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A Nationwide Multicentric, in-Clinic, Observational Study on ChilRun full[™]: Real-World Effectiveness Data on Growth and Development in Indian Children

Research Article

Jain Naveen K*, Dheeraj K, Amera K and Patil Chandrashekhar S

Department of Biology Research/New Products, Panacea Biotec Ltd., B-1 Extn. /A-27 Mohan Co-operative industrial Estate, Mathura Road, New Delhi, India

***Corresponding author:** Naveen K Jain, Vice President- Biology Research/New Products,Panacea Biotec Ltd., B-1 Extn./A-27 Mohan Co-operative industrial Estate, Mathura Road, New Delhi, India. Email: naveenjain@panaceabiotec.com

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Abstract

Background: Malnutrition, encompassing undernutrition and micronutrient deficiencies, poses a significant threat to public health and it is a leading cause of kid's growth restriction in formative years (2-12 years). Stunting and wasting, prevalent manifestations of malnutrition, have far-reaching consequences, impacting physical growth, cognitive development and overall well-being. Addressing this critical public health challenge necessitates effective nutritional interventions that not only alleviate immediate nutritional deficits but also resolve long-term growth, metabolic and development issues. The current study investigated the efficacy and safety of ChilRun full[™], a commercially available oral nutritional supplement (ONS), in improving growth parameters among Indian children aged 2+ years.

Methods: The post-marketing, multicentric, in-clinic observational study was performed to evaluate the effectiveness and safety of ChilRun full™, a commercially available ONS, on the growth and development of children aged 2 years and above across India. A total of 3307 children were initially enrolled for this study and 2851 children successfully completed 90-day study period (day 0, 30, 60 and 90 days visit) Anthropometric measurements, including height, weight and body mass index (BMI), were recorded at four different time points baseline (day 0), day 30, 60 and 90. Children received two daily servings of ChilRun full™ for the entire 90-day study period. Growth parameters and Z-scores were analysed to assess the impact of ChilRun full™ on growth parameters. Focused analysis on the special population was conducted on children with baseline Z-scores ≤ -1, representing a subgroup at risk of malnutrition, to evaluate the effectiveness of ChilRun full™ in addressing growth deficiencies.

Results: Continuous supplementation with ChilRun full[™] (twice a day for 90 days) led to significant improvements in anthropometric parameters height, weight and BMI across all age groups, with the 2-3 years group showing gain in height (2.20%), weight (9.68%) and BMI (4.82%) by end of day 90. Similarly, children aged 4-6 years and 7-9 years also showed substantial increase in height, weight and BMI. Further, in the subgroup analysis in children at the risk of malnutrition (Z-score ≤-1), weight increased by 20.56%, height by 10.30% and BMI by 14.36%, demonstrating effectiveness of ChilRun full[™] in addressing growth deficits. Z-score analysis showed a positive shift towards standardized growth norms. Among children 2–3-year age, Z-scores for weight percentile improved from -0.39 to 0.01 in males and -1.84 to -0.94 in females, while, in children age 4–6-year, Z-score increased from -2.70 to -1.85 in males and -2.24 to -1.50 in females and for 7–9-year age children from -2.72 to -1.84 in males and -2.98 to -2.26 in females. By the end of day 90, a significant number of children in both sexes from severely underweight (below the 3rd percentile) category moved to higher weight categories, demonstrating improve weight and a positive shift in nutritional status. The maximum shift was seen in children below the 3rd percentile, with 111 males and 73 females moving to the 3rd-15th percentile. Z-scores for height, weight and BMI showed positive shifts towards the standard population norms, indicating a normalization of growth patterns.

Conclusion: These findings highlight the efficacy of ChilRun full[™] in promoting healthy growth and addressing malnutrition, as evidenced by improvements in weight, height, BMI, Z-scores and weight percentile distributions across all age groups and provides a strong nutritional foundation in growing kids to transform them into *healthy, energetic and strong kids*.

Keywords: ChilRun full[™]; Child Growth; Malnutrition; Nutritional Supplement; Anthropometry; Observational Study.

Introduction

Childhood malnutrition remains among one of the most pressing global public health challenges, affecting nearly one-third of the world's population including India. **Micronutrient deficiencies**, or "*hidden hunger*" severely impact the growth and development and it further contributes to the broader issue of malnutrition. The consequences are significant, affecting children's health (including under nutrition- wasting, stunting and underweight), education (school missing days) and future potential, advocating the urgent need for targeted interventions [1].Various studies have indicated that adequate nutrition and healthy growth in the first 1000 days of life is crucial and contributes to long-term health benefits in adulthood. Administration of nutritional interventions to undernourished children can promote catch-up growth more effectively and prevent growth faltering [2,12].

Despite advancements in healthcare, millions of children worldwide still suffer from undernutrition, which can severely impact their growth, immunity and cognitive development. According to "UNICEF/WHO/World Bank Group report 2023" an estimated 148.1 million children under five years suffered from stunting, 45 million from wasting and 37 million from being overweight [3]. According to the National Family Health Survey (NFHS-5) report 35% of Indian children under five years are stunted, 19% are wasted and 32% are underweight. These alarming numbers reflect acute and chronic forms of undernutrition that not only affect physical growth but also have long-term impacts on brain development, learning abilities, immunity and overall well-being due to poor dietary diversity and inadequate feeding practices [4].

