Evaluating the Impact of a Polyherbal Formulation on Core Symptoms and Cognitive Function in Children with ADHD: An Open-Label Clinical Trial

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Abstract

Attention-Deficit/Hyperactivity Disorder (ADHD) is a common childhood neurodevelopmental condition marked by inattention, hyperactivity, and impulsivity, often impairing academic and social functioning. While pharmacological treatments remain standard, they may not fully address the disorder's multifactorial nature and are often associated with side effects. Consequently, integrative approaches like herbal therapies are gaining attention. This study evaluates the clinical efficacy of a polyherbal formulation (PHF) in managing core and associated ADHD symptoms. A prospective open-label trial was conducted in 19 children (aged 3–12 years) diagnosed with ADHD, who received PHF for two months in age-specific doses, thrice daily. The formulation included *Withania somnifera*, *Glycyrrhiza glabra*, *Rauvolfia serpentina*, and *Nardostachys jatamansi*, prepared under GMP conditions. Outcome measures—ADHD Questionnaire (ADHD-Q), Vineland Social Maturity Scale (VSMS), Binet-Kamat Test of Intelligence (BKT-IQ), and Digit Span (Forward)—showed statistically significant improvements ($p < .001$) across all domains. These findings suggest PHF may offer a safe, well-tolerated, and cost-effective complementary option for managing pediatric ADHD.

Keywords: ADHD, neurodevelopmental disorder, olyherbal formulation, complementary therapy

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Attention-Deficit/Hyperactivity Disorder (ADHD) is a chronic and multifaceted neurodevelopmental condition characterized by persistent patterns of inattention, hyperactivity, and impulsivity. Typically emerging in childhood and often continuing into adulthood, ADHD significantly affects multiple domains, including cognitive performance, emotional regulation, and social functioning. The disorder is associated with altered brain development and impaired executive functioning, necessitating a multidimensional approach to both its aetiology and management (American Psychiatric Association, 2013; Cabral et al., 2020; Yadav et al., 2021). Children with ADHD frequently struggle with academic challenges especially in areas such as reading and writing as well as with behavioural self-regulation. The core symptoms of distractibility, poor impulse control, and hyperactivity often lead to academic underachievement, social difficulties, and strained family dynamics. Globally, ADHD affects approximately 8% of children and adolescents, with prevalence rates nearly twice as high in boys (10%) compared to girls (5%) (Ayano et al., 2023). Indian epidemiological studies report similar trends, with point prevalence estimates ranging from 1.3% to 28.9%, and a pooled national estimate of 7.1% (Joseph & Devu, 2019). Conventional management strategies, such as stimulant medications, have proven benefits but are associated with limitations like side effects, partial responses, and the need for long-term adherence, which can be challenging for families and clinicians alike (Kaur et al., 2020). Moreover, interventions that address both behavioural dysregulation and cognitive inefficiency simultaneously are limited in scope (Loe & Feldman, 2007). In light of these constraints, there is a growing interest in integrative and holistic approaches that offer broader therapeutic coverage with improved tolerability. Among these, herbal preparations have gained increasing attention for their ability to modulate neurological pathways through

phytochemicals that support overall cognitive and behavioral regulation (Halder et al., 2021). Several research studies with herbal formulations have shown promising effects in improving attention, working memory, neuroprotection, and behavioural control (Kaur et al., 2020; Halder et al., 2021). Their multi-targeted mechanisms may offer integrative benefits with reduced side effects compared to single-agent pharmacological treatments. The present study inquiries into the impact of a polyherbal formulation (PHF) on core symptoms of inattention and impulsivity, as well as cognitive and social functioning in children diagnosed with ADHD. By using validated tools such as the Vineland Social Maturity Scale (VSMS), Binet-Kamat Test of Intelligence (BKT-IQ), ADHD Test Performa, and Digit Span Test, the study aims to assess the clinical utility of the polyherbal compound (PHF) as a potential auxiliary therapy to intensify the outcomes in this vulnerable population. Given the novelty of the formulation and the absence of an established herbal comparator or approved standard therapy in this domain, a placebo-controlled design was deemed ethically challenging. Therefore, an open-label design was adopted for this exploratory study to allow for an initial assessment of safety and efficacy while minimizing ethical concerns related to withholding treatment in children with neurobehavioral conditions.

