CLINICAL EVALUATION OF CERTAIN AYURVEDIC FORMULATIONS IN THE MANAGEMENT OF MENTAL RETARDATION (*MĀNASA MANDATĀ*)

CENTRAL COUNCIL FOR RESEARCH IN AYURVEDA AND SIDDHA
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PREFACE

Mānasa mandatā is not described as a separate disease entity in classical Ayurvedic literatures. *Bhela*, contributor of Ayurvedic text *Bhela Saṃhitā* enumerates genetic factors (*bīj adoṣa*), improper diet (*apathya*), suppression of natural urges (*vegadhāraṇa*) and gynaecological disorders (*yonidoṣa*) during pregnancy as the causative factors for fetal disorders (*garbhavikṛti*) and mental retardation (*mānasa mandatā*).

This monograph is based on the data of clinical trial of selected Ayurvedic herbal preparations in mental retardation (*mānasa mandatā*) conducted at Dr. Achanta Lakshmipati Research Centre for Ayurveda (ALRCA), Chennai of the Council during 1973 to 1975, 1975 to1977 and 1992 to 1995.

I appreciate the active involvement, co-peration and sincere efforts of the in-charges, investigators and technical/non technical staff of Dr. Achanta Lakshmipati Research Centre for Ayurveda (ALRCA), Chennai in carrying out these studies. The untiring efforts put in by Dr. K. Bharathi, Assistant Director (Ay.), National Institute of Indian Medical Heritage, Hyderabad Dr. Gurucharan Bhuyan, Research Officer (Ay), Dr. M.M. Sharma, Research Officer (Ay.), Mr. Upendra Singh, Consultant - Journlism & Mr. Narender Singh (UDC) CCRAS and other staff of publication section of the council are worth mentioning.

I also thank Dr. Shivarama Varambally, Associate Professor, Department of Psychiatry, NIMHANS, Bangalore and Professor Ajay Kumar Sharma, Director, National Institute of Ayurveda, Jaipur for their valuable inputs.

I hope this monograph would receive the attention of academicians, scientists, physicians, research scholars and students as a reference document.

(D. Ramesh Babu)
Director General

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ABBREVIATIONS

च. सू.	चरक संहिता सूत्रस्थान
च. शा.	चरक संहिता शरीरस्थान
सु. सू.	सुश्रुत संहिता सूत्रस्थान
सु. शा.	सुश्रुत संहिता शरीरस्थान
अ. सं. सू.	अष्टांग संग्रह सूत्रस्थान
भे. शा.	भेल संहिता शरीरस्थान
का. खि.	काश्यप संहिता खिलस्थान
I.Q.	Intelligence Quotient

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HINDI SUMMARY

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ENGLISH SUMMARY

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English Summary

This work is a comprehensive compilation of 3 clinical studies carried out on Mānasa mandatā (Mental Retardation) under Central Council for Research in Āyurveda and Siddha. Study - I, II and III were conducted in higher grade mental retardation, mentally normal children and lower grade mentally retarded children respectively. While Studies I and II used the whole plant of Maṇḍūkaparṇī (*Centella asiatica*), Study III employed Brāmhī, Śaṅkhapuṣpī and Vacā as the trial drugs. Total 29 children were selected for Study I, 43 for Study II and 51 for Study III. Standard and culture-fair psychometric tests were administered for the dignosis and assessment. Double blind design was adopted wherever possible and all the studies used placebo as the control. The duration of the study was 6 months for study I and 12 months for study II and III.

The overall results indicate the following points.

1. The increased I.Q score and adaptive behavior score shown by the higher grade Mental Retardates (Study I) in the 6 months of treatment period point to the potent psycho stimulating effect of the drug *Maṇḍūkaparṇī*.

2. In Study II, the mean differences between the drug and placebo groups consisting of mentally normal children with regards to I.Q. scores from the initial and final assessments were not significant (P>0.05). In other words, the drug was not efficacious in normal children.

3. The finding of Study III indicated two important points. A significant rise averaging 7½ months in the non-verbal mental age was shown by the drug group during the one year of treatment as compared with 2½ months rise in the placebo group. There was appreciable increase in verbal mental age also in the drug group when compared to the placebo group. These small but significant gains in the mental growth are very important for the lower-grade mental retardates, whose needs are totally different from the higher-grade mental retardates.

The *Medhya* effect of the drugs viz, Brāmhī, *Maṇḍūkaparṇī*, Vacā and Śaṅkhapuṣpī was found to be useful in the therapy of Mental Retardates. The

drugs being non-toxic with no adverse reactions can be administered for long-term use in all types of mental retardation of varying chronicity.

BACKGROUND

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BACKGROUND

1.1 BACKGROUND

Mental retardation comes under developmental disorders and refers to a subnormal intellectual functioning with defective adaptogenic behavior. 5 - 10 % of children are affected by mental retardation.

1.2 REVIEW OF THE DISEASE

1.2.1 Ayurvedic concept

Various psychological disorders viz *Apasmāra, Unmāda, Atatvābhiniveśa* etc. are described in detail in Ayurvedic classics; but regarding *Mānasa mandatā* very few references are available. It is not described as a special disease entity, but can be considered as Mental deficiency or Mental Retardation by the literal meaning of the term and clinical presentation.

Concept of *Manas*:

All branches of Indian philosophy believe in the existence of *Manas. Ayurveda* also accepts that association of mind is essential for perception. *Manas* is considered as Adhiṣṭhāna of *cikitsādhikṛta puruṣa*[1]. Life is defined as the dynamic harmony between the śarīra, indriya, sattva, and ātmā[2]. It is one of the three pillars of Śarīra[3]. *Caraka* regards that psyche (*Manas*) is related to the past life and rebirth and on the occasion of whose departure the virtues of mind are gone from the body e.g. the inclinations start altering, the sense organs fail in discharging their normal functions, strength of the patient is lost and the diseases get aggravated and ultimately the life ends[4]

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2 'kjhjfUn;lRokRekl;kxk /kkfj thfore
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3 lÙoekRek 'kjhj p =;erfR=n.Mor A
Ykkdfr"Bfr l;kxÙk= lo ifrf"Bre AA Pk- 1@46AA

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The psychic functions and illness are related with *Śiras* and *Hṛdaya* according to *Ayurveda*. The *Śiras* has been considered as an organ, which regulates the senses. When it is injured, psychoses and other psychiatric illnesses are developed. *Hṛdaya* is an important organ for controlling the higher psychic functions such as intelligence and emotional activities. It has an important place in the psychopathology of psychiatric illnesses. In this context *Hṛdaya* may not be considered as the anatomical entity of the heart as it represents the functional entity of the brain.

Functions of *Manas:* The *Manas* is an instrument of all our experiences. The chief functions of *Manas* are assimilation and discrimination. The strength of *Indriyas* is derived from the *Mana.* According to *Cakrapāṇi,* the chief functions of the *Manas* are *icchā* (desire), *dveṣa* (hatred), *sukha* (pleasure), *duhkha* (pain) and *prayatna* (effort) [*Cakrapāṇi* on *Caraka Saṃhitā Sūtrasthāna*, 1:49]. According to *Caraka*, thinking, judgment, argument and conclusion are the objects of mind. The modern physiology also accepts these functions of mind, which is the aggregate of thinking, judgment and conclusion. It directs and controls the senses and helps to control oneself when one is getting away from right thinking, imagination and ideation. Functions of the *Manas* can be classified into four[5], 1. To perceive the sense objects through *Indriyas* 2. Control and withdrawal from sense objects 3. Imagination 4. Constructive thinking. These can be compared to 1. Cognitive processes (*Jñānapradhāna vyāpāra)*, *2.* Affective processes (*Bhāvapradhāna vyāpāra),* 3. Conative processes (*Ceṣṭāpradhāna vyāpāra*).

Manas Swarūpa (Nature of *Manas*): Experiencing the possession of knowledge or ignorance is based on the mental activity[6].

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Aetiopathogenesis of Psychiatric illnesses:

I. As per Ayurveda main causative factors for the Psycho or Somatic or Psychosomatic diseases are: 1. Vibhraṃśa - vitiation of rational thinking (*dhī*), intellect / retaining power of the mind (dhṛti), memory (smṛti), 2. Abnormality or variations of seasons and abnormal conduct (Ayoga of kāla, karma) 3. Improper contact of the senses with their objectives (*Asātmendriyārtha saṃyoga*)[7].

Indulging in negative activities (*aśubhakarma*), after the loss of *dhī, dhṛti, smṛti,* causes the vitiation of all the *doṣa,* which is called as volitional transgression (*prajñāparādha*)[8].

II. ***Manasika doṣas*** - the *Sattva, Rajas, Tamas* (3 states of mind) when in equilibrium, preserve the mind and body of the individual and maintain the healthy state. Due to imbalance of mānasik doṣas various mental diseases are developed.

Sattva -pure state of mind - that is characterized by lightness, consciousness, pleasure and clarity of mind and is free from diseases. It is responsible for the perception of the knowledge through proper mental functioning.

Rajas is the most active *guṇa* among three *Mānasika guṇas*. It also activates the other components. The motion and stimulations are the characteristics of *Rajas.* All types of desires, wishes, ambitions and fickleness are produced due to *rajas.* It is responsible for the production of different motions and plains. Various psychiatric illnesses are produced due to *rajas*.

Tamas is described as heaviness, and resistance. It is the symbol of unconsciousness, inertia and inactivity. It produces disturbance in the process of perception and activities of the mind. Delusion, false knowledge, laziness, apathy, sleep and drowsiness are produced due to increase of *Tamas*.

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8 /kh/kfrLefrfoHk"V%de ;r d#r·'kHke A
lkKkijk/k r fo|kr lonk"kidki.kEkAA p- 'kk- 1@102AA

III. Emotions and Urges (*Vegas*): According to Ayurveda, superssion of certain natural urges like thrust, hunger, sleep, urination is the root cause of all diseases. At the same time negative emotions like greed, anger should be controlled to remain away from psycho-somatic disorders. There urges can be sub-grouped into three psychic, speech and physical impulses.

The psychic impulses that should be controled are greediness, sorrow, fear, anger, pride, over attachment, envy etc. The harsh talking, telling a lie, untimely talk etc are known as the speech impulses. The physical impulses are stealing, violence and inflicting pains on others. When the *Vegas* are not controlled or discharged properly, mental tension and conflicts may arise and various psychological and psychiatric illnesses may originate.