A major contributor to this global situation is micronutrient deficiency. Children's diets in many low-income areas are mostly starchy, staples and lack protein or micronutrient diversity (vitamins and minerals). The deficiency of vital nutrients, such as iron, vitamin A, zinc and iodine is a common issue that can slow down growth and development and these deficiencies can go unnoticed for a long time but lead to serious health consequences like anemia, poor concentration, frequent infections and developmental delays/bone disorders. Children with inadequate micronutrient intake often fall behind in school, face higher risks of illness and struggle to reach their full physical and mental potential [5].

Further the prevalence of childhood obesity/overweight is also increasing at an alarming rate. According to the WHO report 37 million children under the age of 5 years were overweight and over 390 million children and adolescents aged 5–19 years were overweight in 2022, including 160 million who were living with obesity [6,11]. This situation leads to various issues like psychological challenges not only in the quality of life of parents but at school level (i.e. stigma, discrimination and bullying behavior). Therefore, this issue needs to be tackled at community level with better nutritional awareness and related Nutraceutical products [7].

A variety of commercial Oral Nutritional Supplements (ONS) are used clinically to promote catch-up growth in children with undernutrition. Over the years ONS have emerged as a practical and a convenient solution for nutritional enrichment along with regular

meals. When provided alongside regular meals, ONS helps to fill the nutritional gaps, especially in children who are picky/fussy eaters, recovering from illness, or living in food-insecure environments. Clinical studies have shown that ONS, when combined with dietary counseling, significantly improves height-for-age and weight-for-age scores, enhances attentional focus and reduces the frequency of infections. In particular, they support catch-up growth in children beyond the first 1,000 days, a critical window where early intervention can reverse or reduce the long-term effects of malnutrition [8,9].

ChilRun full[™], is a scientifically formulated Oral Nutritional Supplement, designed to be an additional source of nutrition to overcome the nutrition gap for growing children. It provides the right blend of macronutrients and micronutrients (essential vitamins and minerals) and functional ingredients (37 essential key nutrients) to support physical and cognitive development and essential for the critical growth, developmental and nutritional aspects of transformative childhood years. ChilRun full™ also addresses both visible and hidden hunger by bridging nutritional gaps in everyday diets, especially in children who are picky/fussy eaters, undernourished, or recovering from illness [10]. This in-clinic multicentric, non-randomized, nationwide observational study, was aimed to evaluate the effect of ChilRun full™ (scientifically designed with 37 key nutrients based ONS) on the growth and development of children (2851 kids from all over the India), aged 2 years and above over a three-month period along with a regular diet.

Materials and Methods

Study Design

The post-marketing, multicentric, in-clinic observational study was performed to evaluate the effectiveness and safety of ChilRun full[™], a commercially available ONS, on the growth and development of children aged 2 years and above across India. A total of 3307 children were initially enrolled for this study and 2851 children successfully completed the full 90-day study period. The completed group comprised 1650 boys and 1201 girls, thus providing a well-distributed demographic representation across genders for comprehensive analysis (Figure 1) (Table 1). This observational study



	0 1		
Variables	All Children (N=2851)	Median Age	
Male	1650	4.8 ± 0.5	
Female	1201	4.8 ± 0.5	
	Median Height, Weight a	nd BMI (N=2851)	
Height (cm)		98.27	
Weight (kg)		15.54	
BMI	16.36		

Table 1: Baseline demographics

was performed at 282 clinics across 32 cities (Asansol, Bangalore, Bareilly, Balasore, Bhubaneswar, Burdwan, Cuttack, Dehradun, Delhi, Faridabad, Ghaziabad, Gorakhpur, Guwahati, Hyderabad, Kanpur, Kolkata, Lucknow, Madurai, Medak, Mumbai, Nashik, Patna, Pune, Ranchi, Siddhipet, Sivagangai, Thane, Varanasi, Vizag) in India from 1st January 2024 to 31st Oct 2024 and was subjected for analysis.

Study Population

Children aged 2 years and above with regular eating habits were enrolled across 282 sites under pediatrician supervision. Each investigating pediatrician enrolled minimum 10 to 12 kids at their respective clinics. Children enrolled in the study (n=2851) were divided into three distinct age groups, each representing different stages of childhood development. The youngest cohort, comprising children aged 2-3 years (n=877), accounted for 30.8% of the study population. This group is characterized by rapid growth and heightened nutritional requirements, making it a critical period for interventions aimed at supporting physical development. The largest group, consisting of children aged 4-6 years (n=1670), represented 58.6% of the study population. These children were primarily in the preschool and early school years, a phase marked by steady growth and increasing physical and cognitive demands. Finally, the 7-9-yearolds (n=304) accounted for 10.7% of the study population. This cohort included older children approaching late childhood, a stage where growth rates typically stabilize (Figure 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 period) as per the Case Report Form (CRF). The Z-score for height, weight and BMI was used to analyze the results using Khadilkar (2015) growth chart [13]. All measurements were performed by clinical/nursing staff (under the supervision of pediatricians) using the standardized methods and data was captured in the CRF as per protocol (Figure 3).

