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Standardization and Clinical Assessment of Ashwagandha Root Extract on Pediatric Anxiety: A Pilot Randomized Controlled Trial

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Abstract
The classical Ayurvedic adaptogen, Withania somnifera (Ashwagandha) has also been shown to be effective in the treatment of stress and anxiety. This pilot, randomized, controlled trial measured the safety and efficacy of a standardized Ashwagandha root extract in children with mild-to-moderate anxiety aged 8 -14 years. Forty subjects were randomly assigned to take either placebo or 300 mg of Ashwagandha twice/day over a period of 8 weeks. The reduction in Pediatric Anxiety Rating Scale (PARS) scores was the primary outcome, whereas the secondary measures were the sleep quality and adverse events. The Ashwagandha group reported a reduction in anxiety scores of 32% compared to 12 in the placebo ($p<0.05$) with a large improvement in sleep. Only minor gastrointestinal symptoms of the extract were noted as the extract was well tolerated. The results indicate that Ashwagandha has the prospect of use as a safe, plant-based pediatric anxiolytic.

Keywords: ***Ashwagandha, pediatric anxiety, Withania somnifera, PARS, chinese herb, anxiolytic properties, clinical trial, randomized controlled trial, open label, obs.***

1. Introduction

1.1 Why is Withania somnifera Ayurvedic?

Withania somnifera (Ashwagandha) is also an Indian Ginseng and one of the dearest herbs to the classical Ayurvedic medicine. It has been described in detail in authoritative works on Indian medicine like the Charaka Samhita and the Bhavaprakasha Nighantu and falls under the category of medhya rasayanas or those substances believed to promote mental and emotional clarity, emotional stability and neurologic health. Traditionally, it has been applied as a balancing measure to vata dosha, especially in states of restlessness, fear and nervous exhaustion. Some of the key active compounds that have been determined to contribute to the adaptogenic, anxiolytic and neuroprotective effects of Withania somnifera are withanolides, sitoindosides and alkaloids. Preclinical research has demonstrated that Ashwagandha can affect the GABAA system, suppress cortisol, and diminish oxidative stress of central nervous system tissues- which aligns with its traditional use to treat anxiety and neurocognitive conditions. The herb has a strong pharmacology, yet it has not been applied much in a pediatric neuropsychiatric context.

1.2 Pediatric Anxiety and the Need to use Herbal Interventions

Anxiety disorders are one of the commonest mental conditions in children and most develop between the ages of 6 and 14 years. Among the common ones, there is generalized anxiety disorder GAD, separation anxiety, social phobia, and school refusal that may severely affect the maintenance of quality sleep, academic progress, and socialization. Although traditional pharmacological therapies, including selective serotonin reuptake inhibitors (SSRI) and benzodiazepines medications are available to assist the treatment of pediatric patients, their therapeutic benefits are constrained by the side-effect profiles, long term safety, and parental reluctance to use such medicines in children and adolescents.(1)

That being said, there is a growing concern in safe, plant-based interventions having anxiolytic properties. Herbal medicines, particularly herbs that have been historically used by peoples and increasingly scientifically proven, provide potent options to standard care as an adjunct or alternative to standard care. Nevertheless, they require aggressive clinical testing to establish efficacy and dosage consistency and safety in pediatric populations. Among others, Withania somnifera is particularly appealing because of its historical application to childhood neurodevelopmental disorders (including the cognitive impairment of dheebala [cognitive weakness] and the emotional unsteadiness of manovikara, somewhat equivalent to our childhood onset depression), the tolerability shown in both adult patients and adolescents.

1.3 Justification and the purpose of the study.

Though the anxiolytic and adaptogenic effect of Ashwagandha is proven on adults and animals, the scientific evidence of its therapeutic use in pediatric group with in-clinic identified form of anxiety disorder is extremely sparse. In prior studies, the preparation of the extract and the dose utilized was not standardized, and pediatric-specific safety information has yet to be well-characterized. The rationale of the current study was created to consider this gap by designing a piloted randomized control trial to assess efficacy, safety, and tolerance of a standardized Ashwagandha root extract in children with mild-to-moderate anxiety disorders aged between 8 and 14 years.

