

Efficacy of IQ-BITE Chocolate compared to Smriti chocolate in enhancing Intelligence Quotient: A Study protocol for a Randomized Controlled Comparative Clinical Trial

^{1*}Muskan Patel, ²Arun Raj G R and ³Mokindan R

¹⁻³Department of Kaumarabhritya, Parul Institute of Ayurved and Research, Parul University, Ishwarpura, Vadodara - 391760 (India)

Corresponding Author : ^{*1}Dr. Muskan B. Patel

Email: muskanpatel2828@gmail.com

Phone: 9773006575

Abstract

Intelligence Quotient (IQ) is a standardized measure of cognitive ability, traditionally calculated by comparing mental age to chronological age, and defined by David Wechsler as the overall capacity to act purposefully, think rationally, and adapt effectively to the environment. Borderline intellectual functioning, characterized by an IQ range of 70–84, affects around 12–14% of the population and may lead to difficulties in academic, social, and adaptive functioning. With increasing interest in traditional approaches to cognitive enhancement, *Ayurvedic* herbs such as *Brahmi*, *Vacha*, *Aparajita*, *Yashtimadhu*, and *Shankhpushpi* are believed to support memory and learning. IQ Bite Chocolate is a novel, palatable formulation incorporating these five ingredients, and this study aims to evaluate its effectiveness by comparing it with Smriti Chocolate to determine whether it offers a advantage in improving IQ.

A randomized, open-label, double-arm clinical trial will be conducted on 100 children aged 12–13 years with borderline intelligence, assessed using the Malin's Intelligence Scale. The participants will be randomly allocated into two groups using computer-generated randomization, with 50 children in each group. Group 1 will receive IQ Bite chocolate, while Group 2 will receive Smriti chocolate for 60 days. Assessments will be carried out at baseline (0th day) and at the end of the study period (90th day).

The endpoint of the study will be the improvement in IQ score after administering IQ-Bite chocolate for 60 days, as assessed by Malin's Intelligence Scale, in 7th standard students with borderline intelligence.

^{*1,3}PG Scholars, ²Professor & HOD

This study aims to establish IQ Bite Chocolate as a safe, effective, and child-friendly intervention for improving Intelligence Quotient (IQ) in children with borderline intellectual functioning, thereby contributing to evidence-based Ayurvedic practice, while highlighting the need for further large-scale studies to validate its efficacy.

Key words : IQ Bite, IQ Bite Chocolate, Smriti Chocolate, Borderline intelligence.

Intelligence Quotient (IQ) is a standardized score derived from tests that assess human cognitive abilities, calculated by comparing an individual's mental age with their chronological age and multiplying by 100². The term intelligence, derived from the Latin word *Intelligere* meaning "to understand or recognize," is defined by David Wechsler as the global capacity of an individual to act purposefully, think rationally, and deal effectively with the environment¹⁷. Borderline intellectual functioning (BIF), characterized by an IQ range of 70–84¹, affects approximately 12–14% of the population and is associated with difficulties in learning⁶, reasoning, planning, abstract thinking, judgment, and social functioning, although it does not meet the criteria for intellectual disability. According to *Ayurveda*, the acquisition of *Jnana* (knowledge) involves the coordinated interaction of *Indriya* (sense organs), *Indriyarthas* (sense objects), *Mana* (mind), and *Atma* (soul), ultimately leading to the formation of *Buddhi*¹⁰ (intellect), which governs reasoning, decision-making, and memory (*Smriti*). *Buddhi* is influenced by both sensory perception (*Panchendriya-Buddhi*) and mental processes (*Mano-Buddhi*), and plays a crucial role in comprehension, retention, and application of knowledge. *Medhya Rasayana* drugs such as *Brahmi*, *Vacha*, *Aparajita*, *Yashtimadhu*, and *Shankhpushpi* are

traditionally known to enhance cognitive functions and intellect. IQ-BITE chocolate, formulated with these ingredients, is designed to deliver these cognitive benefits in a palatable and child-friendly form. Therefore, the present study aims to evaluate the efficacy of IQ-BITE chocolate in comparison with Smriti chocolate in improving IQ among children with borderline intellectual functioning.

