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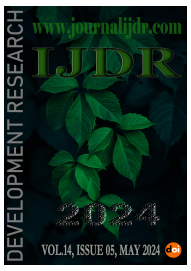

RESEARCH ARTICLE **OPEN ACCESS**

A CLINICAL INVESTIGATION ON THE SAFETY AND EFFECTIVENESS OF DIETARY SUPPLEMENTS: CURCUMIN, VITAMIN C, AND VITAMIN B COMPLEX GUMMIES IN PAEDIATRIC HEALTH

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ABSTRACT

Background: Gummies offer a novel supplement delivery method appealing to children. This study investigates the safety, efficacy, and organoleptic properties of three distinct gummies— Curcumin Gummies, Vitamin-B-complex Gummies, and Vitamin-C Gummies in paediatric health. ***Methods:*** A 30-day open-label, three-arm, parallel design study with 48 children assessed the efficacy, safety, and organoleptic properties of the gummies. Subjects were randomized to receive one of the gummies. Endpoints included sickness frequency, Quality-of-Life hedonic questionnaires. Statistical analysis was done using SPSS software (Version:26.0). Adherence to ICH-GCP, Declaration of Helsinki, ICMR guidelines, and NDCT Rules, was maintained. ***Results:*** In this study, significant improvements were observed across all groups post-supplementation. Prior to intake, subjects reported low energy levels and sickness. Post-supplementation, all subjects reported excellent health, heightened energy levels, calmness and peace. Positive feedback on organoleptic properties further supported the acceptability of the gummies. Further, no adverse event was reported. ***Conclusions:*** This study highlights gummy supplements' clinical efficacy, safety, and palatability. Essential ingredients like Curcumin, Vitamin B Complex, and Vitamin C make them optimal for children's nutritional needs. The delightful taste and convenient form of Noochy™ gummies ensured high subjects' compliance. The absence of adverse events emphasizes their safety profile. This research contributes to paediatric vitamin supplementation, showcasing gummies' potential for promoting comprehensive well-being in children.

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INTRODUCTION

Dietary supplements, encompassing a diverse array of vitamins, minerals, and herbal constituents, play a pivotal role in fortifying human health. Conventionally available in pill, powder, or liquid form, these supplements serve to augment various aspects of well-being, with popular choices including vitamin B complex, calcium, and vitamins B, C, and D (U.S. FDA, 2022). In recent years, a notable evolution in supplement delivery has been witnessed with the rise of gummies—a chewable gel form of vitamins. These gummies, characterized by their ease of swallowing, fragrance, and flavours, have gained widespread popularity, particularly among children and elderly adults (Khatode, Pathan, Datir, & Khaladkar, 2022). The shift towards gummies reflects a strategic consideration of taste, texture, and overall sensory appeal, factors recognized as pivotal in enhancing consumer acceptance, especially among younger age groups (Teixeira-Lemos, et al., 2021).

Within the realm of gummies, certain formulations have emerged as particularly favoured, notably those incorporating vitamin C, vitamin B complex, and curcumin. These gummies not only offer a palatable and enjoyable supplement experience but also harness the inherent health benefits of their constituent ingredients. Curcumin, derived from turmeric, imparts not only a distinctive flavour to foods but also brings forth anti-inflammatory and antioxidant properties (Gunnars & Sharon, 2023). Recognized globally for its immune-boosting effects and antiseptic qualities, curcumin is a compelling inclusion in gummies, marrying health benefits with a sensory appeal (Younkin, 2023). The vitamin B complex, encompassing essential B vitamins, stands as a cornerstone in dietary supplementation. Its role in preventing infections, promoting healthy cell growth, and influencing energy levels and brain function makes it a crucial contributor to the comprehensive nutritional profile of these supplements (Ali, et al., 2022). Vitamin C, a water-soluble vitamin abundantly found in citrus fruits and vegetables, serves a multifaceted role in supporting growth, aiding iron absorption, and contributing to the repair of tissues. Its

antioxidant properties and immune-boosting capabilities make it a compelling supplement, aligning with the broader trend of prioritizing holistic well-being (Crawford, Brown, Costello, & Deuster, 2022). (Higdon & Drake, 2012).