Classification of Mental diseases - *Mānasika Rogas*

The diseases are categorized based on etiology, symptomatology and psychopathology. On the basis of Ayurvedic literature and the study of mental patients, classification of mental diseases can be done in the following groups:

1) Involvement of emotional factors (*Rajas, Tamas*):

They have emotional basis, which may manifest as disease, symptoms of the diseases or causes of various mental illnesses. *Caraka* has enumerated the psychiatric disorders as *rājasika* and *tāmasika* dominance. They are. *kama* (lust) *krodha* (anger) *lobha* (greed), *moha* (delusion), *īrṣyā* (envy), *mana* (pride), *mada* (complex /neurosis), *śoka* (sorrow), *cintā* (grief) *udvega* (anxiety), *bhaya* (fear) and *harṣa* (euphoria) etc. When these emotions are under control the individual is in well being. When they are uncontrolled, they produce various psychiatric illnesses.

2) Psychiatric illnesses due to involvement of emotional and body factors:

This group includes psychoneurosis and psychosis according to modern nomenclature. It also includes epilepsy, alcoholism and organic psychotic disorders. *Unmāda, Apasmāra, Apatantraka, Atattvābiniveśa, Bhrama, Tandrā, Klama, Mada, Mūrcchā, Sanyāsa* and *Madātyaya* are the main diseases of this group as per Ayurveda.

(3) Psychiatric Illnesses due to Personality defects (*Mānas Prakṛti Vikāra*)

The patients of mental deficiency and psychopathic personalities come under this group. The psychopathic personality is the characteristic of *rājas prakṛti.* The *tāmasa prakṛti* includes the individuals having mental deficiency.

(4) Psychosomatic illnesses:

Diarrhoea due to stress / depression (*Śokaja atisāra*) and pyrexia due to lust (*kāma jvara*) are included in this group. The psychological causative factors of these diseases are *Śoka* and' *Kāma.*

Viśiṣta Nidāna / Specific Etiology:

Mānasa mandatā seen below the age of 18 years is mainly due to the intrauterine effect on the fetus by the vitiated *doṣas.* On the basis of this concept, the *Nidāna* are;

1. Genetic factor (*Bīja, Ātmā),* dietary, emotional and behavioral factors of the mother (*Karma, Āśaya, Kāla doṣa, Āhāra, Vihāra*), disturbs the endocrinal system and digestive system, which further leads to abnormalities in the shape, color and emotions of the fetus (*Saṃsthāna,Varṇa, Indriya*)[9]. Here it indicates that, the above factors are causes for the Mental Retardation (*Mānasa mandatā*)

2. Bhela has enumerated genetic factor (*bījadoṣa*) of parents, improper diet (*apathya*), suppression of natural urges (*vegadhāraṇa)* and gynaecological disorders (*yonidoṣa*) as the causative factors for fetal disorders (*garbhavikṛti*) like Mental Retardation (*Mānasa mandatā*)[10]

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LkU/kkj.kk}k oxkuk ;kfunk"k.k o iu% AA Hk- 'kk 3@2&4AA

3. Under destructive factors of the fetus (*garbhopaghātakara bhāvas*), it is mentioned that the lady who consumes alcohol (*madyam*) daily, will deliver child with short memory (*alpasmṛti*), and fickle mind (*asthiracitta*)[11].

4. If the pregnant woman is suffering with fever and does smoking (*dhūmapāna*), fetus is affected severely and becomes crooked armed with weak cognitive and conative organs[12]

5. According to Kāśyapa Non-fulfillment of desires of pregnant women (*dauhṛda avamana*) leads to fetal abnormalities. Suppression of desires vitiates Neurological functions (*vāyu*) of the fetus and produces various diseases like Mental Retardation, abnormalities and even death. (*Jada/ Mandabuddhi*)[13].

6. In the context of *dauhṛda* (longing), Suśruta says that non-fulfillment of longing of pregnant women leads to vitiation of biological factors mainly *vāta doṣa.* Further atheism of parents, bad deeds of previous life are the causes of abnormalities like Kyphosis (*Kubja*)', Crooked arm (*Kuṇi)*, Lame (*Paṅgu*), Dumb (*Mūka*), Nasal voiced (*Minmiṇa*). As these are the features of the Mental Retardation all these are treated as specific etiological factors for *Mānasa mandatā.*

1.2.2 Contemporary Concepts:

Mental Retardation comes under the developmental disorders. It refers to subnormal general intellectual functioning and is associated with impairment in either learning and social adjustment or maturation or both. Mental Retardation can be defined as inadequate mental development, which results or may be expected to

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result in incapacity for independent special adaptation. It is a symptom of cerebral malfunction during prenatal life or infancy. Though the subject is treated primarily as a medical problem, it has important social implications.

Intelligence defined by various tests is described as the intelligence quotient (IQ). IQ is the ratio of mental age to chronological age and it supplies an average of the composite attainments of most of these mental abilities.

$$IQ = \frac{\text{Mentalage}}{\text{Physicalage}} \text{ X } 100$$

Intelligence can be assessed using certain standardized tests, like Binet-Kamat's test, Bhatia's test, Form-board test, Weshler's intelligence test, Shukla's test, etc. If the child is too young or nonco-operative or severely retarded, intelligence is assessed by using various developmental scales like the Vineland Social Maturity Scale.

Mental retardation is characterized by three components, 1. General intellectual functioning is significantly sub average, with IQ below 70 on standard IQ tests. 2. This results into concurrent deficits in adaptive behavior. 3. The individual is impaired in his /her ability to adapt to the environment. Mental Retardation has its onset before the age of 18 years. The American association of mental deficiency and the IV edition of Diagnostic and Statistical manual of mental disorders (DSM-IV) define Mental Retardation as significantly sub-average general intellectual functioning resulting in or associated with concurrent impairments in adaptive behavior and manifested during the developmental period. Thus mental Retardation is neither a disease nor a syndrome but a developmental disorder. DSM IV presents 4 types of Mental Retardation reflecting the degree of intellectual impairment. They are;

1. Mild or Educable - IQ between 50-70
2. Moderate or Trainable - IQ between 35 - 49
3. Severe or Dependent - IQ between 20-34
4. Profound or Life support - IQ below 20

Incidence - Reported incidence of Mental Retardation is between 5 and 10% of children at school going age. Males are affected more than the females. The incidence is higher among the first-born child of the family. In India, the sex ratio of the Mental Retardation is found to be 4 : 1 between boys and girls. It is estimated that 95% of the mentally retarded children are either educable or trainable and only 5 % need life support.

Causative factors

1. Pre-Natal

A. Genetically determined

1. Familial or subcultural
2. Phenyl ketonuria
3. Galactosemia
4. Cerebral lipidosis
5. Cerebral demyelinating diseases
6. Gargoylism
7. Cranial anomalies - Congenital Hydrocephalus, Primary microcephaly
8. Congenital ectodermoses - Tuberus sclerosis, Neurofibromatosis
9. Hereditary cerebral maldevelopment
10. Chromosomal aberrations like Down's syndrome, Klinefelter's syndrome, Turner's syndrome.

B. Prenatal known cause

1. Infection (German measles, toxoplasmosis, cytomegalic infectious diseases)
2. Fetal irradiation
3. Kernicterus (Rh and ABO maternal iso-senisitization, nonspecific neonatal hyperbilirubinamia)

C. Prenatal unknown or indefinite cause and not clinically classifiable

1. Associated with placental abnormalities, toxemia of pregnancy, prematurity, maternal medication, nutritional deficiency, anoxia, poisoning trauma etc.
2. Autosomal dominant disorders like Epiloia, Neurofibromatosis
3. Autosomal recessive disorders like abnormal amino acid metabolism (Phenyl ketonuria), abnormal fat metabolism, abnormal carbohydrate metabolism (Galactosaemia), Wilson's disease, Cretinism, Hypercalcaemia

II. Natal

1. Complications during pregnancy
2. Maternal infections like Rubella, Syphilis, Toxoplasmosis and certain viral infections, malnutrition
3. Complications during delivery - Birth injuries like direct cerebral trauma, hemorrhage and anoxia

III. Post - Natal

1. Blood group incompatibility
2. Cerebral infections - meningoencephalitis, abscess
3. Cerebral trauma
4. Metabolic and endocrine abnormalities and malnutrition
5. Degenerative and Epileptic disorders
6. Neoplasm
7. Hydrocephalus, brain cysts
8. Poisoning - lead, carbon monoxide etc.
9. Cerebrovascular accidents, occlusions and hemorrhages of varying or unknown cause

10. Post immunization encephalopathies (pertusis, smallpox, rabies etc.)

Diagnosis:

The diagnosis of Mental Retardation can be made through a careful history, a standard intellectual assessment and measure of adaptive behavior, which is below the expected level. A history and psychiatric interview are useful in obtaining a longitudinal picture of the child's development and functioning, examination of physical stigmata, neurological abnormalities and laboratory tests. Besides these, psychological assessment is very important to evaluate the psychological level and brain damage. Intelligence assessment plays a major role in the diagnosis, prognosis and therapeutics.

Differential Diagnosis - Since psychological tests are, as a general rule, based on the acquisition of learned experiences, the following conditions, by impairing the learning processes, may also adversely affect the results of these tests and add to the diagnostic difficulties. Most common conditions that may be mistaken for mental retardation or that may so interfere with the capacity to learn are:

I. Delayed maturation, especially Educational

II. Peripheral sensory defects

III. Cerebral palsy

IV. Language and speech disorders

V. Deprivation effects

VI. Environmentally induced psychogenic disorders

VII. Primary personality disorders

Management of Mental Retardation

Treatment of Mental retardation is palliative. From the Psychiatry's point of view, 'proper treatment of Mental Retardation relieves symptoms, reduces morbidity and allows the individual sufferer to operate the best way he can within the limits of his permanent disability'. Viewed in this perspective, as Blackman (1957) pointed out, any drug which makes a 'just noticeable difference' in a positive direction

should be considered to be effective as total cure is ruled out'. The primary goal in the management of Mental Retardation is that the affected individual be helped to reach his optimal developmental potential and be able to cope as effectively as possible with the handicaps side by side. The emphasis is given on family education, education for the child, genetic counseling etc.

Various drugs have been tried in Mental Retardation to improve their intelligence, cognitive functions and the adaptive behavior. They are Glutamic acid (Zimmerman et.al, 1949), vitamins (Del giuidice, 1950) stimulants and energizes like Deanol, Metrazol, Amphetamines etc (Barrett and Lampert, 1957, Blue et a11960) tranquilizers (Tarjan et al1 1957) and Indian herbs (Hakim 1951, Morris et al 1954). In general these studies are ambiguous. Whereas some studies have shown a positive therapeutic effect. Subsequent studies have not stood the test of scrutiny. Many of these studies lack controls, thus precluding the advantages of double blind trials.

In the behavioral area, three models of drug action can be discerned. First model concerns the use of drugs like tranquilizers to treat secondary conditions like anxiety, which interferes with the development of intelligence. Second model uses drugs like stimulants and energizers, which maximize the subject's utility of his/her currently existing resources. Third model concerns use of drugs like vitamins and glutamic acid which improve behavioral processes like attention, arousal etc that underlie global intelligence.