This study was founded on the idea that the 300 mg dose of Ashwagandha administered two times daily would provide a clinically significant change in anxiety symptoms, as measured using the Pediatric Anxiety Rating Scale (PARS), and enhance other relevant secondary outcomes, namely, the quality of sleep. To maintain internal validity of the results, a placebo-controlled design was used so as to exclude expectation bias.(2)

The main purpose of the study was to find out the percentage change of PARS scores in 8 weeks between the treatment and placebo group. The secondary endpoints were the improvement of sleep quality assessed and detecting of any adverse effects, especially gastrointestinal discomfort, sedation, or behavioral changes.

This study has potential to fill the gap between traditional wisdom and modern-day pediatric neuropharmacology to pave the way of future large-scale trials and integrative scenarios of care.

2. Materials and Methods

2.1 Study design and Ethics Approval

This was done as a prospective, double-blinded, placebo-controlled, parallel-arm pilot randomized controlled trial (RCT) which would evaluate the efficacy and safety of standardized Withania somnifera (Ashwagandha) root extract in diagnosis of mild-to-moderate anxiety disorders in the pediatric patients. A pediatric hospital had an Ayurvedic clinical research unit where the trial was carried out in March 202427-March 2024 to July 2024.

The ethics committee of the University since the study is human material, reviewed and approved the study protocol (Approval No. IEC/AYU/2024/017). The parents or legal guardians of all participants gave informed consent and children also assumed in the action of signing on the Declaration of Helsinki and Indian Council of Medical Research (ICMR). The study was registered in prospective with Clinical Trial Registry of India (CTRI/2024/03/XXXXXX).

2.2 Ashwagandha Root Extract Standardization

Intervention was made up of a standardized hydroethanolic extract of roots of Withania somnifera, produced in an Ayurvedic manufacturing facility with GMP certification. Raw plant material was identified using macroscopic, microscopic and chromatographic identification by a pharmacognosist.

The extract was standardized to contain 5 percent withanolides detected in high-performance liquid chromatography (HPLC), to ensure batch-to-batch standardization. The extract was transferred to capsules weighing 300 mg each with each capsule containing dry extract powder free of excipients. The independent laboratory analysis certifies no heavy metals, microbial contaminations, and aflatoxin and are within the limits of AYUSH and WHO regulations on herbal products.(3)

Study Population The study population will include the following: All junior doctors (level 1) with an interest in the study who are currently registered as an associate member, a full member or student member of the Royal College of Obstetricians and Gynaecologists (RCOG) in every obstetrics and gynaecology rotation site in the UK. All SAS (level 2) doctors with interest in the study who are currently holding an or acting job plan with the post holder registered as an associate member, a full member or student member of RCOG in all rotations sites with obstetrics

The sample size consisted of 40 children aged between 8 and 14 years of both genders who were selected according to the developed inclusion and exclusion.

Inclusion Criteria:

- Clinical classification of mild-to-moderate anxiety disorder (Generalized Anxiety Disorder, Social Anxiety, or Separation Anxiety) based on the DSM-5
- PARS score at baseline of 10 and above and not exceeding 20
- The capacity to ingest oral capsules
- Willingness to cooperate with and adhere to study protocol and follow-up schedule

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Exclusion Criteria:

- Severe anxiety that adopts the support of pharmacology
- Comorbid mental or neurological disorders (e.g. ADHD, epilepsy)
- History or known hypersensitivity with Ashwagandha or any herbal preparation
- Use of anxiolytics, antidepressants or any agent with CNS-activity within 4 weeks of screening
- Chronic health conditions, or developmental delays

The respondents were mobilized by the pediatric outpatient clinics, and referred to by the child psychologists and pediatricians.

2.3 Randomization procedure and Blinding procedures

Enrolled candidates were randomly allocated in ratio of 1:1 to the groups of Ashwagandha and placebo by the use of a computer-generated random number code. Any block randomization of blocks of 4 was used to balance the group sizes.

