

COMPACTING CHILD UNDERNUTRITION - AN AYURVEDIC NUTRACEUTICAL FORMULATION

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ABSTRACT

Childhood undernutrition has consequences of growth failure, impaired development and high incidence rate of chronic diseases, hence for maintenance of positive health, judicious food intake occupies paramount position. Purpose was to study efficacy of *Samitadimantha* as nutraceutical formulation on objective parameters of underweight school children aged 6-9 years. An uncontrolled clinical trial with 26 student participants selected purposively from schools were directed to OPD of Swasthavritta, V.P.S.V Ayurveda College, Kottakkal. Intervention was provided for 3 months. Anthropometric measurements and hemoglobin value were assessed on 0th day, 45th day, 90th day and after follow up (120th day). Data was analyzed by RM ANOVA. Height, weight, BMI, Mid-arm circumference showed statistically significant (P 0.000), hemoglobin mean value was insignificant. Study substantiates that *Samitadimantha* as Nutraceutical formulation has efficacy on objective parameters of health of underweight (BMI less than 5th percentile) school children aged 6-9 years. Further studies are needed to use the formulation for community health.

Keywords: Undernutrition; Positive health; Nutraceutical formulation; *Mantha*; *Karshya*

INTRODUCTION

The nutritional requirement of the human body reflects nutritional intake necessary to maintain optimal body function and to meet the body's daily energy needs. Nutritional disorders may result either from deficiency or excess of nutrients¹. Undernutrition is one of the most challenging public health problems, affecting more than 900 million individuals around the world². It is responsible for the highest mortality rate in children especially in developing countries like India³. In 2013, WHO estimated 17% or 98 million children in

developing countries are underweight and 49% of underweight children live in India⁴. In 6-9 years of age 63% are underweight children (NNMB, 2001). Consequences of childhood undernutrition are growth failure, impaired intellectual and physical development, lower resistance to infection and high incidence rate of some chronic diseases⁵. Undernutrition in children has been linked to poor mental development and behavioral abnormalities⁶. Further it burdens increased health expenses⁷.

UNICEF defines under nutrition “as the outcome of insufficient food intake (hunger) and repeated infectious diseases”. Since frequent infections cause weight loss and increase in the requirements of calories, proteins and vitamins, it can be expected that supplementary feeding programmes would help to improve the growth rate and nutritional status of the malnourished children⁸. However, in spite of implementation of national programmes like Balawadi nutrition programme, Mid-day meal scheme, Special nutrition programme; the child undernutrition is highly prevalent, which mandates medical fraternity to explore newer methods for better compliance⁹.

Karshya is nutritional disorder described in Ayurveda Samhita, encompassing undernutrition. *Nidanapari-varjana* (avoiding causative factors), *dipana* (enhancing digestive fire) and *brmhana* (nourishing) are the line of treatment for the management of *karshya*¹⁰. Various herbal formulations have been found to be useful in dealing with *karshya* in children. Among the factors for the maintenance of positive health, judicious food intake occupies paramount position because *ahara* (diet) is the basic medicament¹¹. In *Bhavaprakasa*, varieties of preparations with *sali*, *godhuma*, *mudga*, *maṣa* etc. which are *balya* (strengthening), *brmhana* (nourishing) and *vrshya* (corpulence provider) are mentioned¹². *Mantha*, a strengthening, corpulence provider, digestive fire enhancer is a preparation with *samita* (wheat flour)¹³. Studies show that starch of ragi has a role in undernutrition¹⁴.