Objectives

1. To assess the therapeutic potential of a polyherbal formulation in managing the cardinal symptoms of ADHD.
2. To explore the formulation's effectiveness as a safe and viable herbal alternative for improving attention span, behavioural control, cognitive performance, and social functioning in children with ADHD.

Hypothesis

Polyherbal formulation may improve core symptoms of Attention Deficit Hyperactivity Disorder (ADHD), specifically inattention, impulsivity, and hyperactivity, as well as associated cognitive functions and social behaviour in children diagnosed with ADHD.

Method

Study Design

This was a prospective, open-label, interventional study conducted over a period of two months. The study aimed to evaluate the effect of a polyherbal formulation (PHF) on behavioral and cognitive functioning in children diagnosed with ADHD. As an open-label design, blinding was not employed in treatment administration; however, blinded evaluators conducted the outcome assessments to reduce bias.

Participants

A total of 19 children, aged 3 to 12 years, were recruited using a purposive sampling method from ATIDHI Vazhiyambalam (Ayurveda & Therapeutic Integration for Developmental Habilitative Intervention), Kerala, India, a center specializing in therapeutic care for children with neurodevelopmental disorders such as ADHD, SLD, and ASD. Children attending the center for behavioral or learning difficulties were initially screened by in-house therapists and referred for further assessment. Those who met the preliminary criteria were approached by the clinical team, and caregivers were provided with detailed information about the study objectives and procedures. Following this, families willing to participate were invited for formal diagnostic evaluation by licensed clinical psychologists.

Inclusion Criteria

Formal diagnosis of ADHD based on DSM-5 criteria; Age between 3 and 12 years, and Presence of caregiver-reported symptoms like inattention, impulsivity, or learning difficulties, confirmed through clinical assessment.

Exclusion Criteria

Major neurological disorders (e.g., epilepsy, cerebral palsy, intellectual disability), Severe psychiatric disorders (e.g., psychosis, autism spectrum disorder), Current use of stimulant or antipsychotic medications, and Known acute or chronic systemic illnesses (e.g., tuberculosis, malignancy, or gastrointestinal disorders).

Diagnostic confirmation was done by licensed clinical psychologists using DSM-5 guidelines.

Intervention

The PHF comprised powdered extracts of four herbs traditionally used for cognitive and behavioral regulation: Withania somnifera (Rt), Glycyrrhiza glabra (Rt), Rauwolfia serpentina (Rt), and Nardostachys jatamansi (Rhz).

The formulation was administered three times daily (6:00 a.m., 12:00 p.m., and 6:00 p.m.) after food with lukewarm water, over a duration of two months. Dosage was age-adjusted, following classical Ayurvedic guidelines as outlined in the Sarangadhara Samhita, specifically the Churna Kalpana model (*Sarangadhara, trans. 2002*).. Dosage details are provided in Table 1. The formulation was prepared under Good Manufacturing Practice (GMP)-certified conditions, as per standards approved by the Ministry of AYUSH, Government of India, ensuring quality, safety, and standardization of herbal ingredients (Ministry of AYUSH, 2018). The formulation was developed specifically for this trial by the authors based on classical Ayurvedic principles and clinical experience in pediatric

neurodevelopmental conditions. While not a pre-developed proprietary blend, the individual herbs in the formulation are widely documented in traditional texts and previous studies for their cognitive and behavioral benefits. Furthermore, similar herbal combinations are routinely employed by Ayurvedic practitioners in day-to-day clinical practice for managing neurodiversity, particularly symptoms related to attention, impulse control, and learning. The selection and combination of these herbs were further reviewed and discussed with senior Ayurvedic clinicians to ensure their appropriateness and safety for pediatric ADHD populations. No other pharmacological treatments were allowed during the study period.

