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Prospective, Multi-centric, In-clinic, Observational Study on ChilRun Full™: An Oral Nutritional Supplement for Growth and Development

Research Article

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Abstract

Nutritional supplements have increasingly been recognised as one of the most effective and appropriate strategies for enhancing growth and overall physical health of children. Post-marketing, multi-centric in-clinic observational study, was undertaken to evaluate the effect of ChilRun Full™, an oral nutritional supplement, on the growth and developmental parameters of children aged two years and above. ChilRun Full™ is a 37 nutrient based oral supplement for children 2+ age groups which has balanced macro and micronutrients. In this study, ChilRun Full™ was administered twice a day (serving size either with milk or water) along with routine eating habits under the recommendations of paediatricians) to a total of 665 kids (≥2 years) from the Eastern part of India for a period of three months. During the study period anthropometric measurements including height, weight and body mass index (BMI) were measured at baseline (day 0), on days 30, 60 and 90 of the study period, and data was recorded in Case report Form (CRF).

The assessment of the outcomes was conducted utilizing Z-scores for height, weight and BMI, which served as critical metrics for determining the significance of the findings of growth and development. The results indicate significant improvements in height, weight and BMI across all age categories. In 2-3 years, 4-6 years and 7-9 years age group, the average height increased from 95.96 cm at baseline to 97.57 cm, 110.31 to 111.75 cm and 123.91 to 125.26 cm, respectively by day 90, while the weight increased from 15.09 kg to 16.25 kg, 21.50 to 22.54 kg and 25.56 to 26.31 kg. Similarly, the BMI showed a consistent upward trend, indicating healthy weight gain in proportion to height.

The findings suggest that the ChilRun Full™ nutritional supplement plays a crucial role in supporting the growth and development of growing children and contributing to a significant increase in both height, weight and BMI across the various age groups of children.

Keywords: Oral Nutrition supplement; ChilRun Full™; Growth chart; BMI; Z-score

Introduction

Nutritional supplements play a crucial role in the growth and development of children, particularly in the formative years of growth (2 to 12 years). During this period, children undergo significant physical and cognitive changes that are heavily influenced by their nutritional intake [1]. Inadequate nutrition can lead to several developmental issues, such as stunting, wasting and various forms of malnutrition [2].

Prevention of child malnutrition requires diets providing adequate energy and essential nutrients to promote catch-up growth, strengthen resistance to infection and support normal mental, physical and metabolic development. Long term malnutrition in early age also leads to stunting, wasting, mortality and morbidity. India is home to 31% and 42% of the world's children, who are stunted and underweight, respectively, while many others are affected by micronutrient deficiencies [3]. The Indian Academy of Paediatrics (IAP) recommends use of IAP growth charts for monitoring height

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and weight and determining the need of intervention as appropriate [4].

Oral nutritional supplements (ONS) have been recognized as the most suitable method of improving growth and physical health of children. They are also crucial for early development including cognition [5]. ONS are specially formulated products designed to fill gaps by providing essential nutrients, including vitamins, minerals and calories to children. These supplements are especially beneficial for children with inadequate dietary intake or those facing growth challenges, such as underweight or malnourished children [6]. ONS provides targeted nutrition that can support muscle development, bone health and cognitive growth, all of which are essential during childhood [7].

Studies have demonstrated that ONS can significantly improve growth outcomes in malnourished children by promoting increase in height, weight and overall physical development [8]. By addressing specific nutrient deficiencies ONS ensure that children receive the right balance of nutrients for healthy development. A meta-analysis including 29,814 children from 20 developing countries suggested that nutritional supplementation could improve children's cognitive development (d 0.08, 95% CI 0.03-0.13) [9]. Further, studies have reported positive association between specific nutrient intake such as protein, docosahexaenoic acid (DHA), dietary fibers or calcium with linear growth and development suggesting that intake of certain nutrients may be specifically important to promote growth. Nutritional supplements not only aid in improving the health status of normal children but are also useful for children with Attention-Deficit Hyperactivity Disorder (ADHD), autism etc [10,11].