Additionally, Zinc is a vital micronutrient present in the human body in trace amounts, essential for various physiological functions. It plays a pivotal role in immune function, wound healing, and DNA synthesis, all of which are critical for maintaining overall health. When zinc is combined with vitamin C, synergistic effects are observed, enhancing the benefits of both nutrients. (Prasad, 2008) (Wessels, Maywald, & Rink, 2017). This study endeavours to delve into the safety, efficacy, and organoleptic properties of three distinct gummies—Curcumin Gummies, Vitamin B Complex, and Vitamin C + Zinc Gummies Gummies—in the context of promoting health among children. By systematically examining these dimensions, the study aims to provide scientific insights into the holistic impact of these dietary supplements on the target demographic, aligning with contemporary preferences for nutritional interventions that are both health-enhancing and sensorially satisfying.

METHODS

Ethical conduct of the study: The research meticulously adhered to the ethical standards and regulations outlined by relevant federal government codes, acts, and guidelines, including the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidance E6 (R2) on 'Good Clinical Practice,' as well as guidelines from the Declaration of Helsinki, Indian Council of Medical Research (ICMR), New Drugs and Clinical Trials Rules (NDCT), 2019, and the Food Safety and Standards Authority of India (FSSAI). Before commencing study procedures, ethical approval was obtained from an independent ethics committee for the finalized study protocol (version#01), parental informed consent form (version#01), case report form (version#01), and all other essential documents. Furthermore, this clinical investigation was prospectively registered with ClinicalTrials.gov under the identifier NCT05775237 and the Clinical Trial Registry of India (CTRI) under the registration number CTRI/2023/03/051016. This comprehensive ethical framework ensures the study's compliance with international and national ethical standards, safeguarding the rights, safety, and well-being of all participating subjects.

Study Design: This investigation employed an open-label, three-arm, parallel design to assess the impact of three distinct gummies—curcumin gummies, vitamin C gummies, and vitamin B complex gummies—on the health of children. The recruitment plan aimed at enrolling a maximum of 48 children, distributed evenly across three arms (16 children per arm), with the objective of ensuring the completion of the study by 45 subjects (15 children per arm). The inclusion of qualifying siblings residing within the same household was permitted. The selection process adhered to strict inclusion and exclusion criteria, with the screening conducted subsequent to obtaining written parental informed consent from the subjects' parents or legal guardians. Subjects were randomly assigned in a 1:1:1 ratio to receive test products A, B, or C. Randomisation, controlled for access, used the sequence number as the Randomization ID, ensuring unbiased allocation and enhancing study design robustness.

Efficacy and Safety Assessment: The study incorporated a comprehensive evaluation of the safety, efficacy, and organoleptic properties of the three distinct gummies. The efficacy assessment spanned from baseline on Day 01, before the initiation of test product usage, to Day 30 (+2 days) after test product usage. A primary focus of the efficacy assessment was the reduction in the frequency of sickness episodes among the study subjects. This parameter aimed to discern any notable impact of the test products on the occurrence of illnesses in the children.

Quality of Life (QoL) Assessment: The study incorporated Quality of Life (QoL) subjective questionnaires administered to parents/legal guardians at two distinct time points—before the initiation of the test product (baseline on Day 01) and after the completion of the study (Day 30 + 2 days). This aspect aimed to discern not only the safety and effectiveness of the test products but also their influence on the overall well-being and daily life of the children.

Organoleptic Properties via Hedonic Questionnaire: Another crucial facet of the study involved the assessment of organoleptic properties, examining taste, appearance, touch, smell, packaging, handling, and overall satisfaction. Administered to parents/legal guardians on Day 30 (+2 days) after test product usage, the product perception questionnaires utilized a hedonic scale. This approach provided a detailed understanding of the subjective experiences associated with the gummies, with a quantitative measurement of participants' satisfaction and preferences regarding the organoleptic attributes of the gummies.

Safety Endpoint: The safety of the test products was determined through the identification of product usage-emergent adverse events. Parameters such as nausea, vomiting, diarrhoea, dizziness, and burning sensations were among those assessed by the Principal Investigator to ensure the overall safety profile of the study.