Table 1

Dose of Drug in Age Groups According to Sharangadhara Samhitha

Sl. No.	Age (Years)	Dose (g)
1	3	4.5
2	4	6.0
3	5	7.5
4	6	9.0
5	7	10.6
6	8	12.0
7	9	13.5
8	10	15.0
9	11	16.5
10	12	18.0

Note. Dose is given in grams based on the age of the child. All values are rounded to one decimal place for consistency.

Tools and Measures

All participants were assessed pre- and post-treatment using the following standardized tools:

ADHD Questionnaire (ADHD-Q). A validated parent-report tool that assesses symptoms of inattention and hyperactivity (DuPaul et al., 1998).

Vineland Social Maturity Scale (VSMS). Assesses social competence across domains like communication, daily living skills, and self-help (Doll, 1953)

Binet-Kamat Test of Intelligence (BKT-IQ). A culturally adapted test measuring cognitive functioning and intelligence, including verbal comprehension, memory, and reasoning (Kamat, 1967).

Digit Span (Forward) – a subtest from Malin's Intelligence Scale for Indian Children (MISIC) Evaluates short-term auditory memory and attention span (Malin, 1969).

All assessments were conducted in a distraction-free environment by trained, blinded evaluators.

Procedure

After obtaining approval from an independent ethical committee, written informed consent was secured from the parents or legal guardians of all participating children. Additionally, administrative approval was obtained from the hosting institution (ATIDHI Vazhiyambalam).

Following eligibility screening, baseline assessments were conducted using the tools described above. Participants then received the polyherbal formulation for a duration of two

months as per the prescribed dosing schedule. This two-month period was selected based on classical Ayurvedic texts, which indicate that a minimum of two months is generally required to achieve desirable therapeutic outcomes, particularly in conditions involving behavioral and cognitive imbalances Post-intervention assessments were carried out using the same standardized tools. Throughout the study period, children were monitored weekly for compliance and adverse events.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics version 25. Paired-sample t-tests were applied to compare pre- and post-treatment scores on each outcome measure.