This in-clinic, multicentric, non-randomised, observational study was aimed to evaluate the effect of ChilRun Full™ (scientifically formulated with 37 key nutrients) on the growth and development of children (665 Kids from the Eastern part of India) aged two years and above over a three-month period along with a regular diet.

Materials and Methods

This post-marketing, multicentric, in-clinic observational study was performed in the Eastern region (Kolkata, Guwahati, Bhubaneshwar, Cuttack, and Balasore) of India to assess the effectiveness and safety of ChilRun Full™ in children aged 2 years and above. Total 681 children were enrolled for the study and only 665 completed (including male = 365 and female = 300) the study for a duration of 90 days (Figure 1) (Table 2). Anthropometric measurements in terms of weight, height and BMI were measured during the visits on Day 0 (baseline), 30, 60 and 90 (end of the study) as per the CRF. The Z-score for height, weight and BMI was used to analyze the results using Khadilkar (2015) growth chart [12]. All measurements were performed by clinical staff (under the supervision of paediatricians) using the standardized methods and data was captured in case report forms (CRF) as per protocol (Table 1).

Children aged 2 years and above with regular eating habits were enrolled across 50 sites in the Eastern region of India under the supervision of paediatricians. Each investigating paediatrician enrolled minimum 10 to 12 kids at their respective clinics for the

Table 1: Case Report Form (CRF)

Visit 1 (day 1)			
Date of visit	DD-MM-YYYY		
DEMOGRAPHIC DATA			
Gender	M/F		
Date of Birth	DD-MM-YYYY		
Current Age			
ANTHROPOMETRIC MEASUREMENTS			
Weight	Kg		
Height	cm		
BMI			
Visit 2 (day 30)			
Date of visit	DD-MM-YY**YY**		
ANTHROPOMETRIC MEASUREMENTS			
Weight	Kg		
Height	cm		
BMI			
Doses taken twice daily	Yes	No	Remarks
Visit 3 (day 60)			
Date of visit	DD-MM-YYYY		
ANTHROPOMETRIC MEASUREMENTS			
Weight	Kg		
Height	cm		
BMI			
Doses taken twice daily	Yes	No	Remarks
Visit 4 (day 90)			
Date of visit	DD-MM-YY		
ANTHROPOMETRIC MEASUREMENTS			
Weight	Kg		
Height	cm		
BMI			
Doses taken twice daily	Yes	No	Remarks

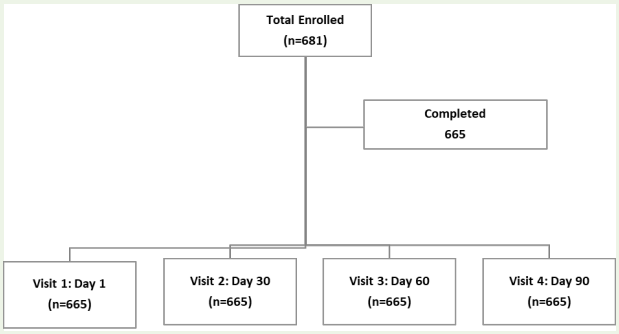

Figure 1: Flow chart on children enrolled for study

Table 2: Baseline demographics

Variables	All Children (N=665)
Male	365
Female	300
Height (cm)	107.9
Weight (kg)	20.17
BMI	16.97

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study initiation. Anthropometric measurements in terms of weight, height and BMI during the visits on baseline (Day 0), 30, 60 and 90 (end of the study) and this data were analysed based on kids age group as 2-3 years, 4-6 years and 7-9 years. Only completed CRF in terms of all readings on Day 0, Day 30, Day 60 and Day 90 were considered for study analysis. Children with 1) Concomitant systemic infection or clinically significant diseases and with stomach infection, infestations and suspected liver disorders were not included in the study as per protocol and 2) Child diagnosed with Lactose intolerance or Galactosemia or has any other clinically significant medical conditions or is known to be allergic or intolerant to any ingredient found in the study product according to medical records or Legal Guardian (LG)/parent report were not enrolled in the study.