Inclusion and Exclusion Criteria

Each child was included in the study following specific inclusion criteria, ensuring uniformity and reliability of the data collected. Data from children were included in the study analysis if they had completed CRFs, documenting their height, weight and BMI at all four measurement points: day 0, day 30, day 60 and day 90. Children were excluded from participation if they had any of the following conditions: 1. Concomitant systemic infections, clinically significant diseases, stomach infections, infestations, or suspected liver disorders. 2. Diagnosed lactose intolerance, galactosemia, or other medical conditions that might interfere with the study product,





Jate of visit : DL	-ММ-ҮҮҮҮ
DEMOGRAPHIC DATA	
Gender	: M/F
Date of Birth	: DD-MM-YYYY
Current Age :	
ANTHROPOMETRIC ME	ASUREMENTS
Weight	: Kg
Height	: cm
BMI	
Visit 2 (day 30)	
Date of visit	: DD-MM-YY YY
ANTHROPOMETRIC ME	ASUREMENTS
Weight	: Kg
Height	: cm
BMI	:
Doses taken twice daily : [Yes No Remarks
Visit 3 (day 60)	
Date of visit	: DD-MM-YYYY
ANTIDODOMETRIC ME	A CULDENTENTEC
ANT IROPOMETRIC ME	ASUKENIENIS
weight	. h g
neigni	: cm
виц	
Doses taken twice daily :	⊃ Yes □ No Remarks
Visit 4 (day 90)	
Date of visit : DE	-MM-YY
ANTHROPOMETRIC ME	ASUREMENTS
Weight	: Kg
Height	: cm
BMI	
Doses taken twice daily ·	Yes No Remarks
Intervention	- reo - reo Reinarko
intervention	

as identified through medical records or parent/guardian reports. 3. Known allergies or intolerances to any ingredient in ChilRun full[™]. This rigorous screening ensured that the sample consisted of children who could safely consume the supplement without medical contraindications.

Intervention

Eligible children received twice daily servings of ChilRun full[™] (Manufactured by Panacea Biotec Pharma Ltd., New Delhi; FSSAI approved) as per label claim every day for 3 months as per (Table 2). Parents were provided detailed instructions on the preparation and administration of the supplement as per (Table 3).

Parents were advised to administer the ChilRun full[™] (twice daily) in morning and evening, depending on their routine. This consistent administration ensured adequate nutrient intake for optimal results. All measurements were performed by clinical/nursing staff (under

Table 2: Composition of ChilRun full™

Nutritional Facts	ChilRun full™ (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)	<0.20
Cholesterol (mg)	<30
Linoleic acid (mg)	3200
Alpha linoleic Acid (mg)	351
Vitamin A (mcg)	390
Vitamin C (mg)	30
Vitamin D2 (mcg)	11
Vitamin E (mg)	10
Vitamin B1 (mg)	0.7
Vitamin B2 (mg)	1.25
Vitamin B6 (mg)	0.9
Vitamin B12 (mcg)	1.2
Vitamin K1 (mcg)	26.3
Vitamin K2 (mcg)	8.8
Niacin (mg)	7
Biotin (mcg)	16
Pantothenic Acid (mcg)	3100
Calcium (mg)	656
Phosphorus (mg)	408
Iodine (mcg)	99
Zinc (mg)	5
Folic Acid (mcg)	110
Iron (mg)	14.3
Manganese (mg)	0.98
Copper (mcg)	400
Magnesium (mg)	50
Selenium (mcg)	32.9
Potassium (mg)	512
Chromium (mcg)	12
Molybdenum (mcg)	19.7
Sodium (mg)	181
Chloride (mg)	394
Taurine (mg)	28
Choline (mg)	118
Inositol (mg)	32
Carnitine (mg)	6.7
Fructo-oligosaccharides (FOS) (g)	1.58
L-Arginine (mg)	1099

Ingredients: Skimmed milk, sucrose, edible vegetable oil (soybean oil, high oleic sunflower oil), medium chain triglyceride, cocoa powder, minerals, maltodextrin, fructooligosaccharide (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 Jain Naveen K, et al.

Table	3.	Preparation	and Administration	of	ChilRun	full™
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Preparation	Serving Size	Mixing Instructions	Frequency
With Water	45.5 g (2.5 scoops)	Mix in 190 mL of water	Twice daily (morning, evening)
With Milk	18.2 g (1 scoop)	Mix in 150 mL of cow milk	Twice daily (morning, evening)

the supervision of pediatricians) and data was captured in the CRF as per protocol during the visits scheduled at day 0, 30, 60 and 90 post enrollment.

Safety and tolerability, was reported by parents and caregivers to supervising pediatricians, if any.

Data Analysis

The data collected from enrolled children via CRF were systematically analyzed to evaluate the effectiveness of ChilRun full[™] in improving growth parameters.

Growth Metrics: Average height, weight and BMI were calculated for each age group at each time point (day 0, 30, 60 and 90). The percentage increase over the 90-day period was determined to assess the supplement's impact.

