

Clinical Study of Vitamin C + Zinc, Vitamin B complex and Curcumin Gummies

NOOCHY
Tasty Supplement



Background:

Dietary supplements, including vitamins, minerals, and herbal constituents, are essential for human health. Traditionally in pill, powder, or liquid forms, popular supplements like vitamin B complex, calcium, and vitamins B, C, and D support various aspects of well-being. Recently, gummies have become popular due to their ease of swallowing and pleasant flavors, especially among children and the elderly. Curcumin, with its anti-inflammatory and antioxidant properties, and vitamin B complex, crucial for preventing infections and promoting cell growth, are significant components. Vitamin C, found in citrus fruits and vegetables, aids growth, iron absorption, and tissue repair, and when combined with zinc, offers enhanced health benefits. This study endeavors to delve into the safety, efficacy, and organoleptic properties of three distinct gummies—Curcumin Gummies, Vitamin B Complex, and Vitamin C + Zinc Gummies—in the context of promoting health among children.

This was a proof-of-concept, open-label, three-arm, parallel, safety and organoleptic properties testing clinical study of three different gummies (Curcumin gummies, Vitamin C gummies, and Vitamin B complex gummies) on healthy children. The trial received approval from the ACEAS Ethics Committee and is registered with the Clinical Trial Registry of India (CTRI) under the registration number CTRI/2023/03/051016, with registration dated March 23, 2023. Furthermore, this clinical investigation was prospectively registered with ClinicalTrials.gov under the identifier NCT05775237.

Methodology:

A total of 48 children, aged 2 to 12 years, were enrolled in the study, with 45 completing the 30-day duration. The parents of the participated children were given instructions to visit the research facility, where the Investigator and trained study staff explained the study details to them. This explanation included information about the test products, visit schedules, potential benefits, and possible safety concerns such as nausea, headache, diarrhea, and dizziness.

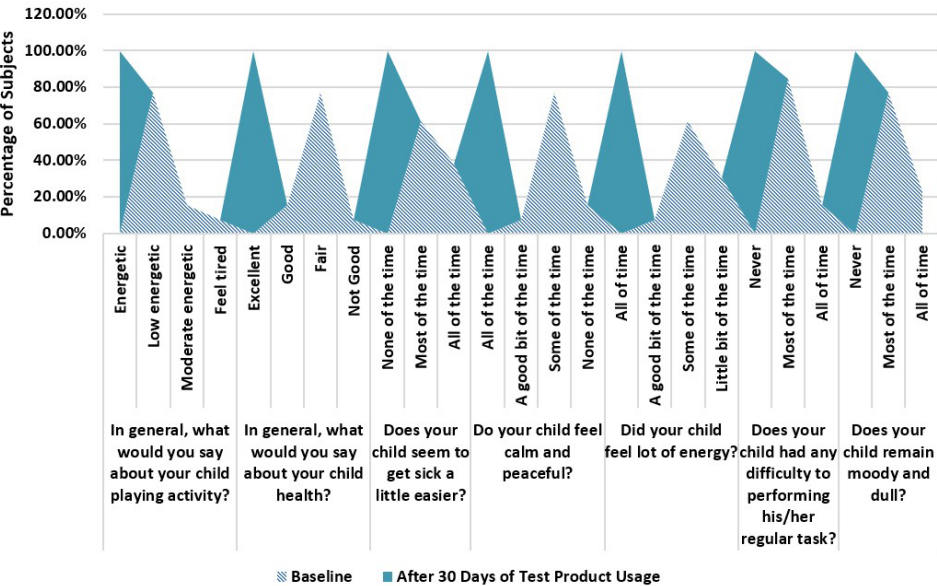
To ensure the children's willingness to participate, the parents | legal guardians, preferably the mother, were asked to sign the parental informed consent form on behalf of their child. They were given time to understand the procedures and encouraged to ask any questions. Copies of the children's and parents' | legal guardians' identification was taken and filed in the study binder.

The parents were instructed to bring their children for two specific visits: Visit 01 (Day 01) served as the screening and enrollment visit. Prior to this visit, the subjects underwent pre-screening by the screening department at NovoBliss Research, and the recruiting department contacted them by phone before the enrollment visit. Visit 02 (Day 30) marked the end of the study, with evaluations conducted from Day 01 (baseline, before using the test product) to Day 30 (after using the test product) to assess the safety, efficacy, and organoleptic properties of the test product. The effectiveness of the test vitamin C gummies was evaluated by reduction in the frequency of sickness episode and consumer feedback on their children health and organoleptic parameter like smell, texture and overall satisfaction. Upon completion of the Clinical Phase of the study, all raw data were reviewed, and an Excel spreadsheet with raw data was shared with Biostatistician. Statistical analysis was performed by Biostatistician Team using R Software (Version#4.2).