Each eligible subject received two servings of ChilRun Full™ (Manufactured by Panacea Biotec Pharma Ltd., New Delhi; FSSAI approved) every day for 3 months. The commercially available ChilRun Full™, composition as detailed in table 4 was prepared by mixing 2.5 levelled scoops or 45.5 g of powder in 190 mL water or mixing 1 levelled scoops or 18.2 g of powder in 150 mL cow milk. Enrolled kids' parents were advised to provide ChilRun Full™ in the morning and the afternoon/or evening as per serving size for a period of 90 days, and advised to visit their respective paediatrician for body/ weight and height measurement on day 30, 60 and 90 days. Safety and Tolerability, was reported by parents and caregivers and verified by study physicians.

Results

The data obtained from studies conducted at 68 clinics across 5 cities in Eastern part of India from 1st January 2024 to 31st June 2024 was subjected for analysis. A total of 681 children were enrolled and received the nutritional supplement ChilRun Full™ out of 681 enrolled subjects 665 completed the study. The demographics and baseline characteristics are presented in Table 2. The median age was 4.88 ± 0.5 years (range 2 - 12 years) and the gender distribution included 365 males and 300 females. None of the children enrolled had wasted (Z score ≥ -2).

On continuous use of ChilRun Full™ changes in height, weight and BMI were observed on days 30, 60 and 90 (Table 3). A substantial increase in all three parameters among all age groups was observed at the end of 90 days on consumption of ChilRun Full™ (in comparison to baseline values prior to start of ChilRun Full™ initiation). The data suggests that the ChilRun Full™ had a positive effect on the growth metrics on continuous 90 day use :

Table 3: Change in height, weight & BMI from baseline to day 30, 60 & 90

Age	Parameter	Baseline	Day 30	Day 60	Day 90	% Increase
2-3 yrs.	Height (cm)	95.96	96.49	96.88	97.57	1.67
	Weight (kg)	15.09	15.47	15.73	16.25	7.69
	BMI	16.14	16.39	16.43	16.87	–
4-6 yrs.	Height (cm)	110.31	110.59	110.78	111.75	1.31
	Weight (kg)	21.50	22.02	22.13	22.54	4.84
	BMI	17.46	17.70	17.73	17.83	–
7-9 yrs.	Height (cm)	123.91	124.24	124.71	125.26	1.09
	Weight (kg)	25.56	25.95	26.44	26.91	1.37
	BMI	16.60	16.75	16.93	17.09	–

Table 4: Composition of ChilRun Full™

Nutritional Facts	ChillrunFull™ (label claim per 100 g)
Energy (kcal)	454
Protein (g)	14.1
Carbohydrates (g)	64.74
Total Sugars (g)	42.54
Added Sugars (g)	24.1
Total Fat (g)	15
Saturated Fatty Acids (g)	≯14.14
Monounsaturated Fatty Acids (g)	6.34
Polyunsaturated Fatty Acids (g)	4.67
Trans Fatty Acids (g)	≯0.2
Linoleic acid (mg)	3200
Alpha linoleic Acid (mg)	351
Cholesterol (mg)	≯30
Calcium (mg)	656
Phosphorus (mg)	408
Vitamin D2 (mcg)	11
Vitamin K1 (mcg)	26.3
Vitamin K2 (mcg)	8.8
Iodine (mcg)	99
Zinc (mg)	5
Folic Acid (mcg)	110
Iron (mg)	14.3
Magnesium (mg)	50
Manganese (mg)	0.98
Copper (mcg)	400
Selenium (mcg)	32.9
Vitamin A (mcg)	390
Vitamin C (mg)	30
Vitamin E (mg)	10
Vitamin B1 (mg)	0.7
Vitamin B2 (mg)	1.25
Vitamin B6 (mg)	0.9
Vitamin B12 (mcg)	1.2
Niacin (mg)	7
Pantothenic Acid (mcg)	3100
Biotin (mcg)	16
Potassium (mg)	512
Choline (mg)	118
Taurine (mg)	28
Inositol (mg)	32
Carnitine (mg)	6.7
Chromium (mcg)	12
Molybdenum (mcg)	19.7
Sodium (mg)	181
Chloride (mg)	394
Fructo-oligosaccharides (FOS) (g)	1.58
Arginine (mg)	1099

