International Journal of Science and Research Archive
eISSN: 2582-8185
Cross Ref DOI: 10.30574/ijsra
Journal homepage: https://ijsra.net/

(RESEARCH ARTICLE)

Check for updates

Efficacy of a protein-micronutrient dietary supplement in preschool children with acute malnutrition: A randomized controlled clinical trial

Pranit Yadaw Ambulkar *, Bhagwat Chandrakant Tambe and Prabhakar Ramachandra Jadhav

Department of Research and Development- Health-Care, Netsurf Research Lab., Pune, India.

International Journal of Science and Research Archive, 2024, 13(02), 1543–1548

Publication history: Received on 18 October 2024; revised on 25 November 2024; accepted on 27 November 2024

Article DOI: https://doi.org/10.30574/ijsra.2024.13.2.2319

Abstract

Malnutrition remains a critical health challenge among children in both rural and urban regions of India. While financial constraints play a role, the predominant contributing factor is a lack of awareness regarding individual nutritional needs and appropriate strategies to address them. Efforts by organizations such as the WHO, government bodies, medical institutions, and social workers aim to mitigate this widespread issue. This study evaluates the efficacy of *Naturamore for Kids*, a protein-multivitamin-nootropic supplement, in managing acute mild and moderate malnutrition in 370 preschool children aged 2 to 6 years over a three-month intervention.

The results demonstrated statistically significant improvements in anthropometric parameters within the trial group compared to the control group, which received milk and traditional nutritional remedies. Height increased by 3.06% in the trial group versus 2.34% in the control group, while weight increased by 9.08% in the trial group compared to -6.31% in the control group ($p < 0.001$). The superior outcomes may be attributed to the formulation's optimized blend of proteins (whey, soy, rice, and peas), fortified vitamins and microminerals, and herbal nootropics such as *Ashwagandha* and *Brahmi*. These findings highlight the potential of *Naturamore for Kids* as an effective intervention for improving growth and nutritional status in malnourished preschool children.

Keywords: Malnutrition; Supplement; Protein; WHO-Z score; Children; Pre-school

1. Introduction

Child malnutrition remains a critical concern in India. Preschool children continue to face a substantial obstacle in the form of undernutrition, which frequently takes the form of stunting (chronic malnutrition), wasting (acute malnutrition), and underweight. The National Family Health Survey-4 (NFHS-4), a crucial data source delineating the prevalence of child malnutrition in India, revealed that approximately 35.7% of children under 5 years exhibit moderate to severe underweight (thin for age), 38.4% exhibited moderate to severe stunting (short for age), and around 21% are moderate to severe wasted (thin for height) (1).

The lack of adequate intake of protein is an important aspect of the larger problem of malnutrition in India. Due to the fact that proteins are necessary for a child's development, immune system function, and overall health, including them in their diet is absolutely necessary. 73% of Indians are deficient in protein while above 90% are unaware of the daily requirement of protein. (2) This deficiency, which hinders children's physical and cognitive development, is contributed to, in part, by the lack of nutritional diversity that exists, particularly among vulnerable groups. (3).

The lack of certain micronutrients might be thought of as a hidden cause for malnutrition. Micronutrient insufficiency, sometimes known as hidden hunger, is a widespread issue that affects children in India who are between the ages of 2 and 6. This deficit includes key vitamins and minerals including iron, vitamin A, and iodine, which are crucial for a

* Corresponding author: Pranit Yadaw Ambulkar

variety of processes throughout the body (4). According to the WHO, 45% of deaths in children aged <5 years are linked to undernutrition.

The investigational dietary supplement product 'Naturamore for Kids' is specially developed health supplement for children with unique wholesome formulation containing essential vitamin, minerals, herbal extracts together with a blend of whey, soy, pea, rice and milk solids. The goal was to assess efficacy of Naturamore for kids on managing acute mild to moderate malnutrition in preschool children of age 2 to 6 years.

Objective

Evaluation of growth improvement in height, weight, (WHO Z-score) in malnourished preschool children of age 2 to 6 years over the period of 90 days.

2. Methods

Naturamore for kids dietary supplement, containing 30% proteins from dairy and plant source. The protein blend included Whey protein, soy protein, rice protein, pea protein and milk proteins and colostrum. The nootropic ingredients in the products were Omega 3 DHA, Brahmi extract, and Ashwagandha extract. The micronutrient blend had Around 25% RDA of essential vitamins and minerals like Vitamin A, B1, B2, B3, B5, B6, B7, B9, B12, C, D2, E, K1, calcium, magnesium, iron, manganese, zinc, copper, selenium, potassium, sodium, and choline.