Table 1. Details of the test products

Test Products and their constituents:	Noochy™ Curcumin Gummies Active ingredient: *Curcumin*. Inactive ingredients: *Corn syrup, sugar, water, gelling agent (INS440), acidity regulators (INS 330 and 331), carnauba wax, ripe mango flavour and food colour.* Noochy™ Vitamin B Complex Gummies Active ingredients:*Vitamin B12, Vitamin A, Vitamin C, Vitamin D, Vitamin E, Zinc, Iodine, Folate and Magnesium.* Inactive ingredients: *Corn syrup, sugar, water, gelling agent (INS440), acidity regulators (INS 330 and 331), carnauba wax, mix fruit flavour and food colour.* Noochy™ Vitamin C Gummies Active ingredients: *Vitamin C and Zinc.* Inactive ingredients: *Corn syrup, sugar, water, gelling agent (INS440), acidity regulators (INS 330 and 331), carnauba wax and food colour.*
Storage Condition:	The test products were stored in cool and dry place below 25 ° C.
Dosage Form:	Chewable oral gummies
Dosage:	Two gummies daily. Chew gummy thoroughly and completely before swallowing
Route of Administration:	Oral
Marketed by:	Nuvoly Consumer Products

Test Products: Noochy™ Curcumin Gummies, Noochy™ Vitamin B Complex Gummies, and Noochy™ Vitamin C Gummies, developed by Nuvoly Consumer Products, showcase distinct formulations. Curcumin Gummies incorporate turmeric-derived curcumin for natural anti-inflammatory benefits, while Vitamin B Complex Gummies and Vitamin C Gummies encompass essential vitamins tailored for their respective health contributions. Refer Table 1 for test details about the test products.

Study Participation Criteria: This study enrolled subjects aged 2 to 12 years, inclusive, at the time of parental consent, ensuring their overall good health through a thorough medical examination and history evaluation by the investigator. Voluntary written informed consent from all subjects' mothers/legal guardians, indicated by the signed parental informed consent form, was a prerequisite. The mothers/legal guardians committed to completing study activities and participating in regular follow-up visits with the subjects. Additionally, a condition for inclusion involved the subjects' mothers/legal guardians adhering to and complying with the study protocol. Furthermore, enrolled subjects were not concurrently participating in any other clinical study, and all subjects agreed to maintain their current level of activity throughout the study duration.
This study excluded subjects with a known history of allergies or specific allergic reactions to curcumin, vitamins, zinc, and pantothenic acid. Additionally, individuals currently enrolled in an active investigational study or who had participated in such a study within 30 days prior to enrolment were excluded. Subjects deemed ineligible for enrolment by the investigator or expert physician, as well as those unwilling to provide consent, were also excluded from the study.

Study Disposition: A total of 48 paediatric subjects were randomised into 3 arms after enrolment – resulting in 15 subjects receiving curcumin gummies, 17 subjects receiving vitamin C gummies, and the remaining 16 subjects receiving vitamin B complex gummies at Visit 1 (Day 01). By Visit 2 on Day 30, 42 subjects (87.50%) successfully completed the study. A total of 6 subjects (12.50%) discontinued from the study. Refer Figure 1.

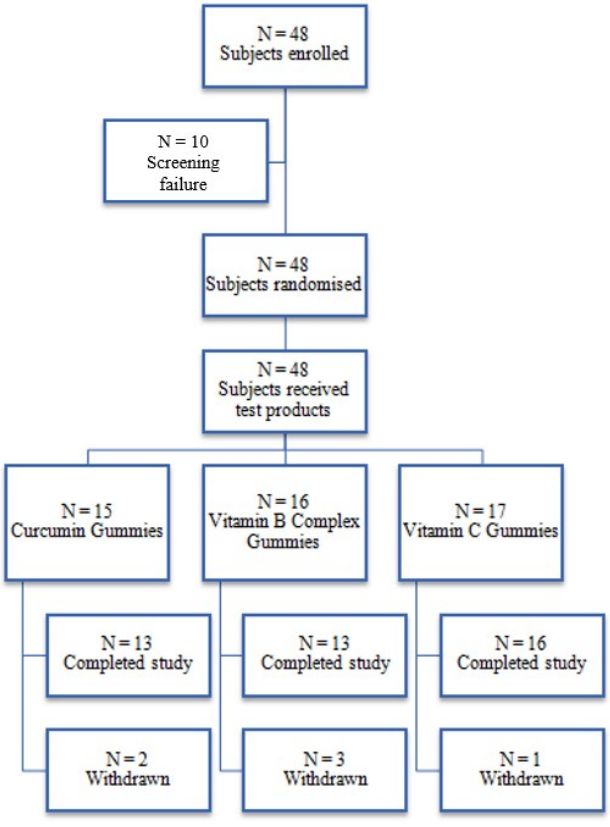

Figure 1. Disposition of subjects

Statistical Analysis: Continuous variables were described using standard descriptive statistics, presenting the number of observations (N), mean, standard deviation (SD), median, minimum, and maximum values. Categorical variables were represented through frequency and percentage, complemented by graphical presentations when necessary. The statistical analysis was conducted using SPSS software (Version: 26.0) with a significance level set at 5%. Data from withdrawn subjects were excluded from the statistical analysis to ensure the integrity and accuracy of the results.