*Ingredients: Skimmed milk, sucrose, edible vegetable oil (soybean oil, high oleic sunflower oil), medium chain triglyceride, cocoa powder, minerals, maltodextrin, fructo-oligosaccharide (FOS), Flavoring(s) (natural, nature identical, and artificial flavouring substances- Chocolate), L-Arginine HCL, vitamins, inositol, taurine, L-carnitine, Colour Caramel Powder, and **Lactobacillus acidophilus**. (flavors available vanilla, Chocolate, kesarbadam and Mango). Above ingredient facts is based on Chocolate flavor*

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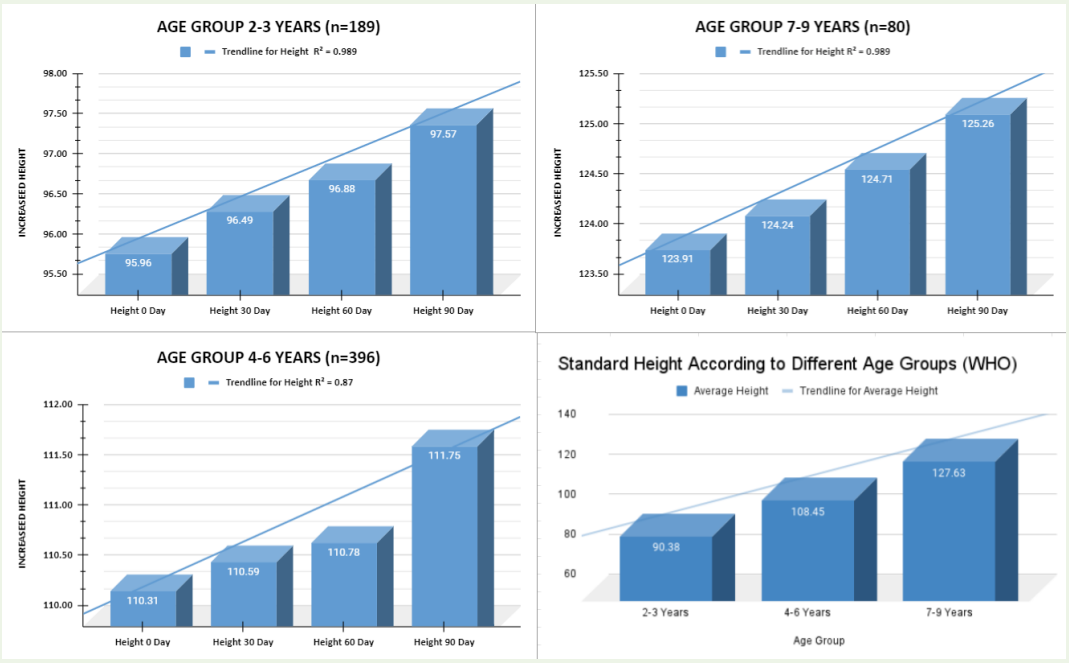

Figure 2: Trend line, R^2 (linear line of regression)for height for age groups 2-3 years, 4-6 years, 7-9 years and WHO standard height for different age groups.