2.1. Method

The study was designed as a randomized, controlled clinical study. After, receiving ethics committee's approval for study protocol, clinical study was registered with CTRI. Children aged between 02 to 06 years of age were screened for eligibility criteria.

Young children of age between 2 to 6 years inclusive (both gender) were included in the study. Malnutrition of grades 1 and 2 as per I.A.P. Grading of Malnutrition and subjects suffering from PEM were included in the study. The subject's whose parents aware of all of the research methods and limits, and willing, able, and very likely to comply with them were included in the study.

Children with systemic diseases, congenital diseases, infections and communicable diseases and where parent's consent was unavailable were excluded from the study. Children who had been evaluated with other grades of PEM, i.e., normal, grade 3, and grade 4 as per the IAP classification, were also excluded. Kids already on some other dietary supplements, medications or therapy were also excluded.

On screening visit, a written informed consent was obtained from parent or legal guardian of subject confirming participation in the study. We screened 447 and enrolled 390 subjects in the study. There were total 370 completers at the end of the study. Among these, 282 were randomized to the test group, while 88 were assigned to the control group.

At baseline and at every follow up visit (except final visit), subjects parents/guardians were provided with investigational products. Parent/guardians were advised to provide 10 gm of investigational product with milk in morning for test group subjects for 3 months (90 days). Control group subjects received milk in the morning for 3 months (90 days). Both the groups received dietary advice regarding home remedies for better nutrition. Investigational product compliance was assessed based on compliance diary filed by parents/ guardians.

Parents/guardians with subjects were called at respective study sites for follow up visits on day 30 (visit 1), 60 (visit 2) and 90 (visit 3). Growth changes in height and weight by WHO Z-score, Safety evaluations were done throughout the study. Subjects were closely monitored for any adverse event throughout the study.

Height and weight by WHO Z-score: The Z-score is the deviation from the median value of the reference population, divided by the standard deviation of the reference population. Z-scores describe how far a measurement is from the median (average) measurement of the reference population.

After completion of 3 months of study treatment, Parent/guardian of the subject were asked to stop investigational product and take advice of investigator for further treatment.

The improvement in growth parameters in both the groups were recorded and analysed statistically to derive statistical significance.

3. Observations and Results

Table 1 Demographic observations

Gender	**Trial**		**Control**	
	Male (n=130)	**Female (n=152)**	**Male (n=40)**	**Female (n=48)**
Mean Age (years)	3.58±1.1		3.473±1.01	

Table 2 Assessment of physical growth

Parameters	**Duration**	**Test**	**Control**	***p* value (between group)**
Body Height (cm)	Screening	90.8 ± 9.22	89.72 ± 10.68	0.624
	Day 90	93.53 ± 9.21	91.82 ± 10.82	0.001
% Change		3.06%	2.34%	
Body Weight (kg)	Screening	10.57 ± 1.87	11.57 ± 8.76	0.176
	Day 90	11.53 ± 1.88	10.84 ± 2.19	<0.001
% Change		9.08%	-6.31%	

Data was analysed using dependent student t-tests (within group) and independent student t-tests (between group). Significant at p <0.05.