Methodological flaws in Mental Retardation

Mainly, the research deficiencies are four, 1. Many of these studies suffer from personal bias, lack of controls and relatively little use of statistical tests of significance to evaluate improvement 2. Improvement demonstrated by the individual children seems to be the characteristic action of specific drugs, usually in the form of reduction in the behavioral symptoms of hostility, hyperactivity and combativity 3. Many investigators who report favorable effects avoid a thorough interpretation of these results and are at a loss to explain them 4. Many studies use non-objective measures of assessment and Heterogenous population and sample.

In general, dramatic reports of striking changes in the behaviors of children attributed to specific drugs must be viewed with caution. Hence it is becoming

obvious that other environmental changes accompanying the administration of a drug may play an important role in altering the child's behavior as the drug itself. For Mentally Retarded children at any rate, new agents cannot be considered cures or panaceas but their most important advantage is to enable the child to participate in therapeutic program such as psychotherapy, habit training, occupational therapy, remedial instruction etc.

Need for alternate therapies:

Medical treatment of Mental Retardation has offered little hope for its total or even partial alleviation. Physical methods of treatment and training programmes are useful in controlling emotional disturbances, hyperactivity and other behavioral disturbances. Much emphasis has been made in modern line of treatment about 'enrichment' to be given to the Mental Retardates by way of counseling, psychotherapy, play therapy, occupational therapy etc. Wherever there are behavioral problems like hyperactivity, loss of concentration etc. they are treated with minor or major tranquilizer soporific medications etc., which further depress the mind. Hence, the mental retardates residing in Institutions, further regress in intelligence as age advances. They become remote and inaccessible.

Our ancient Ācāryas have laid much emphasis on the promotion of mental health under the topic *'Medhya Rasāyana* Therapy'. Under this therapy, they have classified many drugs like *Vacā, Yaṣtimadhu*, *Śaṅkhapuṣpī, Maṇḍūkaparṇī* to mention a few in promoting mental development and alleviating mental illnesses as well.

When the scientists all over the world are turning to other systems of medicine in fields where Allopathy has failed to make a dent with the hope of finding new therapeutic measures, the drugs mentioned under *'Medhya Rasāyana* Therapy' by our ancient physicians are worth experimenting.

Caraka Saṃhitā mentions that Maṇḍūkaparṇī, *Guḍucī, Yaṣtimadhu* and *Śaṅkhapuṣpī* are wholesome for intellect and among them *Śaṅkhapuṣpī* is the drug par excellence.

According to Suśruta, *Medhya Rasāyana* drugs tend to promote growth, strength, memory and intellect and invigorate mental faculties. Among these *Medhya* drugs,

Maṇḍūkaparṇī and *Vacā* when administered as decoction and *Kalka* to children act as infantile elixers. *Śaṅkhapuṣpī* is mentioned as *Medhya Rasāyana* and *Mānasa roganūt*.

Review of Previous Studies:

Among the medhya rasāyana drugs *Maṇḍūkaparṇī* was much experimented. The alcoholic extract produced tranquilizing effect in rats. Brahmosides isolated from the plant were found to produce sedative action, acting on the cholinergic mechanism. In studies on human volunteers, for 42 months, *Maṇḍūkaparṇī* showed anabolic heamatinic effect, increased vital capacity and total protein. Enhancement in the general mental ability and adaptive behavior was reported in mentally retarded children of the educable kind.

Vacā (*Acorus calamus*) is another important *Medhya* drug. Administering paste of the rhizome in ghee to infants is one of the first post-natal rituals of Indian mothers for the proper development of intellect of the infant. Neuropharmacological action of the oils isolated from the plant showed sedative, transquisilising action on rats, cats and dogs.

Śaṅkhapuṣpī (*Convolvulus pluricaulis*) is an important ingredient in nootropic formulations like *Brāhma Rasāyana, Aindrā Rasāyana, Agastyaharītakī, Mānasamitra vatakam* etc. At the dose of 30 ml/day, the drug exhibited anti-anxiety effect with reduction in the physiological symptoms of anxiety. The drug also offered protection to stress induced bio-chemical changes in thyrotoxicosis. *Śaṅkhapuṣpī* showed tranquillizing effects in addition to anti-thyroid property.

Bharathi (1997) took a review of the efficacy of *Medhya Rasāyana* drugs in various mental illnesses. In convulsive disorders (*Apasmāra*); *Medhya vati, Sārasvatāriṣta and Aśwagandhā cūrnam* were administered to patients for one year and the results showed that the frequency of fits, their duration and severity were found to decrease.

Aśwagandhā (*Withania somnifera*) and *Kapikacchu* (*Mucuna prurita*) were studied in 25 patients of endogenous and reactive depression. After 02 months of drug administration, the degree of anxiety and depression was decreased.

In acute Schizophrenia, *Brāhmyādiyoga* was found to be an equivalent to

chlorpromazine.

In anxiety reactions (*Cittodvega*), a combination consisting of *Maṇḍūkaparṇī*, *Yaṣti, Jatāmāṃsī* and *Kṣīrabalā taila* was tried in 12 patients of generalized anxiety disorders using sequential cross-over design. The drug combination was found effective in (1) acute and chronic states of anxiety (2) in old age with no apprehension about age related hazards (3) without fear of physical or psychological dependence (4) and in cases presenting both the somatic and psychological symptoms.

A different combination of *Maṇḍūkaparṇī*, *Jyotiṣmatī, Śaṅkhapuṣpī* and Carrot was tried in older people in the age range of 50-60 years who were displaying minimal impaired functions in -psychological tests. The drug was administered for 6 months. There was a statistically significant increase in mental control, logical memory and visual reproduction.

DRUG PROFILE

Blank

2. DRUG PROFILE

The following three different herbo-mineral formulations were selected for the study based on the Ayurvedic principles for clinical evaluation in the management of Mānasa mandatā (Mental Retardation).

Study I: *Maṇḍūkaparṇī*

Study II: *Maṇḍūkaparṇī*

Study III: Coded drug AYUSHMAN-8 containing Brāmhī, *Śaṅkhapuṣpī* &*Vacā*

2.1 *MAṆḌUKAPARṆĪ*

Sanskrit Name	:	Maṇḍūkaparṇī
Botanical Name	:	*Centella asiatica* (Linn).
Syn	:	*Hydrocotyle asiatica* Linn.
Natural Order	:	Apiaceae
Part used	:	Whole Plant
Pharmacodynamics	:	*Rasa*: *Tikta*, *Kaṣāya, Madhura* *Guṇa: Laghu, Sara* Vīrya: Śīta Vipāka: Madhura Prabhāva: Medhya

b). Pharmacognosy:

A slender herbaceous creeping plant. Stem long, prostrate, filiform, and often reddish, with long internodes, rooting at the nodes. 1-3 leaves arise from each node of the stem. Stipules adnate to the petiole. Leaf has paracytic and diacytic type of stomata on both surfaces. Palisade two layered; spongy parenchyma three layered with many intercellular spaces, some containing rosette crystals of calcium oxalate. Midrib region shows 2 - 3 layers of collenchymacells below the epidermis, petiole shows 7 vascular bundles within parenchymatous zone. (Ref: Database on

Medicinal Plants used in Ayurveda, Vol-I, CCRAS, 2000, pp264-267).

c). Details of standardization:

Physical constituents:

Foreign organic matter-not more than 2.0%; Total ash-Not more than 26.0%, Acid insoluble ash-Not more than 7.0%, Saponin content-Not less than 1.0%. (Ref: Database on Medicinal Plants used in Ayurveda, Vol-I, CCRAS, 2000, pp264-267).

Analysis of the leaves gave the following values: Moisture, 87.2; Protein, 1.7; Fat, 0.7; Carbohydrates, 4.8; Crude fiber, 3.4; Ash, 2.3gms/100gm; Calcium, 176.0; Phosphorus, 72.0; Iron, 12.0; Vitamin-C, 42.0; Niacin 0.8mg/100g; Carotene 2004mg/100gms; Energy, 32.0K.Cal/100gms. (Mooss, 68; Quisumbing, 685; Fl Malesiana, Ser. I, 4,117; Chem.Abstr, 1988, 108, 203524; Prum et al, Pharmazie, 1983, 38, 423; Chopra et al, Indian J. Pharm, 1956, 18, 364; Sengupta & Pal, Sci &Cult, 1968, 34, 374; Basu *et a*l, J. Indian Cehm. soc, 1947, 24, 358) (The Wealth of India, vol.-3:Ca-Ci, CSIR, 1992, pp428).

Chemical Constituents:

Asiaticoside, medacassoside, brahmoside, Maṇḍūkaparṇīnoside, alkaloid-hydrocotylin, vellarine, a new triterpene glycoside-thankuniside and new triterpenic acid-thankunic acid anthrone of asiaticoside, Asiatic acid, madegascaric or madecassic acid, madecassoside, isothankuniside and Maṇḍūkaparṇīc acid, centelloside, centic acid, centellic acid and centoic acid, indocentoic acid, indocentelloside and new oligosaccharide centellose were reported. (Ref: Database on Medicinal Plants used in Ayurveda, Vol-I, CCRAS, 2000, pp264-267).

The flavanoids, 3-glucosylquercetin, 3-glucosylkaemferol and 7- glucosyl kaempferol have been isolated from the leaves.

Two glycosides, asiaticoside and madecassoside have been isolated from the plant grown in Malagasy.On hydrolysis, these glycosides yield the triterpene acids, Asiatic acid and madegascaric acid (madecassic acid), respectively. These acids are also present in free form in the plant. Samples of the Indian plants collected from different places showed the presence of the following glycosides: Indocentelloside, brāhmoside, Maṇḍūkaparṇīnoside, asiaticoside, thankuniside and isothankuniside.

The corresponding triterpene acids obtained on hydrolysis of the glycosides are: indocentoic, Maṇḍūkaparṇīc, Asiatic, thankunic and isothankunic. These acids except the last two are also present in free form in the plant besides iso

Maṇḍūkaparṇī and betulic acids. Presence of mesoinositol, a new oligosaccharide, 'centellose', keampferol, quercetin and stigmasterol has been reported. (Bhattacharya, J Indian chem. Soc, 1956, 33, 893; Rastogi et al, J sci industry Res, 1960, 19B, 252; Dutta & Basu, ibid, 1962, 21B, 239; Dutta & Basu, Indian J chem., 1967, 5, 586; Dutta & Basu, Bull nat Inst Sci India, No. 37, 1968, 178; Singh & Rastogi, Phytochemistry, 1969, 8, 917; Rao & Seshadri, curr Sci, 1969, 38, 77).

