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Efficacy of Intel-Up Gummies in Children with Borderline Intellectual Functioning: A Randomized Controlled Open-Label Comparative Clinical Trial Protocol

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Abstract

Background: Borderline intellectual functioning (BIF) represents a clinically significant yet under-recognized cognitive state characterized by subaverage intellectual performance that does not meet the criteria for intellectual disability. Children within this range frequently exhibit academic difficulties, reduced cognitive efficiency, and impaired adaptive functioning, yet often remain outside the scope of structured therapeutic interventions. Current management is largely supportive and does not directly target cognitive enhancement, highlighting a need for safe and effective therapeutic options. Objective: To evaluate and compare the efficacy of Intel-Up Gummies, a polyherbal Medhya Rasayana formulation, with Brahmi Gummies in improving intelligence and memory among children with borderline intellectual functioning. Methods: This randomized, controlled, open-label, parallel-group comparative clinical trial will include 90 children aged 10–11 years with IQ scores between 63–74 assessed using the Binet–Kamat Test. Participants will be randomly allocated into two groups (n=45 each). Group A will receive Intel-Up Gummies, and Group B will receive Brahmi Gummies for a duration of 90 days. The primary outcome will be change in intelligence quotient, while secondary outcomes include memory performance and academic parameters. Expected Outcomes: The study is expected to demonstrate improvement in cognitive functions in both groups, with potential additional benefits in the polyherbal formulation group. Conclusion: This study aims to generate clinical evidence for the use of Medhya Rasayana in cognitive enhancement and may contribute to the development of practical and accessible therapeutic strategies for children with borderline intellectual functioning.

Key words : Borderline intellectual functioning; Medhya Rasayana; Cognitive enhancement; Intelligence quotient; Binet–Kamat Test; Ayurvedic gummies.

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Intelligence is a complex and multifaceted construct encompassing reasoning ability, learning capacity, memory, and adaptability to environmental demands[12]. In the context of child development, cognitive competence plays a decisive role in academic achievement, behavioral regulation, and social integration. Intelligence quotient (IQ), derived from standardized psychometric assessments, remains one of the most widely accepted tools for quantifying cognitive ability and identifying deviations from normative development. Borderline intellectual functioning (BIF) represents an intermediate cognitive state situated between normal intelligence and intellectual disability. According to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), BIF is characterized by an IQ range of 70–84[2]. Although not classified as a formal disorder, it is increasingly recognized as a condition of clinical relevance due to its association with academic underachievement, reduced cognitive efficiency, and impaired adaptive functioning. Epidemiological data suggest that a considerable proportion of school-aged children fall within this range, yet they often remain under-identified and inadequately supported[5]. Children with BIF typically exhibit subtle but persistent deficits across multiple cognitive domains, including attention, working memory, processing speed, and executive functioning[1]. These impairments often manifest as difficulty in comprehension, poor academic performance, reduced problem-solving ability, and limited capacity for abstract thinking. Unlike children with intellectual disability, those with BIF frequently remain within mainstream educational systems without access to specialized interventions, resulting in a cumulative disadvantage over time. This creates a paradoxical situation in which a clinically vulnerable group remains largely underserved. Current approaches to the management of BIF are predominantly educational and behavioral in nature. Remedial teaching, individualized learning strategies, and behavioral interventions form the cornerstone of management. While these approaches are valuable, they do not directly address the underlying neurocognitive mechanisms contributing to cognitive inefficiency. Pharmacological interventions, where used, are generally aimed at managing comorbid conditions such as attention-deficit hyperactivity disorder rather than enhancing cognitive capacity itself. This highlights a significant therapeutic gap and underscores the need for safe and effective cognitive-enhancing interventions.

Ayurveda offers a comprehensive and conceptually rich framework for understanding cognitive function. The faculties of Medha (intellect), Smriti (memory), and Buddhi (higher cognitive processing) are considered central to mental functioning[6]. Impairment in these faculties, described as Medha Mandya, is attributed to disturbances in Dosha equilibrium, particularly involving Kapha and Tamas, leading to obstruction of the Manovaha Srotas—the channels responsible for mental activity. Therapeutic approaches in Ayurveda aim not only to alleviate symptoms but also to restore functional balance and enhance cognitive capacity at a fundamental level. Within this framework, Medhya Rasayana occupies a prominent position. These are a group of rejuvenative formulations specifically indicated for enhancing intellect, memory, and learning ability. Classical texts describe several Medhya drugs, among which Mandukaparni (*Centella asiatica*), Yashtimadhu (*Glycyrrhiza*