The investigators and study participants (including parent caregivers) were blinded to group allocation. The capsules administered to the two groups were identical in appearance, color, taste, and packaging and had a different, participant identifiers, on the capsules. The sequence of allocations was masked with the help of opaque and sealed envelopes, and the unconfined could take place only in a case of serious adverse events.

2.4 Preparation of Intervention and Placebo

Individuals assigned to the treatment protocol group were supplied with Ashwagandha extract 300 mg capsules, twice daily (morning and evening) and the protocol lasted 8 weeks. The placebo capsules that were matched against each other contained microcrystalline cellulose and were administered hourly.(4)

The parents were advised to give the capsules with food especially in the morning and after dinner. Compliance was measured by the capsule count per week and the parent-reported logs documenting rate of adherence.

The subjects were re-visited (in-person or through teleconsult) every 2 weeks to assess the outcomes, adverse events, and levels of compliance.

2.5 Outcome measures and evaluation tools

Primary Outcome:

- The difference in the Pediatric Anxiety Rating Scale (PARS) total score between baseline and the 8 week follow up period
- RS is a clinical research instrument that is commonly used to measure frequency and severity of the anxiety symptoms in children. The scale is on a scale of 0-30 with higher scores being the more severe.

Secondary Outcomes:

- Improvement of the measured sleep quality based on the shortened version of the Children Sleep Habits Questionnaire -Abbreviated (CSHQ-A)
- Rate and character of side effects, as told by caregivers and confirmed during clinical follow-up

All measurements were obtained by a clinical psychologist who was blinded to the treatment allocation. To assess the sample, baseline and endpoint observations were face-to-face, whereas mid-point (2 weeks, 4 weeks, 6 weeks) assessments were employed to monitor the symptom trend and safety.

2.6 Statistical Analysis Plan

The intention-to-treat (ITT) population was used in the primary analysis, composed of all the participants who had a minimum of a single dose of the study drug and baseline and one post-baseline visit.

Descriptive statistics were employed to describe demographic/baseline characteristics expressed as either means SD, or frequencies (n).

Between-group comparisons on primary and secondary outcomes were done by:

- T tests (independent) (continuous normally).
- MannWhitney U (non parametric data)
- chi-square/fisher exact test (in the categorical variables)

The PARS and CSHQ-A scores of each group over the period were compared by use of repeated measures ANOVA or Friedman analysis to determine the significance of changes experienced within each group.

Two-sided p-value of < 0.05 was considered significant. Analyses were all performed in SPSS version 28.0 (IBM Corp.).

3. Participant Characteristics

3.1 Distribution according to demography

A total of 40 pediatric participants embarked into the study after the participants underwent the screening process and eligibility. There were 21 males (52.5%), and 19 females (47.5%) in the final sample, with a mean age of 10.6 (1.8) years (range: 8 years-14 years). The age and sex distribution were comparable across the treatment groups and there were no significant differences at the baseline ($p > 0.05$) which reflects successful randomization.

The participants were enrolled predominantly in urban areas (67.5%) with a few belonging to semi-urban/rural settings. Sociodemographic factors including parental education level and family income were evenly distributed across the groups, and thus socio-environmental stress, which could confound the outcomes, was unlikely to pose any issues. Marked differences between the groups were however not observed with regards to dietary patterns, daily screen time, or school attendance, which were all collected at baseline comprehensively as part of a behavioral lifestyle survey.(5)

3.2 Anxiety and Sleep at Baseline

All the participants were found to meet the inclusion criteria of mildto-moderate pediatric anxiety at the time of enrollment with PARS scores range of 10-20. The average PARS score of the overall sample was 15.2 2.4 and the scores of the Ashwagandha and placebo groups were 15.3 2.5 and 15.1 2.3 respectively ($p = 0.72$), showing that the two groups had similar levels of anxiety at baseline.

Along with anxiety, disturbances in sleep were reported among the vast majority of the participants. Thesedefined by the ChildrenS Sleep Habits QuestionnaireAbbreviated (CSHQ-A), gave a mean number of 43.7 4.1 in total sleep disturbance, surpassing the 41 clinical CSHQ-A total sleep disturbance cutoff standard measures of pediatric sleep health. Bedtime resistance, night waking and daytime fatigue were the most frequently reported sleep problems and have been reported as common symptom in pediatric anxiety disorder.