An alcoholic extract of the herb gave an essential oil possessing the strong odour of the herb, fatty oil, tannin and a resinous substance.

The major terpenoidal constituents identified in the ether extract of the herb are Beta- caryophyllene, trans - beta- farnesene, germacrene-D and an unidentified terpenic acetate. Presence of sotisterol, stigmasterol and campesterol is also reported. The fatty oil consists of the glycerides of palmitic stearic, lignoceric, oleic, linoleic and linolenic acids. An alkaloid hydrocotylin has been isolated from the dried plant. A bitter principle, vellarine and peptic acid are present in the leaves and roots (Asakawa *et. al.*, phytochemistry, 1982, 21, 2590).

An Ethanolic extract (80%) of the plant showed the presence of a number of free Amino acids (George & Gnanarethinam, Cur.Sci, 1975, 44, 790). (The Wealth of India, vol.-3: Ca-Ci, CSIR, 1992, pp 428)

d) Pharmacological Actions:

Antiprotozoal, spasmolytic, alterative, astringent, anti-inflammatory, antifertility, sedative, CNS depressant, antitubercular, antileprotic, hepatoprotective, antispasmodic, antiamoebic, hypotensive. (Ref: Database on Medicinal Plants used in Ayurveda, Vol-I, CCRAS, 2000, pp 264-267)

The plant is valued in indigenous medicine to improve memory. In pharmacological and clinical trails it has been found to improve the power of concentration and general ability and behavior of mentally retarded children.

2.2 *BRĀMHĪ*

Sanskrit Name	:	Brāmhī
Botanical Name	:	*Bacopa monnieri (Linn) Pennell*
Syn. *Herpestis monnieria* (Linn) H.B.K; *Bacopa monnieria* (linn) Wettst.		
Natural Order	:	Scrophulariaceae
Part used	:	Whole Plant
Pharmacodynamics	:	*Rasa: Tikta,* *Guṇa: Laghu* Vīrya: Uṣṇa Vipāka: Kaṭu Prabhāva: Medhya

b). Pharmacognosy

Transverse section of leaf shows lack of differentiation of mesophyll into palisade and spongy tissue. Stomata are anisocytic, trichomes glandular. Prismatic crystals of calcium oxalate are present in mesophyll. No distinct midrib present.

c). Details of standardization:

Physical constituents:

Foreign matter-not more than 2.0%; Total ash-not more than 18.0%, Acid insoluble ash-not more than 6.0%, Alcohol soluble extractive-not less than 6.0%, Water soluble extractive-not less than 22.0%, (Ref: Database on Medicinal Plants used in Ayurveda, Vol-I, CCRAS, 2000, pp93-101).

Analysis of leaves and stalks gave: moisture, 88.4; protein, 2.1; fat, 0.6; carbohydrates, 5.9; crude fiber, 1.05; and ash, 1.9gms/100gms; calcium, 202.0; phosphorus, 16.0; iron, 7.8; ascorbic acid, 63.0; nicotinic acid, 0.3 mg / 100 gms; and energy, 38 cals / 100 g. (The Wealth of India, vol.-2:B, CSIR, 1988, pp3).

Chemical Constituents:

Alkaloids Maṇḍūkaparṇīne, herpestine and nicotine, saponin monierin, hersaponin, Bacoside-A, -B and four sapogenins bacigenin-AI-A4, some steroids, triterpene,

Bacosine are the important components reported. (Ref: Database on Medicinal

Plants used in Ayurveda, Vol-I, CCRAS, 2000, pp93-95)

Monnierin, on hydrolysis, gave glucose, arabinose and anaglycone where as, bacosides A and B gave glucose, arabinose and bacogenins A1, A2, A3 and A4; bacogenins A1 and A2 are epimers, and A4 is an ebelin lactone.

Other constituents present in the plant are D- mannnitol, betulic acid, beta-sitosterol, stigmasterol and its esters, heptacosane, octacosane, nonacosane, triacontane, hentriacontane, dotriacontane, nicotine, 3-formyl-4 - hydroxy-2H pyran, luteolin and its 7- glucoside. The presence of alpha- alanine, asperatic acid, glutamic acid and serine is also reported. (The Wealth of India Vol-2: B CSIR, 1988 pp 2)

The Saponins on hydrolysis gave a common aglycone identified as jujubogenin. (Jain and Kulshreshtha, Phyto chemistry, 1993, 33,449; Rastogi et al, ibid, 1994, 36,133).

d) Pharmacological Actions:

It has been shown to cause prolonged elevated level of cerebral glutamic acid and a transient increase in GABA level. It is thus assumed that endogenous increase in brain glutamate may be helpful in the process of learning, but the exact mechanism of action is not yet known.

Hersaponin is reported to possess cardio tonic, sedative and spasmodic properties. It produced mild inhibitory effect in vitro on respiration of rat brain, which was partially reduced by LSD-25 and, potentiated by 5-HT. It was also found, as in the case of reserpine, to deplete nor adrenaline and 5-HT content of the rat brain.

An alcoholic extract of the plant in a dose of 50 mg/ kg, produced tranquilizing effect on albino rats and dogs but the action was weaker than that produced by chlorpromazine.

Administration of aqueous suspension of an alcoholic extract (40 mg/kg, p.o) for three or more days is reported to improve the performance of rats in various learning situations. (Malhotra and Das Indian J Med Res , 1959,47 ,294; Malhotra *et al*, J Pharm Pharmacol,1961,13,447; Aithal and Sirsi, Indian J Pharm 1961,23,2; Bhakuni *et al,* Indian J Exp Biol 1969, 7, 261; Singh and Dhavan, J EhanoPharmacol, 1982,5,205). (The Wealth of India, vol 2: B 1988 CSIR New

Delhi pp2).

2.3 *ŚAṄKHAPUṢPĪ*

Sanskrit Name	:	*Śaṅkhapuṣpī*
Botanical Name	:	*Convolvulus prostrates Forsk.*
Syn. *C. microphylyllus* Sieb. Ex Spreng; *C. Pluricaulis* Choisy		
Natural Order	:	Convolvulaceae
Part used	:	Whole Plant
Pharmacodynamics	:	*Rasa: Tikta, Kaṭu, Kaṣāya* *Guṇa: Snigdha, Picchila, Sara* *Vīrya: Śīta* *Vipāka: Madhura* *Prabhāva: Medhya*

a). Pharmacognosy:

Root-Usually branched, cylindrical, ribbed having some rough stem nodules and small secondary roots 1-5 cm long, O.I-OAcm thick, yellowish-brown to light brown. Transverse section of root appears nearly circular in outline; cork composed of 10-15 layers of tangentially elongated, thick-walled cells; cortex composed of 6-10 layers of oval to elongated, elliptical, parenchymatious cells and yellowish-brown, tanniniferous, secretory cells present in this region; phloem composed of sieve elements, phloem parenchyma and phloem rays; xylem consisting of usual elements; vessels solitary or in groups of two with simple pits; fibres and tracheids aseptate and pitted; medullary rays 1-3 cells wide and multicellular in length; starch grains solitary or in groups, simple and compound, composed of 2-3 components, round to oval in shape, measuring 3-8 u in diam., present in cortex, phloem, xylem rays and parenchyma. Stem - Slender, cylindrical, about 1-2mm in thickness with clear hairy nodes and internodes; light green. Transverse section of stem shows single layered epidermis, covered with thick cuticle; at places unicellular hairs present; cortex lR differentiated in two zones, 2-3 upper collenchymatous and 1-2 lower parenchymatous layers, both having round to oval, elongated, thin walled cells; endodennis single layered; pericycle present in the

form of single strand of fibres; phloem a narrow zone, mostly composed of sieve elements and parenchyma; xylem consists of vessels, fibres and parenchyma; medullary rays and tracheids not distinct, vessels mostly solitary with spiral thickening; fibres aseptate having pointed ends and narrow lumen; strand of internal phloem present around the slightly lignified pith.

Leaf - Shortly petiolate, linear-Ianceolate, acute, hairy, both surfaces; 1 .5-7.0 x O.3-0.8cm; light green.

Midrib-Appears convex in lower and concave in upper side; epidermis single layered, covered with thick cuticle; lower epidennis followed by 2-3 layers of cholrenchymatous cells; vascular bundle bicollateral, composed of usual elements of phloem and xylem; rest of tissue between chlorenchyma and vascular bundles composed of 4-5 layers of parechymatous cells.

Lamina-Shows epidermis on both surfaces covered with thick cuticle; hairs unicellular, present on both surfaces, palisade two layered, spongy parenchyma 4-5 layered; a few bicollateral vascular bundles present in spongy parenchyma; palisade ratio 6-9; vein islet number 21-25 per sq.mm, stomatal index in lower surface 17-20, in upper surface 13.8-17.0; stomatal number in lower surface 184-248, and in upper surface 202-238 per sq.mm. (Ref: Database on Medicinal Plants used in Ayurveda, Vol-VII, CCRAS, 2005, pp433-437)

b). Details of standardization:

Physical constituents:

Foreign matter-not more than 2%; Total ash-not more than 17%; Acid insoluble ash-not more than 8%; Alcohol-soluble extractive-not less than 6%; Water soluble extractive-not less than 10%. (Ref: Database on Medicinal Plants used in Ayurveda, Vol-VII, CCRAS, 2005, pp433-437)

Chemical Constituents:

Microphyllic acid (plant resin); 6-methoxy- 7 -hydroxycoumarin, glucose, maltose, kaempferol-kaempferol-3-glucoside, 3,4 dihydroxycinnamic acid, rhamnose, sucrose, n-hexacosanol, n-octacosanol, n-triacontanol, B-sitosterols, E-sitosterols, 20-oxyodotriacontanol, tetratriacontanoic acid, Śaṅkhapuṣpīne, ceryl alcohol (plant).

(Ref: Database on Medicinal Plants used in Ayurveda, Vol-VII, CCRAS, 2005, pp433-437).

The plant is greatly valued for its asiaticoside content in leaves.

The essential oil from the aerial parts of the plant from Malaysia contains the sesquiterpenoids, beta cayophyllene, 26.8; alpha-humulene, 33.7; and geremacrene-D,10.0 %. from the leaves of the plants growing in Malagasy two glycosides, quercetin-3-glycoside and kaempferol-3-glycoside have been isolated. Glucosylation of thiocolchicine, a hemi synthetic substrate obtained from natural colchicines, by a cell suspension culture of the plant is reported from France. Thiocolchicine is converted to its 2-O- and 3-O -monoglucosyl derivatives (Wong & Tan, J. Essent Oil Res, 1994, 6, 307; Bagchi & Puri, Herba hung, 1989,28(1-2), 127;Solet et al, Phytochemistry, 1993,33,817). (The Wealth of India, First supplement series Vol-1: A-Ci, NISCAIR, CSIR, pp 242).

c) Pharmacological Actions:

The plant shows spasmolytic, hypotensive, sedative, antifungal, antimicrobial, anti-inflammatory, antistress, CNS depressant, hypoglycaemic, antiulcer, hypolipidaemic, anti-anxiety activities. (Ref: Database on Medicinal Plants used in Ayurveda, Vol-VII, CCRAS, 2005, pp433-437).