As one of the important factors for underweight is the insufficient food intake it is better to be resolved by food itself. The Nutraceutical is one such attempt, defined as “A food or a part of food or nutrient that provides medical or health benefits including the prevention and treatment of a disease”. It provides extra health benefits in addition to the basic nutritional value found in foods. *Avalehaka*lpana may be correlated with Nutraceuticals. The components like medicinal drugs along with jaggery, sugar, honey, ghee, oil, milk etc. fulfils the Nutraceutical needs; both nutrition and pharmaceutical effects¹⁵. This study attempted to study the efficacy of an Ayurvedic Nutraceutical formulation in improving the health status among underweight school

children. An uncontrolled clinical trial was carried out to assess the efficacy of *Samitadimantha* as Nutraceutical formulation on objective parameters of underweight (BMI less than 5th percentile) school children aged 6-9 years. *Samitadimantha* comprising of *samita*, *sita*, *ghrta*, *ela*, *lavanga*, *marica*, and *karpura* fortified with ragi was given in the form of *avaleha* considering palatability in children and shelf life.

2. Materials and Methods

2.1 Trial design

This study was an uncontrolled clinical trial, as these are more accurate for determining the efficacy in the initial step of a new formulation. Ethical clearance was obtained for the study from the Institutional Ethics Committee of V.P.S.V Ayurveda College, Kottakkal. Approval no: (IEC/CL/22/16 dated 28/04/2016) and amended on 04/05/2018.

2.2 Study Participants

Three schools from Edarikode panchayath were selected randomly and participants following standard diet pattern as per mid-day meal programme were screened. Participants within age group 6-9 years irrespective of sex, caste & religion, BMI for age less than 5th percentile (CDC gender specific BMI for age reference-2000)¹⁶, with *pravara* and *madhyama* state of *agni*¹⁷ (Annexure 1) and who were willing to give informed consent were included in the study. Assent was obtained from the minor student participants along with consent of the parents or guardian. Exclusion criteria included participants with systemic diseases like tuberculosis, congenital and hereditary problems, malignancies, mal absorption syndrome, metabolic error, chronic gastrointestinal disorders, undergoing any medications and with *avara* state of *agni*¹⁷. Eligible participants were selected by purposive sampling and directed to the OPD of Swasthavritta, V.P.S.V Ayurveda College, Kottakkal.

2.3 Formulation

The Nutraceutical formulation, *Samitadimantha* contained *samita* (wheat flour), ragi flour, sugar, water, *ela*, *lavanga*, *marica*, *karpura* and ghee was prepared from Arya Vaidya Sala factory, Kottakkal (GMP certified company) in the form of *avaleha* as per The Ayurveda Pharmacopoeia of India¹⁸ and packed as 150gm in

each bottle (Batch No. SP02702 & SP02782), (illustrated in Figure 1. Nutraceutical formulation). Properties¹⁹ and nutritive value of the ingredients of *Samitadimantha* are described in Table 1 and 2 respectively. This was initially tested for its safety and palatability by the colleagues.

2.4 Intervention

For the selected participants the study formulation (*Samitadimantha*) was given in a dose of 5g twice daily (morning and evening) after food for a period of 90 days. The participant received the study formulation for two weeks during first visit. Next stock was provided on 14th day after obtaining the finished bottle from the participant. This was done along with daily assessment chart to ensure the proper consumption of the formulation. Efforts to maintain compliance and detect undesirable events if any, included regular communication with parents and concerned teachers.

2.5 Outcomes

For evaluation of efficacy of the intervention, anthropometric measurements such as height, weight, BMI, mid arm circumference²⁰ and hematological estimation were used for objective parameters. The parameters were assessed before intervention (0th day), 45th day, 90th day and after follow up of 1 month (120th day). The observations were made and recorded in the CRF of each participant at every assessment.

2.6 Sample Size

Sample size was calculated using the formula²¹, $n = (z\alpha)^2 pq/d^2$ with prevalence of 63% and precision of 20. Sample size was finalized to 26 by considering a drop out of 10%. Among the screened participants, 26 participants satisfying the inclusion and exclusion criteria were selected for the study.

2.7 Statistical Analysis

Data was tabulated, analyzed and presented with the help of tables and graphs. Normality of data was tested by Q-Q plot in SPSS version 16.0. Repeated measures ANOVA was done to assess difference between observations at 0th, 45th, 90th and 120th day. Bonferroni Multiple Comparisons test was done for comparisons. Statistical analysis was done by using Microsoft Office 2013 Excel and IBM SPSS Statistics version 16.