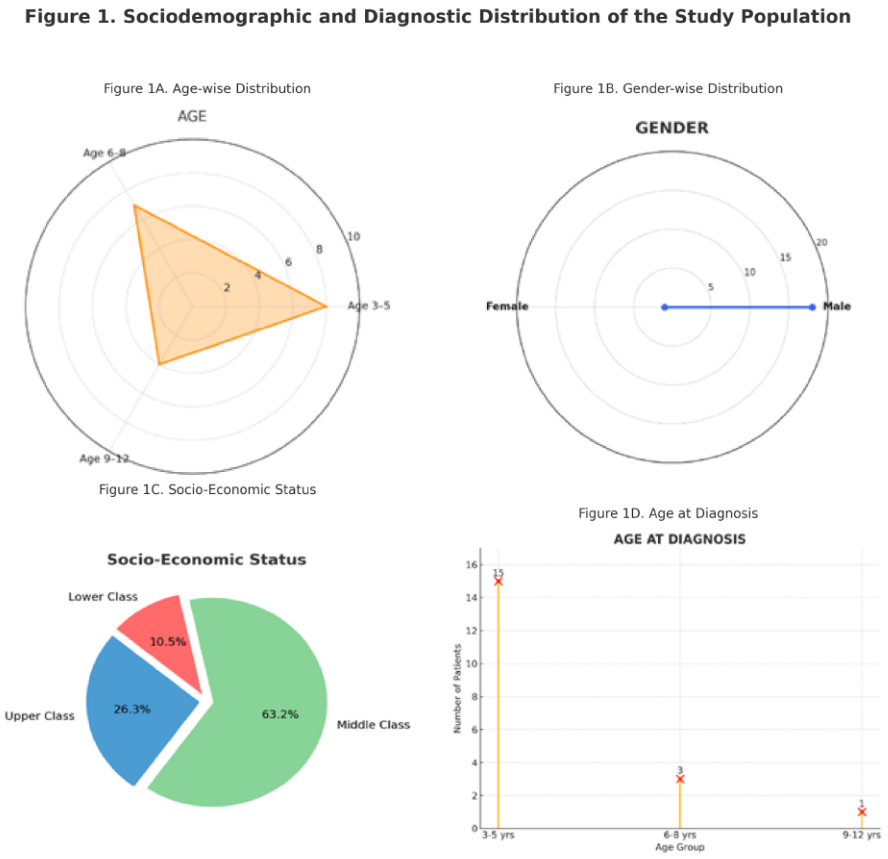
Results

Sociodemographic and Diagnostic Distribution of the Study Population

The sociodemographic profile of the study population revealed that the majority of children (42.1%) were in the 3–5 years age group, followed by 36.8% in the 6–8 years age group. Only 21.1% were aged 9–12 years. In terms of gender distribution, 63.2% of the participants were male, and 36.8% were female. Regarding socio-economic status, 57.9% belonged to the middle-income group, 26.3% to the lower-income group, and 15.8% to the upper-income group. Additionally, 47.4% of the children were diagnosed between the ages of 3 and 5 years, 31.6% between the ages of 6 and 8 and 21.1% between the ages of 9 and 12

Figure 1

Sociodemographic and Diagnostic Distribution of the Study Population



Note. Figure 1A shows the age-wise distribution of children included in the study, while Figure 1B illustrates gender distribution. Figure 1C presents the socio-economic status classification, and Figure 1D depicts the age at which diagnosis was confirmed. Together, these diagrams provide an overview of participant characteristics relevant to the clinical and demographic context.

Data relating to Outcome Measures and Statistical Findings

The effectiveness of the polyherbal formulation was evaluated by comparing pre and post intervention scores across four outcome measures: ADHD-Q (behavioral symptoms), Vineland Social Maturity Scale (VSMS), Binet-Kamat Test of Intelligence (BKT-IQ), and Digit Span Forward (attention span). Paired-sample t-tests were used to determine the statistical significance of changes observed after the two-month intervention. The results are summarized in Table 2.

Table 2

Pre- and Post-Intervention Scores of ADHD-Q, VSMS, BKT-IQ, and Digit Span Among Children Receiving Polyherbal Formulation

Measure	*Mean (BT)*	*N*	*SD (BT)*	*SEM (BT)*	*Mean (AT)*	*SD (AT)*	*SEM (AT)*	*t*	*p*
ADHD-Q Total Score	94.42	19	10.70	2.46	90.00	11.05	2.53	7.27	< .001
VSMS Score	88.26	19	18.84	4.32	94.74	17.65	4.05	4.88	< .001
BKT-IQ Score	102.47	19	11.76	2.70	108.11	12.09	2.77	7.47	< .001
Digit Span (Forward)	3.47	19	0.61	0.14	4.00	0.58	0.13	4.47	< .001

Note. BT = Before Treatment; AT = After Treatment; SD = Standard Deviation; SEM = Standard Error of the Mean; N = Number of participants. A paired t-test was used for statistical comparison.

Statistical analysis showed a significant decrease in ADHD-Q scores, $t(18) = 7.27$, $p < .001$. VSMS scores significantly increased after the intervention, $t(18) = 4.88$, $p < .001$. BKT-IQ scores also showed a significant increase, $t(18) = 7.47$, $p < .001$. A significant improvement was observed in Digit Span Forward scores as well, $t(18) = 4.47$, $p < .001$.

Discussions

This open label clinical trial examined the therapeutic effects of a polyherbal formulation (PHF) on children diagnosed with Attention-Deficit/Hyperactivity Disorder (ADHD), targeting the core symptoms of inattention, impulsivity, and hyperactivity, along with associated deficits in cognition and social functioning. The findings indicate meaningful improvements in behavioral regulation and cognitive performance, reinforcing the formulation's potential as an integrative treatment option.

The behavioral enhancements observed post-intervention suggest that the formulation may extend benefits beyond conventional symptom control. Participants exhibited more adaptive behavior patterns, better attention regulation, and reduced impulsivity, changes that align with prior evidence regarding the neurocognitive effects of herbal compounds (Lakhan & Vieira, 2010). The cognitive domains of working memory and intelligence, which are integral to academic functioning and executive processes, also demonstrated favorable responses. These improvements may stem from the combined neuroprotective, adaptogenic, and antioxidant properties of the herbs used in the formulation (Anju et al., 2019; Sarris et al., 2011).