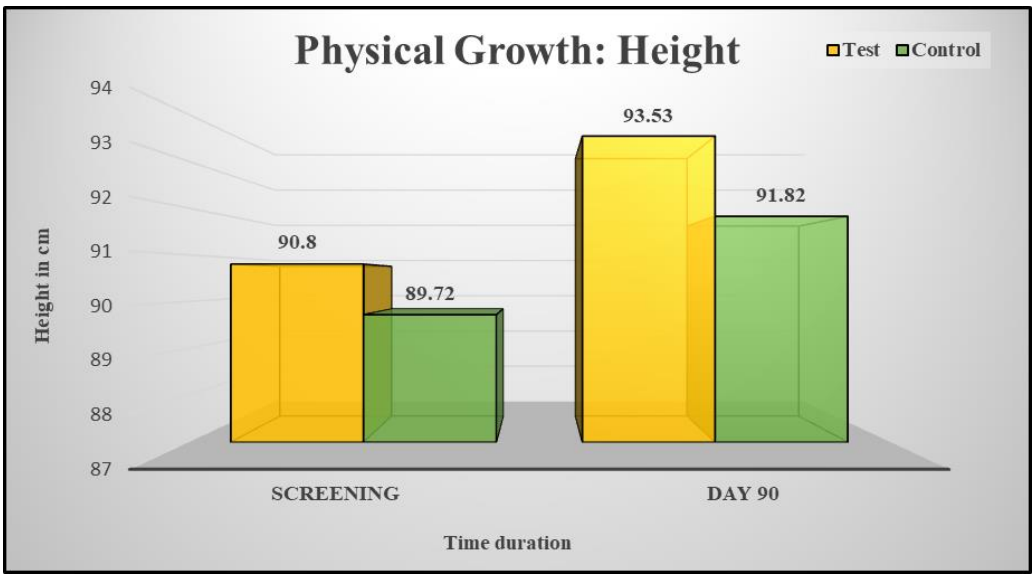

Figure 1 Assessment of changes in height over the period of 3 months

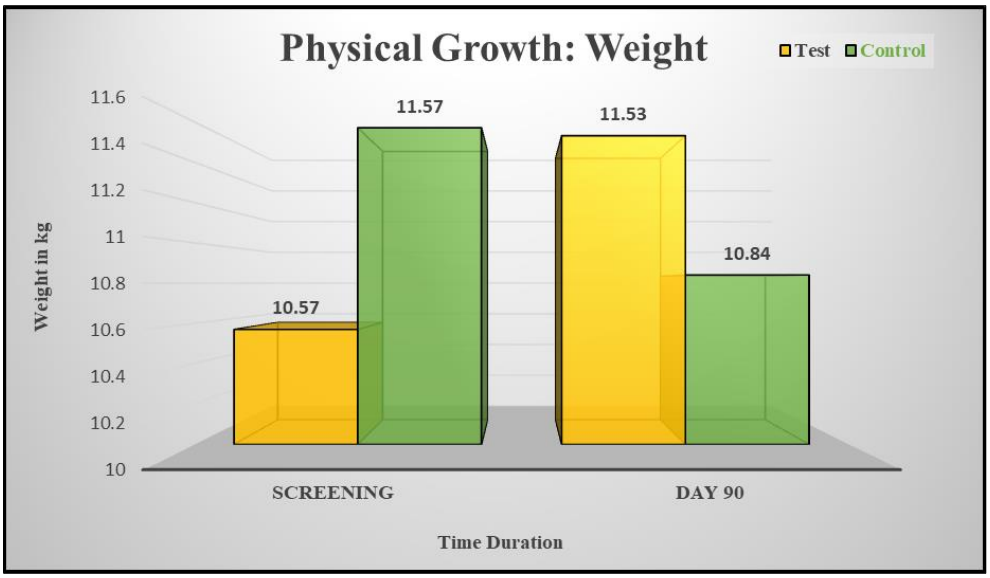

Figure 2 Assessment of changes in weight over the period of 3 months

3.1. WHO-Z SCORES

The data presented in the table 3 indicates the comparison between the test and control groups at screening and after 90 days. The Height to Age Z Score was homogenous at screening. However, by day 90, the test group exhibited a notable improvement with a mean of -1.39 ± 1.70, while the control group experienced a decrease to -1.83 ± 1.85, and this difference between the groups was statistically significant.

Similarly, for the Weight to Age Z Score at screening, there was no significant difference between the test group and the control group was observed. However, by day 90, the test group demonstrated improvement, as the mean shifted to -2.17 ± 0.95, while the control group improvement to -2.69 ± 1.04, and this difference between groups was highly significant.

In summary, the Height to Age Z Score and Weight to Age Z Score data indicate that, over the 90-day period, the test group experienced positive changes compared to the control group. These improvements in the test group suggest a positive impact of the test intervention, emphasizing its potential efficacy in addressing malnutrition.

Table 3 WHO Z Scores

Parameters	Duration	Test	Control	p value (between group)
Height to Age Z Score	Screening	-2.12 ± 1.67	-0.23 ± 1.83	0.272
	Day 90	-1.39 ± 1.70	-1.83 ± 1.85	0.0069
Weight to Age Z Score	Screening	-2.89 ± 1.04	-2.80 ± 1.08	0.521
	Day 90	-2.17 ± 0.95	-2.69 ± 1.04	<0.001

The Z scores were computed utilising the WHO ANTHRO SURVEY ANALYSER software. Data was analysed by dependent student t tests (within groups) and independent student t tests (between groups). Significant at $p < 0.05$.

During the study, participating children appreciated the taste and mouth feel of the test product. The test product had outstanding palatability and mixability. During the trial, individuals showed complete compliance. Moreover, there no adverse events reported throughout the study duration in any of the subjects indicating the safety of the product.