RESULTS

In this study, 48 subjects were divided into three groups, each receiving a specific type of gummy supplement: Curcumin Gummies, Vitamin B Complex Gummies, or Vitamin C Gummies. The demographic profile of each group, reflecting the gender distribution, age, height, and weight is mentioned in Table 2. Before initiating Curcumin Gummies, 76.92% of subjects reported low energy levels during play, and 61.54% felt sick most of the time. Guardians perceived their children's health as fair in 76.92% of cases. Remarkably, after a 30-day regimen, changes were evident, with 100% of subjects reporting excellent health, heightened energy levels during play, and consistent states of calmness and peace, and none of the subjects feeling moody, dull or sick. Refer Figure 2.

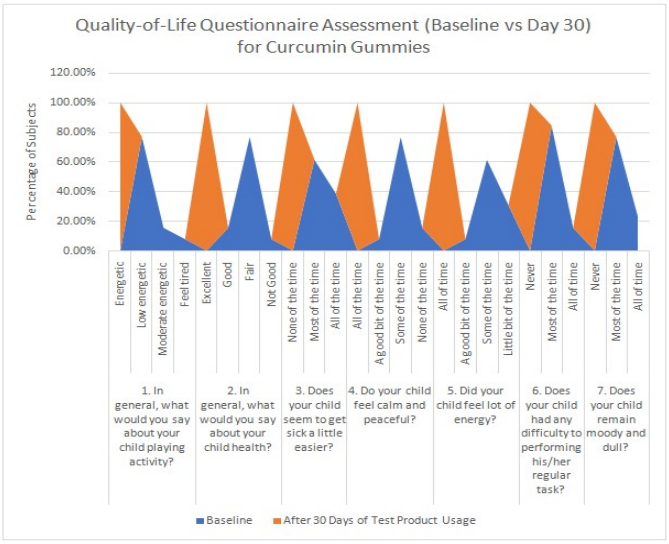

Figure 2. Quality-of-Life Questionnaire Assessment (Baseline vs Day 30) for Curcumin Gummies

Vitamin B Complex Gummies exhibited a similar pattern, with 76.92% reporting low energy levels and 69.23% feeling sick most of the time before intake. Guardians of 23.08% subjects felt that their child seemed to get sick a little easier all of the time. Guardians of 53.84% subjects reported the health of their children to be fair, and 23.08% reported the health as 'Not good'. Post a 30-day regimen of Vitamin B complex gummies, all subjects reported notable improvements, with none of the subjects feeling moody, dull or sick, and all 100% citing excellent health, energetic play, and sustained states of calmness and peace. Refer Figure 3.

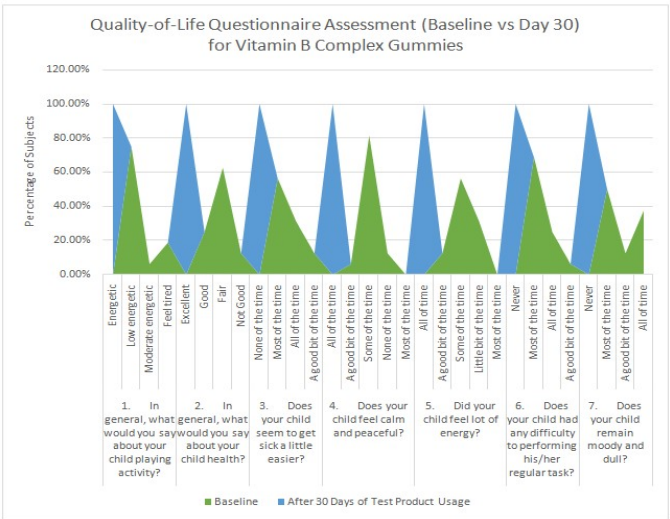

Figure 3. Quality-of-Life Questionnaire Assessment (Baseline vs Day 30) for Vitamin B Complex Gummies