Study design and settings :

This study is designed as a randomized, open-label, double-arm comparative clinical trial. The research will be conducted in the *Kaumarbharitya* OPD of Khemdas Hospital, under the Parul Institute of *Ayurved* and Research, located in Vadodara, Gujarat.

Eligibility criteria :

Inclusion criteria :

Children aged 12 to 13 years with an IQ score between 70 and 84 as assessed by the Malin's Intelligence Scale for Indian Children (MISIC), who are able to understand and follow simple instructions, presenting with mild difficulties in academics, attention, or memory recall, who are physically healthy, have normal hearing and vision or are corrected to normal, and whose parents/guardians provide consent along with the

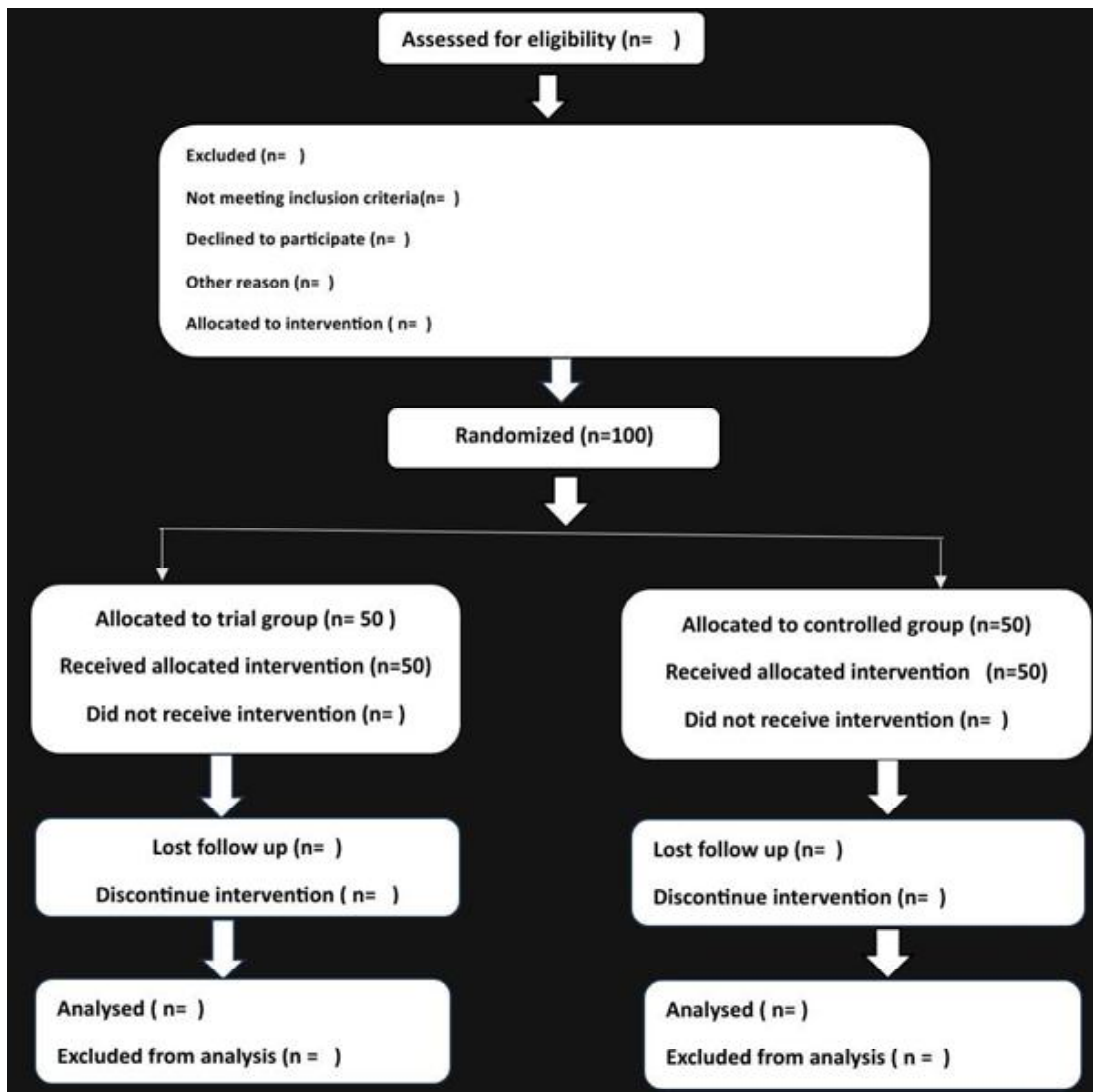


Figure 1. Proposed study plan

child's assent will be included in the study.