glabra), Guduchi (*Tinospora cordifolia*), and Shankhapushpi (*Convolvulus pluricaulis*) are widely recognized[6,10]. Contemporary pharmacological research has provided evidence supporting their neuroprotective, antioxidant, anti-inflammatory, and neurotransmitter-modulating properties, thereby offering a plausible scientific basis for their traditional use[3,4,9,11]. Despite this growing body of evidence, the clinical application of Medhya Rasayana in pediatric populations remains limited. One of the major challenges is poor palatability and acceptability of traditional dosage forms such as powders and decoctions, which often lead to poor compliance among children. The development of gummy-based formulations represents a novel and pragmatic approach to overcome this limitation. By improving taste and ease of administration, such formulations have the potential to enhance adherence and, consequently, therapeutic effectiveness. Another important gap in the existing literature is the lack of well-designed randomized controlled trials evaluating polyherbal Medhya formulations in children with borderline intellectual functioning. Most available studies focus on individual herbs or are limited by methodological constraints. Furthermore, comparative studies evaluating polyherbal formulations against established single-herb interventions are scarce.

The present study is therefore designed to evaluate the efficacy of Intel-Up Gummies, a polyherbal Medhya Rasayana formulation, in comparison with Brahmi Gummies, a commonly used single-herb preparation. By adopting a randomized controlled design and employing standardized cognitive assessment tools, the study aims to generate clinically relevant evidence on the role of Medhya Rasayana in improving cognitive function among children with borderline intellectual functioning.

Rationale and Need for the Study :

Borderline intellectual functioning represents a critical yet insufficiently addressed area within pediatric neurocognitive health. Although children within this cognitive range exhibit measurable deficits in attention, memory, and learning capacity, they often remain outside the purview of structured clinical or educational interventions. This results in a progressive accumulation of academic difficulties, reduced self-efficacy, and impaired psychosocial development over time. The current standard of care for such children is largely limited to educational support, including remedial teaching and behavioral strategies. While these interventions may improve functional outcomes to some extent, they do not directly target the underlying neurocognitive processes responsible for impaired learning and information processing. Furthermore, pharmacological interventions are not routinely indicated unless comorbid neuropsychiatric conditions are present, thereby leaving a substantial therapeutic gap in the management of borderline intellectual functioning.

In recent years, there has been growing interest in cognitive enhancement strategies that operate at a neurobiological level. In this context, Ayurveda offers a well-established framework through the concept of Medhya Rasayana, which encompasses a group of formulations specifically indicated for improving intellect, memory, and mental performance. Classical descriptions emphasize not only symptomatic improvement but also

enhancement of cognitive capacity through nourishment and stabilization of neural substrates. Modern pharmacological investigations have provided supporting evidence for the neuroprotective, antioxidant, and neurotransmitter-modulating effects of several Medhya drugs[3,6,8-11]. However, translation of this knowledge into clinical practice—particularly in pediatric populations—remains limited. One of the primary barriers is poor acceptability of traditional dosage forms, which often results in suboptimal compliance. The development of gummy-based formulations represents a significant advancement in this regard. By improving palatability and ease of administration, such formulations have the potential to enhance adherence, particularly in children, thereby improving the consistency and effectiveness of therapeutic interventions. Additionally, existing literature reveals a lack of well-designed randomized controlled trials evaluating polyherbal Medhya formulations in children with borderline intellectual functioning. Most studies focus on individual drugs or lack methodological rigor. There is also limited evidence comparing polyherbal formulations with established single-herb preparations, which is important for understanding the added value of formulation complexity.

The present study is therefore conceptualized to address these gaps by evaluating the efficacy of Intel-Up Gummies, a polyherbal Medhya Rasayana formulation, in comparison with Brahmi Gummies. By employing a randomized controlled design and standardized outcome measures, the study aims to generate clinically meaningful evidence and contribute to the development of integrative therapeutic strategies for cognitive enhancement in children.

Aims and Objectives :

Aim :

To evaluate the effect of Intel-Up Gummies on intelligence quotient in children with borderline intellectual functioning.

Objectives :

- To assess the effect of Intel-Up Gummies on memory performance using the PGI Memory Scale
- To evaluate changes in academic performance following intervention
- To compare the efficacy of Intel-Up Gummies with Brahmi Gummies.