Table 2. Disposition of subjects

Parameter	Descriptive Statistics	Total (n = 48)	Curcumin Gummies (n=15)	Vitamin B Complex Gummies (n=16)	Vitamin C Gummies (n=17)
Gender, n (%)	Female	30 (62.5%)	10 (66.67%)	11 (68.75%)	9 (52.94%)
	Male	18 (37.5%)	5 (33.33%)	5 (31.25%)	8 (47.06%)
Age (years)	n	48	15	16	17
	Mean (SD)	5.81 (2.73)	6.13(2.53)	6.00 (3.18)	5.35 (2.55)
	Median	5.50	6.00	6.50	5.00
	Min, Max	2.00, 11.00	2.00, 10.00	2.00, 11.00	2.00, 11.00
Height (cm)	n	48	15	16	17
	Mean (SD)	108.96 (18.00)	110.67 (16.71)	109.31 (22.50)	107.12 (15.04)
	Median	110.50	114.00	107.50	104.00
	Min, Max	79.00, 147.00	79.00, 147.00	83.00, 142.00	82.00, 128.00
Weight (kg)	n	48	15	16	17
	Mean (SD)	17.57 (7.66)	18.48 (9.12)	18.58 (8.15)	15.82 (5.69)
	Median	16.00	17	16.00	14.00
	Min, Max	6.70, 48.00	7.00, 48.00	10.00, 32.00	6.70, 3.00

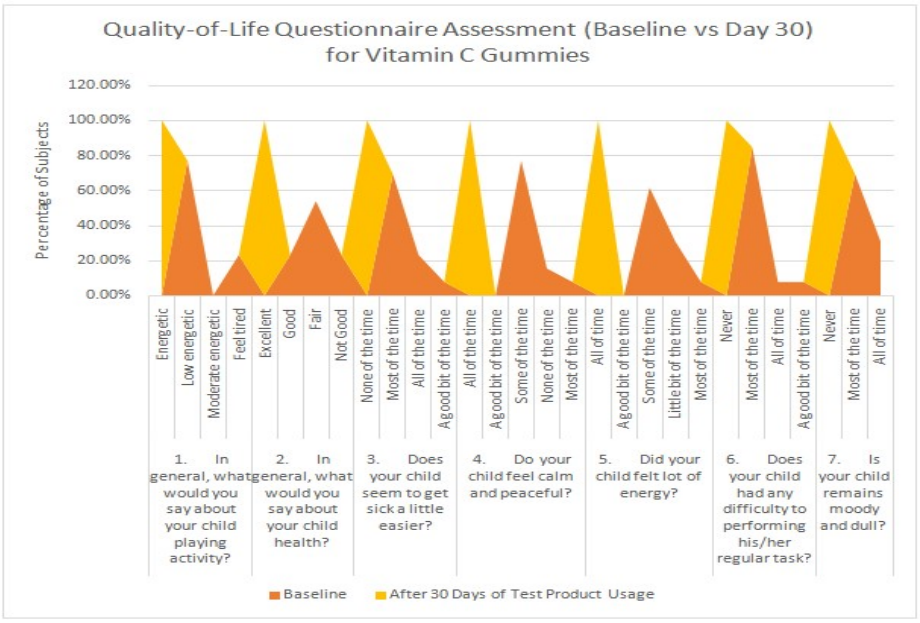

Figure 4. Quality-of-Life Questionnaire Assessment (Baseline vs Day 30) for Vitamin C Gummies

