

Raison Biotech Co., Ltd

Abstract of Clinical Study Report

Study Code	24-RD-06-SBT-001
Study Name	A Clinical Study on the Effect of DHA & ARA Candy on the Cognitive Improvement in Preschool Children
Manufacturer of Study Products	Sponsor: Shandong Sibote Biotechnology Co., Ltd Address: Floor 11, Block b, Dongmen Continental Electromechanical Hospital, 786 Xinluo Street, Lixia District, Jinan City, Shandong Province 251619, China Contract Manufacturing Organization: Shandong Jejing Biotechnology Co., Ltd. Address: Building A, 2240 Xinxing Street, Industrial Park, Shanghe County, Jinan City, Shandong Province 251619, China Food Manufacturing License Number: SC11337012600809 Place of Origin: Jinan, Shandong Province
Study Duration	From June 25, 2024 to August 10, 2024
Ethics Committee Approval No.	Lishen [2024] No. 002
ClinicalTrials.gov Registration No.	NCT06532435
Clinical Study Report Date	August 23, 2024

Objective: Assess the effects of DHA & ARA algae oil gel candy on preschool children to enhance cognitive abilities.

Study Method: A single group open-label clinical study was conducted, enrolling 30 qualified subjects aged 2 to 6 years based on predefined inclusion and exclusion criteria. This cohort comprised 5 participants aged 2 to 3 years and 25 participants aged 4 to 6 years, ensuring that at least 25 individuals completed the study. All subjects received DHA&ARA algae oil gel candy daily, with a dosage of one to two capsules per day for a duration of four weeks. Participants were assessed through interviews conducted on Day 0, Day 14, and Day 28, with evaluation metrics including height, weight, body mass index (BMI), Wechsler Preschool and Primary Scale of Intelligence Fourth Edition (WPPSI-IV), Conners' Teacher Rating Scale (TRS) for children, a comprehensive dietary review over the past twenty-four hours, as well as monitoring for adverse events.

Result: The administration of DHA&ARA algae oil gel candy for a duration of 4 weeks demonstrated significant effects on subjects in the following areas:

1. After 4 weeks of consuming DHA&ARA algae oil gel candy, notable improvements were observed across various cognitive domains in terms of WPPSI-IV scores among subjects. The overall intelligence level improved by 16% ($P < 0.0001^*$), with Verbal Comprehension Index (VCI) improved by 16.2% ($P < 0.0001^*$), Visual Spatial Index (VSI) improved by 8.9% ($P < 0.0001^*$), Fluid Reasoning Index (FRI) improved by 10.2% ($P < 0.0001^*$), Working Memory Index (WMI) improved by 15.7% ($P < 0.0001^*$), and Processing Speed Index (PSI) enhanced by 7.4% ($P = 0.002^*$). Additionally, Vocabulary Acquisition Index (VAI) improved significantly at a rate of 20.2% ($P < 0.0001^*$), Nonverbal Index (NVI) improved by 13.1 % ($P < 0.0001^*$), General Ability Index (GAI) improved by 15.7 % ($P < 0.00001^*$) and cognitive proficiency index (CPI) improved by 14.7 % ($P < 0.0001^*$).
2. After 2 weeks of consuming DHA&ARA algae oil gel candy, the score of TRS showed a reduction in hyperactivity concerns by 27.1% ($P = 0.001^*$). After 4 weeks of

consuming DHA&ARA algae oil gel candy, the score of TRS showed the hyperactivity concerns were significantly reduced by 47.9 % ($P<0.0001^*$), inattention-passive behavior were reduced by 23% ($P=0.003^*$) and the hyperactivity index were reduced by 25.6% ($P=0.003^*$).

Conclusion: This research primarily assessed the efficacy of DHA&ARA algae oil gel candy in enhancing brain cognitive abilities among preschool children while also evaluating its impact on their attention spans as well as short- and long-term memory capabilities. In summary, consumption of DHA&ARA algae oil gel candy over four weeks can significantly enhance cognitive abilities in preschool children, particularly improving their attention spans along with both short-term and long-term memory capacities.

Taking DHA&ARA algae oil gel candy for two weeks resulted in significant improvements among subjects in the following areas:

- ✓ Hyperactivity issues showed notable enhancement.

After four weeks of consuming DHA&ARA algae oil gel candy, subjects exhibited substantial advancements in several domains:

- ✓ Enhancements were observed in overall intelligence, verbal comprehension, visuospatial skills, fluid reasoning, working memory, and processing speed. Additionally, improvements were noted in verbal reception, non-verbal abilities, general cognitive capacity, and cognitive efficiency;
- ✓ Attention and initiative capabilities improved alongside reductions in hyperactivity.

In conclusion, a 4-week intervention of DHA&ARA algae oil gel candy can effectively enhance the cognitive abilities of preschool children. It significantly contributes to improving both attention span as well as short-term and long-term memory abilities among this age group.