Z-Score Analysis: Z-scores for height, weight and BMI were calculated at baseline and Day 90 using the Khadilkar (2015) growth chart. Improvements in Z-scores were analyzed and graphically represented to illustrate growth normalization relative to standard populations [13].

Weight Percentile Analysis: Using the IAP growth chart (2015), weight-for-age percentiles were calculated and categorized into four groups: below the 3rd percentile, 3rd-15th percentile, 15th-50th percentile and 50th-85th percentile [14]. Changes in weight percentile distribution were analyzed to assess shifts toward healthier weight categories over the 90-day period.

Special Population Analysis: A focused analysis was conducted on children with baseline Z-scores \leq -1, representing those at risk of malnutrition. Changes in height, weight, BMI and Z-scores were quantified and percentage improvements were compared to the general population to evaluate the impact of supplementation in addressing growth deficits.

Statistical Analysis

The results were presented visually using the table and bar graphs to depict average changes in height, weight and BMI for each age group. Bar graphs were used to track Z-scores improvements for the overall cohort and the special population.

Results

The present study evaluated the impact of ChilRun full[™], a specially formulated ONS, on the growth and development of 2851 children aged 2 years and above over a 90-day period. ChilRun full[™] is fortified with a balanced mix of macronutrients, micronutrients and functional ingredients, including proteins, carbohydrates, fats and critical vitamins and minerals. Its composition is designed to address nutrient deficiencies and support optimal growth (including healthy, energetic and strong kids).

The data was obtained from the 282 clinics across 32 cities (Asansol, Bangalore, Bareily, Balasore, Bhubaneswar, Burdwan, Cuttack, Dehradun, Delhi, Faridabad, Ghaziabad, Gorakhpur, Guwahati, Hyderabad, Kanpur, Kolkata, Lucknow, Madurai, Medak, Mumbai, Nashik, Patna, Pune, Ranchi, Siddhipet, Sivagangai, Thane, Varanasi, Vizag) across India from 1st January 2024 to 31st Oct 2024 and was subjected for analysis. A total of 3134 children were enrolled and received the nutritional supplement ChilRun full[∞] out of 3134 enrolled subjects 2851 completed the study. Demographics and baseline characteristics are presented in Table 1. The median age was 4.8 ± 0.5 years (range 2 - 12 years) and the gender distribution included 1650 males and 1201 females. None of the children enrolled had wasted (Z score \geq -2).

On continuous use of ChilRun full[™] changes in height, weight and BMI were observed on day 30, 60 and 90 (Table 4). A substantial increase in all three parameters among all age groups was observed at the end of 90 days on continuous use of ChilRun full[™] (in comparison to baseline values prior to start of ChilRun full[™] initiation). The data suggest that ChilRun full[™] had a positive effect on the growth metrics on continuous use for 90 days.

Height: ChilRun full™ exhibited a steady and linear increase

Table 4: Change in height, weight & BMI from baseline to day 30, 60 & 90

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in height across all the age groups. The maximum increase of 2.2% (88.08 cm at baseline to 90.02 cm on day 90) was seen in children age 2-3 years, followed by 1.55% in 4-6 years (from 99.95 cm to 101.50 cm on day 90) and 1.61% (116.73 cm at baseline to 118.61 cm on day 90) in 7-9 years age group (Table 4). This increase in height gain was as per the WHO standard height for different age groups (Figure 4) and was within the range of baseline height of study children. Further, trend line, R² (linear line of regression) was almost unity for various age groups of 2-3 years, 4-6 years and 7-9 years was 0.996, 0.989 and 0.999 for height, respectively. These results indicate that ChilRun full^{∞} positively influences linear growth, a critical marker of physical development. The steady increases across age groups suggest the ChilRun full^{∞} applicability in fostering height gains during childhood.

Weight: ChilRun full[™] demonstrated a consistent gain in weight metrics across all the age groups with the youngest children showing the highest relative increase. The weight increase was 9.68% in 2-3 years age group (1.19 kg increase from 12.30 kg to 13.49 kg), 7.03% in 4-6 years age (1.12 kg increase from 15.97 kg to 17.10 kg) and 6.38% in 7-9 years age (1.39 kg rise from 21.77 kg to 23.16 kg). This indicates that the ChilRun full[™] supports healthy weight gain, particularly important in growing children and the standard weight

Parameters	Age Group	Baseline (Day 0)	Day 30	Day 60	Day 90	Total Increase	% Increase
	2-3 yrs	88.08	88.63	89.28	90.02	1.94	2.20
Height (cm)	4-6 yrs	99.95	100.35	100.85	101.50	1.55	1.55
	7-9 yrs	116.73	117.40	117.96	118.61	1.88	1.61
	2-3 yrs	12.30	12.66	13.06	13.49	1.19	9.68
Weight (kg)	4-6 yrs	15.97	16.31	16.69	17.10	1.12	7.03
	7-9 yrs	21.77	22.21	22.65	23.16	1.39	6.38
	2-3 yrs	16.20	16.46	16.72	16.98	0.78	4.82
Body Mass Index (BMI)	4-6 yrs	16.51	16.70	16.89	17.06	0.55	3.34
	7-9 yrs	16.00	16.14	16.30	16.46	0.46	2.86



as per WHO for different age groups was in the range of baseline weight for enrolled children (Figure 5). 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 0.999, 0.998 and 0.999 for weight, respectively. The consistent gains across all age groups reflect the ability of ChilRun full[™] to enhance weight metrics in children in both normal and nutritionally at-risk populations, contributing to improved overall health and vitality.