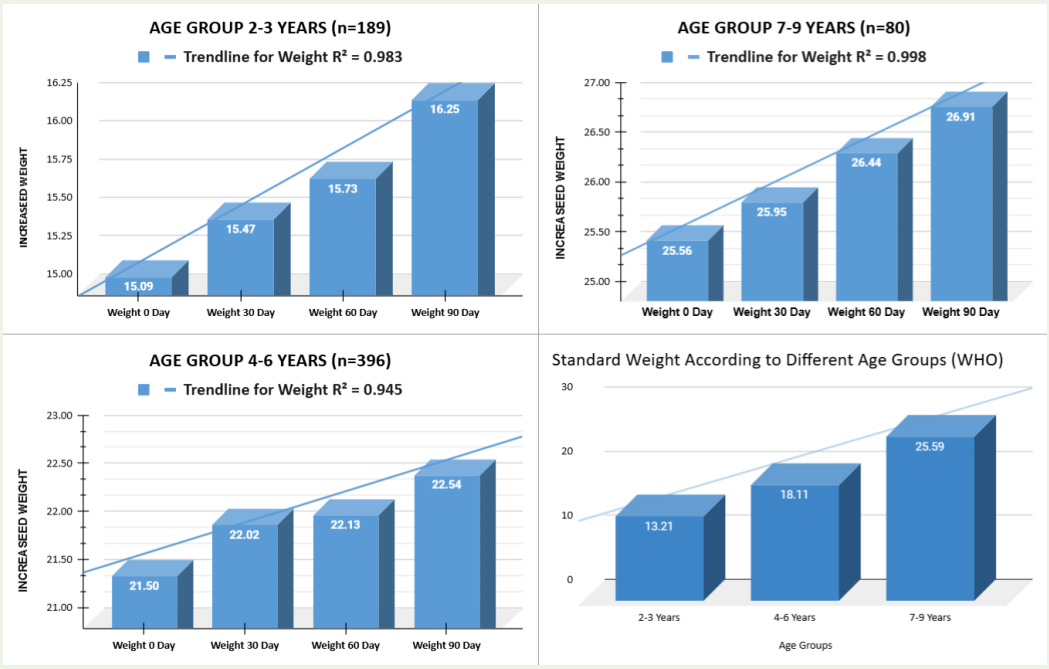

Figure 3: Trend line, R^2 (linear line of regression)for weight for age groups 2-3 years, 4-6 years, 7-9 years and WHO standard weight for different age groups.

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- **Height**: All age groups exhibited linear growth, with an increase in height of approximately in the range of 1.35 to 1.61 cm over 90 days, with most substantial height gain was observed in the 2-3 years group. The standard height as per WHO for different age groups is also shown in Figure 2, and it is in the range of baseline height of study participants (Table 3).
- **Weight**: Weight gain was consistent across all groups, with an increase ranging from 1.04 kg to 1.35 kg. This demonstrates that the ChilRun Full™ supports healthy weight gain, particularly important in growing children (Figure 3). The standard weight as per WHO for different age groups is also shown in Figure 3, and it is in the range of baseline weight of study participants (Table 3).
- **BMI**: BMI values also showed a positive upward trend, indicating proportional growth in both height and weight, thereby, reflecting overall balanced growth supported by ChilRun Full™ (Figure 4). The standard BMI as per WHO for different age groups is also shown in Figure 4, and it is in the range of baseline BMI of study participants (Table 3).

In the children aged 2-3 years, the Z-scores for height, weight and BMI improved from 0.5, -0.05 and 0.01 respectively, at baseline to 0.62, 0.15 and 0.25 at day 90. Similar results were noted for age group 4-6 years (Z scores for height, weight and BMI improved from 0.21, -0.63 and 0.72 respectively, at baseline to 0.37, 0.80 and 0.81) and 7-9 years (Z scores for height, weight and BMI improved from -0.31, 0.39 and 0.29 respectively, at baseline to 0.05, 0.65 and 0.44) at day 90 (Figure 5). The improvements were significant in weight, height and BMI Z-score.

ChilRun Full™ was well tolerated by all the kids, and no adverse event was reported by parents on continuous use for 90 days.

The trend line, R^2 (linear line of regression) for various age groups of 2-3 years, 4-6 years and 7-9 years was 0.989, 0.87 and 0.989 for height, 0.983, 0.945 and 0.998 for weight and 0.894, 0.891 and 0.999 for BMI, respectively (Figures 2, 3 & 4).

ChilRun Full™ exhibited linear rise in the height, weight and BMI, with a similar trend to the WHO standard data. This study reveals that the continuous use of ChilRun Full™ over the 90-day period led to notable improvements in height, weight and BMI across all age groups.