Exclusion criteria :

Children with an IQ below 70 or above 84, those unable to cooperate with test instructions, those diagnosed with intellectual

disability, ADHD, or autism, children with a history of seizures, cerebral palsy, or brain trauma, those with severe hearing or visual impairment, and those whose parents or the child refuse to provide consent will be excluded from the study.

Interventions (Dosage, Duration and Mode of Administration) :

A total of 100 eligible patients will be equally divided into two groups, with 50 participants in each group. Group 1 will receive 3 grams of IQ Bite chocolate twice daily for a duration of 60 days, while Group 2 will receive 3 grams of Smriti chocolate twice daily for the same duration. Both interventions will be administered orally.

Outcome measures and Timeline :

The study will begin with initial screening using the Draw-A-Man Test, followed by confirmatory assessment using Malin's Intelligence Scale for Indian Children (MISIC). Children who meet the inclusion criteria, specifically those with an IQ score between 70 and 84, will be enrolled in the study. Assessment using the MISIC scale will be conducted on the 0th day and the 90th day. Outcome measures will be evaluated based on the MISIC scores. The primary endpoint of the study will be the improvement in IQ scores after administering IQ-Bite chocolate for a duration of 60 days, as assessed by Malin's Intelligence Scale, in 7th standard students with borderline intelligence. Follow-up observations will be conducted on the 30th and 60th days after completion of the treatment.

Sample size :

Sample size will be calculated using the Cochran formula based on previous research data. minimum of 50 participants per group will be required.

Randomization and allocation concealment:

Randomization will be performed using computer-generated random numbers, and allocation concealment will be ensured using sequentially numbered opaque sealed envelopes (SNOSE).

Data collection :

Data will be collected using a predesigned Case Record Form (CRF) specially prepared for the study. Comprehensive baseline data will be collected, which includes demographic information (age, gender, socioeconomic status), clinical history, duration of illness, exposure to risk factors, and prior treatment history. Data collection will commence with initial screening using the Draw-A-Man Test, followed by confirmatory assessment using Malin's Intelligence Scale for Indian Children (MISIC). Children fulfilling the inclusion criteria, specifically those having an IQ score between 70 and 84, will be enrolled in the study. Baseline data will be recorded on the 0th day using the MISIC scale. The intervention will be administered for a duration of 60 days, and follow-up assessment will be conducted on the 90th day using the same scale. All outcome measures will be based on the comparison of MISIC scores obtained at baseline and at the end of the study period, to evaluate changes in IQ among 7th standard students with borderline intelligence.

Statistical Analysis Plan :

The collected data will be entered and analyzed using appropriate statistical software. Descriptive statistics will be applied to summarize baseline characteristics, with continuous variables like IQ scores expressed as mean $\pm$ standard deviation. Within-group

comparisons of IQ scores between baseline (0th day) and post-intervention (90th day) will be performed using the paired t-test for normally distributed data or the Wilcoxon signed-rank test if normality is not met. For between-group analysis, the mean change in IQ (difference between 90th day and baseline) will be calculated for each participant and compared between the two groups using the independent t-test or Mann–Whitney U test as appropriate. Normality will be assessed using the Shapiro–Wilk test, and a p-value of <0.05 will be considered statistically significant.

Borderline intellectual functioning (IQ 70–84) represents a substantial yet under-addressed segment of pediatric neurocognitive health, with affected children experiencing persistent deficits in attention, memory, and executive functions that impair academic performance and psychosocial development. Despite its clinical significance, this population remains largely neglected, as most existing interventions focus on intellectual disability or normal cognition. Although *Medhya Rasayana* drugs have demonstrated cognitive-enhancing potential, their clinical applicability in children is limited by poor palatability, low adherence, and insufficient evidence regarding their combined efficacy in standardized formulations. Furthermore, there is a lack of integration between Ayurvedic cognitive concepts and modern neuropsychological assessment frameworks. Therefore, the present study is needed to evaluate a novel, palatable polyherbal formulation, IQ-Bite Chocolate, and to generate comparative clinical evidence regarding its efficacy in improving intelligence quotient, thereby contributing to the scientific validation and evidence-based integration of *Ayurvedic* therapeutics in pediatric cognitive health.