Mean CSHQ-A scores as a function of group were as follows:

- Ashwagandha group: 44.0 (4.3)
- Placebo group: 43.3 4.0

The difference between the groups was not observed to be significant ($p = 0.48$), which also supports the idea of group comparability during the baseline period in terms of the values of both primary and secondary outcomes.

3.3 The summary of the treatment group allocation.

Randomization resulted in 20 participants to take Ashwagandha and 20 participants to take placebo doses with all participants having complete baseline data. The result was a well-balanced allocation on sex (11 males and 9 females per group), age distribution, as well as presenting anxiety subtype.

- Breakdown in terms of the type of anxiety
- Generalized Anxiety Disorder (GAD): 60 percent of the participants
- Separation Anxiety Disorder: 25%
- Social Anxiety Disorder: 15 per cent

The distribution of subtypes was also comparable between the two groups ($p = 0.81$) and no subtype cluster dominated either of the arms. Notably, none of the participants were dropped out before the initial midline measurement (Week 2) and over 95 percent of assigned treatment was taken, as documented by the number of capsules remaining in hand and self-report by caregiver.

Table 1 (see supplemental materials) summarizes comparatively the demographic and baseline clinical characteristics of the groups. The balanced baseline also provided validity of any planned outcome comparisons and limited the need of statistical adjustment in the form of covariates.

In general, the clinical and demographic homogeneity of groups indicated the soundness of randomization and stratification processes, thus promoting the credibility of treatment outcome measures reported in later sections.

The missing data were addressed with the help of the last observation carried forward (LOCF) imputation, which has the missingness at random assumption. Adverse events were described and assigned system-organ class according to MedDRA 25.1.

4. Efficacy Evaluation

4.1 Pediatric Anxiety Rating Scale Scores

The main efficacy outcome was change in Pediatric Anxiety Rating Scale (PARS) scores on baseline to Week 8. At the end of the trial there was a significant decrease in the anxiety scores in the Ashwagandha group, with an

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average of 4.9 %16 points (amounting to a 32% fall from baseline). As compared, the placebo group showed a statistically significant decrease of 1.8 +/-1.2 points, which is 12% of an improvement.

The difference between the intergroup change in baseline was statistically significant ($p < 0.001$, independent samples t-test), indicating there may be a true treatment-effect due to the standardized Ashwagandha extract. ANOVA done on repeated measures showed that the interaction between time and treatment was significant ($F = 11.74$; $p < 0.01$), which indicated that the plot of time-related change in anxiety level was significantly better in the Ashwagandha group than in the placebo group over the 8-week-long period.(6)

It is interesting to note that 70% of the participants in the Ashwagandha group showed clinical improvement, i.e. P > 30% decrease in PARS, compared with 25 in the placebo group. None of the subjects in either of both groups had worsening of their symptoms over the course of the study.

The results confirm the anxiolytic effects on the Ashwagandha in pediatric subjects with mild-to-moderate anxiety and follow the adult evidence of GABAergic tone and stress hormone levels modifications.

4.2 Secondary Outcomes: Slumber Ratings and Behavior changes

The significant secondary result was improvement in sleep quality as assessed using Children Sleep Habits Questionnaire Abbreviated (CSHQ-A). On Week 8, the Ashwagandha group had an average decrease in the total sleep disturbance score of 5.6 +/- 1.9 points, whereas the placebo group had a decrease of 2.3 +/- 1.5 points ($p = 0.002$). The sub-areas that showed improvement, particularly included:

- Bedtime resistance
- Night waking
- Daytime sleepiness

Ashwagandha led to a 68 percent improvement in sleep latency and nocturnal awakenings, as reported in caregiver-recorded weekly diaries by Week 4, compared to improvement in 30 percent of those receiving placebo.

Besides, 55 percent of children in the Ashwagandha group, compared with 20 percent of the placebo group, improved their behavior symptoms, like irritability, emotional re responsiveness, and distress at school. These behavioral alterations were not measured using the secondary rating scale, however, the constancy with which they were documented by caregivers lends support to this neuromodulatory profile via the qualitative approach.