Study Design :

This study is designed as a randomized, controlled, open-label, parallel-group comparative clinical trial to evaluate the efficacy of a polyherbal Medhya Rasayana formulation (Intel-Up Gummies) in comparison with a single-herb preparation (Brahmi Gummies) in children with borderline intellectual functioning.

Study Setting :

The study will be conducted at the Department of Kaumarabhritya, Khemdas Hospital, Vadodara, a tertiary-level facility providing comprehensive pediatric care. Participants will be recruited through outpatient screening and in collaboration with nearby schools to ensure adequate representation of the target population. The flow of participants through different stages of the study will be depicted using a CONSORT flow diagram (Figure 1).

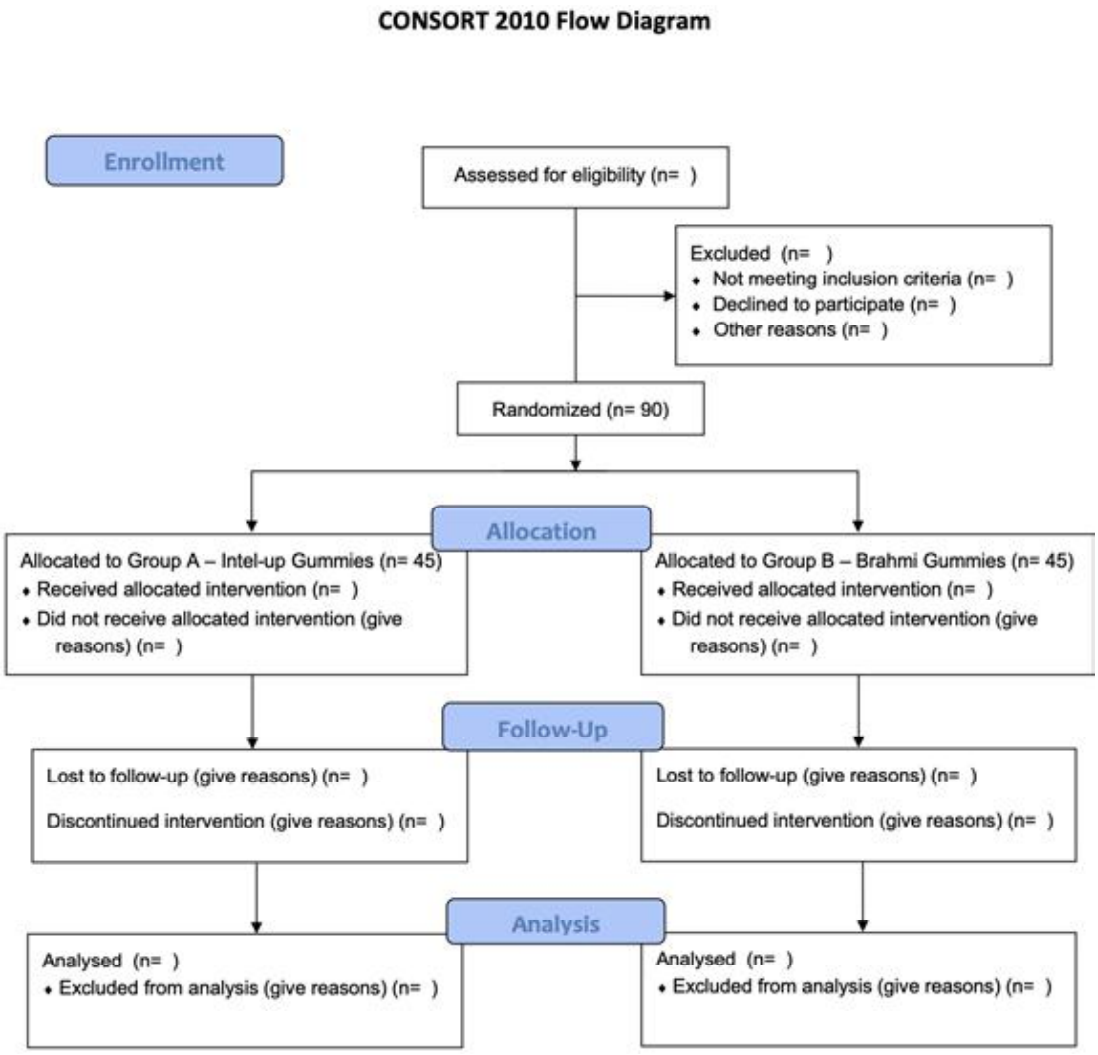

Figure 1. CONSORT Flow Diagram of proposed study plan

Study Population :

The study population will comprise school-going children aged 10–11 years, studying in the fifth standard, who are identified as having borderline intellectual functioning based on assessment using the Binet–Kamat Test (BKT).