Pharmacological action of individual drugs:

Medhya Rasayana drugs including *Bacopa monnieri* (L.) Pennell (*Brahmi*), *Clitoria ternatea* L. (*Aparajita*), *Acorus calamus* L. (*Vacha*), *Glycyrrhiza glabra* L. (*Yashtimadhu*), *Convolvulus pluricaulis* Choisy (*Shankhpushpi*), and *Tinospora cordifolia* (Thunb.) Miers (*Guduchi*) exert cognitive-enhancing effects through multifactorial mechanisms involving modulation of central cholinergic neurotransmission (↑ acetylcholine, acetylcholinesterase inhibition), antioxidant and anti-inflammatory neuroprotection, and enhancement of hippocampal synaptic plasticity^{3,4,5,7,9,13}. *Brahmi* and *Aparajita* predominantly improve memory acquisition and retention via cholinergic facilitation and long-term potentiation^{9,13}, while *Vacha* enhances alertness and synaptic transmission through CNS stimulation⁵. *Yashtimadhu* and *Shankhpushpi* contribute through antioxidant, anxiolytic, and neuroprotective actions that improve attention and learning processes^{3,4}, whereas *Guduchi* supports neuronal survival and plasticity via regulation of oxidative stress and intracellular signaling pathways (ERK/AKT)⁷. Collectively, these effects enhance memory, learning capacity, and cognitive performance in children, which may indirectly support improvements in intellectual functioning, though direct evidence for IQ enhancement remains limited.

IQ Bite Chocolate (intervention) :

The IQ-BITE formulation comprises five medicinal drugs with specific properties and proportions. *Aparajita* (*Clitoria ternatea*) possesses *tikta* and *madhura rasa*, *sheeta*

virya, and *madhura vipaka*, its root, leaves, and flowers are used, containing active constituents like triterpenoids, flavonoids, anthocyanins, alkaloids, saponins, and glycosides, and it is known for its *medhya* and *smrutibuddhi*-enhancing properties¹², used in a ratio of 1 part. *Brahmi* (*Bacopa monniera*) has *tikta* and *kashaya rasa*, *sheeta virya*, and *madhura vipaka*, the whole plant (*panchanga*) is utilized, with active components such as bacosides A and B and brahmimioside, and it exhibits *laghu* and *medhya guna*¹², used in a ratio of 1 part. *Vacha* (*Acorus calamus*) is characterized by *katu* and *tikta rasa*, *ushna virya*, and *katu vipaka*; its root and bark are used, containing asarone, acorin, and eugenol, and it has *kapha-vata hara*, *medhya*, and *lekhaneeya* properties¹², used in a ratio of 1/6 part. *Yashtimadhu* (*Glycyrrhiza glabra*) has *madhura rasa*, *sheeta virya*, and *madhura vipaka*; the root is used, with active constituents such as glycyrrhizin, glabridin, and liquiritigenin, and it is *tridosahara* and *rasayana* in action¹¹, used in a ratio of 1/2 part. *Shankhapushpi* (*Convolvulus pluricaulis*) possesses *madhura* and *kashaya rasa*, *sheeta virya*, and *madhura vipaka*; the whole plant (*panchanga*) is used, containing convoline, convolamine, and sterols, and it has *balya*, *ayushya*, *kaphahara*, *medhya*, *pittahara*, and *rasayana* properties¹², used in a ratio of 1 part. The synergistic combination of these five drugs acts as a potent *medhya rasayana*, targeting *manovaha srotas* and promoting *dhi*, *dhriti*, and *smriti*. The predominance of *sheeta virya* drugs helps in pacifying *pitta* and *vata dosha*, thereby stabilizing mental functions, while *Vacha* with its *ushna virya* removes *kapha*-induced obstruction and enhances cognitive clarity. Collectively, the formulation maintains

tridosha balance. Thus, due to their complementary Ayurvedic attributes and pharmacological actions, the formulation may exhibit a synergistic effect that enhances memory, learning ability, attention, and overall IQ.