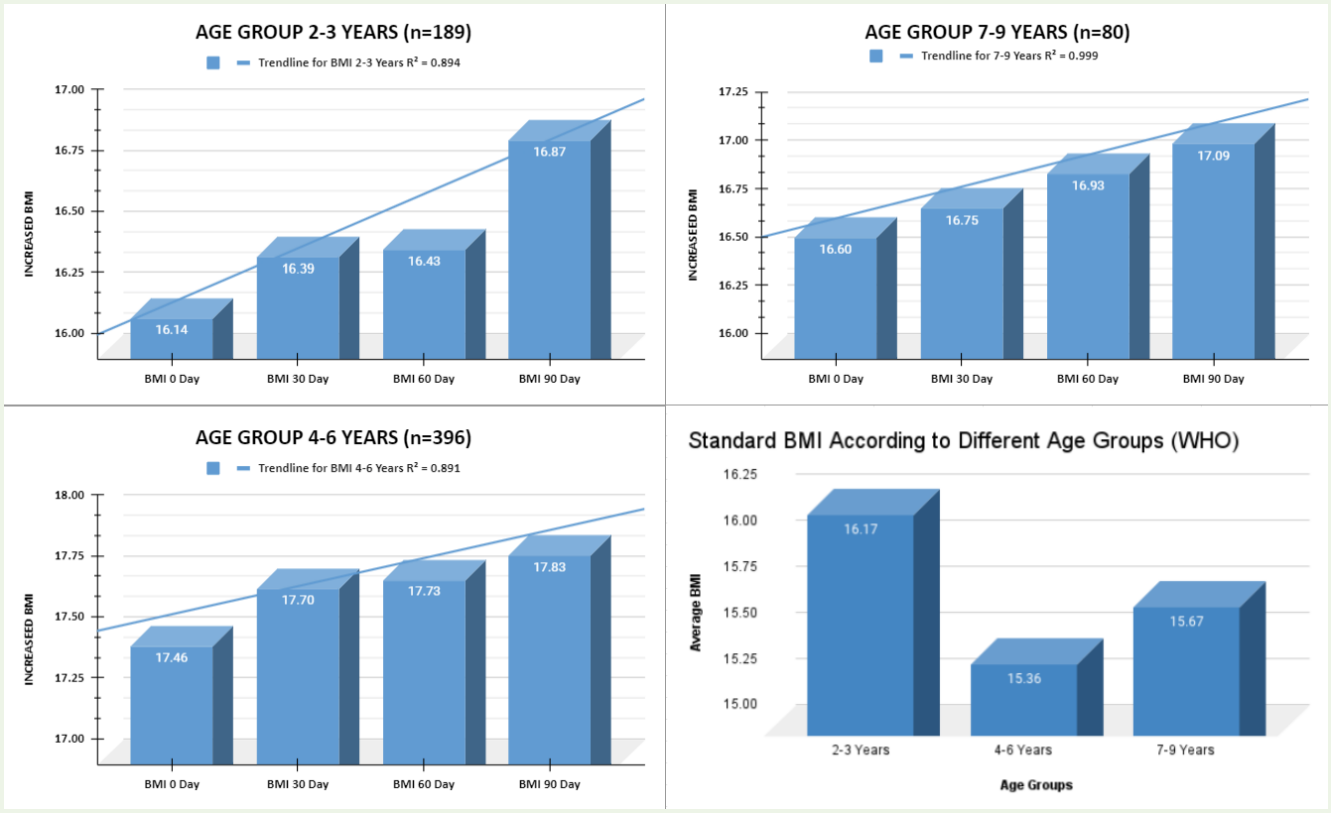

Figure 4: Trend line, R2 (linear line of regression)for BMI for age groups 2-3 years, 4-6 years, 7-9 years and WHO standard BMI for different age groups