Screening Procedure :

Initial screening of participants will be conducted using the Draw-a-Man Test (DAMT), a rapid, non-verbal screening tool for assessing cognitive maturity in children. This tool will be employed in school settings to identify children with possible cognitive deficits

in a time-efficient and practical manner. Children who are identified as having potential borderline intellectual functioning based on DAMT screening will subsequently undergo detailed intelligence assessment using the Binet–Kamat Test (BKT). Only those children who meet the predefined IQ criteria on BKT will be considered eligible for inclusion in the study.

Eligibility Criteria :

Children will be considered eligible if they are aged between 10 and 11 years and have an intelligence quotient ranging from 63 to 74 as assessed using the Binet–Kamat Test (BKT). Only children attending regular school and capable of understanding and following instructions will be included. Written informed consent will be obtained from parents or legal guardians, along with assent from the children.

Children will be excluded if they have a diagnosis of moderate or severe intellectual disability, neurological disorders such as epilepsy or neurodegenerative conditions, or psychiatric disorders requiring pharmacological intervention. Those with significant sensory impairments, including visual or auditory deficits that may interfere with cognitive assessment, will also be excluded. Additionally, children currently receiving cognitive-enhancing medications or undergoing structured cognitive therapy will not be included in the study.

Case Definition :

Borderline intellectual functioning is defined as an intelligence quotient ranging from 70 to 84 according to DSM-5 criteria[2]. However, in the present study, intelligence assessment is conducted using the Binet–Kamat Test, a standardized and culturally adapted intelligence scale for the Indian population[7]. Due to differences in test standardization and scoring, the corresponding borderline IQ range in BKT is considered to be 63–74. Accordingly, this range will be used for participant selection to ensure methodological consistency and validity.

Sample Size Estimation :

A total of 90 participants will be enrolled in the study, with 45 participants allocated to each group. The sample size has been determined based on feasibility considerations, anticipated effect size from previous studies on cognitive enhancement, and an allowance for potential attrition during the study period.

Randomization and Allocation Concealment:

Eligible participants will be randomly allocated into two groups using a computer-generated randomization sequence. Allocation concealment will be ensured through the use of sequentially numbered opaque sealed envelopes (SNOSE), which will be opened only after participant enrollment, thereby minimizing the risk of selection bias.

Blinding :

Blinding is not feasible in the present study due to perceptible differences between the formulations used in the two groups. However, to minimize potential bias, outcome assessments will be performed using standardized and validated tools, and uniform assessment

procedures will be followed for all participants.

Intervention :

Participants will be allocated into two groups. The trial group (Group A) will receive Intel-Up Gummies, a polyherbal formulation containing Mandukaparni (*Centella asiatica*), Yashtimadhu (*Glycyrrhiza glabra*), Guduchi (*Tinospora cordifolia*), and Shankhapushpi (*Convolvulus pluricaulis*). The control group (Group B) will receive Brahmi Gummies.

Both groups will receive the respective intervention at a dose of 4.3 grams per day in divided doses for a duration of 90 days. Participants will be instructed to consume the gummies regularly under parental supervision. Compliance will be monitored through parental reporting and periodic follow-up visits.

Outcome Measures :

The primary outcome measure will be the change in intelligence quotient as assessed using the Binet–Kamat Test. Secondary outcome measures will include memory performance assessed using the PGI Memory Scale, academic performance based on school records and teacher feedback.

Timeline of Assessment :

Baseline assessments will be conducted prior to the initiation of the intervention. Follow-up visits will be scheduled at regular intervals on the 31st, 61st, and 91st day of the study to monitor compliance, clinical progress, and any adverse events. Outcome assessments will be performed at baseline and at the end of the intervention period (on the 91st day) to evaluate changes in intelligence quotient, memory, and academic performance.

Data Collection :

Data will be collected using structured case record forms. Baseline demographic details, clinical characteristics, and cognitive assessment scores will be recorded. Follow-up evaluations will document changes in outcome measures over time.

