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Enhancing Innate Immunity through Gummies Enriched with a Prebiotic Fiber (β-Glucan) and Micronutrients: IMMUNO SHIELD TRIAL, Proof of Concept, Single Arm, Open Label Trial in Children Aged 3 - 6 Years

Anuradha Khadilkar[1*], Rachana Bhoite[2], Sukhada Bhatte[2], Vinita Satyavrat[2], Sagar Katare[2], Manasa P. Sadananda[2], Arti Sanghavi[2], Rayees Unnisa[2]

[1]Jehangir Clinical Development Centre, Jehangir Hospital Premises, Pune, India
[2]Nutrition Science-Nutraceuticals, Dr. Reddy's Laboratories Ltd., Hyderabad, India
Email: *anuradhavkhadilkar@gmail.com

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Abstract

Background: Undernourishment occurs when the body is deficient in essential nutrients, which impacts growth and overall bodily functions. It can be caused by an inadequate diet, poor nutrient absorption, economic challenges, and illnesses. The function of the innate immune system is weaker in young children compared to later stages of life, and building strong immunity is crucial for safeguarding them against various diseases. Children with robust immune systems are better equipped to fight infections and recover more quickly from illnesses. Improving the nutritional intake of young children with a daily supplement that contains a prebiotic fiber-β-glucan and iron, along with other micronutrients, can significantly enhance the immunity, nutritional status as well as iron status in children. **Objective:** This single-arm, open-label study investigates the impact of gummies containing prebiotic fiber-β-glucan and micronutrients on the innate immunity and iron status of children aged 3 to 6 years with haemoglobin concentration between 9 and 11 g/dL and a history of at least two infections in the past three months. **Method:** Following informed consent from parents or legally acceptable representatives, 44 subjects were enrolled, with 38 completing the study. The intervention involved daily consumption of three gummies over three months. Clinical evaluations were conducted at baseline, one month, and three months. Primary outcomes included innate immunity markers such as Natural Killer (NK) cell activity, including CD3, CD3/CD (16 + 56), Absolute Neutrophil Count, Immunoglob-

ulins IgA and IgE levels, and C-Reactive Protein. Secondary outcomes included type and number of episodes of infection and the adapted KIDSCREEN QOL-27 quality of life questionnaire. Iron status was also assessed through various indicators. **Results**: The study found significant improvements in innate immunity markers, including increased NK cell activity, increased CD3 (Total Cells) (%) (p value = 0.0213) and CD3/CD (16 + 56) (%) (p value = 0.0013) counts at 3 months from baseline, increased IgA levels (p value = 0.0009), and decreased CRP levels, indicating enhanced innate immunity. Additionally, a significant reduction in episodes of cold, occurrences of runny nose, and composite respiratory illness parameters such as all flu like respiratory symptoms cold, cough, runny nose and fever were observed at month 1 and month 3 when compared against baseline using McNemar test $p < 0.0001$ for cold episodes, p value = 0.0020 for runny nose, and $p < 0.0001$ for composite respiratory illness parameters. Iron status indicators also showed significant improvement. **Conclusion:** Nutritional supplementation with prebiotic fiber-β-glucan and other micronutrients can positively impact paediatric respiratory health and iron status, enhancing innate immunity and reducing the frequency of respiratory infections in children.

Keywords

Prebiotic Fiber, Nutritional Gummies, Innate Immunity, Immunity Markers, Iron Status, Child Health

1. Introduction

Children are vulnerable to infections, hence, building their immunity is crucial to a healthy childhood. The innate immune system, which includes neutrophils, monocytes, macrophages, and dendritic cells, acts as the first line of defense against pathogens [1]. However, this system is underdeveloped in young children, and with increased exposure to pathogens during the growing age, providing nourishment to build immunity is critical. Children who are more susceptible to frequent and severe infections tend to miss more school days and are at risk of chronic health issues like acute respiratory distress syndrome (ARDS) [2].