SMRITI Chocolate (control) :

Smriti chocolate is a polyherbal formulation containing four Medhya drugs *Mandukaparni* (*Centella asiatica*), *Yashtimadhu* (*Glycyrrhiza glabra*), *Guduchi* (*Tinospora cordifolia*), and *Shankhapushpi* (*Convolvulus pluricaulis*). From an Ayurvedic perspective, *Yashtimadhu* possesses *Madhura rasa* and *Madhura vipaka* with *Shita guna* and *virya*; *Mandukaparni* exhibits *Tikta*, *Kashaya*, and *Madhura rasa* with *Laghu guna* and *Shita virya*; *Guduchi* has *Katu* and *Tikta rasa* with *Madhura vipaka*, *Laghu guna*, and *Ushna virya*; while *Shankhapushpi* is characterized by *Kashaya rasa* and *Ushna virya*. Pharmacologically, *Yashtimadhu* exhibits antioxidant and neuroprotective activity, reducing oxidative stress and enhancing memory; *Mandukaparni* improves cognitive function by modulating neurotransmitters and promoting neuronal growth; *Guduchi* enhances learning and memory through neurotransmitter regulation and immunomodulation; and *Shankhapushpi* acts as a brain tonic with anxiolytic and memory-enhancing effects. Clinical observations have shown significant improvements, including a 75% increase in Vitamin B12 levels and 50–60% enhancement in cognitive function (Short MoCA), along with subjective improvements in concentration, memory, and confidence. These findings suggest that Smriti chocolate is an effective cognitive enhancer, thereby justifying its use as a comparative control group in the present study⁸.

Comparative Assessment of Pharmaceutical Forms :

The present comparative study aims to evaluate whether IQ-BITE chocolate is equally or more effective than Smriti chocolate in improving intelligence quotient. The findings are expected to generate evidence-based data supporting the clinical efficacy of these formulations.

Furthermore, this study contributes to the scientific validation of *Ayurvedic* polyherbal formulations and facilitates their integration into modern clinical practice. By combining traditional knowledge with contemporary research methodology, it promotes the rational and evidence-based application of *Ayurvedic* therapeutics in pediatric cognitive enhancement.

Strength and limitation :

The present study demonstrates several important strengths. It specifically targets children with borderline intellectual functioning (IQ 70–84), a population that remains under-researched despite being highly vulnerable to academic and cognitive challenges. The use of a randomized controlled comparative clinical trial design enhances the scientific validity and reliability of the findings. Additionally, the incorporation of a novel IQ-Bite chocolate formulation containing *Medhya Rasayana* drugs represents an innovative approach that improves palatability, acceptability, and compliance among school-aged children, overcoming a major limitation associated with traditional *Ayurvedic* dosage forms. The study also attempts to bridge the gap between classical *Ayurvedic* concepts and modern neuropsychological assessment by evaluating cognitive outcomes

through standardized tools such as MISIC, thereby contributing to integrative medicine research.

The present study is limited by a relatively small sample size and a short duration of intervention, which may restrict the generalizability and long-term applicability of the findings. Moreover, the single-center, open-label design introduces the possibility of observer and performance bias. The absence of blinding may further influence the assessment of subjective outcomes.

Future implication :

Further scope of the study lies in expanding the research to multicentric settings with larger and more diverse sample sizes to improve external validity and generalizability of results. Long-term studies with extended duration of intervention and follow-up are needed to assess the sustainability of cognitive improvements. Future research should also focus on exploring the pharmacological and neurobiological mechanisms of *Medhya Rasayana* drugs using advanced techniques such as neuroimaging and biochemical markers. Comparative studies with standard nootropic therapies or educational interventions could provide deeper insights into relative efficacy. Additionally, evaluating the formulation across different age groups, varying degrees of cognitive impairment, and multiple cognitive domains such as memory, attention, and executive function would further strengthen the clinical applicability of the findings.

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