Statistical Analysis :

Data analysis will be performed using appropriate statistical software. Continuous variables will be expressed as mean ± standard deviation (SD) for normally distributed data and as median with interquartile range (IQR) for non-normally distributed data. The normality of data distribution will be assessed using the Shapiro–Wilk test. Intragroup comparisons between baseline and post-intervention values will be carried out using the paired t-test for normally distributed data or the Wilcoxon signed-rank test for non-normally distributed data, while intergroup comparisons will be performed using the independent samples t-test or Mann–Whitney U test, as appropriate. The primary outcome, namely the change in intelligence quotient (IQ) scores from baseline to post-intervention, will be compared between the two groups, and secondary outcomes, including memory performance and academic parameters, will be analyzed similarly. An intention-to-treat (ITT) approach will be adopted for all analyses, and missing data, if any, will be handled using appropriate methods such as last observation carried forward (LOCF). A p-value of less than 0.05 will be considered statistically significant.

Ethical Considerations :

The study will be conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Ethical approval has been obtained from the Institutional Ethics Committee before the initiation of the study (Approval No.: PIAyR/2026/73/IEC-PIAR HR, Date: 20/01/2026). Written informed consent has been obtained from the parents or legal guardians of all participants, along with assent from the children. Confidentiality of participant data will be strictly maintained throughout the study. Participants are free to withdraw from the study at any stage without any impact on their routine medical care. The trial has been prospectively registered in the Clinical Trials Registry of India (CTRI) (Registration No.: CTRI/2026/02/104343).

Borderline intellectual functioning represents a clinically significant yet insufficiently addressed domain in pediatric neurocognitive health. Despite its relatively high prevalence, it remains under-recognized due to its intermediate position between normal intelligence and intellectual disability. Children within this spectrum frequently experience persistent academic challenges, reduced cognitive efficiency, and impaired adaptive functioning, yet often remain outside the scope of structured therapeutic interventions. This creates a substantial unmet need for targeted and evidence-based strategies aimed at cognitive enhancement.

The present study has been conceptualized to address this gap through an integrative approach that combines classical Ayurvedic principles with contemporary clinical methodology. The evaluation of Intel-Up Gummies, a polyherbal Medhya Rasayana formulation, reflects an effort to translate traditional cognitive-enhancing therapies into a modern, pediatric-friendly context.

Ayurvedic and Neurobiological Basis of Cognitive Dysfunction :

From an Ayurvedic perspective, higher mental functions are governed by *Medha*, *Smriti*, and *Buddhi*. Impairment in these faculties is described as *Medha Mandya*, often resulting from imbalances in *Doshas*, particularly *Kapha* and *Tamas*, leading to obstruction of the *Manovaha Srotas*. Medhya Rasayana drugs are believed to restore cognitive function by enhancing clarity of perception, improving retention, and facilitating efficient processing of information. Importantly, these interventions are not limited to symptomatic relief but are considered to act at a foundational level by promoting nourishment and functional integrity of neural tissues (*Majja Dhatu*). When interpreted in the context of modern neuroscience, cognitive deficits in borderline intellectual functioning can be associated with alterations in synaptic plasticity, neurotransmitter dynamics, oxidative stress, and low-grade neuroinflammation[1,12]. The pharmacological profile of the selected ingredients in Intel-Up Gummies suggests that they may collectively target these mechanisms through complementary pathways.

Pharmacological Basis of Individual Components :

Mandukaparni (*Centella asiatica*) has been shown to enhance neuronal connectivity by promoting dendritic branching and synaptic density, particularly within hippocampal regions

involved in learning and memory[3,4]. Its influence on neurotrophic factors such as brain-derived neurotrophic factor (BDNF) further supports its role in facilitating neuroplasticity and cognitive adaptability[9].

Shankhapushpi (*Convolvulus pluricaulis*) is recognized for its nootropic and anxiolytic effects, potentially mediated through modulation of cholinergic neurotransmission[10]. By enhancing acetylcholine activity, it may improve memory encoding and retrieval processes. Additionally, its anxiolytic properties may reduce cognitive interference associated with stress, thereby improving attention and task performance.

Guduchi (*Tinospora cordifolia*) contributes through its neuroprotective and immunomodulatory actions[11]. By reducing oxidative stress and modulating inflammatory pathways, it helps preserve neuronal integrity and functional efficiency. Emerging evidence linking neuroinflammation with cognitive dysfunction further strengthens the rationale for its inclusion.

Yashtimadhu (*Glycyrrhiza glabra*) provides antioxidant and anti-inflammatory benefits and may also influence neuroendocrine pathways, particularly those related to stress regulation[8]. By modulating cortisol levels and reducing oxidative damage, it may support sustained cognitive performance.