Undernourishment, often due to poor diet or illness, impairs growth and weakens immunity [1]. Iron deficiency anemia (IDA) is common in developing countries, affecting children's energy, cognitive function, and infection resistance [3]. Picky eating leads to nutritional deficits, particularly iron deficiency, impacting immunity and school performance [4]. A study found that 58.9% of children were picky eaters, which affected eating habits and overall growth [4] [5]. Proper nutrition, including vitamins A, C, D, E, and minerals like zinc and iron, is crucial for immune health [6]. Clinical research highlights the use of probiotics, prebiotics, and β-glucans as effective in improving iron absorption and immune health [7] [8].

Clinically proven baker's yeast β-glucan (β 1,3/1,6)-Wellmune®, enhances immunity by priming innate immune cells. It supports digestion, reduces sick days,

and improves energy levels [9] [10]. Prebiotic fiber-β-glucan is an ingredient used in foods, beverages, and supplements and is clinically proven to strengthen the immune system, helping to maintain and enhance well-being. Baker's yeast β-glucan is a naturally occurring polysaccharide derived from the cell wall of Baker's yeast (Saccharomyces cerevisiae) [11]. The beneficial effects of prebiotics are mediated primarily through fermentation in the colon by intestinal microflora by producing short-chain fatty acids (SCFAs), which lowers the pH and facilitates mineral (iron) absorption in the gut [12]. β-Glucans have been demonstrated to have health benefits in children. The versatility of β-glucan is observed in alleviating respiratory symptoms, enhancing immunity to help fight common illnesses, reducing sick days, and improving gut health for better digestion. They also boost overall energy levels and may reduce allergy symptoms by modulating immune responses [13]. This proof-of-concept study aims to evaluate the effects of prebiotic fiber-β-glucan supplementation along with iron and other micronutrients on immune function, quality of life, and iron status in 3 - 6-year-old children, highlighting its potential to enhance overall health and well-being.

2. Methodology

2.1. Study Participants

The study recruited children (≥3 to 6.0 years) with haemoglobin concentration of ≥9 - ≤11 g/dl and who had experienced at least two episodes of infection in the previous three months spanning from summer to the early rainy season. Subjects were excluded if they had consumed iron or micronutrient supplements within 6 months, had blood transfusions, used probiotics or immune support products within 30 days, had allergies to the investigational product, hematologic disorders, recent gastrointestinal bleeding, severe infections, renal failure, encephalopathy, malignancies, diabetes, comorbidities, acute infections, inflammatory conditions, or hospitalization for infections within 4 weeks. Conditions affecting protein and calorie absorption or participation in another clinical study within the last month, were used as disqualification criteria. Investigational product was gummies with prebiotic fiber-β-glucan fiber and other micronutrients like folic acid, Selenium, Zinc, and Vitamins B6, C, A, D, and E. Subjects were screened only after receiving the signed informed consent from parents or Legally Acceptable Representatives (LARs), and eligible subjects were enrolled in the study.

The IMMUNO SHIELD TRIAL was conducted at Jehangir Clinical Development Centre, Pune, India, approved by the Institutional Ethics Committee of Jehangir Clinical Development Centre and registered with the Clinical Trial Registry of India under registration number CTRI/2023/03/050188. The study adhered to the ethical guidelines outlined in the "Ethical Principles for Medical Research Involving Human Subjects" as specified in the Helsinki Declaration.

2.2. Study Design

This was a single center, prospective, single arm, interventional, open label proof

of concept study. The investigational product consisted of oral chewable immuno gummies with prebiotic fiber-β-glucan (1000 mg) and other micronutrients such as vitamin A (2500 mcg), D3 (2000 IU), E (50 mg), C (375 mg), B6 (5 mg), B12 (5.1 mcg), Sodium (134 mg), Folic acid (41 mcg), Iron (75 mg), Zinc (40 mg), Selenium (100 mcg) and dietary fibre (fructooligosaccharide, 34 g)/per 100 g. One serve (3 gummies) of nutrition supplement was consumed in the morning after breakfast once daily for 3 months. The study consisted of three visits for the purpose of clinical evaluation: Visit 1, called the Baseline visit, Visit 2 at 1 month and Visit 3 at 3 months from baseline, respectively.