The extract reduced the spontaneous motor activity of mice, the reduction being more marked in amphetamine treated hyperactive mice (Sharma *et al* 1965.). The hypotensive activity and the barbiturate hypnosis potentiation effect of the plant are reported. (Mudgal *et al* 1972). Alcoholic extract potentiated barbiturate hypnosis in rats (J.Res.Ind.Med. Yoga & Homoco.1979, 14,132 -136). In a clinical study C. Pluricaulis provided significant relief in symptoms besides a quantitative reduction in anxiety level and neuroticism in the cases of Anxiety neurosis (J.Res.Ind.Med. Yoga & Homoco.1977, 12:3)

2.4 *VACĀ*

Sanskrit Name	:	*Vacā*
Botanical Name	:	*Acorus calamus* Linn.
Natural Order	:	Araceae

Part used	:	Rhizome
Pharmacodynamics	:	*Rasa: Kaṭu, Tikta* *Guṇa: Laghu, Tīkṣṇa, Sara* Vīrya: Uṣṇa Vipāka: Kaṭu Prabhāva: Medhya

a). Pharmacognosy

Rhizome is light brown with long internodes, root and leaf scars and soothing aromatic odour. Transverse section shows narrow cortical and large stellar regions. Cortex consists of thin walled parenchymatous cells arranged in chains leaving large intercellular spaces, sheathed collaterial vascular bundles and bundles of fibres. Endodermal cells are barrel shaped and possess abundant starch grains. Mostly leptocentric and a few collateral vascular bundles in association with leptocentrics are observed in the ground tissue of stele. Fibres are thick walled and pitted. Large oil cells with yellowish content, cells containing dark brown oleoresin content and starch grains are scattered in the ground tissue of both cortex and stele. Solitary polygonal crystals of calcium oxalate are present in each cell of the storied row of cells running parallel to the fibres. (Ref: Database on Medicinal plants used in Ayurveda, Vol-I, CCRAS, 2000, pp469-472)

b). Details of standardization:

Physical Constituents

Moisture-l 0.26%, Dry matter-89.74%, Total ash-6.481%, Acid insoluble ash-0.878%, Water soluble extractive-28.15%, Ethanol (80%) soluble extractive-42.02%. (Ref: Database on Medicinal plants used in Ayurveda, Vol-I, CCRAS, 2000, pp 469-472)

The roots contain moisture, 9.43; protein, 6.37; fat, 0.71; carbohydrates, 6.53 and ash, 2.09%, calcium, 0.25 and iron, 10mg/100g. Tryptophan is predominant amino acid. The sesquiterpenoids, calamenone, calamendiol, and isocalamendiol have been isolated from the roots. (Chem Abstr, 1987, 107, 151207; 1994, 121, 198538; Saxena et al, Indian Perfum, 1987, 31, 150; singh et al, ibid, 1991, 35, 35). (Ref: The Wealth of India I suppli, series vol-I A-Ci pp 20).

Chemical Constituents:

Asarone, b-asarone, calamenol, calamene, calamenone, eugenol, methyl eugenol, a-pinene and camphene, various fatty acids, calamol, calamone acoradin, azulene, two selinane type sesquiterpenes-acolamone and isoacolamone, sugars, glucosides-acorin, calameon, calamusenone, a flavenone lueolin-6, 8-C-diglucoside, new natural products acoramone, asarylaldehyde, carcinogen, B-asarone and epoxyisoacoragermacrone are the main chemical constituents reported from this plant. (Ref: Database on Medicinal plants used in Ayurveda, Vol-I, CCRAS, 2000, pp469-472)

The rhizome contains b-cis-asarone, asaraldehyde, acoradin, phenylindane and a phenyl propane derivative, l-(p- hydroxyphenol)-l-(O-acetyl) prop-2-ene. It also contains Ca, 1.724; Fe, 0.66; Mg, 0.859; Na, 10.62mg/100g with traces of Cd, Mn, Ni, and Zn. Besides, during early spring the rhizomes accumulate large amounts of arginine (Chowdhury et al, pharmazie, 1993, 48, 786; Lohar et al, Indian Drugs, 1992, 29, 271; Chem. Abstr, 1988, 109, 208535). (The Wealth of India I suppli, series vol-I A-Ci pp 19).

The chemical constituents of essential oil are: 1,8-cineole, linalool, terpinolene, a-terpineol, eugenol methyl ether and sesquiterpene alcohol. Presence of methyleugenol, cis-methylisoeugenol, b-farnesene, and a,b and asarone has been reported in tetraploid plants. However the North Americal variety, A. calamus var. americanus (Raf.) Wuf., has been found to be asarone free. (Nigam et al, Indian Perfum, 1990, 34, 282; Motley, Econ Bot, 1994, 48, 397; Abel, Planta Med, 1987, 53, 251). (Ref: The Wealth of India I suppli, series vol-I A-Ci pp 20).

c) Pharmacological Actions:

Alcoholic extract of the plant causes sedative and analgesic effects, moderate depression in blood pressure and respiration. Other pharmacological activities are hypothermic, hypotensive, spasmolytic, CNS depressant, anticonvulsant, carcinogenic, antimicrobial, anthelmintic, insecticidal, antibacterial and sedative tranquillizing. (Ref: Database on Medicinal plants used in Ayurveda, Vol-I, CCRAS, 2000, pp469-472)

The essential oil free alcoholic extract of the rhizome was found to possess sedative and analgesic properties and to cause a moderate depression of blood

pressure and respiration. The oil when administered intraperitonially to experimental animal reduces spontaneous movement, muscle tone, and response to tactile and auditory stimuli. Doses of more than 25 mg/kg produced generalized depression of the nervous system. Elimination of phenolic and aldehydic fractions from the oil results in the increase in toxicity and sedative potentiating activity. (Kaul *et al*, Curr. Sci, 1977, 46, 724). (The Wealth of India, Vol-I: A, CSIR, Reprinted 2003, pp64-65).

Administration of aqueous and alcoholic extracts of rhizome reduce the severity of electric shock - induced seizures in rats; it is recommended for treating petitmal type of epilepsy (Borthakur, Fitoterpia, 1992, 63, 486; Shimizu *et al*, *Shoyakugaku Zasshi*, 1993, 47, 1).

1. Alcoholic extract of the plant exhibited anti-convulsant activity against MES, cardiozol, and strychnine induced convulsion in rats after injections[1].
2. Asarone from rhizome of A. Calamus protected hyperactivity of rats and also Amphetamine induced aggression in mice[2].
3. Asarone 50mg/kg, i.p. and b-asarone in the same dose potentiated hypnosis caused by pentobarbitone, hexobarbitone and ethanol intrapertonially[3].
4. Flavone from A. calamus potentiated pentobarbitone-sleeping time in mice[4].

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1. Athanossova-Shopova, S. and Roussinov, K.: Pharmacological studies on Bulgarian plants with a view to their anticonvulsant effect. *Compt Rand. Acad. Bulg. Sci*. 18 (7): 691-694, 1965 (Biol. Abstr. 48 (1): 2517, 1967)
2. Dandiya, P.C and Memon, M.K.: Interaction of Asarone with mescaline, amphetamine and themorine, Life Sci. 4: 1635, 1965.
3. Dandiya, P.C and Sharma.J.D: Studies on Acorus calamus, part-V, Pharmacological actions of Asarone and b-asarone on Central nervous system. Indian **J**. Med. Res. 50(1): 46 - 60, 1962.
4. Patra, B.B *et al*.: Some observations on the pharmacological activity of a flavone from Acorus calamus. Presented to the XI Annual conference of Indian pharmacological society, New Delhi, 1978. Indian J. Pharmacol.11;51,1979.

Method of Preparation of Study Drugs and Placebo

Maṇḍūkaparṇī was received from Central Drug Research Institute, Lucknow. *Ayushman-8* was supplied by the Regional Research Institute (Ay.), Bangalore.

Study I & II: The whole plant of *Maṇḍūkaparṇī* was dried under shade, powdered and made into 500 mg tablets. Placebo was made of starch powder and suitably coloured to match the trial drug.

Study III: The coded drug Ayushman-8 was prepared by combining the ingredients in following proportion and the tablets were prepared by adding binding material (10% Gum kikkar and 5% starch).

Brāmhī (aqeous extract of whole plant)	-	1000 mg
Śaṅkhapuṣpī (whole plant)	-	380 mg
Vacā (Rhizome)	-	20 mg

The Placebo used was plain sugar.

Brāmhī- *Bacopa monnieri* (Linn) Pennell

Maṇḍūkaparṇī - *Centella asiatica* (Linn). Urban

Vacā - *Acorus calamus* Linn.

Śaṅkhapuṣpī - *Convolvulus prostrates* Forsk.

CLINICAL STUDIES

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3. CLINICAL STUDY

3.1 MATERIAL AND METHODS:

3.1.1 Aims and Objectives:

Aims and objectives of all the 3 studies were:

1. To assess the Clinical effect of single and combination herbal preparations in the management of Mental Retardation (*Mānasa mandatā*).

2. To Develop the evidence based support on the effect of Herbal formulations

3.1.2 Centre of study:

Studies on Mental Retardation (*Mānasa mandatā*) were carried out at special care homes for Mental Retardation and outpatient department of Dr. Achanta Lakshmipathi Research Centre for Ayurveda, Chennai.

3.1.3 Sample size & Methodology:

a) No. of Clinical studies: 3

Number of Groups - Two groups in all the 3 studies

b) Period of study & No. of patients in each study

Clinical trial studies	No of patients	Period of study
Clinical study-I	29	1973 April - 1975 March
Clinical study-II	43	1975 - 1977
Clinical study-III	51	1992 December - 1995 March

Study-I: *Maṇḍūkaparṇī* (*Centella asiatica* (Linn). Urban) in the higher-grade mental retardates

Study-II: *Maṇḍūkaparṇī* (*Centella asiatica* (Linn). Urban) in mentally normal children.

Study-III: AYUSHMAN-8 - Brāmhī (*Bacopa monnieri* (Linn) Pennell) *Śaṅkhapuṣpī (Convolvulus prostrates* Forsk.) and *Vacā* (*Acorus calamus* Linn.) in low grade mental retardates

Type of Study:

Study I	:	Double blind
Study II	:	Double blind
Study III	:	Open Controlled

Level of Study: Domiciliary treatment.

