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# Clinical study to evaluate the efficacy of Mentosoothe Compound in the management of Attention Deficit / Hyperactivity Disorder

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## ABSTRACT

**Introduction:** DSM-5 defines Attention-Deficit/Hyperactivity Disorder as having a persistent pattern of hyperactivity or inattention. This affects social, emotional, cognitive, and academic performance, behavioural skills in children and adolescents. The suffering child should have more than 6 symptoms of a particular type. Due to aetiology of *Dhee Dhriti* and *Smriti*, which results in imbalance of *Kala* and *Karma* and leads to incorrect interaction of the senses with their aims (*Asatmyendriyarth Samyoga*), gives rise to inattention, hyperactivity and impulsivity. Considering the nature of symptomatologic manifestation, it can be correlated with *Unmada*, more specifically *Vata-Pittaja Unmada*. Ayurveda addresses ADHD with both internal medicines and external therapies. Mentosoothe compound is such a polyherbal compound it contains *Medhya*, *Balya*, *Deepana* and *Rasayana* drugs in extract form. **Aim** of the present study to evaluate the efficacy of mentosoothe compound in the management of Attention-Deficit/Hyperactivity Disorder. **Objective** of the study is to promote cognitive performance with improvement in the quality of life by providing an effective and safe treatment option. **Materials and Methods:** The present study will be conducted as a randomized clinical study including minimum 40 patients, divided into two groups. Mentosoothe compound A and Mentosoothe compound B will be given to groups with fixed dosages. Assessment will be done on every 15<sup>th</sup> day during 2 months of clinical trial and final follow up will be done one month after completion of clinical trial. **Result:** The results will give the data on comparative effectiveness of the Mentosoothe compounds on ADHD. **Discussion and Conclusion:** The outcome of this trial will render a way forward to effective management of ADHD in children.

**Key words:** ADHD, *Unmada*, Mentosoothe Compound, *Medhya*

## INTRODUCTION

Attention-Deficit/ Hyperactivity Disorder is a condition in which according to Diagnostic and Statistical Manual

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for Mental Disorder (DSM-5) of American Psychiatric Association (APA), ADHD is characterized by persistent pattern of inattention or hyperactivity/impulsivity.<sup>[1]</sup> It is one of the most common neurodevelopmental disorders in children and adolescents which affect the social, learning and behavioral abilities, with increasing incident rate. The global estimated prevalence of this disorder is 5.29%, in India it ranges from 2-17%,<sup>[2]</sup> in Jaipur 9.7%,<sup>[3]</sup> 5-10% in children and 4-6% in adults.<sup>[4]</sup> The American Academy of Pediatrics recommends evaluating any child between 4 and 18 years of age for ADHD.<sup>[5]</sup> The disorder is often chronic with one third to one half of those affected, retaining the condition into adulthood.<sup>[6]</sup> An improper synchronization of functional neurons and their antecedent neural dynamics in the human brain as well as

neurophysiological human mind can cause a wide range of attention deficit problems.<sup>[7]</sup> Strong genetic component is important factor results in the disease. Antenatal history of Mother may include birth complication such as prolonged labor, toxemia, and complicated delivery. Drug abuse and addiction of mother are also being recognized as risk factors. However, the precise etiological reason for ADHD is uncertain. Brain traumas, low birth weight, birth asphyxia, trauma, brain abnormalities, lack of family discipline, food additives, toxic substances, etc. are known to have some part in its development. It has been linked to a wide range of negative effects in those affected, as well as a significant financial cost on families and society, making it a significant public health issue. Untreated ADHD can have a number of negative emotional and physical effects, such as low self-esteem, mishaps, injuries, drug usage, sleep issues, enuresis, anxiety, autistic spectrum disorder, and learning impairments. Lack of sleep, stress, excessive stimulation and inappropriate use of technology are some of the major triggers of ADHD.<sup>[8]</sup> There are several ways to manage ADHD but pharmacotherapy is standard approach, which includes psychostimulant drugs like amphetamine/methylphenidate and tricyclic antidepressants (TCAs) such as imipramine and nortriptyline. These drugs have some major side effects, like methylphenidate can cause loose motions, anorexia, insomnia etc., whereas TCAs can cause anticholinergic side effects like dry mouth, weight gain, convulsions etc.<sup>[9]</sup> The results with these approved medications for ADHD are often unsatisfactory. FDA has approved Viloxazine (Qelbree) a new nonstimulant, nonscheduled drug to treat attention-deficit/hyperactivity disorder (ADHD) in children and adolescents.<sup>[10]</sup>

In recent years various publications in *Ayurveda* have investigated this subject and found significant results in term of effectiveness. In *Ayurveda* there are no direct references of ADHD but some references about abnormal behavior are discussed under features of *Unmada- Mano Vibhrama, Buddhi Vibhrama, Smriti Vibhrama, Sheela Vibhrama, Cheshta Vibhrama* and *Achara Vibhrama*, and considering nature of

symptomatological manifestation, it can be correlated with *Unmad*. It is a *Vata-Pitta Pradhan Sarva-Dosha (Sharirik+Mansik) Prakopak Vyadhi*.