The combination of these agents in a single formulation is expected to produce a synergistic effect, wherein multiple neurocognitive pathways are modulated simultaneously. This aligns with the Ayurvedic principle of polyherbalism, which emphasizes the use of multiple drugs to achieve a broader and more sustained therapeutic effect.

Comparative Role of Polyherbal and Single-Herb Intervention :

The comparative design of this study allows evaluation of the relative efficacy of a polyherbal formulation versus a single-herb preparation. Brahmi (*Bacopa monnieri*), used as the control intervention, is a well-established Medhya drug with documented cognitive-enhancing effects, particularly in memory and learning. However, its pharmacological action is relatively specific when compared to polyherbal combinations. Intel-Up Gummies, by incorporating multiple Medhya drugs, may provide broader therapeutic coverage by simultaneously targeting multiple neurobiological pathways[13]. This comparative evaluation is expected to provide insights into the added value of polyherbal synergy in cognitive enhancement.

Role of Gummy-Based Drug Delivery in Pediatric Compliance :

An important translational aspect of this study is the use of a gummy-based dosage form. Pediatric compliance is a critical determinant of treatment success, particularly in interventions requiring prolonged administration. Traditional Ayurvedic formulations often face challenges related to palatability, leading to inconsistent adherence. Gummies offer a practical solution by improving taste, ease of administration, and acceptability among children. Improved adherence may directly influence therapeutic outcomes, particularly in cognitive enhancement therapies that require sustained drug exposure. This represents a

significant advancement in adapting Ayurvedic formulations to modern pediatric practice.

Strengths and Limitations :

The present study possesses several methodological and clinical strengths. It adopts a randomized controlled design, which enhances internal validity and allows for a systematic comparison between interventions. The use of standardized and culturally validated cognitive assessment tools, such as the Binet–Kamat Test and PGI Memory Scale, ensures reliable and contextually appropriate evaluation of cognitive outcomes. Another important strength lies in the evaluation of a novel, child-friendly dosage form. The use of gummy-based formulations addresses a critical challenge in pediatric therapeutics—poor compliance associated with conventional dosage forms. By improving palatability and ease of administration, the study incorporates a pragmatic approach that enhances real-world applicability. Furthermore, the comparative design of the study enables assessment of a polyherbal Medhya Rasayana formulation against a single-herb preparation. This provides valuable insights into the potential advantages of polyherbal synergy, an important concept in Ayurvedic pharmacology, and contributes to evidence-based formulation strategies. Despite these strengths, certain limitations must be acknowledged. The open-label design introduces the possibility of performance and observer bias, which may influence outcome assessment. Although standardized tools are employed to minimize subjectivity, the absence of blinding remains a methodological constraint. The lack of a placebo control group limits the ability to distinguish specific pharmacological effects from non-specific improvements such as learning effects or environmental influences. Additionally, cognitive outcomes in children are inherently influenced by external factors, including educational environment, parental involvement, and individual motivation, which cannot be entirely controlled within the study design. The relatively limited sample size may also affect the generalizability of the findings. Larger, multicentric studies would be required to validate the results across diverse populations.

The present study is designed to evaluate the efficacy of a polyherbal Medhya Rasayana formulation in improving cognitive function among children with borderline intellectual functioning. By focusing on a population that often remains under-recognized and underserved, the study addresses an important clinical gap in pediatric cognitive care. If proven effective, Intel-Up Gummies may offer a safe, well-tolerated, and practical therapeutic option for enhancing cognitive functions such as memory, attention, and learning ability. The use of a child-friendly gummy-based dosage form further enhances its clinical applicability by improving treatment adherence in pediatric populations. The findings of this study may contribute to the development of early intervention strategies aimed at improving academic performance and overall functional outcomes in children with borderline intellectual functioning. Additionally, it may provide a basis for incorporating Medhya Rasayana into routine pediatric practice as a supportive approach for cognitive enhancement.

Future research should focus on larger multicentric trials with extended follow-up periods to evaluate long-term cognitive

outcomes and sustainability of effects. Incorporation of objective neurobiological markers, such as neuroimaging, electrophysiological studies, or biomarker analysis, may further elucidate the mechanisms underlying cognitive improvement. Additionally, comparative studies exploring different Medhya Rasayana formulations and dosage forms could contribute to optimization of therapeutic strategies.

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