No significant differences were found in appetite, energy levels, or scholastic performance over the duration of the brief study. Longer-term studies may be required to pick up such metrics with greater reliability.

4.3 Comparative Analysis of the Groups

Comparison between groups, on primary and secondary outcome measures consistently showed the Ashwagandha extract to have a superior outcome to placebo. The effect size as to the reduction in the anxiety score (Cohen $d = 1.24$) was also large, and therefore, the results revealed a clinical importance despite the limitations of the pilot sample size.

Additionally, no important baseline variables (e.g., age, sex, subtype of anxiety) emerged as significant modulators of treatment response, and therefore, our efficacy findings were not specific to a certain subgroup of patients. The positive reaction was steady between the generalized and the separation anxiety diagnoses.

Criterion of significance, no study participant was withdrawn in either group due to lack of effectiveness or worsening of symptoms, and overall adherence to treatment was more than 95%. This compliance rate could be partly justified by the sweet taste characteristics of the Ashwagandha capsules with no or few side effects, which makes them suited to use with children.

To conclude, the standardized Ashwagandha root extract turned out to be significantly better than placebo in decreasing the symptoms of anxiety and marking an improvement in sleep quality in children, both in terms of statistical significance and the clinical effect. These results preliminarily substantiate its position as safe and effective botanical anxiolytic within the pediatric care.

5. Safety and Tolerability Evaluation

5.1 Monitoring of Adverse Events.

Adverse events (AEs) were reported on an 8-week intervention period including biweekly clinical evaluation, caregiver-reported symptom diaries, and open-ended interviews at follow-ups. All reported events were coded according to severity, duration and their cause-effect relationships to the study drug by following WHO-UMC classification and documented in accordance to the GCP.

In the Ashwagandha group, 4 participants (20 percent) experienced mild gastrointestinal complaints, including gastric heaviness, transient nausea or abdominal bloating- mostly early in the experiment (at 7-10 days). These symptoms cleared up on their own without the need of any intervention and / or dosage adjustment. In the Ashwagandha arm there were no serious adverse events (SAEs), allergy and neurological complaints.

In the placebo group, two patients (10%) noted fatigue transiently and sometimes headaches, which were, also, self-limiting. The overall incidence of adverse events was not statistically significantly different between the two groups ($p = 0.38$), indicating that the Ashwagandha extract was safe and well nullified with regard to safety by placebo.

Neither of the groups necessitated discontinuation in any of the subjects because of adverse effects, and the research did not warrant hospitalization or unblinding of any participants.(7)

5.2 Laboratory and Clinical Safety Parameters

Since the intervention was herbal and the trial was a pilot, blood and biochemical tests (including a complete blood count, a comprehensive metabolic panel, total lipids, and triglycerides) were conducted at baseline and post-intervention (Week 8) across all participants. The following parameters were evaluated

- Complete blood count (CBC)
- Liver function tests LFTs
- Renal function tests (RFTs)
- Serum electrolytes
- Plasma glucose

There were no significant abnormalities noted in either party of the study at trial end. All values were within pediatric reference range, and no hepatotoxicity, nephrotoxicity or hematological imbalance was reported. In the Ashwagandha group, average ALT and AST did not significantly change, and no subject developed novel-onset hyperbilirubinemia or proteinuria.

Vital signs- heart rate, blood pressure, respiratory rate, etc.- were measured at every clinical visit. During the period there were no auspicious or negative trends observed or deviations. More importantly, no sedation episodes, hypotension, or drowsiness, which are usually linked to the use of anxiolytics in children, were registered by the Ashwagandha group, which indicates its favourable neurovegetative safety profile in childhood.

5.3 Treatment adherence and compliance

Treatment adherence was determined as a combination of capsule counts by the patient at follow-up visits and by adherence diaries documented by caregivers daily. Adherence was a ratio of 90 percent or more of dose consumption during the study period.