3. Results

3.1 Study Population

One hundred participants within the age group six to nine years were screened for assessing eligibility. Forty-five met exclusion criteria. Among fifty-five eligible, thirty participants were selected. Those who were satisfying inclusion criteria and those who were willing to give an informed written consent from parents were included. Twenty-six participants included by purposive sampling had completed the study; no drop out were observed (Figure 2. Flow Diagram of Participants).

3.1.1 Baseline Data

Participants were in the age group of 6-9 years of having male female ratio in percentage 62:38. Residence was rural. Meal pattern per day was 2 meals or less than 2 meals was seen in 96%. Only 20% were taking more than 75% of their recommended daily allowance of energy. Average daily intake of energy was lower than recommended RDA. Socio demographic characteristics are described in Table 3.

3.2 Effect Analysis

Mean height at the end of the study period was 122.56cm (SD: 8.3) showing an increase of 1.85cm. Mean weight had a difference of 1kg. The change in BMI to 13.17kg/m² (SD: 0.64) at the end of the study period showed mean BMI was above the 5th percentile. Mean values of assessments on objective parameters are shown in Table 4. This difference was statistically significant at 0.1% level (P 0.000) on height, weight, BMI and mid arm circumference. There was no significant difference in mean score of hemoglobin and was not significant at 5% level (P 1.000). Mean differences at end of trial are described in Table 5.

3.3 Adverse Events

No adverse effect was reported during intervention and review period.

DISCUSSION

The ingredients used in this study formulation have previously been studied individually. Wheat, when combined with other food proteins exhibit excellent nutritional complementarity²². Ragi is very high in calcium and fibre and has a better energy content than other cereals²³. Moreover, the formulation was seen to

assist in balancing and maintenance of *agni*. Ultimate result might have helped in proper digestion of food and contributed to the formation of proper *rasadhātu*. These might have improved the health status of underweight children. The main drivers for this formulation are the easy availability, cost effective and can be accessibility in household. However stringent vigil needs to be maintained during preparation and storage to keep aloof fungus infestation.

Our study does not reveal household's socio-economic status as a predictor for undernutrition which is contrary to some previous studies²⁴. Henjum et al. illustrates that the inadequate dietary intake has contributed to the high levels of underweight among the children²⁵. However, in the present study it was found that most of the families use rice daily and consumption of wheat/ragi /pulses /vegetables/ egg /fish/meat and milk was confined to once or twice in a fortnight. Banerjee S et al. stated that energy intake of underweight students was significantly lower than the recommended daily allowance²⁶. Further, children may not eat much food at a time and providing food at divided interval is necessary for them²⁷. In our study also a major proportion of participants had a tendency to skip breakfast. The regular breakfast skipping could swish down energy levels and negatively impact on memory, since higher level of resting metabolism is reported by those taking regular breakfast²⁸.

Children in growing phase are reported a height gain of around 1.25 cm and weight gain of around 500-750 g in three months²⁹. In this study, observed height gain was 1.85cm and weight gain is 1kg. This shows, in addition to normal changes during growth, the Nutraceutical formulation provided an added effect. Percentage of improvement in height was 1.66%, weight-5.43%, BMI-2.2% and in mid-arm circumference was 3.3%. The stagnant result of hemoglobin may be because of the absence of deworming. Study by Blumberg et al. shows that the dietary advice given, and the shorter duration of administration resulted in insignificant result³⁰. In this study after one and a half months of administration, participants had an issue of decreased palatability.

The authors strongly suggest sustained strategy for nutraceutical administration among children. Limitation includes shorter follow up period. Procurement of enhanced results by long term clinical study with control group in larger population and Immunoglobulin would render the formulation useful in community health programmes.

CONCLUSION

The present study was seen to improve height, weight, BMI and mid arm circumference of underweight (BMI less than 5th percentile) school children. The study shows that the Ayurvedic Nutraceutical formulation (*Samitadimantha*) has efficacy on objective health parameters pertaining to underweight (BMI less than 5th percentile) school children aged 6-9 years. Extended studies are required for facilitating use of the formulation in community.