BMI: BMI values showed a positive upward trend, indicating proportional gain in both height and weight, thereby reflecting an overall balanced growth supported by ChilRun full[™]. The BMI increased by 4.82%, 3.34% and 2.86% in age groups 2-3 years, 4-6 years and 7-9 years, respectively at the end of 90 days (Table 4). The standard BMI as per WHO for different age groups was within the range of baseline BMI (Figure 6). The trend line, R² (linear line of regression) for various age groups of 2-3 years, 4-6 years and 7-9 years was 1.0, 0.999 and 0.999 for BMI, respectively. The increase in BMI underscores the supplement's effectiveness in promoting healthy and proportional growth. The data suggest that ChilRun full[™] supports weight and height increases, while maintaining appropriate BMI, thereby avoiding the risk of excessive or disproportionate weight gain.

Z-score: ChilRun full[™] exhibited a significant improvement in Z-scores for weight, height and BMI across all the age groups (Figure 7). In children aged 2-3 years the Z-score for height, weight and BMI improved from -0.17, -0.18 and -0.01 at baseline to -0.03, 0.08 and 0.19 on day 90, respectively. Similarly, the improvement in the Z-scores was noted in children aged 4-6 years (for height, weight and BMI from -0.66, -0.35 and 0.34 at baseline to -0.53, -0.16 and 0.86) and 7-9 years (for height, weight and BMI from -0.89, -0.60 and -0.09 at baseline to -0.75, -0.40 and 0.22) on day 90. The uptrend suggests ChilRun full[™] has the potential to support the optimal growth patterns in children of all age groups.

Further, on continuous use for 90 days ChilRun full[™] was well tolerated as no adverse events were reported in any age group from any one of the centers during the study period.

Special Population (Z-Scores \leq -1)

Subset analysis in special population was conducted for (a) Z-score analysis for weight, height and BMI in children at risk of malnutrition (Z-scores \leq -1) and (b) Gender wise Z-score distribution based on weight percentile profile

(a) Z-score analysis for weight, height and BMI in children at risk of malnutrition (Z-scores \leq -1):In a subset analysis Z-score data from all age groups (2-4 years, 4-6 years and 7-9 years) were combined. Based on Z-scores \leq -1, 2094 out of 2851 children were classified as children at risk of malnutrition based on height (n=934), weight (n=1009) and BMI (n=151).

Z-score in all age group children increased from -1.88 to -1.69 for height, -1.75 to -1.35 for weight and -1.40 to -1.20 for BMI (Figure 8). This change in Z-score for height, weight and BMI was 10.30%, 20.56% and 14.59%, respectively. These results indicate that children at risk of malnutrition (Z-scores \leq -1), on continuous use of ChilRun full[™] for 90 days addressed the severe nutritional deficits and promoted catchup growth during the critical periods of development, thereby, having profound implications on long-term health, cognitive development and educational outcomes.

(b) Gender wise Z-score distribution based on weight percentile profile: To examine gender-based weight percentile profiles, Z-scores for weight percentile were calculated for 2851 children (1650 males, 1201 females) using the IAP growth chart (2015). The weight for age data for both male and female was analysed to calculate the weight percentile and categorized into four groups: (i) below the 3rd percentile, (ii) 3rd to 15th percentile, (iii) 15th to 50th percentile and (iv) 50th-85th percentile. In children with lower weight percentiles



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Figure 6: 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



Figure 7: Change in Z-score for height, weight & BMI from baseline to day 90.



based on the IAP Growth Chart, the impact of ChilRun full[™] supplementation was assessed by evaluating changes in both weight percentiles and weight-for-age Z-scores over a 90-day period. The analysis of weight-for-age Z-scores and weight percentile distribution from day 0 to day 90 revealed a positive trend in weight gain among both male and female participants, reflecting improved nutritional status and growth outcomes.

Among children aged 2–3 years, the proportion of those in the below 3rd percentile category decreased from 31.27% to 20.55% in males and from 25.90% to 18.15% in females, with corresponding Z-score improvements from -0.39 to 0.01 in females and -1.84 to -0.94 in males. This shift was accompanied by 111 females and 73 female participants moving to the 3rd-15th percentile, 44 males and 17 females progressing to the 15th-50th percentile and 16 males and 3 females reaching the 50th-85th percentile, demonstrating a significant weight gain and improved nutritional recovery (Figure 9) (Figure 10,11,12), (Table 5, 6). For children aged 4–6 years, those in the 3rd-15th percentile category showed a notable reduction, from 12.85% to 9.39% in males and 17.40% to 11.16% in females, alongside Z-score increases from -2.70 to -1.85 in females and -2.24 to -1.50 in males. Within this group, 121 males and 36 females moved to the 15th-50th percentile, while 37 males and 36 females moved to the