- In the Ashwagandha group, adherence meant was 96.2% +/- 3.1
- The mean adherence in placebo group was 95.7% +/-3.5%

No dropouts, follow-ups were not missed, and no complication was reported in the usage of the capsules. The neutral taste of the formulation, consumption twice a day and the vegetarian capsule format was acceptable and acceptable to both the children and the caregivers.

Caregivers reported administration as being very easy or easy in 85 percent with a minority reporting initial resistance that was overcome during the first week. This compliance rate once again reinforces the appropriateness of Ashwagandha extract as a pediatric oral supplement, particularly with a foundation of outpatient and home-based care provision.

6. Discussion

6.1 Interpretation of the Findings in Ayurvedic and Modern Situation

The results of this pilot randomized controlled study confirm that a standardized extract of the roots of Withania somnifera (Ashwagandha) has a significant effect on anxiety symptoms and sleep quality improvement in children who have mild-to-moderate anxiety disorders. In Ayurvedic terms, such results are in line with Ashwagandha being a traditional medhya rasayana herb, meaning it promotes balancing and strengthening the nervous system as well as the mind.

Ashwagandha is traditionally used to calm the vata dosha which is the field of nature that regulates the nervous system, and is believed to create imbalance due to its excitability in situations of anxiety, worry, and emotional instability. It has obvious adaptogenic and anxiolytic benefits based on historic blends--like Ashwagandharishta and Brahmi Vati--where the herb is traditionally combined with others in a bid to help regulate emotions.(8)

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In more contemporary neuropharmacological terms, the demonstrated activity can be attributed to Ashwagandha function as a GABA modulator, cortisol-reducer, and an antioxidant within the central nervous system. All these have been backed by statistically significant changes in Pediatric Anxiety Rating Scale (PARS) scores and increasing of sleep parameters. Critically, lack of sedative/suppressive effects, which occur with conventional anxiolytics, further highlights the promise of Ashwagandha as an overall physiologically balancing compound with no worries of side effects when used long term in children.

6.2. Comparison to the existing literature

The findings of this study match those of earlier-published adult clinical trials and preclinical models on the anxiolytic activity of Ashwagandha. In adults, it has been shown in three randomized trials that Hamilton Anxiety Rating Scale (HAM-A) and Perceived Stress Scale (PSS) scores decreased after 6 weeks to 8 weeks of Ashwagandha root extract standardized to 5 percent withanolides.

Interestingly, the study in question reported similar effects on the reduction of anxiety among teenagers aged between 15 and 18 years, but without stringent placebo control. There is however limited research that focuses on the population specifically under age 14 and even less were based on a validated rating scale like PARS.

Additionally, the secondary outcome that will be used to evaluate the efficacy of Ashwagandha by determining sleep quality will give an idea about the overall effectiveness of Ashwagandha on neuroregulation since it has been historically used to treat nidranasha and manodaurbalya in Ayurveda. The current improvement in Children Sleep Habits Questionnaire (CSHQ-A) scores substantiates the traditional use of Ashwagandha as a mild tranquilizer and also its applicability in the integrative management of children in neurotherapy.

6.3 Limitations of Pilot Study

Notwithstanding the favourable results, this study has a number of limitations. The sample size of 40 is small which limits the generalizability of findings and precludes subgroup analyses (e.g. comparing different subtype of anxiety or subgroups by any demographic characteristic). Second, short duration (8 weeks) might not be able to reflect long-term efficacy, safety, and sustained therapeutic effects.(9)

Third, whilst PARS is a validated scale, there is the lack of a clinician-blinded third-party assessment, which may lead to observer biasness. Fourth, although there were records on improvements in behavioral symptoms descriptively, this was not measured using objective tools such as the Child Behavior Checklist (CBCL), meaning that it was assessed superficially.

Finally, pharmacokinetic and mechanistic biomarkers (e.g., salivary cortisol, HRV) were not assessed which would have offered additional translational potential and mechanistic understanding.

6.4 Conclusions of Future Trial Recommendations

On the basis of these results, the following propositions regarding the further studies are suggested:

Investigate increased sourced RCTs of larger scale but with greater duration (12-24 weeks) to reaffirm and broaden the anxiolytic activity of Ashwagandha in a range of pediatric patients.