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Properties of ingredients described below shows that *Samitadimantha* works as *brmhana*, *balya*, *vrshya*, *ruchya* and *agnidipana*.

Table 1: Ayurvedic properties of the ingredients of *Samitadimantha*

Drug	Rasa	Guna	Veerya	Vipaka	Karma
Godhuma	Madura	Snigdha, Guru	Seeta	Madura	Vrushya, Balya, Rasayana, Brmhana, Varnya, Sthairyakara, Jeevaniya, Ruchiprada, Kasaghna
Ragi	Madura	Snigdha, Guru	Seeta	Madura	Brmhana, Balya, Vrushya
Ela	Katu, Madura	Laghu, Ruksha	Seeta	Katu	Hridya, Sukranasana, Deepana
Lavanga	Katu, Tikta	Laghu, Snigdha	Seeta	Katu	Chakshushya, Ruchya, Deepana, Pachana
Maricha	Katu	Laghu, Teekshna	Ushna	Katu	Deepana, Krimihara
Karpura	Tikta, Katu, Madhura	Seeta, Guru, Snigda	Seeta	Madura	Medya, Pachana, Kriminasana
Sita	Tikta, Madura, Kashaya	Guru	Seeta	Madura	Vatapittasamaka, Dahatrishnahara
Ghrta	Madura	Guru, Snigda	Seeta	Madura	Vatapittasamaka, Deepana

Table 2: Nutritive value of the ingredients in *Samitadimantha*

	Moisture g	Protein g	Fat g	Minerals g	Crude fibre g	Carbohydrates g	Energy kcal	Calcium mg	Phosphorus mg	Iron mg
Wheat	12.8	11.8	1.5	1.5	1.2	71.2	346	41	306	5.3
Ragi	13.1	7.3	1.3	2.7	3.6	72.0	328	344	283	3.9
Sugar	-	-	-	-	-	99.98	387	-	-	-
Ghee	-	-	100.0	-	-	-	900	-	-	-
Cardamom	20.0	10.2	2.2	5.4	20.1	42.1	229	130	160	4.6
Cloves	25.2	5.2	8.9	5.2	9.5	46.0	286	740	100	11.7
Pepper	18.2	11.5	6.8	4.4	14.9	49.2	304	460	198	12.4

Table 3: Socio demographic characteristics of underweight school children aged 6-9 years

Variables	N=26
Male: Female	16:10
Socio economic status (upper: middle: lower)	1:13:12
Type of delivery (normal: caesarean)	17:9
Birth weight (below 2.5kg: above 2.kg)	10:16
Immunization (full: partial)	24:2
Energy intake (<50%: 50-75%: >75%)	4:17:5
Regularity of meals (yes: no)	20:6
Performance of child in the class (average: below average)	22:4

Descriptive statistics of effect of the Nutraceutical formulation on parameters recorded on assessments was charted below.

Table 4: Baseline and assessments of clinical characteristics of underweight school children aged 6-9 years

Objective parameters	Mean (SD)			
	0 th day	45 th day	90 th day	120 th day
Height (cm)	120.71 (8.3)	121.69 (8.5)	122.56 (8.3)	122.88 (8.4)
Weight (kg)	18.82 (2.8)	19.48 (3)	19.89 (3)	19.93 (3.1)
BMI (kg/m ²)	12.86 (0.54)	13.09 (0.65)	13.17 (0.64)	13.13 (0.69)
Mid arm circumference (cm)	15.16 (0.9)	15.37 (0.92)	15.68 (0.99)	15.75 (0.98)
Hemoglobin (g/dL)	11.16(0.91)	11.13(1.06)	11.06(0.82)	11.07(1.06)

To assess the variance due to intervention between assessments mean values of objective parameters Repeated Measure ANOVA was carried out. Further multiple comparisons using Bonferroni test, was done between assessments.