Anthropometric measurements included both height and weight. The primary outcome variable assessed key markers of innate immunity viz., Natural Killer (NK) Cells (CD3 and CD 16+56), Immunoglobulin levels (IgA, IgE), Absolute Neutrophil Count (ANC), and C-reactive protein (CRP) levels at baseline and after three months of supplementation to ascertain the effect on immunity.

Conclusions on immunity status were also established by type and number of episodes of infection and the adapted KIDSCREEN QOL-27 quality of life questionnaire covering 5 domains, such as physical well-being, psychological well-being, family and leisure, social relations and education, designed for children aged 8 - 18 years [11]. The questionnaire was adapted for the study age range or 3 - 6 years and was administered with the help of the subject's parents/LAR while providing responses to the questionnaire. Additionally, blood was collected at Visit 1 (month 1) and Visit 3 (month 3) (approximately 12.0 ml at each prick) from the subject. The study evaluated the impact on children's iron status through assessments including hemoglobin concentration, Absolute Neutrophil Count (ANC), Serum total Iron, Serum Ferritin (SF), Serum Hepcidin (SH), Total Iron Binding Capacity (TIBC), Transferrin Saturation, soluble Transferrin Receptor (sTfR), and Erythrocyte Protoporphyrin Levels.

All the laboratory investigations were performed at a National Accreditation Board for Testing and Calibration Laboratories (NABL) accredited and ISO 13485:2016 certified laboratory using validated methods as per laboratory standard operating procedures. Natural Killer (NK) Cells (CD3 and CD 16 + 56) estimation was performed using Attune NxT Acoustic focusing flow cytometer and Invitrogen antibodies kit. The measurement of immunoglobulin levels included IgA, which was quantified using the Roche Cobas c311 system via the Immunoturbidimetric principle for *in vitro* testing. IgE levels were determined using the Roche/Hitachi Cobas e411 system with the Electrochemiluminescence Immunoassay (ECLIA) method, based on the sandwich principle. The Absolute Neutrophil Count (ANC) was assessed using the principle of Electrical Impedance. C-reactive protein (CRP) was quantitatively measured with the Roche Cobas c311 system using the particle-enhanced immunoturbidimetric assay. Hemoglobin concentration was determined using the Yumizen H550 spectrophotometer, relying on the photometry principle. Serum total iron levels were quantitatively measured *in vitro* with the Roche Cobas c311 system, based on a colorimetric assay.

Serum Ferritin (SF) was analyzed using the Roche Cobas E411 system and the Electrochemiluminescence Immunoassay (ECLIA) method, based on the sandwich principle. Serum Hepcidin (SH) was measured using the Hepc GENLISATM ELISA kit through the sandwich ELISA technique. Total Iron Binding Capacity (TIBC) and Transferrin Saturation for Unsaturated Iron Binding Capacity (UIBC) were quantified *in vitro* using the VITROS 5600/250 system and Roche Cobas c311 system, respectively, applying the direct determination method with Ferrozine. Soluble Transferrin Receptor (sTfR) was measured using the ELISA kit through the ELISA method based on the sandwich principle. Erythrocyte Protoporphyrin was assessed using the EP GENLISATM ELISA kit, which employed the sandwich ELISA technique.

2.3. Sample Size

Being a proof-of-concept study, a total of 44 subjects were enrolled to achieve 40 evaluable subjects for final data analysis. This convenience sample size of 40 was selected on the basis of available data in a similar age group [14] [15].