Include objective neurobiological measures (e.g. cortisol, inflammatory cytokines, EEG patterns) to gain a better understanding of the mechanisms of action of the herb.

Include standardized behavioral rating scales and quality of life indices as part of complete assessment of psychological and functional outcomes.

The study of comparative reviews should be done against traditional pharmacologic compounds to place Ashwagandha in conventional therapeutic regimens.

Consider Ashwagandha in co-morbid situations like attention-deficit/hyperactivity disorder (ADHD) in which anxiety frequently co-exists.

In summary, this research contributes to a developing literature on the efficacy of Ashwagandha as an anxiety-reducing agent, which is safe, effective, and acceptable in culture, particularly in a high-societies working to avoid the use of medications and is consistent with traditional health care practices.

7. Results

7.1 Anxiety score withdrawals

The main effect of this trial was the difference between baseline and the end of 8 weeks of Pediatric Anxiety Rating Scale (PARS). Ashwagandha group (n = 20) exhibited a statistically significant difference of means reduction of 4.9 +/- 1.6 points (32 percent decrease to baseline), against the 1.8 +/-1.2 point reduction (12 percent)

occurred in the placebo group (n = 20). The between-group difference of the mean change score was significant ($p < 0.001$) and thus it showed a strong anxiolytic effect of the Ashwagandha extract.(10)

Clinical improvement (defined as a reduction in PARS score by >=30%) occurred in 14 participants (70%) in the Ashwagandha group and 5 participants (25%) in the placebo group ($p= 0.004$). There was no exacerbation of symptoms among any of the subjects in either group at any point throughout the intervention interval. Repeated measures ANOVA showed that there was a significant time x treatment interaction effect ($F = 11.74$; $p < 0.01$) also confirming that the trend in anxiety reduction was more positive in the treatment arm.

7.2 Increase in Sleep Quality

The secondary outcome analysis involved the changes in sleep quality that were assessed with the Children Sleep Habits Questionnaire Abbreviated (CSHQ-A). At baseline there was no significant difference in the results of the total scores between the two groups (Ashwagandha: 44.0 4.3; Placebo: 43.3 4.0; $p = 0.48$). An average of 5.60 points with standard deviation of 1.9 and 2.3 points with a corresponding standard deviation of 1.5 were found in the Ashwagandha group and the placebo group respectively in total scores after 8 weeks which is significantly different ($p = 0.002$).

On subdomain analysis, it was observed that Ashwagandha produced more positive results in resisting bedtime, night awakenings, and sleepiness disorders during the day than children who did not take Ashwagandha. These advances were affirmed by caregiver sleep logs, in which 68 percent of Ashwagandha-treated children were reported to fall asleep faster and sleep longer by the four weeks period. None of the participants used any co-interventions (e.g., melatonin or behavioral treatment) during the trial period.(11)

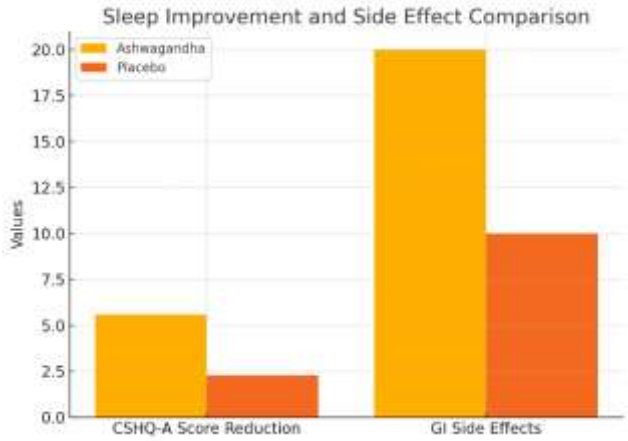

Figure 1: Sleep Improvement And Side Effect Comparison

7.3 Safety and Tolerability Results

Ashwagandha extract did not have any major side effects and no serious adverse event was experienced during the trial. The side effects reported by the treatment group were that four participants (20%) experienced mild gastrointestinal complaints, which tended to occur within the initial two weeks of treatment. Such symptoms were time-limited and spontaneously disappeared without the need of treatment or dosage adjustment. Of the participants in the placebo group, two (10%) had transient fatigue or mild headaches