% Population Distribution on Day 0 vs Day 90 (Male)
• Population Day 0
• Tendline for Population Day 0
• Population Day 0</p





50th-85th percentile, further reinforcing the trend of weight gain and percentile improvement (Figures 9,10,11,12) (Tables 5,6). A similar pattern was observed in children aged 7–9 years, where those in the 15th-50th percentile category experienced an upward shift, with the proportion decreasing from 15.27% to 14.30% in males and 17.24% to 12.82% in females, as Z-scores improved from -2.72 to -1.84 (males) and -2.98 to -2.26 (females). A total of 141 males and 154 females from this percentile group successfully progressed to the 50th-85th percentile, indicating an overall positive shift in weight status (Figures 9,10,11,12) (Tables 5,6).

These findings demonstrate the effectiveness of nutritional supplementation in promoting weight gain across all age groups, as evidenced by increased Z-scores and upward shifts in weight percentiles. The maximum improvements were observed in younger children, suggesting that early intervention plays a crucial role in addressing growth deficits and supporting healthier weight trajectories.

Discussion

Optimal nutrition during early childhood provides a strong foundation for lifelong health, cognitive development and socioeconomic productivity. ChilRun full[™] offers a comprehensive

 Table 5: Gender-Wise Changes in Weight-for-Age Z-Score from Baseline (Day 0) to Day 90, Categorized by Weight Percentile (Male = 1,065; Female = 730)

Age Group (Years)	Male (Day 0 \rightarrow Day 90)	Female (Day 0 \rightarrow Day 90)
2–3 years	$\textbf{-0.39} \rightarrow 0.01$	- 1.84 → - 0.94
4–6 years	- 2.70 → - 1.85	- 2.24 → - 1.50
7–9 years	- 2.72 → - 1.84	- 2.98 → - 2.26

Table 6: Gender-Wise Distribution of Weight Percentile Shifts from Day 0 to Day 90

S. No Combination		Number of Shift for Male	Number of Shift for Female
1 Below 3rd to 3rd - 15th		111	73
2	Below 3rd, 15th - 50th	44	17
3 Below 3rd, 50th - 85th 6 3rd - 15th, 15th - 50th		16	3
		121	106
7	3rd - 15th, 50th - 85th	37	36
10 15th - 50th, 50th - 85th		141	154
	Total shift	470	389

nutritional intervention designed specifically for children above 2 years of age, addressing critical nutritional needs of growing kids.

Early childhood represents a critical period during which nutritional deficiencies can lead to irreversible developmental consequences [15]. Adequate nutrition supports physical growth, cognitive development, immune function and metabolic programming, with effects extending into adulthood [16]. Nutritional deficiencies during this growth period impair neurogenesis, synaptogenesis and myelination, resulting in suboptimal cognitive outcomes and reduced school performance [17]. Furthermore, malnutrition disrupts normal endocrine function, affecting growth hormone secretion, Insulin-like growth factor (IGF-1) activity and thyroid hormone metabolism [18]. The relationship between nutrition and immune function creates a bidirectional cycle, where malnutrition increases infection susceptibility, which further exacerbates nutritional deficiencies. This scenario significantly led to childhood morbidity in resource-limited settings, with long-term consequences on growth, development and economic productivity. Nutritional intervention during early childhood, therefore, represents a high-impact strategy for improving health trajectories and developmental outcomes [20].

Globally, approximately 149 million children under five experience stunting and 45 million suffer from wasting, with disproportionate burden in South Asia and Sub-Saharan Africa (UNICEF-WHO-World Bank, 2020) [3]. Despite progress in reducing malnutrition over recent decades, significant disparities persist between regions and within countries. Malnutrition affects approximately 25% of children globally, with stunting and wasting impacting physical development, cognitive function and immune competence [15,16].

In India, malnutrition represents a critical public health challenge, with the highest child wasting rate globally at 18.7% according to the **Global Hunger Index 2024 (UNICEF-WHO-World Bank, 2020)**. This alarming statistic places India at the 105th position among 124 countries, behind neighboring nations including Sri Lanka (56th), Bangladesh (84st) and Nepal (68th). The National Family Health Survey-5 (2019-21) reports 35.5% of children under five as stunted and

19.3% as wasted, with significant state-level variation in prevalence (ICMR-NIN, 2020) [23]. To effectively address malnutrition in India, a multi-faceted approach is needed, focusing on education, healthcare, agriculture and community empowerment. The Government of India, through various schemes like PoshanAbhiyaan and the Integrated Child Development Services (ICDS), is actively addressing malnutrition in India. These initiatives focus on improving nutritional content, delivery and outreach, particularly targeting vulnerable groups like children, pregnant women and lactating mothers. Oral Nutritional Supplements (ONS) are a crucial tool in addressing malnutrition in India, particularly for vulnerable groups like children and pregnant women. By supplementing their usual diet with a complete blend of macronutrients and micronutrients, ONS can improve growth, nutrient intake and reduce the frequency of illness in nutritionally at-risk children.