Table 5: Baseline and end of trial clinical characteristics of underweight school children aged 6-9 years

Objective parameters	End of study		
	Mean difference	Standard error	P
Height	-1.846	.170	.000
Weight	-1.069	.135	.000
BMI	-.312	.060	.000
Mid arm circumference	-.519	.082	.000
Hemoglobin	.099	.168	1.000



Figure 1: Nutraceutical formulation

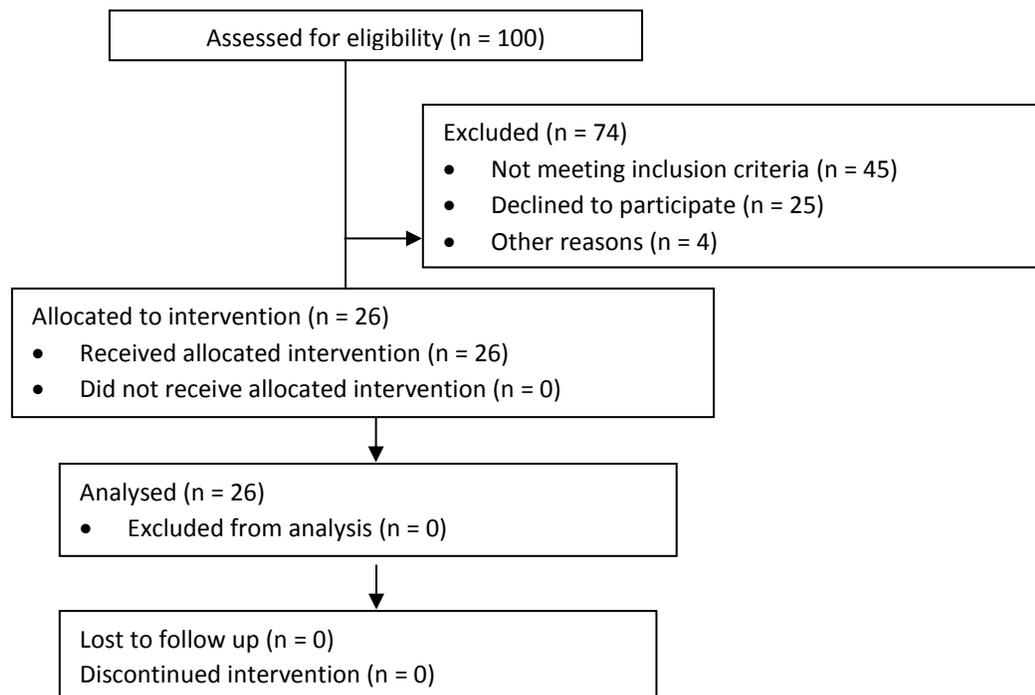


Figure 2: Flow Diagram of Participants

Assessment of Agni

(A) Evaluation of Jaranasakti (Digestive capacity) Utsaha (enthusiasm), Laghuta (lightness), Udgarasuddhi (clear eructation), Kshudha (hunger), Trishna (thirst) and Yathochitamalotsarga (bowel movement)

Lakshana	Score	Remarks
Absence of all the symptoms	0	
Presence of one symptom	1	
Presence of two symptoms	2	
Presence of three symptoms	3	
Presence of four symptoms	4	
Presence of all the five symptoms	5	

(B) Assessment for Abhyavaharanasakti (Capacity to eat)

Lakshana	Score	Remarks
The person not at all taking food	0	
Person taking food in less quantity once in a day	1	
Taking food in less quantity twice a day	2	
Taking food in moderate quantity twice a day	3	
Taking food in normal quantity twice a day	4	
Taking food in excessive quantity twice or thrice	5	

(C) Evaluation for Ruchi factor (Appetite)

Lakshana	Score	Remarks
Totally unwilling for meal	0	
Unwilling for food, but could take the meal	1	
Willing towards only most liking food, and not to other	2	
Willing towards only one among pungent, sour or sweet etc. food stuffs	3	
Willing towards some specific food or taste	4	
Equal willing towards all the food stuffs	5	

Source of Support: Nil

Conflict of Interest: None Declared

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