to confirm the efficacy of both drugs.

Harms

Subjects and their guardians reported no adverse drug reactions, and no signs were observed during or after the trial.

Limitation

The completed clinical study, with a small sample size and a short 60-day trial, offers preliminary results for future exploration with a larger sample. Acknowledging biases and emphasizing accurate concept interpretation, paves the way for fruitful research aiding children with *Balashosha*/Malnutrition, expected to yield valuable insights upon further investigation.

Generalizability

Multicentric studies with larger sample sizes across diverse pediatric age groups, longer durations, and specified subjective, anthropometric, age-specific developmental, and laboratory parameters are recommended to validate and authenticate the results of both trial drugs.

Interpretation
The disease *Balashosha* can be treated as protein-energy malnutrition due to similarities in symptoms, and it can be managed with Ayurvedic intervention, such as Mashadi yoga.

Registration
The study had taken IEC approval (IEC/ACA/2021/02-33, dt.01.09.2021) and was prospectively registered in CTRI via CTRI/2022/04/052996, dt. 20.04.2022.

Protocol
The full trial can be assessed at https://nia.edu.in/thesispage.php, or by the permission of HOD *Kaumarbhritya* (Balrog) or by the permission of Dean P.G., NIADU, Jaipur, Rajasthan.

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