2.4. Data Analysis

The data collected was analyzed using R Version 4.3.1, for effectiveness and safety of the nutritional supplementation intervention. The results at baseline, 1 month, and 3 months are derived from the same subjects, with only those having complete data at all time points included in the analysis. All comparative analysis was based on two-tailed tests with a significance level of $\alpha = 0.05$. The study endpoints were tested for statistical significance using a paired t test, Wilcoxon signed rank test, and McNemar's test as appropriate.

3. Result

In the screening phase, 70 participants were assessed, and 44 subjects were enrolled. About 38 participants completed the study and were considered for final analysis. A total of 6 subjects discontinued their involvement, due to loss to follow-up or gave the reason of lack of willingness to continue. The subjects consisted of Indian children aged 3 to 6 years, comprising 27 girls (65.9%) and 14 boys (34.1%) with a mean age of 4.3 (±1.15) years. Anthropometric measurements indicated average height and weight of 100.8 (±10.54) cm and 14.05 (±3.00) kg, respectively. Product compliance was high, with an overall compliance rate of 94%. To ensure compliance, subjects maintained a diary to record IP consumption. During site visits, the study team reviewed these diaries and verified compliance by collecting used and unused product bottles and counselled the LARs to maintain the compliance. Additionally, to prevent misplacement of the product, only the required amount was dispensed until the next scheduled visit. Additionally, the average compliance to the prebiotic fiber-β-glucan being 94% indicates that, on average, subjects adhered to the prescribed intake of the prebiotic fiber-β-glucan 94% of the time. The formula below was used for calculating IP compliance.

$$\text{Test product compliance} = \frac{\text{Actual Consumption} \times 100}{\text{Expected Consumption}}$$

Primary outcome assessment revealed significant improvements in NK cell activity as shown in Table 1, as evidenced by increased CD3 (Total Cells) (%) ($p = 0.021$) and CD3/CD (16 + 56) (%) ($p = 0.001$) counts at 3 months from baseline. IgA levels significantly increased ($p = 0.001$), potentially contributing to improved immunity. C-reactive protein levels decreased, indicating reduced inflammation. Although IgE and Absolute Neutrophil Count (ANC) increased, statistical significance was not achieved.

Table 1. Impact of nutritional supplement on immunity markers for children.

Immunity Markers (Unit)	n, mean (SD)	n, mean (SD)	CI	p-value
	Baseline	Month 3	Change From Baseline	
CD3 (Total Cells) (%), by Flowcytometry	41, 62.1 (15.65)	36, 70.1 (9.53)	5.8 [0.9, 10.77]	0.021*
CD3/CD (16 + 56) (%), by Flowcytometry	41, 5.3 (5.19)	36, 7.9 (4.96)	2.9 [1.2, 4.7]	0.001*
Immunoglobulin (IgA) (g/L), by Immuno turbidimetric	41, 1.0 (0.38)	37, 1.2 (0.49)	0.1 [0.0, 0.2]	0.001*
Immunoglobulin (IgE) (IU/ml), by ECLIA	41, 358.53 (371.6)	37, 418.2 (417.0)	41.9 [−28.4, 112.3]	0.234
Absolute neutrophil count (/cumm), by WBC-Electrical Impedance	41, 3507.1 (1878.85)	36, 4212.0 (1851.37)	624.6 [−195.9, 1445.2]	0.131
C-reactive protein (mg/L), Immuno turbidimetric	41, 2.1 (7.9)	37, 1.6 (2.42)	−0.6 [−3.6, 2.2]	0.631

Note: N = Total number of subjects in treatment arm, n = Total number of non-missing subjects in specified category, SD = Standard Deviation, CI = Confidence Interval. Baseline is defined as the last results obtained prior to IP, CFB = Change from Baseline, p-value has been carried out using paired t-test, *Significant p-value, Efficacy direction = Greater is better.

The results of the immune biomarkers for innate immunity were supported by the findings of the secondary outcome of the frequency of episodes of infection.