Each herb in the PHF appears to contribute synergistically to these effects. *Withania somnifera* (Ashwagandha) possesses GABA-mimetic and adaptogenic properties that support stress modulation and attentional control (Choudhary et al., 2017). *Nardostachys jatamansi*

has documented sedative and neuroprotective effects mediated by sesquiterpenes such as jatamansone and nardosinone, which may help modulate hyperactivity and stabilize neural excitation (Panickar & Nampoothiri, 2021). *Glycyrrhiza glabra* is known for enhancing cognitive functions through its antioxidant and neurotrophic mechanisms (Singh et al., 2022), while *Rauwolfia serpentina* contains alkaloids such as reserpine that affect central dopamine levels, contributing to behavioral regulation (Kulkarni et al., 2008).

These pharmacological effects likely operate through modulation of cholinergic and dopaminergic pathways, enhancement of synaptic plasticity, and reduction of oxidative stress all implicated in the neurobiology of ADHD. The observed outcomes are thus consistent with the hypothesized mechanisms of action of these phytoconstituents.

Beyond pharmacodynamics, the psychosocial context of the study may have played a facilitative role. The open-label design, involvement of caregivers, and structured observation likely promoted greater parental engagement and treatment adherence, which are critical factors in behavioral interventions for children (Evans et al., 2014). These supportive dynamics can positively influence behavior through reinforcement, routine, and increased caregiver awareness.

The demographic profile of the sample adds another layer of interpretation. The predominance of male participants is consistent with established prevalence patterns in ADHD and related neurodevelopmental disorders (Willcutt, 2012; Loomes et al., 2017), lending external validity to the findings. Importantly, the age distribution reflects a commendable trend toward earlier diagnosis, with most children identified before the age of nine, a timeframe earlier than national norms (Malhi & Singhi, 2018; Raman et al., 2020). This may be attributed to enhanced public health surveillance, greater awareness among

caregivers and educators, and Kerala's robust health infrastructure (Ministry of Health and Family Welfare, 2021). Early identification is critical for improving long-term developmental outcomes (Dawson et al., 2010; Reichow et al., 2012).

However, the sample's socioeconomic composition largely from middle and upper-class families' raises concerns about access disparities. The cost of private care may have excluded lower-income participants, thereby introducing selection bias. This limitation underscores the need for broader, more inclusive studies to ensure findings are applicable across diverse socioeconomic strata (Emerson, 2004; Saxena et al., 2006).

Despite the promising outcomes, this study has several methodological limitations. The small sample size limits statistical power and generalizability. The short duration of the intervention prevents assessment of sustained efficacy and long-term safety. The open-label nature of the trial, while ethically suited for pediatric populations, introduces potential observer and expectancy biases. Given the absence of an established herbal comparator and the ethical concerns surrounding placebo use in children with neurobehavioral disorders, an open-label design was adopted as an initial step to explore therapeutic effects. This approach enabled early-phase evaluation of efficacy and safety without withholding treatment from participants. Additionally, compliance with Ayurvedic interventions in pediatric cohorts can vary, potentially affecting treatment consistency.

To build upon these preliminary findings, future research should prioritize randomized controlled trials (RCTs) with blinded designs and larger, more diverse participant pools. Longitudinal studies with extended follow-up are essential to confirm durability and safety. Disaggregating the formulation to evaluate individual herb contributions could enhance understanding of specific mechanisms. Biomarker-based assessments may also help

in tracking objective neurobiological changes and facilitate more targeted, personalized treatment protocols.

In conclusion, this study provides encouraging preliminary evidence supporting the potential of a polyherbal formulation in improving core symptoms of ADHD and enhancing cognitive and social functioning. The multidimensional benefits observed are suggestive of a broad-spectrum mechanism involving neurochemical modulation, synaptic regulation, and stress adaptation. Given its natural origin, favorable tolerability, and cultural acceptance, the formulation offers promise as a complementary or adjunctive option for pediatric ADHD management. However, larger and more rigorous trials are warranted to confirm efficacy, evaluate long-term outcomes, and assess the formulation's potential for integration into mainstream clinical practice.

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