3.1.4 Drug, Dosage and other Schedules:

Study I: The whole plant of *Maṇḍūkaparṇī* was dried, powdered and made into 500 mg tablets. Placebo was made of starch powder and suitably coloured to match the trial drug tablets.

Dosage: 1gm thrice in a day for both the groups for 06 months.

Study II: The whole plant of *Maṇḍūkaparṇī* was dried, powdered and made into 500 mg tablets. Placebo was made of starch powder and suitably coloured to match the drug tablets.

Dosage: 1gm thrice a day for both the groups for 12 months

Study III:

Brāmhī	-	1000 mg	} AYUSHMAN - 8
Śaṅkhapuṣpī	-	380 mg	
Vacā	-	20mg	

Ayushman-8, 1400 mg was given with honey in 2 divided doses at 12 hours interval for 12 months. The Placebo was 1400 mg of plain sugar given 12th hourly in two divided doses for 12 months.

Source of procurement of drug:

Study-I and II - The whole plant of *Maṇḍūkaparṇī* (*Pañcāṅga*) was procured from Himalayan Terrains by the Central Drug Research Institute, Lucknow and supplied to this institute.

Study-III - The drugs *Brāmhī, Śaṅkhapuṣpī* and *Vacā* under the code name *Ayushman-8* were supplied by the Regional Research Institute (Ay.), Bangalore.

3.1.5 Criteria for inclusion:

1. Children in the age range of 05-16 years
2. Children displaying symptoms of mental retardation, like delayed milestones, speech disorders, hyperactivity and mental development and behavior not proportionate with chronological age as per the conditions laid down by Diagnostic and Statistical Manual of Mental Disorders - III, were included.

3.1.6 Criteria for exclusion:

1. Cases with uncontrolled epilepsy, hyperkinesis, psychosis and organic brain diseases, aminoaciduria and other inborn errors of metabolism, encephalitis etc.
2. Patients with other severe systemic disorders.
3. Patients exposed to neurotoxic drugs in utero.
4. Patients of mental impairment other than mental retardation.
5. Patients in whom another investigational drug was used within 03 months prior to entry in this study.
6. Patient's guardian who could not be able to comply with the study procedures or unwilling to give informed consent.
7. The patient with a congenital or acquired severe immuno deficiency, a history of cancer or lymphoproliferative disease, or he/she has received total lymphoid irradiation.
8. The patient identified as HIV positive status defined by either a positive blood test or clinical diagnosis.
9. History of major traumatic injury, malignancy.
10. The patient with previous history of usage of corticosteroids within 04 weeks prior to study.

3.1.7 Criteria for withdrawal:

1. Sustain serious clinical events requiring specific treatment
2. On patients request.
3. Irregular follow-ups treated as drop-outs.

3.1.8 Routine examination and Assessment:

Examination and assessment of trial patients was carried out as per the Protocol & Proforma. Laboratory investigations were carried out before and after study.

3.2 Duration of Treatment:

Study I: Maṇḍūkaparṇī (*Centella asiatica*) - 06 months

Study II: Maṇḍūkaparṇī (*Centella asiatica*) - 12 months

Study III: *AYUSHMAN* - 8 - 12 months

Follow-up:

Follow-up assessments were done once in 03 months up to one year for all the groups.

3.1.9 Criteria for assessment of Results of treatment:

Good Response	-	75% or above improvement
Fair Response	-	50 to 75 % of improvement
Poor Response	-	25 to 50% of improvement
No Response	-	0 to 25 % improvement

Study I: The Binet-Kamat Test was selected for intelligence testing. The adaptive behavior was assessed by a checklist mentioned below.

1. Memory
2. Attention
3. Comprehension
4. Speech (coherence and relevance)

The overall general adjustment was rated on the basis of:

1.	Silly giggling and grimacing.	6.	Repetitive movements.
2.	Scant and trivial conversation.	7.	Self- Muttering.
3.	Fixed faces and blank stare.	8.	Irrelevant and incoherent responses.
4.	Strained postural movements.	9.	Apathy /indifference to the test.
5.	Overt tension.	10.	Restlessness / fidgetiveness.

Before treatment if a child displayed 3 or less than 3 symptoms out of 10 symptoms it was considered as good adjustment; 3-6 as fair adjustment and more than 6 symptoms as poor adjustment.

Study II: Same as study I.

Study III: Seguin form-board Test for non-verbal and Binet-Kamat Test for verbal intelligence were used for this group. Vineland Social Maturity Scale was also used to know the child's standing in the social ladder in areas like self-help such as eating, dressing, communication, socialization, occupation etc. Eight aspects of *Manasa* viz, *Manovahasrotas, Budhivibraṃśa, Manavibraṃśa, Smṛtivibraṃśa, Acāravibraṃśa. Bhaktivibraṃśa, Śīlavibraṃśa, Ceṣṭāvibraṃśa* were studied.

3.1.10 Statistical Analysis:

Study-I: The data was analyzed by means of student 't' test and 'F' test and non-parametric X^2 - test.

Study-II: The data was analyzed by means of student 't' test.

Study-III: The data was analyzed by means of student 't' test.

3.1.11 Trial monitoring and data analysis:

The selected children were allocated to drug and placebo groups as per double blind random order. The intelligence tests and adaptive behavior ratings were from Standard Psychometric test batteries and Indian adaptation of the tests (culture-fair). Medical team monitored drug administration to the children. The assessment was done at the end of 03 months, 06 months, and 12 months.

3.1.12 Ethical Review:

Informed consent was obtained from all subjects or his/her guardian in the prescribed format before starting the clinical trial.

3.2 OBSERVATIONS:

3.2.1 CLINICAL STUDY - I

Total 29 cases i.e. 15 in drug group and 14 cases in placebo group were included in study-I and the data on the various aspects are provided here as follow:

3.2.1.1 DEMOGRAPHIC DATA:

Table-I: Distribution of cases according to age and sex:

Age in years	Trial drug group				Placebo group				Total
	Male		Female		Male		Female		
	No	%	No	%	No	%	No	%	
5-10	06	50	02	66.67	04	57.14	04	57.14	16
11-14	03	25	00	00.00	02	28.57	02	28.57	07
15 & above	03	25	01	33.33	01	14.28	01	14.28	06
Total	12	100	03	100	07	100	07	100	29

Table II - Raw data of initial behavioral ratings:

S.No.	Behavioral items	Group-I (Drug) n= 15			Group-II (Placebo) n= 14		
		Poor	Fair	Good	Poor	Fair	Good
1.	Co-operation	07	01	07	05	03	06
2.	Attention and Concentration	08	06	01	08	03	03
3.	Memory	05	09	01	03	10	01
4.	Speech	06	07	02	09	02	03
5.	Overall general adjustment	07	06	02	09	03	02

3.2.1.2 CLINICAL DATA:

Table III: Statistical analysis of I.Q. by 't' test of Mentally Retarded Children-High graders:

Groups	Mean I.Q at initial examination	Mean difference + Standard Error of I.Q	
		Initial Vs. 3 months	Initial Vs. 6 months
Maṇḍūkaparṇī (n=15)	32.3	7.596 - 0.923	7.881 - 0.947
Placebo (n=14)	37.7	3.183 - 0.634	4.261 - 0.777
Difference between drug & placebo groups		4.413	3.6
'P' value		**<0.001**	**<0.05**

Table IV: Statistical analysis of I.Q by 'F' test of Mentally Retarded Children-High graders:

Groups	Mean I.Q at initial examination	Mean I.Q		Adjusted mean by ANOCOVA	
		At 3 months	At 6 months	At 3 months	At 6 months
Drug (n=15)	32.3	39.8	40.2	42.3	42.6
Placebo (n=14)	37.7	40.9	42.0	37.8	38.9
Difference				4.5	3.7
P value				<0.001	<0.05

Table V - Comparison between Drug and Placebo groups in Behavioral Ratings at the end of 3 months and 6 months of *Maṇḍūkaparṇī*

Behavioural items	Treatment	Initial Vs 3 months			Initial Vs 6 months		
		Improved	Not improved	P Value	Improved	Not improved	P Value
1. Co-operation	Drug	03	12	N.S.	05	10	N.S
	Placebo	02	12		03	11	
2. Attention and Concentration	Drug	04	11	N.S.	08	07	<0.05
	Placebo	02	12		02	12	
3. Memory	Drug	02	13	N.S.	03	12	N.S
	Placebo	02	12		02	12	
4. Speech	Drug	02	13	N.S.	03	12	N.S
	Placebo	03	11		02	12	
5. Overall general adjustment	Drug	06	09	N.S.	09	06	<0.05
	Placebo	03	11		03	11	

Note: N.S - Not significant

3.2.1.3 OBSERVATIONS:

This study was conducted in 29 mentally retarded children (High graders in adaptive behavior). The demographic data and results of the study of Maṇḍūkaparṇī on the IQs of mentally retarded children - high graders are presented in table-I to V.

The mean and S.D of I.Q at the initial examination were found to be 32.3 and 11.6 for the drug group and 37.7 and 15.4 for the placebo group respectively. Statistical analysis of I.Q at the end of 3 months and 6 months were done by two different approaches. Firstly the mean change in I.Q at the end of 3 months and 6 months in the drug group and placebo group were compared by means of 't' test. The results are tabulated in table-III. Secondly as the mean initial I.Q for the drug group was low when compared with that of the placebo group analysis of covariance was applied to assess the changes in I.Q after correcting the initial values and synchronizing it at the same level. Adjustment values were tested by means of 'F' test and the results are tabulated in table - IV.

From tables III and IV, it can be observed that both the approaches lead to the same conclusion. The results of analysis of covariance confirmed the findings of the first approach, because the regression co-efficient was found to be almost equal to one.

The results show that the increase in the I.Q shown by the *Maṇḍūkaparṇī* group as compared to the placebo group was highly significant at $P < 0.001$ at the end of three months. The increase in the I.Q. shown by the *Maṇḍūkaparṇī* group as compared to the placebo group was significant at $P < 0.05$ at the end of six months.

The children were drawn from the same special care home and hence formed a homogenous sample with regards to environment, nutrition and human care. All the other things being equal, the mean increase of 3 I.Q points shown by the placebo can be attributed to the process of development. For a mentally normal child, for every chronological year, there will be a corresponding increase of one year in mental age. But for mental retardates this proportion is not maintained. If the ratio of chronological age to mental age is 1: 1 for a normal child, it may be 1: 0.5 or 1: 0.25 for mental retardates, depending upon the severity of retardation.

Thus, the placebo group affecting an increase of 3 I.Q points is taken as the process of maturation. When compared to the Placebo group, the drug group showed an increase of 7.5 IQ points. If left untreated, the drug group would have also shown the same increase of 3 points. Thus, it can be concluded that the drug group had scored an extra 4 .5 points over the placebo group and this can be taken as the effect of the drug, since all the other conditions remained the same.