Results presented in Table 2 compare the same subjects at baseline, 1 month and 3 months. It demonstrates a statistically significant reduction in the incidence of episodes of cold, occurrences of runny nose, and composite respiratory illness parameters at month 1 and month 3 when compared against baseline using McNemar test ($p < 0.0001$ for cold episodes, $p = 0.002$ for runny nose, and $p < 0.0001$ for composite respiratory illness parameters). Similarly, as per Table 2, no change was noted in the number of episodes of diarrhoea at month 1 and month 3 compared to baseline ($n = 1$). A statistically significant reduction was observed at month 1 and month 3 in the frequency of episodes associated with composite respiratory illness parameters ($p < 0.0001$). Composite respiratory illness captures all flu-like respiratory symptoms, including cold, cough, runny nose and fever considered together.

Table 2. Summary of types and number of episodes of Infection.

Type of Episodes	n (%)	n (%), p-value[a]	n (%), p-value[a]
	Baseline	**1 Month**	**3 Months**
Diarrhoea	1 (2.4)	0 (0.0), 1	0 (0.0), 1
Cold	27 (65.9)	1 (2.4), <0.0001	1 (2.4), <0.0001*
Cough	9 (22.0)	2 (4.9), 0.065	3 (7.3), 0.146
Fever	4 (9.8)	3 (7.3), 1	3 (7.3), 1
Runny nose	10 (24.4)	0 (0.0), 0.002	0 (0.0), 0.002*
Composite for respiratory illness parameters	41 (100.0)	5 (12.2), <0.0001	5 (12.2), <0.0001*
Number of Episodes	**n, mean (SD)**	**n, mean (SD)**	**p-value[b]**
	Baseline	**3 Months**	**Change from Baseline (CFB)**
Diarrhoea	41, 0.0 (0.31)	41, (0.0), 0.00	1
Composite for respiratory illness parameters	41, 3.0 (1.50)	41, (0.3), 1.46	<0.0001*

Note: Baseline is defined as the last results obtained prior to IP, N = Total number of subjects in treatment arm, n = Total number of non-missing subjects in specified category, SD = Standard Deviation, CFB: Change from Baseline, a = p-value has been carried out using McNemar's Test, b = p-value has been carried out using Wilcoxon Signed Rank test, Number of episodes = Number of times the episodes were reported in a month, *Significant p-value.

This study also assessed the impact of nutritional supplementation on children's Quality of Life (QoL) using the adapted KIDSCREEN QOL-27 questionnaire (Table 3). No significant changes were observed in composite domain levels at visit 3 compared to baseline.

The study also evaluated the impact of gummies with β-glucan, micronutrients, and iron on hemoglobin concentration and iron status.

Table 4 shows a significant increase in hemoglobin at month 3 post-supplementation. A statistically significant increase in serum total iron, ferritin, hepcidin, transferrin saturation, and erythrocyte protoporphyrin levels at month 3 compared to baseline suggests an improvement in iron status. Throughout the study duration, no adverse events were reported, all vital signs and physical examinations remained normal, indicating a favorable safety profile. The baseline and 3-month dietary recall data indicated a similar dietary pattern at both end points, with the addition of micronutrients and β-glucan from the gummies. The average energy, carbohydrate, protein, fat, and fibre intake at baseline was 1043 ± 212, 145.89 ± 30.98, 24.79 ± 4.67, 39.61 ± 11.21, and 15.99 ± 7.22, respectively. The intake remained unchanged at Visit 3. The average energy, carbohydrate, pro-

tein, fat, and fibre intake at Visit 3 was 1007 ± 141, 142.7 ± 22.7, 26.75 ± 7.35, 39.987 ± 10.76, and 17.033 ± 4.21, respectively.

Table 3. KIDSCREEN QOL-27 health questionnaire for quality of life at each composite domain level.