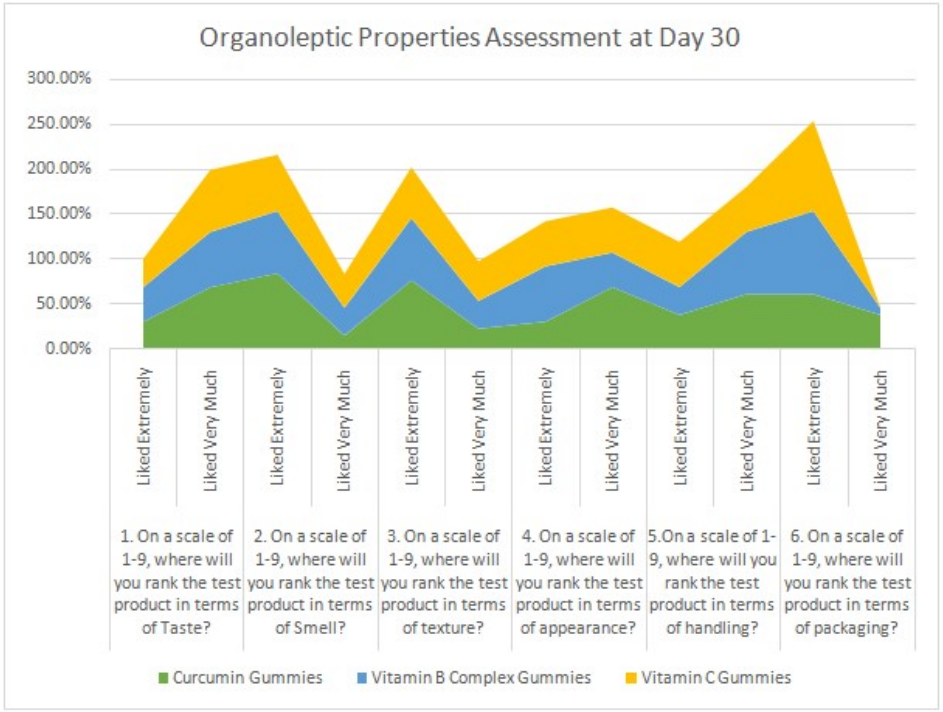

Figure 5. Organoleptic Properties Assessment at Day 30

In the case of Vitamin C Gummies with Zinc, 75.00% of subjects reported low energy levels during play, 56.25% felt sick most of the time, and 31.25% felt sick all of the time before intake. Guardians perceived their children's health as fair in 62.50% of cases, and in 12.50% of cases as 'Not good'. After 30 days, all subjects demonstrated significant enhancements, with 100% reporting excellent health, sustained calmness, and heightened energy levels, and none of the guardians reported the subjects feeling moody, dull or sick. Refer Figure 4. Evaluation of organoleptic properties at Visit 2 (Day 30) for Curcumin Gummies revealed positive responses. A substantial 69.2% expressed a strong preference for the gummies' taste, while 84.6% and 76.9% extremely liked the smell and texture. Additionally, 61.5% had a strong liking for the gummies' handling, and 61.5% and 38.5%, respectively, expressed extreme and very much liking for the packaging. For Vitamin B Complex Gummies, positive feedback on organoleptic properties included 61.5% expressing a strong liking for the taste, 69.2% and 69.2% extremely liking the smell and texture, and 92.3% expressing extreme liking for the packaging. Vitamin C Gummies' organoleptic properties garnered positive feedback as well, with 68.8% expressing a strong preference for the taste, 62.5% and 56.3% extremely liking the smell and texture, and 100% expressing extreme liking for both handling and packaging. Refer Figure 5. Throughout the study duration, monitoring for product usage-emergent adverse events was conducted to ensure the safety of the test products. Parameters including nausea, vomiting, diarrhoea, dizziness, and burning sensations were assessed by the Principal Investigator. Remarkably, no adverse events were observed among the study participants receiving Curcumin Gummies, Vitamin C Gummies, or Vitamin B Complex Gummies, suggesting their suitability for consumption by children within the study population. In conclusion, this comprehensive analysis illustrates the profound impact of Curcumin Gummies, Vitamin B Complex Gummies, and Vitamin C Gummies on subjects' well-being, perceptual health, and energy levels. The positive reception of the gummies' organoleptic properties further reinforces the potential acceptability and efficacy of these formulations within the target demographic. The statistical improvements before and after the gummies' administration underscore the positive changes attributed to their intake.