4. Discussion

There is an urgent need to increase knowledge on the most effective treatment techniques for children who have poor growth and undernutrition, especially because some outcomes of undernutrition can have long-term detrimental repercussions on their life. The treatment goal should be to provide the child with a diet that is adequate and balanced

in terms of macronutrients and micronutrients. This lowers the likelihood of poor linear growth and underweight (5). Certain nutritional supplements have been demonstrated in systematic reviews and meta-analyses to offer some growth benefits by lowering mild underweight and improving height and weight (5, 6).

According to the study, the Ashwagandha extract employed in the test product has outstanding immunomodulatory along with anti-inflammatory and antioxidant properties. Research have shown that Ashwagandha can boost both innate and acquired immunity (8). The micronutrient supplementation in the test product, such as vitamin C and D, has the potential to boost immunity. Colostrum, which is employed as a component in the test product, has immunity-modifying capabilities that may help with infection resistance (9, 10). Likewise, in the current study, Naturamore for Kids supplements fortified with both macro and micronutrients demonstrated significant effectiveness in enhancing the weight, height, weight-to-age Z-score, and height-to-age Z-score in the 2-6 years old participants

The average weight in control group was observed reducing over the trial period. This suggest that mere addition of milk and advise of home remedies was not sufficient to tackle the malnutrition. Whereas we know home based food with good nutritional value may show positive results in malnutrition, however, may be the environment at home, educational status of the guardians, spending capacity of the family etc. various factors may have played a lore in this; and this needs to be further investigated.

5. Conclusion

In conclusion, the results affirm that the Naturamore for Kids dietary supplement is safe and effective in promoting growth and development in malnourished children. It improved growth of children indicated by Height to age and weight to age Z scores defined by WHO significantly more as compared to the control group. It could be due to the right nutrition provided by Naturamore for Kids. The right blend of proteins like whey, soy, rice, and peas along with vitamin and micro mineral fortification and the addition of potential herbal extracts like Ashwagandha and Brahmi is definitely providing better assimilation of the product and efficacy.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

References

[1] De, P. and Chattopadhyay, N. (2019) Effects of malnutrition on child development: Evidence from a Backward District of India, Clinical Epidemiology and Global Health. Available at: https://cegh.net/article/S2213-3984(18)30097-6/fulltext (Accessed: 04 November 2023).

[2] Suri, S. (2020) India's protein deficiency and the need to address the problem, ORF. Available at: https://www.orfonline.org/expert-speak/indias-protein-deficiency-and-the-need-to-address-the-problem/#:~:text=The%20recommended%20dietary%20allowance%20of,the%20daily%20requirement%20of%20protein. (Accessed: 04 November 2023).

[3] National Consultation on Family Medicine Programme 2013: Report and recommendations convened by National Health System Resource Centre (NHSRC) National Health Mission (NHM) MHOFW (Ministry of Health and Family Welfare) Government of India' (2016) Journal of Family Medicine and Primary Care, 5(1), p. 197. doi:10.4103/2249-4863.184687.

[4] Streit, L. (2023) Micronutrients: Types, functions, benefits and more, Healthline. Available at: https://www.healthline.com/nutrition/micronutrients (Accessed: 04 November 2023).

[5] Venkatesh, U. et al. (2021) Micronutrient's deficiency in India: A systematic review and meta-analysis, Journal of nutritional science. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8727714/ (Accessed: 04 November 2023).

[6] 6- Malik F, Singh J, Khajuria A, et al. A standardized root extract of Withania somnifera and its major constituent withanolide-A elicit humoral and cell-mediated immune responses by up regulation of Th1-dominant polarization in BALB/c mice. Life Sci. 2007;80(16):1525-1538. doi:10.1016/j.lfs.2007.01.029

[7] Roberts J.L., Stein A.D. The impact of nutritional interventions beyond the first 2 years of life on linear growth: A systematic review and meta-analysis. Adv. Nutr. 2017;8:323–336. doi: 10.3945/an.116.013938.

[8] https://www.hindustantimes.com/lifestyle/health/top-food-components-for-growing-kids-nutrients-that-must-be-in-a-child-s-plate-101669720931364.html

[9] Cameron F. Gunville et. al., the Role of Vitamin D in Prevention and Treatment of Infection, Inflamm Allergy Drug Targets. 2013 Jul 11; 12(4): 239–245.

[10] Yeom, C., Park, Y., Choi, S. et al. Association of peripheral BDNF level with cognition, attention and behavior in preschool children. Child Adolesc Psychiatry Ment Health 10, 10 (2016). https://doi.org/10.1186/s13034-016-0097-4