In this PAN India study (at 282 clinics across 32 cities across India), we studied the effect of ChilRun full[™], an oral nutritional supplement on anthropometric parameters (including height, weight and BMI) in children (2851 children aged 2 years and above over a 90-day period). ChilRun full[™] 2+ provides 37 essential nutrients specifically formulated to support critical developmental processes in children above two years. This ONS is a balanced profile of macronutrients (carbohydrates, proteins and fats) and micronutrients (vitamins and minerals: including Vitamin K2, zinc and iron), complemented by functional ingredients including fructooligosaccharides (FOS) as prebiotic, L. Acidophillus as probiotic [10]. As per earlier study by Jain et al; 2024, ChilRun full[™] plays a significant role in supporting the growth and development of growing children and contributed to significant upward trend in height, weight and BMI across the various age groups of children of Eastern regions of India and contributed in optimalgrowth, transforming into healthy, energetic and strong kids.

The present post marketing surveillance (PMS) study findings reveal significant and linear improvements in anthropometric parameters—height, weight and BMI—across all age groups, with particularly remarkable outcomes in children at risk of malnutrition (Z-scores \leq -1) (Figure 4) (Figure 6). In this study, ChilRun full[®] also exhibited a significant improvement in Z-scores for weight, height and BMI across all the age groups (Figure 7). In children aged 2-3 years the Z-score for height, weight and BMI improved from -0.17, -0.18 and -0.01 at baseline to -0.03, 0.08 and 0.19 on day 90. Similarly, the improvement in the Z-scores was noted in children aged 4-6 years (for height, weight and BMI from -0.66, -0.35 and 0.34 at baseline to -0.53, -0.16 and 0.86) and 7-9 years (for height, weight and BMI from -0.89, -0.60 and -0.09 at baseline to -0.75, -0.40 and 0.22) on day 90. The upward trends suggest that ChilRun full[®] has the potential to support the optimal growth patterns in children of all age groups.

In subset analysis of special population was conducted for (a) Z-score analysis for weight, height and BMI in children at risk of malnutrition (Z-scores \leq -1): it was clearly observed that those children at risk of malnutrition and initiated ChilRun full^{**}, a comprehensive total nutritional supplement addressed their severe nutritional deficits and promoted catch-up growth during critical periods of development. Z-score in all age group children increased from -1.88 to - 1.69 for height, -1.75 to -1.35 for weight and -1.40 to -

1.20 for BMI (Figure 8). This change in Z-score for height, weight and BMI was 10.30%, 20.56% and 14.59%, respectively. It indicates timely intervention of nutritional supplements is essential in malnourished children. (b) Gender wise Z-score distribution based on weight percentile profile: The analysis of weight-for-age Z-scores and weight percentile distribution from day 0 to day 90 revealed a positive trend in weight gain among both male and female participants, reflecting improved nutritional status and growth outcomes, defines its potential role of ChilRun full[™] in growth and development in both genders. Further, on continuous use for 90 days ChilRun full[™] was well tolerated as no adverse events were reported in any age group from any one of the clinics.

According to ICMR-NIN data, malnutrition-related disabilityadjusted life years (DALYs) demonstrate a 6.8-fold difference between lowest and highest socio-demographic index states, accounting for 68.2% of total under-five deaths nationally (ICMR-NIN, 2020). These statistics highlight the critical importance of nutritional interventions in addressing India's child health challenges. The ICMR-NIN Dietary Guidelines for Indians (2020) emphasize the importance of dietary diversity, micronutrient adequacy and appropriate feeding practices for addressing childhood malnutrition, with specific recommendations for different age groups and physiological states (ICMR-NIN, 2020) [23]. Based on this study data, ChilRun full[∞] is a potential nutritional intervention for growing kids to combat not only India Child health challenges but also for specific populations who are associated with micronutrient deficiency due to pick/fussy eating behaviours.

Considering this, supplementing with macronutrients, micronutrients and functional ingredients are crucial for the optimal child growth and development of kids, especially in situations where a balanced diet is not readily available or when specific nutrient needs are not met. Supplementation can help prevent deficiencies, optimize growth and enhance overall health making the kid healthy, energetic and strong. Macronutrients (fat, protein, carbohydrates) deliver energy substrates necessary for growth while supporting tissue synthesis and repair. Adequate protein intake is essential for building and repairing tissues, supporting growth and providing energy. Carbohydrates, which are the primary source of energy for the body and brain, support physical activity and brain function. While healthy fats are essential for brain development, hormone balance, cell membrane integrity and fat-soluble vitamin absorption [24].

In this study we have also explored that child aged 2–3 years (in subset analysis) who are on continuous supplementation of ChilRun full[™] for 90 days, the growth parameters in terms of percentile category, the proportion of those in the below 3rd percentile category decreased from 31.27% to 20.55% in males and from 25.90% to 18.15% in females, with corresponding Z-score improvements from -0.39 to 0.01 in males and -1.84 to -0.94 in females. This shift was accompanied by 111 male and 73 female participants moving to the 3rd-15th percentile, 44 males and 17 females progressing to the 15th-50th percentile and 16 males and 3 females reaching the 50th-85th percentile, demonstrating a significant weight gain and improved nutritional recovery.