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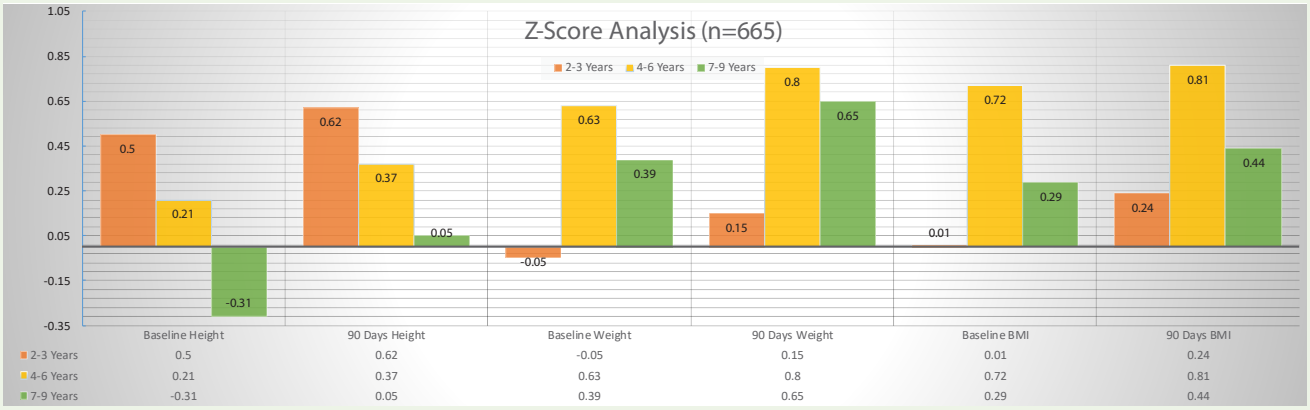

Figure 5: Change in Z-score for height, weight & BMI from baseline to day 30, 60 & 90.

Discussion

Poor nutrition during critical growth periods is quite important and associated with a number of health issues i.e repeated infections, growth and developmental issues and metabolic imbalance. The challenge of malnutrition persists as a vital public health issue, both around the world and in India, influencing the lives of numerous children [13]. The World Health Organization highlights (2023 report) that roughly 148 million children younger than five years old experience stunting, with 45 million affected by wasting, and 37 million categorized as overweight [14]. These statistics highlight the persistent nature of the dual burden of malnutrition—defined by the concurrent existence of both undernutrition and over nutrition within the same demographic, often affecting children aged 2 to 12 years. The scenario is particularly concerning in India, where the prevalence of undernutrition among children remains extensive despite the nation's economic advancements [15].

In India, the prevailing challenges related to child health and nutrition are profoundly alarming, as evidenced by the findings of the National Family Health Survey-5 (NFHS-5), which indicates that an alarming 35.5% of children under five years old exhibit stunted growth, while 19.3% are classified as wasted and a distressing 32.1% are considered underweight [16]. Furthermore, it is critical to acknowledge that the disparities in malnutrition rates across regions are significant with states such as Bihar, Madhya Pradesh and Uttar Pradesh showing the most concerning rates, whereas Kerala, Goa, and Tamil Nadu report much lower statistics and as a result better nutritional prospects for their younger demographics [16].

A balanced blend of macronutrients (carbohydrates, proteins, and fats) paired with micronutrients (vitamins and minerals) is essential for fostering robust growth and development in children particularly during the critical developmental age of 2 to 12 years. During the developmental phase, children undergo rapid physical growth, cognitive maturation and significant metabolic transformations all of which necessitate an adequate intake of essential nutrients. Macronutrients furnish the requisite energy and structural constituents for developing tissues whereas, micronutrients are integral to vital biochemical mechanisms such as enzymatic activity, immune functionality and neurological progression [17].

Proteins are particularly essential for the formation of new tissues and the maintenance of muscle integrity while fats are crucial for neurological development and the absorption of fat-soluble vitamins such as A, D, E, and K. Micronutrients, which include iron, zinc, calcium and an array of vitamins play essential roles in the prevention of anemia, the augmentation of immune response, and the promotion of adequate skeletal development [18]. Insufficiency in these nutrients during pivotal growth periods can lead to severe ramifications including diminished cognitive capabilities, compromised immune resilience and inhibited physical growth [19].

In the present study, we studied the effect of ChilRun Full™, an oral nutritional supplement on anthropometric parameters (height, weight and BMI) in children of age groups of 2-3 years, 4-6 years, and 7-9 years. ChilRun Full™ provides a balanced mix of essential macronutrients and micronutrients, designed to support the physical and cognitive development of children. The formulation includes high-quality proteins, carbohydrates, and fats along with a comprehensive blend of vitamins and minerals such as vitamin D, vitamin K2, L-arginine, calcium, iron and zinc which are critical for bone health, immune function, and overall growth (composition mentioned in (Table 4).