This is a *Manovaha Sroto Vikara* with predominance of *Raja* and *Tama Guna*.<sup>[11]</sup> *Acharya Kashyap* in *Vedna-Adhyay* has also mentioned *Pralap, Vaichitya, Arti* in *Unmada Vyadhi*.<sup>[12]</sup> Further, the features of *Rakshas Rajasik Manas Prakriti* and *Matsya Tamsik Manas Prakriti* are almost on the same wavelength of ADHD. The causes may be the vitiation of *Dhee* (rational thinking), *Dhriti* (intellect/retaining power of mind), *Smriti* (memory) which leads to abnormal behavior such as inattention, hyperactivity, and impulsivity etc. due to improper contact of senses with their objectives.<sup>[13]</sup> With different aspect knowledge of ADHD in *Ayurveda*. With ancient treasure of knowledge, there come newer dimensions for treating ADHD. Hence the drugs which are *Tridosha-Shamak, Manas Dosha Chikitsa (Dhee, Dhriti, Smriti, Jyan, Vijyan, Sukhakar Shabda* etc.), *Medhya Rasayan, Panchakarma* procedures like *Shirodhara, Basti, Nasya* etc. that gives stability to all components of *Mana (Dhee, Dhriti, Smriti)* will have better effect on ADHD. Understanding the efficacy of *Ayurveda* intervention i.e., modification of diet, drug according to *Prakriti*, may allow appropriate options and improve the quality of life of the child.

The trial drug of the present study is Mentosoothe compound A which contains drugs such as *Tagar (Valeriana wallichii DC), Vacha (Acorus calamus Linn.), Brahmi (Bacopa monnieri Linn.), Ashwagandha (Withania somnifera Linn), Trikatu [Pippali (Piper longum Linn.), Marich (Piper nigrum Linn.), Shunthi (Zingiber officinalis Roxb)]*, while Mentosoothe compound B contains drugs such as *Jatamansi (Nardostachys Jatamansi DC.), Shankhpushpi (Convolvulus pluricaulis Chois.), Guduchi (Tinospora cordifolia Willd.), Chitrak (Plumbago zeylanica Linn), Trikatu [Pippali (Piper longum Linn.), Marich (Piper nigrum Linn.), Shunthi (Zingiber officinalis Roxb)]*. It contains *Medhya, Rasayan, Balya Dravyas* which are known to be beneficial in making proper synchronization of neurons, and hence can be very effective in ADHD.

## MATERIALS AND METHODS

The study will be conducted under a strict protocol to prevent bias and to reduce the source of error in study. Following materials and methods will be adopted for conducting the present clinical trial.

### Selection of Cases for Clinical Trial

- **Source** - Subjects will be randomly selected from O.P.D & I.P.D of Balarog/Kaumarbhritya Dept. of N.I.A Jaipur and associated hospital
- **Sample size** - 40 (20 in each group) [Sample size according to prevalence (9.7%) in Jaipur is approx. 126, but due to limitation of funds we will take 40 subjects]
- **Study type** - Double blind, Randomized, Comparative Trial
- **Method of allocation concealment** - Sequentially numbered, opaque, sealed envelopes (SNOSE)

### Diagnostic Criteria

Pre diagnosed subjects of ADHD or subjects those having clinical features of ADHD will be screened on the basis of DSM 5 (Diagnostic and Statistical Manual for Mental Disorders Vol-5).

### Inclusion Criteria

1. Children of either sex in between age group of 5 to 10 years.
2. Known case of ADHD.
3. Children with average/normal IQ
4. Subjects satisfying DSM-5 criteria of diagnosis

### Exclusion Criteria

1. Children with any critical mental diseases.
2. Children with known gross physical disability.
3. Children with any known genetic disorder and congenital disorder.
4. Children with any associated long term or fatal disease
5. Children with known systemic disorder like Diabetes Mellitus, Nephrotic syndrome etc.

## Execution Plan of Study

### Dose and Duration

- Dose - 250 mg BD
- Route - Oral
- Duration - 3 months (2-month clinical trial + 1 month post clinical period)

Group A		Group B	
<b>Mentosoothe compound A</b>		<b>Mentosoothe compound B</b>	
<b>Volume in each capsule (250 mg)</b>		<b>Volume in each capsule (250 mg)</b>	
<i>Tagar</i> *	56.25 mg	<i>Jatamansi</i> *	56.25 mg
<i>Vacha</i> *	56.25 mg	<i>Shankhpushpi</i> *	56.25 mg
<i>Brahmi</i> *	56.25 mg	<i>Guduchi</i> *	56.25 mg
<i>Ashwagandha</i> *	56.25 mg	<i>Chitrak</i> *	56.25 mg
<i>Trikatu</i>	25 mg	<i>Trikatu</i>	25 mg

\*Aqueous extract

Criteria for discontinuing or modifying allocated interventions will be withdrawal from intervention if any harmful incidence, signs of drug allergy or any problem will occur, if the patient is not willing to participate in trial study, then the patient also have right to discontinue the treatment. The primary outcomes of the effect of trial drugs Mentosoothe compound A and Mentosoothe compound B will be assessed on the basis of change in scoring/grading of symptom of ADHD on NICHQ Vanderbilt Assessment scale.