KIDSCREEN QOL-27 Health Questionnaire's Domain Level	n	mean (SD)	n	mean (SD)	CI	p-value
	Baseline		3 Months		Change From Baseline	
Physical activities and health	41	4.1 (0.69)	38	3.8 (0.53)	−0.2 [−0.5, −0.0]	0.039*
General mood and feelings about yourself	41	4.1 (0.39)	38	4.1 (0.35)	0.0 [−0.1, 0.2]	0.632
Family and free time	41	3.9 (0.59)	38	3.9 (0.67)	−0.1 [−0.2, 0.0]	0.168
Friends	41	3.8 (0.67)	38	3.7 (0.72)	−0.1 [−0.3, 0.0]	0.174
School and learning	41	4.4 (0.60)	38	4.2 (0.56)	−0.2 [−0.4, −0.0]	0.032*

Note: N = Total number of subjects in treatment arm, n = Total number of non-missing subjects in specified category, SD = Standard Deviation, CI = Confidence Interval, Baseline is defined as the last results obtained prior to IP, CFB = Change from Baseline, p-value has been carried out using paired t-test, Efficacy direction = Greater is better.

Table 4. Summary of iron status parameters.

Haemogram Test (Unit), Method of analysis	n = 41, Mean (SD)	n = 36, Mean (SD)	Difference [95% CI]	p-value
	Baseline	3 Months	Change from baseline	
Haemoglobin (g/dl), by Spectrophotometric	10.4 (0.78)	11.5 (1.15)	0.9 [0.64, 1.34]	<0.0001*
Iron Status (Unit)	**n = 41, Mean (SD)**	**n = 37, Mean (SD)**	**Difference [95% CI]**	**p-value**
	Baseline	3 Months	Change from baseline	
Serum total iron (µg/dl), by Colorimetric	50.8 (32.033)	72.3 (37.97)	20.95 [7.3, 34.5]	0.004*
Serum ferritin (SF) (ng/ml), by ECLIA	19.4 (26.20)	33.7 (24.24)	15.1 [7.9, 22.3]	0.000*
Serum hepcidin (SH) (ng/ml), by ELISA	3.0 (6.57)	21.8 (8.07)	18.6 [15.1, 22.1]	<0.0001*
Total iron binding capacity (TIBC) (µg/dl), by UIBC-FerroZine and TIBC-calculated	409.9 (73.05)	374.0 (65.88)	−35.7 [−55.4, −15.9]	0.001*
Transferrin saturation (%), by UIBC-FerroZine and TIBC-calculated	13.18 (9.56)	19.8 (11.06)	6.7 [3.1, 10.3]	0.001*
Soluble transferrin receptor (sTfR) (mg/L), by ELISA	0.6 (0.59)	0.69 (0.723)	−0.0 [−0.1, 0.1]	0.634
Erythrocyte protoporphyrin (ng/ml), by ELISA	403.7 (328.95)	499.4 (399.18)	71.7 [27.8, 115.6]	0.002*

Note: N = Total number of subjects in treatment arm, n = Total number of non-missing subjects in specified category, SD = Standard Deviation, CI = Confidence Interval, Baseline is defined as the last results obtained prior to IP, CFB = Change from Baseline, p-value has been carried out using paired t-test, *Significant p-value.

4. Discussion

The study demonstrates the beneficial effects of a supplement containing prebiotic fiber-β-glucan and other micronutrients on immune markers among Indian children aged 3 to 6 years. The significant increase at 3 months from baseline in NK cell activity and IgA levels suggests enhanced innate immunity and improved leukocyte response to pathogens. NK cells are composed of heterogeneous subsets of lymphocytes, whose roles are important in both innate and for facilitating an appropriate adaptive immune response [14] [15] against pathogens. Findings confirm that supplementing with immuno gummies with β-glucan and other micronutrients enhanced the gut-associated NK cells' activity [14] [16] as well as leukocytes' ability to respond to bacteria by helping them locate infections faster and activating the innate immune system's defenses against non-self-cells [13]. The decrease in C-reactive protein levels further supports reduced inflammation [17]. Use of immunogummies with β-glucan and other micronutrients may have augmented IgA secretion and function. IgA is predominantly distributed in the mucosa/lining tissues of intestine and oral and nasal cavities. Increase in IgA may assist in protecting the barrier function of these linings [18], which may facilitate better immunity [19]. Additionally, results show an increase in IgE and an increase in Absolute Neutrophil Count (ANC). However, the change could not attain statistical significance. It is noteworthy to state here that an increase in counts for IgA, IgE and ANC is found to be within the clinically defined normal ranges. Hence, this can be inferred as an improvement in immunity and not as a sign of infection.