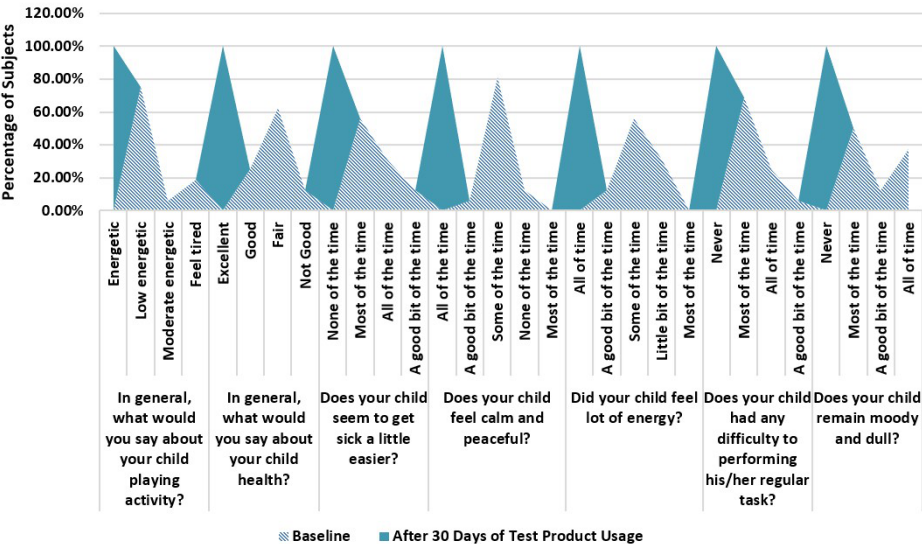


Before usage of test product Curcumin Gummies, 76.92% of subjects reported low energy levels during play, and 61.54% felt sick most of the time. Guardians perceived their children's health as fair in 76.92% of cases. Remarkably, after a 30-day regimen, changes were evident, with 100% of subjects reporting excellent health, heightened energy levels during play, and consistent states of calmness and peace, and none of the subjects feeling moody, dull or sick. 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 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.

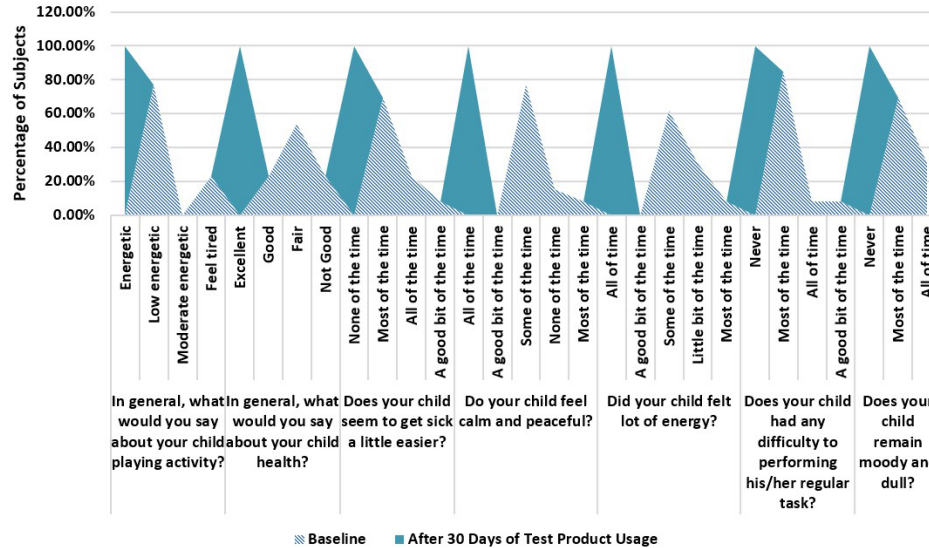
Quality-of-Life Questionnaire Assessment (Baseline vs Day 30)
for Curcumin Gummies



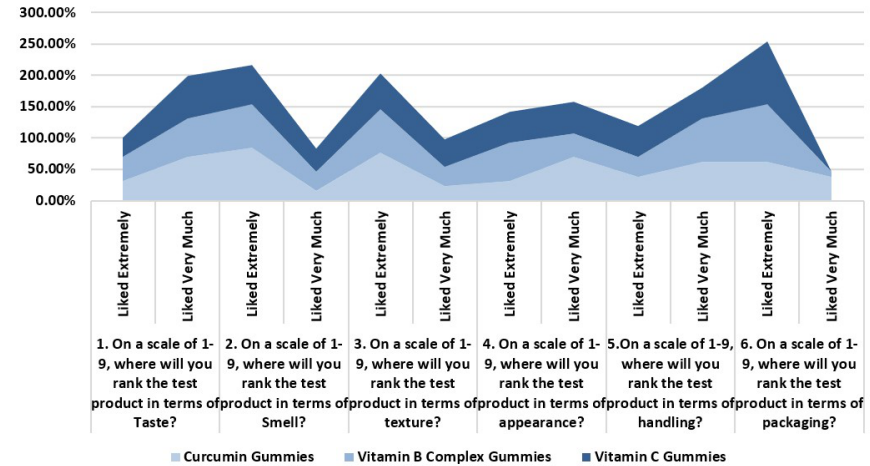
Quality-of-Life Questionnaire Assessment (Baseline vs Day 30)
for Vitamin B Complex Gummies



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



Organoleptic Properties Assessment at Day 30



Overall 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 wellbeing in the younger population.