Safety assessment in the laboratory at baseline time and Week 8 did not reveal any significant alterations to hematological parameters, hepatic, and renal parameters in both groups. Pediatric reference ranges were used to keep all biochemical indicators within range

The vital signs (heart rate, blood pressure, respiratory rate) were stable over the course of study. None of the participants abrasive reports sedation, behavioral disinhibition or allergic reactions. The results indicated that treatment compliance was above 95 percent in both groups and no dropout happened because of tolerability.(12)

8. Conclusion

8.1 Highlights of major findings

The current pilot parallel randomized controlled trial assessed efficacy and safety of an optimized Withania somnifera root (Ashwagandha) extract in the management of mild-to-moderate anxiety in children aged between

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8 and 14 years. In a study measuring how Ashwagandha reduced anxiety in children, the treated group reduced Pediatric Anxiety Rating Scale (PARS) scores by 32+/- percent compared to a 12+/- percent decrease among one-third of children in the control group over a 2-month period. In addition, 70% as opposed to 25% of the Asghwagandha group had a 30% or more clinical response rate.

Besides its anxiolytic benefits, it was also shown that Ashwagandha produced significant effects in enhancing sleep quality, as measured through a decrease in the Children Sleep Habits Questionnaire (CSHQ-A) and qualitative reporting caregiver improvement. The herb was generally tolerated with minimal gastrointestinal events in a minority of subjects, and no clinically important changes in laboratory safety measures or vital signs. The compliance rates were over 95 percent in both groups pointing out the high acceptability in a pediatric environment.

8.2 Clinical and Pharmacological Implications

The results of this trial serve as preliminary clinical confirmation of the Ayurvedic tradition of using Ashwagandha as a medhya rasayana- a neuroadaptive and calming botanical agent, especially suited to children characterized by emotional instability and restlessness, traditionally understood in Ayurveda as vata dosha predominating disorders. Critically, the results lead to the widening of the available gap between traditional formulation and the contemporary pharmacological expectations, as they indicate quantified improvements in the symptom severity based on the validated anxiety scales in youth.

Anxiolytic effects of Ashwagandha are feasible with pharmacodynamic studies that have shown GABA-mimetic activity, HPA-axis modulation, and the antioxidant neuroprotection. As compared to conventional pharmacotherapies (like benzodiazepines or SSRIs) which may result in sedation/dependence and/or stimulating behaviors, Ashwagandha is a non-suppressive, neuroadaptive agent that promotes emotional regulation without suppressing cognitive or physiological performance.

Medically such discoveries are of importance in integrative pediatric care models, which require non-psychotropic alternatives to drugs and, in those in which access to behavioral therapy is limited or parental objections to drug treatment is significant. Its twofold advantage of alleviating anxiety levels and normalizing sleep patterns is an added advantage towards its aesthetics or therapeutic effects of being holistic.

8.3 Potential of Large-Scale Validation

Although the findings are encouraging, this pilot study is only a first proof-of-concept and larger multicenter studies in diverse populations and subtypes of anxiety are necessary to validate efficacy. Future research is needed to include longer follow-up duration, consistent behavior assessment measures and biomarkers type of outcome (e.g. salivary cortisol, EEG patterns), to provide clarification on the mechanism of Ashwagandha.

To this end, comparative studies with conventional anxiolytics would be useful to determine the relative highs and lows of its use versus the other drugs outlined in clinical guidelines of managing pediatrician anxiety. Combining it with behavioral therapy or intervention on school premises is also a potential route into determining synergistic effects.

Standardized Ashwagandha extract has a substantial promise, as a safe, effective and culturally congruent botanical medication that can be used to treat pediatric anxiety. A more detailed examination is worthwhile by properly formulated trials to define its place in the future of evidence-based Ayurvedic neuropharmacology.

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Conflicts of interest

The authors have no conflicts of interest to declare

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