Table-II shows the baseline data with regard to behavioral adjustments of the drug and placebo groups at the initial examination. The drug and placebo groups were found at the same level in adaptive behavior before treatment.

While analyzing the assessment at the end of 3 months and 6 months, the child was rated as improved or not improved without taking in to consideration the degree of improvement. The data was analyzed by means of X^2 - test and the results are given in Table V.

It can be seen that at the end of six months the drug brought a positive change in attention and concentration and overall general adjustment. These processes underlie global intelligence and hence we could conclude that the drug may prove to be a useful therapy in Mental Retardation.

3.2.2 CLINICAL STUDY - II:

Totally 43 cases - 24 in the drug group and 19 in placebo group were included for study-II and the data on the various aspects are provided here under.

3.2.2.1 DEMOGRAPHIC DATA:

Table-I. Distribution of age and sex:

Age in years	Trial drug group				Placebo group				Total
	Male		Female		Male		Female		
	No	%	No	%	No	%	No	%	
5-10	05	29.41	03	42.86	06	40	00	-	14
11-14	12	70.59	04	57.14	09	60	03	75	28
15 & above	00	-	00	-	00	-	01	25	01
Total	17	100	07	100	15	100	04	100	43

3.2.2.2 CLINICAL DATA:

Table - II. IQ scores in mentally normal children before & after treatment:

Group	Sample No.	06 months			12 months			
		Mean difference	Variance	t	Mean difference	Variance	t	p
Drug	24	1.68	3.17	NS	2.16	4.06	NS	>0.5
Placebo	19	1.12	1.44	NS	1.98	2.10	NS	>0.5

NS: Not significant

3.2.2.3 OBSERVATIONS:

This study was undertaken in mentally normal children. The results of the study of *Maṇḍūkaparṇī* on the mental ability of normal children are presented in this section. The study was conducted on the same line as Study - I. The children were selected from a nearby orphanage and their initial I.Q scores ranged from 90 - 110. The statistical analysis of the data is presented in Table II.

It can be observed from the table, that the drug and placebo groups did not differ significantly in I.Q either at 06 months or at 12 months. In other words the drug *Maṇḍūkaparṇī* did not produce any effect in mentally normal children while the same drug has shown improvement in I.Q and adaptive behavior in mentally retarded children of high grade in study -I.

3.2.3 CLINICAL STUDY-III

Total 51 cases were registered in this study out of which 12 cases were dropped out and 39 cases were completed the study. Out of 39 cases, 19 were included in the drug group and 20 were included in placebo group. The data on the various aspects are provided here under.

3.2.3.1 DEMOGRAPHIC DATA:

Table - I Distribution of age and sex

Age in years	Trial drug group				Placebo group				Total
	Male		Female		Male		Female		
	No	%	No	%	No	%	No	%	
5-10	06	31.57	04	57.14	04	20.00	03	60.00	17
11-14	12	63.16	02	28.57	14	70.00	02	40.00	30
15 & above	01	05.26	01	14.28	02	10.00	00	00.00	04
Total	19	100.00	07	100.00	20	100.00	05	100.00	51

3.2.3.2 CLINICAL DATA:

Table -II: Effect of the drug (AYUSHMAN-8) on the psychological parameters at the end of six months treatment:

Parameters	Treatment group	Initial mean + S.E	At the end of 6 months	Mean Diff. + S.E	Level of Significance
Binet Kamat Test (verbal test)	Drug	52.25 + 3.47	59.62 + 3.35	7.38 + 1.41	$P < 0.05$
	Placebo	46.50 + 3.02	52.62 + 3.85	6.12 + 1.28	
Seguin form Board Test (Non-verbal test)	Drug	51.08 + 4.72	58.50 + 4.67	7.42 + 5.21	Not significant
	Placebo	51.83 + 3.84	55.94 + 5.63	4.11 + 4.56	
Vineland social maturity scale	Drug	52.79 + 1.75	54.00 + 1.85	1.21 + 0.93	Not significant
	Placebo	51.88 + 1.37	54.44 + 1.35	0.56 + 0.31	

TABLE - III: Effect of the drug (AYUSHMAN-8) on psychological parameters at the end of 12 months treatment:

Parameters	Treatment group	Initial mean + S.E	At the end of 12 months	Mean Diff. + S.E	Level of Significance
Binet Kamat Test (verbal test)	Drug	52.25 + 3.37	62.23 + 3.56	10.11 +1.62	P < 0.05
	Placebo	44.53 + 2.96	53.47 + 3.70	8.94 + 1.18	
Seguin's form Board Test (Non-verbal test)	Drug	54.61 + 5.92	62.17 + 5.78	7.56 + 2.94	P < 0.05
	Placebo	53.78 + 4.53	56.36 + 503	2.58 + 3.57	
Vineland social maturity scale	Drug	52.56 + 1.84	56.55 + 1.84	4.00 + 1.76	Not significant
	Placebo	53.15 + 1.86	57.15 + 2.02	4.00 + 1.81	

TABLE-IV: Effect of the drug on (AYUSHMAN-8) clinical and anthropometric parameters at the end of 12 months treatment:

Parameters	Treatment group	Initial mean + S.E	Mean Diff. + S.E	Level of Significance
Height (in cm)	Drug	138.47 + 2.76	3.05+0.74	Not significant
	Placebo	139.17 + 2.75	3.52 + 0.84	
Weight (in Kg)	Drug	35.28 + 2.04	0.38 + 0.46	Not significant
	Placebo	33.68 + 1.62	-0.03 + 1.14	
Pulse	Drug	81.33 + 0.45	-2.56 + 0.33	Not significant

(Rate/min.)	Placebo	80.70	+ 0.64	-2.34 + 0.74
Heamoglobin	Drug	9.56 + 0.43	-0.72 + 0.62	Not significant
(gm.)	Placebo	9.90 + 0.26	-0.73 + 0.43	

TABLE - V showing the effect of the drug (AYUSHMAN-8) on 8 Ayurvedic aspects of *Manas*

(Manasa viz, *Manovahasrotas, Budhivibraṃśa, Manavibraṃśa, Smṛtivibraṃśa, Acāravibraṃśa. Bhaktivibraṃśa, Śīlavibraṃśa, Ceṣṭāvibraṃśa)*

Groups	Number of children			
	Improvement	No change	Deterioration	Total
Trial drug (Ayushman-8)	15	04	00	19
Placebo	16	03	01	20

Table -VI: Response in the drug and placebo groups:

Groups	Results of the Treatment						
	Good Response	Fair Response	Poor Response	No Response	Death	LAMA / Drop Out	Total
Ayushman-8	05 (26.31%)	08 (42.10%)	02 (10.53%)	04 (21.06%)	00	07*	26
Placebo	00	11 (55.00%)	03 (15.00%)	06 (30.00%)	00	05*	25

*Drop out / LAMA were not included for assessment

3.2.3.3 OBSERVATIONS:

While Study -I and II used single drug i.e. *Maṇḍūkaparṇī,* in Study-III a compound preparation i.e. *Brāmhī*, *Vacā* and *Śaṅkhapuṣpī,* under the coded name

of *AYUSHMAN* - 8 was used. The drugs individually are known for psychotherapeutic value as mentioned in classical texts and reputed by research studies.

This study was conducted on Mental Retardates (Low graders in adaptive behavior) and a significant increase was found in the verbal and non-verbal mental ages between drug and placebo groups during the one-year of treatment (Ref: Table II & III). A significant rise averaging 71/2 months in the non-verbal mental age was shown by the drug group during the one year of treatment as compared with 21/2 months rise in the placebo group. There was appreciable increase in verbal mental age also in the drug group when compared to the placebo group. These small but significant gains in the mental growth are very important for the lower grade mental retardates, whose needs are different from the high-grade mental retardates.

Table-IV shows the effect of the drug (Ayushman-8) on some clinical and anthrpometric parameters at the end of 12 months treatment. The parameters showed non-significance between the drug and placebo.

There was no significant difference between the drug and placebo groups on 8 aspects of Manasa (Ref: Table-V).

It can be seen from Table-VI, that 68.41% of cases in the Ayushman-8 group have shown good and fair response against 55.00% in the placebo group.

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DISCUSSION

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4. DISCUSSION

W.H.O. has classified the Mental Retardates in the following manner;

I.Q. range	Classification	Broad classification
68-8352-67	BorderlineMild	High graders (Educable)
36-5120-35	Moderate	Severe Low graders (Trainable)
Under 20	Profound	Custodial care

The prognosis is favorable for high-graders, as they are educable; poor for low-graders and very poor for mental retardates who's Intelligence Quotient (1.Q) is below 20 and custodial care is essential for such profound retardates.

In this clinical study series **Study - I, II** and **III** dealt with high-graders (higher-grade mental retadates), low-graders (lower-grade mental retadates) and with mentally normal children respectively to assess the effect of the drug in mental retardation.

Generally, the drug studies with mentally retarded children suffer from four methodological defects (1) Lack of proper controls (2) Use of non-objective tests to measure intelligence (3) Generalization from small groups to larger population (4) Heterogeneous samples. Care was taken to avoid most of these flaws in these present studies.

All three studies- (1) Used 'Placebo' as a Control (2) Employed double blind random allocation (3) Used standard culture-fair tests of intelligence (4) the study groups were homogenous in nutrition, environment and human care. With most of the flaws rectified, the conclusions drawn out of these studies can be claimed by the investigators as valid.

The chemical compounds used for mental retardation include minor and major tranquilizers, mood-elevators and anti-depressants. The hyper-activity, motility and aggressiveness in a Mental Retardate respond well to these chemical formulations.

But, the core mental faculties like concept formation, language stimulation, articulation, numerical ability etc. seem to be unaffected by the synthetic drugs. Though they are potent in some specific areas, they are not potent in core areas. Moreover there is general agreement on which stringent precautions against toxicity must always be taken.

Herbal drugs score over the chemical compounds due to non-toxic, anti-oxidant and beta-keratin properties. ***Maṇḍūkaparṇī*** has anabolic and ***Śaṅkhapuṣpī*** has a well-known protein sparing effect. While the whole plant is used to prepare drug in case of ***Maṇḍūkaparṇī***, ***Brāmhī*** and ***Śaṅkhapuṣpī***, the rhizome is used in case of ***Vacā***. Thus the herbal drugs used in these studies are psychotherapeutically potential as mentioned in classical texts and reported by clinical studies.