The observational study conducted over 90 days demonstrated the positive impact of ChilRun Full™ on the growth parameters of children across the specified age groups. The results indicate significant improvements in height, weight, and BMI across all age categories. Further, Z-score analysis supports these findings, which demonstrated notable improvements in height, weight, and BMI scores over the 90-day period. The Z-scores for height improved in the children aged 2-3 years, the Z scores for height, weight and BMI improved from 0.5, -0.05 and 0.01 respectively, at baseline to 0.62, 0.15 and 0.25 at day 90. Similar results were noted for age group 4-6 years (Z scores for height, weight and BMI improved from 0.21, -0.63 and 0.72 respectively, at baseline to 0.37, 0.80 and 0.81) and 7-9 years

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(Z scores for height, weight and BMI improved from -0.31, 0.39 and 0.29 respectively at baseline to 0.05, 0.65 and 0.44) at day 90. Overall, the result indicates the effectiveness of ChilRun Full™ in supporting the growth and development of children, emphasizing its potential as a valuable nutritional intervention in paediatric nutrition.

ChilRun Full™ exhibited linear rise in the body weight, height and BMI, with a similar trend to the WHO standard data. Based on WHO Z-score categories, the study results indicate excellent growth outcomes across all age groups following the 90-day supplementation with ChilRun Full™. The observed increases in height, weight, and BMI Z-scores suggest that the supplement effectively supports healthy and positive growth trajectories, bringing children closer to or maintaining them within the upper range of the WHO-defined normal growth standards. This outcome is particularly notable in children who began the study with below-average Z-scores as they demonstrated the significant improvements, aligning their growth with expected standards. The positive impact on growth and development of enrolled kids is due to the balanced composition of ChilRun Full™ (which is based on 37 essential nutrients including L-Arginine and Vitamin K2). Further, ChilRun Full™ contains Vitamin K2 and L-arginine that are critical for bone health each contributing through unique mechanisms. Vitamin K2 is essential for calcium metabolism, facilitating the activation of osteocalcin which enables calcium binding to the bone matrix and strengthens the bones [20]. L-arginine plays a role in bone formation by stimulating nitric oxide production, which enhances osteoblast activity and inhibits osteoclasts, essential for bone remodelling [21]. Combination of Vitamin K2 and L-arginine not only improve calcium utilization but also stimulate bone regeneration, making them vital to build stronger and longer bones in children. ChilRun Full™ also helps in maintaining a healthy gut microbiome in growing children through the inclusion of both prebiotics (i.e. *FOS*) and probiotics (i.e. *Lactobacillus acidophilus*) [22]. A balanced microbiota is crucial as it regulates various immunomodulatory functions and supports optimal digestive health [23].

ChilRun Full™ was found to be safe and well-tolerated and did not exhibit any adverse effect up to 90 days.

ChilRun Full™ formulation is also comprised of linoleic acid (3200 mg/100 gm) and alpha linolenic acid (351 mg/100 gm). As studies have shown malnourished children may have lower stores of essential fatty acids (EFAs), especially ALA and DHA, therefore regular supplementation of EFAs is critical for growing kids [24]. This is in line with the reports of the European Food Safety Authority (EFSA) which noted that young child formulae and supplement consumption is the shortest way to cover the EFSA nutrient requirements of UK children [25].

ChilRun Full™ supplementation in children of age 2 years and above led to an increase in height, weight and BMI. ChilRun Full™ was found to be safe & well-tolerated. Some limitations of this current 3 month study include absence of a comparator, and limited assessment parameters. However, this study paves a way for recognising a nutritional need (based on 37 essential nutrients) in growing kids and its importance as total nutrition in correcting malnutrition/recurrent illness.

Conclusion

These results support that continuous use of ChilRun Full™ showed a positive impact on growth and developmental parameters in children (2+ above) as complete nutrition. Further it also highlights that the balanced nutritional supplement (with macro and micronutrients- 37 essential nutrients) is an essential hallmark for healthy growth and development of growing kids, and its continuous use may prevent a number of nutritional deficiencies. In addition, long term studies upto 6-12 months are also required to explore its full potential in prevention of school absenteeism due to recurrent illness/infection and defining its role in growth and development as Total Nutrition.

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