DISCUSSION

The exploration into the potential benefits and applications of gummy supplements for paediatric populations stands as a significant advancement in the realm of paediatric nutrition. Focusing primarily on perceptual health indicators, including energy levels, feelings of sickness, and overall well-being, the study revealed transformative changes across all three gummy formulations after a 30-day regimen. Subjects initially reporting low energy levels and frequent sickness experienced a notable shift, with 100% reporting excellent health, heightened energy levels during play, and sustained states of calmness and peace. This consistent positive outcome underscores the potential of gummy supplements to enhance children's perceptual health, addressing a crucial gap in existing literature. The natural anti-inflammatory properties of curcumin have been extensively documented in scientific literature, showcasing its potential benefits in various health aspects. Curcumin, derived from turmeric, has been associated with anti-inflammatory, antioxidant, and neuroprotective effects (Aggarwal, Yuan, Li, & Gupta, 2013). These characteristics make it a compelling candidate for addressing perceptual health indicators in children. In this study, the subjects consuming Curcumin Gummies reported improvements in overall well-being, aligning with the established anti-inflammatory properties of curcumin. The positive impact observed on energy levels during play and sustained states of calmness resonates with previous research on curcumin's potential to influence mood and cognitive function (Hewlings & Kalman, 2017). The incorporation of curcumin in gummy form presents a promising avenue for paediatric supplementation, catering to the holistic well-being of children. The Vitamin B Complex Gummies featured a blend of essential B vitamins recognized for their pivotal roles in energy metabolism and neurological health. The B vitamins have proven importance in supporting cognitive function and energy production (Kennedy, et al., 2010). In our study, subjects consuming Vitamin B Complex Gummies reported heightened energy levels during play, reinforcing the potential benefits of this formulation in addressing perceptual health indicators in children. They further reported enhanced overall health and lowered episodes of sickness. Additionally, the study's exploration of Vitamin C Gummies is significant. Vitamin C is well-known for its immune-boosting properties (Crook, Horgas, Yoon, Grundmann, & Johnson-Mallard, 2022). It has a potential role in enhancing immune health among paediatric populations. Scientific research has demonstrated that the combination of zinc and vitamin C collaborates to fortify the immune system and shield cells from oxidative stress-induced damage. This synergy underscores the significance of these nutrients in providing comprehensive nutritional support. In our findings too, subjects consuming Vitamin C + Zinc gummies exhibited a shift from frequent sickness to excellent health. (Beveridge, Wintergerst, Maggini, & Hornig, 2008)

Furthermore, the examination of organoleptic properties demonstrated a positive reception among subjects for taste, smell, texture, handling, and packaging across all three gummy formulations. This positive response emphasizes the crucial role of palatability in supplement compliance, particularly in paediatric populations. The potential acceptability and efficacy of these formulations within the target demographic encourage sustained consumption, with significant implications for paediatric healthcare. The gummy form of formulation used in our study aligns with research indicating its acceptability among children. Gummy formulations are not only well-received by children but also provide a convenient and enjoyable way to administer supplements, potentially improving adherence to nutritional interventions (Tireki, Sumnu, & Sahin, 2021). This supports our observations of positive responses among subjects, emphasizing the practicality and effectiveness of gummy supplements in promoting perceptual health among paediatric populations. The methodological choices, including a controlled intervention design, diverse gummy formulations, a mixed-methods approach, and a longitudinal design, enhance the internal validity and depth of the study. However, limitations, such as a small sample size and the absence of a placebo control group, require careful interpretation of findings. Generalizability necessitates consideration of population diversity, cultural influences, health status variations, socioeconomic factors, educational and healthcare system differences, and the sustainability of effects over time. Addressing these factors in future research designs will contribute to a more widely applicable knowledge base. The study's findings have practical implications for tailoring paediatric supplement formulations, addressing health indicators, enhancing compliance, introducing gummies as alternative delivery methods, promoting holistic approaches to paediatric health, and educating stakeholders on supplement choices. Gummy supplements offer a promising avenue for improving nutritional interventions in children.

CONCLUSION

In conclusion, this study highlights the clinical efficacy of gummy supplements in enhancing health among paediatric populations. The inclusion of key ingredients like Curcumin, Vitamin B Complex, and Vitamin C, supported by established research, positions the studied Noochy™ gummy formulations as an optimal choice for children's nutritional needs. The observed transformative changes, improved energy levels, and enhanced immune health underscore the significant positive impact of these gummy supplements. With their delightful taste and convenient form, these gummies ensured high compliance. Moreover, the absence of adverse events further emphasizes their safety profile, making them a preferred option for parents and caregivers seeking effective, safe and enjoyable nutritional interventions for children. This research contributes substantially to the evolving landscape of paediatric vitamin supplementation, emphasizing the potential of gummies to foster comprehensive well-being in the younger population.

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Declarations

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Clinical Trials.gov Registration: NCT05853757
CTRI Registration: CTRI/2023/04/051587

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