On combining findings from **Table 2** and **Table 3** of biomarker levels and incidences of infection, results suggest that supplementation with immuno gummies was effective in enhancing the innate immunity, especially against respiratory infections in paediatric populations [20], indicating a beneficial impact on respiratory health. The QOL questionnaire assessed the general well-being and subjective health of the children. Since this is not an objective test, the statistical significance needs to be interpreted cautiously.

As seen in **Table 4**, improvement in haemoglobin concentration and iron status suggests a favorable increase in iron availability to tissues. Total iron and ferritin levels reflect the amount of iron stored in the body [21], while transferrin saturation indicates the percentage of iron-binding sites on transferrin that are occupied [22]. Hepcidin is a key regulator of iron metabolism, and its increase suggests a response to increased iron stores [23]. Lower erythrocyte protoporphyrin levels are indicative of iron deficiency anemia [24], and the increase observed may suggest a reversal of this condition. Additionally, a significant reduction in iron binding capacity was noted, suggesting increased iron availability in the blood. However, no significant difference was observed in soluble transferrin receptor levels. Soluble transferrin receptor is reduced in conditions with decreased erythropoietic activity, while it is increased in conditions with higher erythropoietic activity, such as in hemolysis. Thus, the soluble transferrin receptor is a marker used to evaluate the rate of erythropoiesis [25]. When there are changes in erythropoietic

activity as well as iron status (as when supplementation is carried out), the interpretation is difficult. Thus, sometimes the soluble transferrin receptor and other iron parameters may not increase in the same way. These findings collectively suggest a positive impact of the immunogummies on iron status markers, potentially benefiting children diagnosed with iron-deficient anemia.

Overall, the results of the clinical study indicate encouraging conclusions in children aged ≥ 3 to 6.0 years, the primary and secondary outcomes coupled with a good safety profile as indicated by the absence of adverse events and normal findings for vitals and physician examination throughout the study. These findings are relevant to the findings of another study on children in the age group 1 to 4 years and underscore the consistency and reliability of the observed outcomes [9].

This proof of concept, single-center study, while promising, is limited in its generalizability due to a small sample size and lack of a control group. Only 38 of 40 participants completed the study, and the absence of a control group with subjective symptom recording indicates a need for larger studies. Further multi-center randomized control trials with objective biomarkers of immunity, a broader age range including older children, and consideration of seasonal variations in infection rates are needed to validate our findings. These enhancements will help validate the observed benefits of β-glucan and micronutrient supplementation in the IMMUNO SHIELD TRIAL and provide a deeper insight into their role in pediatric immune health.

5. Conclusion

In conclusion, this interventional study with children aged ≥3 to 6.0 years showed statistically significant improvements in innate immunity markers. The immuno gummies with β-glucan and other micronutrients positively impacted gastrointestinal health, resulting in improvement in innate immunity. This is evidenced by a significant reduction in episodes of flu-like symptoms such as cold, runny nose and respiratory illnesses. The immuno gummies also showed benefits in improving haemoglobin concentration and iron stores of the body, thus enhancing efficacy outcomes. Thus, the findings support the potential effectiveness, safety, and feasibility of incorporating the immuno gummies with β-glucan and other micronutrients into children's routines.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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