## RESULT

Subjects will be enrolled from August 2023. The study will be completed within one and half year following the registration of first case. The statistical analysis will be based on appropriate statistical tools. The expected results will give the data on comparative effectiveness of the mentosoothe compounds on ADHD.

## DISCUSSION

The present study comprises comparison of the efficacy of two mentosoothe compounds on ADHD. Most of these drugs have *Tikta*, *Kashaya Rasa*, *Katu Vipaka* and *Ushna Virya* and *Medhya* properties.

### Probable mode of action of the drugs

*Tikta Rasa* is predominant in *Vayu* and *Akasha Mahabhuta*. These *Mahabhuta* helps in clearing the *Srotrodha* by reducing *Kapha*, thereby reducing *Tama Guna* which increases *Sattva Guna*. *Kashaya Rasa* is predominant in *Vayu* and *Prithvi Mahabhuta*, later has property called *Sthira Guna* provides the stability in hyperactivity and impulsivity. *Laghu Guna* is predominant in *Vata Mahabhuta*. By lowering *Tama*, it strengthens *Sattva*. It has *Deepana* property that causes *Agni* to grow as *Mandagni* corrodes *Sattva*, *Raja*, and *Tama*. By boosting *Vata*, *Katu Vipaka* aids in the elimination of *Prakupita Kapha*, which is the cause of inattention. Most of these medications are *Tridosahara*, which means they stabilize *Sattva Guna* by balancing all the *Doshas*. *Kapha* is lessened by *Ushna Veerya*, and *Tama* and *Raja Guna* follow. Some medications increase *Sthira Guna* in the body by having *Madhura Vipaka*, which reduces a child's restless conduct. These medications also contain *Medhya* characteristics, which are known to have nootropic effects such as improving cognition, memory, reasoning skills, and other intellectual abilities.

Mentosoothe compound A contains *Tagar*, *Vacha*, *Brahmi*, *Ashwagandha*, *Trikatu*. *Tagar* is known to have Beneficial effect on performance and alertness,<sup>[14]</sup> *Vacha* have Antidepressant<sup>[15]</sup> Neuroprotective,<sup>[16]</sup> *Brahmi* possess Improves motor learning, acquisition<sup>[17]</sup> Psycho-neurological deficits,<sup>[18]</sup> There is evidence that *Ashwagandha* has Calm down anxiety, Control inattention, Hyperactivity, impulsivity and distractibility.<sup>[19]</sup>

Mentosoothe compound B contains, *Jatamansi* which has Antioxidant, Sedative, Tranquilizing, Antidepressant-activity, Anticonvulsant-activity,<sup>[20]</sup> *Shankhpushpi* possess' Neuroprotective activity, Intellect promoting activity, Antioxidant activity,

enhances memory function,<sup>[21]</sup> *Guduchi* known to have Learning and memory enhancing activity,<sup>[22]</sup> Neuro-protective activity Antioxidant activity, Anti-stress activity,<sup>[23]</sup> *Chitrak* is evident to have Antioxidant,<sup>[24]</sup> memory enhancing effect, CNS stimulation,<sup>[25]</sup> *Trikatu* known to have Bioavailability enhancement activity, Immunomodulatory, Antioxidant,<sup>[26]</sup> properties. *Trikatu* is a combination of three herbs - ginger, black pepper, and long pepper - that is commonly used in *Ayurvedic* medicine to improve digestion and reduce inflammation. While there is limited research on *Trikatu's* effect on ADHD specifically, it may be beneficial in reducing inflammation in the brain and improving overall health, which may indirectly improve ADHD symptoms.

Both the groups have drugs which acts as *Medhya* and involved in enhancement of cognition, intellect and behavioural activity. By this study we are trying to get a compound that is more effective than the other in the management of ADHD. *Ashwagandha*, *Shankhpushpi*, *Brahmi*, *Tagar*, *Vacha*, *Guduchi*, *Trikatu*, and *Chitrak* are all herbs that have been traditionally used in *Ayurvedic* medicine for various health benefits. One potential benefit of using natural remedies for ADHD is that they may have fewer side effects than prescription medications. Stimulant medications, such as methylphenidate and amphetamines, can cause side effects such as decreased appetite, insomnia, and headaches. Natural remedies may be a safer alternative for individuals who experience side effects from prescription medications.

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