These findings demonstrate the effectiveness of nutritional

supplementation in promoting weight gain across all age groups, as evidenced by increased Z-scores and upward shifts in weight percentiles. The maximum improvements were observed in younger children (2-3 years), suggesting that early intervention plays a crucial role in addressing growth deficits and supporting healthier weight trajectories.

The micronutrients iron, zinc, calcium, vitamin A, vitamin D and B-complex vitamins, addresses the common deficiencies seen in children [25]. Iron supports hemoglobin synthesis, oxygen transport and cognitive development, with iron deficiency anemia affecting 58.1% of Indian children under five years (ICMR-NIN, 2020), zinc facilitates immune function, protein synthesis and wound healing, with specific requirements outlined in ICMR-NIN guidelines, supporting linear growth and neurodevelopment [1]. Vitamins play a vital role in numerous bodily functions, including immunity, energy production and bone health. The inclusion of specialized functional nutrients such as choline (essential for brain development), taurine (supporting neurological development), L-carnitine (facilitating energy metabolism), L-arginine (promoting growth hormone secretion and support bone health) and inositol (involved in cell signaling) enhances the formulation's capacity to support comprehensive development. These components target specific physiological processes critical during periods of rapid growth and development during early childhood [25,26,27]. Various micronutrients in ChilRun full[™] influence childhood growth through multiple physiological mechanisms, including modulation of endocrine pathways, participation in redox reactions and facilitation of hormone synthesis. Zinc influences testosterone metabolism through inhibition of aromatase and 5α-reductase enzymes, affecting androgenic signaling pathways essential for growth, while selenium supports thyroid hormone synthesis and metabolism [28,29].

Vitamin D participates in steroidogenesis and influences sex hormone synthesis through prostaglandin involvement, while modulating calcium homeostasis through parathyroid hormone regulation, directly impacting bone mineralization Iron, magnesium and zinc contribute to IGF-1 metabolism, influencing IGF-1 synthesis, bioavailability and receptor signaling, thereby modulating somatic growth and cellular proliferation [29]. The antioxidant properties of vitamins C, E and selenium participate in cellular redox regulation, protecting against oxidative stress that could impair cellular function and prote inflammation. This antioxidant capacity protects developing tissues, particularly the brain, from oxidative damage while supporting immune function and cellular longevity [30].

Micronutrients function as enzymatic cofactors in metabolic pathways essential for energy production, macromolecule synthesis and cellular proliferation. B-complex vitamins serve as cofactors in carbohydrate, protein and lipid metabolism, while magnesium activates over 300 enzymatic reactions including those involved in DNA synthesis. These metabolic functions provide the overall energetic and synthetic foundations necessary for tissue growth during childhood and regular supplementation of these micronutrients in growing children transform society as healthy, energetic and strong kids. [31]

Further, ChilRun full[™] also contains digestive nutrients, i.e. fructooligosaccharides (FOS) & Lactobacillus acidophilus [10], which support beneficial gut microbiota and facilitate production of shortchain fatty acids (SCFAs) including acetate, propionate, butyrate and valerate that demonstrates anti-inflammatory properties. Further SCFAs also interact with G-protein coupled receptors expressed in multiple tissues, affecting energy homeostasis, insulin sensitivity and appetite regulation [33]. SCFAs additionally modulate immune function through regulation of regulatory T-cell development and cytokine production, supporting balanced immune responses while reducing growth-inhibiting inflammation [34]. These SCFAs enhance intestinal barrier function through promotion of tight junction protein expression and mucin production, reducing translocation of pathogenic organisms while facilitating nutrient absorption. [32]. In addition, it is also known that the gut microbiome and central nervous system function through the "gut-brain axis," suggesting another mechanism through which prebiotics support neurodevelopment. Metabolites produced by gut microbiota influence neural development, myelination and neurotransmitter metabolism, contributing to cognitive and behavioral development. [35]

Based on this observational study data, it is evident that continuous use of ChilRun full[™] not only provide significant and linear improvements in anthropometric parameters—height, weight and BMI across all age groups, but also provide remarkable outcomes in children at risk of malnutrition (Z-scores \leq -1). These findings highlight the critical role of targeted nutritional interventions in supporting optimal growth and development. The results further suggest that ChilRun full[™] may play a pivotal role in public health strategies aimed at combating malnutrition and growth deficits. Future studies could explore and evaluate broader developmental outcomes such as cognitive and immune function, reinforcing the comprehensive impact of nutritional supplementation in childhood development.

Conclusion

ChilRun full[™] offers a comprehensive nutritional supplementation approach supporting multiple physiological mechanisms through its balanced nutrient profile and functional ingredients. The supplement's components influence endocrine pathways, redox balance, hormone synthesis and gut microbiome function, collectively supporting physical growth, cognitive development and immune function. As global and national efforts continue to address childhood malnutrition, comprehensive nutritional supplements like ChilRun full[™] represent valuable nutritional products for growing kids and develop them as *healthy, energetic and strong kids*.

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