The needs of lower graders are different from the high graders. All therapies including drug, special education, counseling, habit training etc. are mostly aimed at the high-graders. The lower grade mental retardates residing in an Institution lack motivation, carry poor prognosis and they intellectually regress as age advances. The absence of external stimulation renders them remote and inaccessible. In the light of these facts, the findings of **Study -III** assume significance and indicate two important points; (1) A significant rise averaging 7½ months in non-verbal mental age was shown by the drug group during the one year treatment as compared with 2½ months rise in the placebo group. (2) These small but significant gains in mental growth are very important for lower grade mental retardates.

In **Study -I**, the results show that the increase in the Intelligence Quotient (I.Q) shown by the *Maṇḍūkaparṇī* group as compared to the Placebo group was highly significant ($P < 0.001$) at the end of three months. The increase in the Intelligence Quotient (I.Q) shown by the *Maṇḍūkaparṇī* group as compared to the Placebo group was significant at $P < 0.01$ at the end of six months. After the completion of six months, the drug had shown a positive change in attention and concentration and overall general adjustment. In experimental group, 09 (60%) cases out of 15 and in control group 03 (21.43%) out of 14 cases had shown improvement on over all general adjustment. Improvement was also seen in attention and

concentration in 08 (53.33%) cases out of 15 from the experimental group and 02 (16.66%) out of 14 from control group.

The drug *Maṇḍūkaparṇī* used in Group-I is *tikta, kaṣāya, madhura rasa, śīta vīrya, madhura vipāka, tridoṣa śāmaka* and *medhya.* Improvement shown by this drug may be due to its *Medhyarasāyana* and *tridoṣa śāmaka* especially *Vātahara* property. *Maṇḍūkaparṇī* contains maṇḍūkaparṇīcacid, isomaṇḍūkaparṇīcacid, brahmoside and Maṇḍūkaparṇīnoside. On pharmacological screening it was found that the drug has psychotropic, sedative, anti-convulsant, CNS depressant, hypotensive and hepatoprotective properties.

In **Study -II**, study was undertaken to see the effecacy of *Maṇḍūkaparṇī* in the developmental skills of mentally normal children. The drug and placebo groups did not differ significantly in Intelligence Quotient (I.Q) either at 06 months or at 12 months. In other words the drug Maṇḍūkaparṇī did not produce any effect in mentally normal children while the same drug has shown improvement in Intelligence Quotient (I.Q) and adaptive behavior in mentally retarded children of high grade.

The possible reason for not finding any effect in mentally normal children may be as follows; for example, in a seven-year-old severely retarded child exhibiting various behavioral defects in the area of speech, judgment etc, a development-enhancing drug is likely to work gradually, additively, selectively and directionally. If the underlying processes do not show any change, then no change is likely to be there on the global level. In other words, the observed signs of subnormal mental functioning like defective concentration, inability to plan, lack of pre vision, repetition of observed errors failure to comprehend the simplest and failure to manipulate items of knowledge previously acquired, preservations in speech etc are not present in normal children. Therefore the drug which had improved the behavioral processes thereby bringing about an increase in the intellectual status in mental retardates could not beneficially act in normal children in whom these defects are not present.

Study-III was taken up in Lower grade mental retardates with below 50 Intelligence Quotient (I.Q) points.

A significant rise averaging 7½ months in the non-verbal mental age was shown by the drug group during the one year of treatment as compared with 2½ months rise in the placebo group ($P<0.01$). There was appreciable increase in verbal mental age also in the drug group when compared to the placebo group.

In this group, the drugs administered under the name of AYUSHMAN - 8 were *Brāmhī, Vacā* and *Śaṅkhapuṣpī. Brāmhī,* is *Uṣṇa vīrya, Kaphavāta śāmaka* and *medhya. Vacā* is *tīkṣṇa guṇa, uṣṇa vīrya, kaphavāta śāmakam. Śaṅkhapuṣpī* well known *medhyadravya,* having *madhura vipākam, tridoṣa-śāmaka* properties. *Śaṅkhapuṣpī* is spasmolytic, hypotensive, sedative, antistress, CNS depressant. *Vacā* is sedative, tranquillizer, CNS depressant, Anti convulsant, contains asarone, B-asarone, calamenol, calamene, calamenone, eugenol etc. The active ingredients of *Maṇḍūkaparṇī* are saponins and bacosides. All the three drugs are well known *medhya rasāyana*. It can be said that these drugs acted as nootropics. In this study it is observed that there is effect in behavioral modification, and improvement in memory and attention span of mentally retarded children.

CONCLUSION

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5. CONCLUSION:

Although great advances have been made in the management of Mental Retardates, it's treatment is still inadequate and palliative. The encouraging results of the studies reported in this monograph offer hope and scope for future management and treatment of Mental Retardates with further validation. The encouraging results were reported in the study:

1. The increased I.Q scores and adaptive behavior scores shown by the higher grade Mental Retardates (Group-I study) during 6 months of treatment period point to the potent psycho therapeutic effect of the drug *Maṇḍūkaparṇī.*

2. The intellectual regression is faster in lower grade Mental Retardates than in high graders. The Ayurvedic drugs were able to arrest this regression to a certain extent both at the non-verbal and verbal levels as observed in Group - III.

3. The statistically significant increase in non-verbal mental age and appreciable numerical increase in verbal mental age in the drug group during the one year of treatment point to the potent psycho stimulating effect of Ayushman -8 (Group-III).

The drugs studied were found to be anabolic and protein sparing and rich in anti oxidant and beta-keratin properties.

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ANNEXURE

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CENTRAL COUNCIL FOR RESEARCH IN A YURVEDA AND SIDDHA CLINICAL EVALUATION OF AYURVEDIC FORMULATIONS IN THE MANAGEMENT OF *MĀNASA MANDATĀ* (MENTAL RETARDATION)

PART-I (Screening of the Cases)

Name of the participant .....

Address .....

1. Centre .....

2. Code No. (of clinical trial) .....

3. Participant No. .....

4. Group No. First ..... Second .....

Third ..... Fourth .....

CRITERIA OF SELECTION

5. Age between 5-16 years of either sex

Yes [1] No [2]

6. Duration of disease up to 10 years

Yes [1] No [2]

7. Presence of cardinal symptoms of diseases

Yes [1] No [2]

CRITERIA OF EXCLUSION

8. Age below 5 and above 16 years

Yes [1] No [2]

9. Duration more than 10 years

Yes [1] No [2]

10. Patients with uncontrolled epilepsy, hyperkinesis, psychosis, tuberculosis and organicity

Yes [1] No [2]

11. Others (specify) .....

CENTRAL COUNCIL FOR RESEARCH IN A YURVEDA AND SIDDHA CLINICAL EVALUATION OF AYURVEDIC FORMULATIONS IN THE MANAGEMENT OF *MĀNASA MANDATĀ* (MENTAL RETARDATION)

PART-II (Admission Form)

Name of the participant .....

Address .....

1. Centre .....
2. Code No. (of clinical trial) .....
3. Participant No. .....
4. Group No. First ..... Second .....
   Third ..... Fourth .....
5. Age of participant in years .....
6. Educational status

Illiterate	1	Read & write	2
Primary school	3	Middle school	4
High School	5	College	6
Others (Specify)	7	INA	8

7. Occupation

Desk work	1	Field work	2
Field work with physical labour			3
Field work-intellectual			4

   Indicate nature of work .....

   Total income of the family in rupees .....

8. Total family members .....

9. Income per capita per month in rupees .....

Chief Complaints with duration:

10.	Delayed milestones	Yes	1	No	2
11.	Speech handicap	Yes	1	No	2
12.	Seizures	Yes	1	No	2
13.	Mental age not proportional with chronological age	Yes	1	No	2
14.	Adaptive behaviour	Impaired	1	Not impaired	2
15.	Hyperactivity	present	1	absent	2

16. Maladaptive signs (tick if present)

Twitches & tics			
Silly giggling			
Dribbling of the saliva			
Destructive & harmful			
Inopportune laughing/crying/shouting	1		2
Fixed eyes			
Lack of personal hygiene			

History of present illness:

17.	Onset of disease	Acute	1	Insidious	2

18. Duration of disease .....

19. Treatment given so far :

Ayurvedic medicine	1	Modern medicine	2	Unani	3
Homoeopathy	4	Siddha	5	Mixed	6

Medicines given ..... Results obtained .....

20. Factors aggravating the disease/chief complaints .....

21. Factors relieving main complaints .....

22. History of past illness having relation with present illness

Yes [1] No [2]

If yes, specify .....

Family History if any

23. Mental disease

Yes [1] No [2]

24. Mental retardation

Yes [1] No [2]

25. Consanguineous marriage

Yes [1] No [2]

Personal History

26. Diet

Veg [1] Non-veg [2] Lacto-ova veg [3]

27. Sleep

Good [1] Disturbed [2] Insomnia [3]

28. Emotional stress

Yes [1] No [2]

29. Bowel Habit

Regular [1] Constipation [2] Loose motion [3]

30. Addiction

Yes [1] No [2]

If yes, specify .....

31. Prakṛti

Vātaj	1	Pittaj	2	Kaphaj	3
Vāta-kaphaj	4	Vāta-pittaj	5	Pitta-kaphaj	6
Sannipātaj	7				

32. Mānas prakṛti

Sattva	1	Rajas	2	Tamas	3
Sattva-Rajas	4	Sattva-Tamas	4	Rajas-Tamas	6
Sama	7				

Physical Examination:

Build

Lean	1	Medium	2	Heavy	3

Physical Examination:

33. Body weight Kg .....

34. Blood Pressure (Systolic) .....

Blood Pressure (Diastolic) .....

35. Body temperature .....

36. Respiration .....

37.	Cyanosis	Present	1	Absent	2
38.	Anemia	Present	1	Absent	2
39.	Jaundice	Present	1	Absent	2
40.	Pigmentation	Present	1	Absent	2
41.	Clubbing of fingers	Present	1	Absent	2
42.	Deformities	Present	1	Absent	2
43.	Lymphadenopathy	Present	1	Absent	2

Systemic examination

44. CVS with chest : Normal [1] Abnormal [2]
If abnormal, specify abnormalities

45. CNS Normal [1] Abnormal [2]
If abnormal, specify abnormalities

46. Digestive system Normal [1] Abnormal [2]
If abnormal, specify abnormalities

47. Urogenital system Normal [1] Abnormal [2]
If abnormal, specify abnormalities

Samprāpti (Pathogenesis) of the disease

48. Anubandhyaśārīrika Doṣa

Vāta [1] Pitta [2] Kapha [3]

49. Anubandhaśārīrika Doṣa

Vāta [1] Pitta [2] Kapha [3]

50. Anubandhyamānasika Doṣa

Rajas [1] Tamas [2]

51. Anubandhamānasika Doṣa

Rajas [1] Tamas [2]

52. Kṣīṇa Śārīrika Doṣa

Vāta [1] Pitta [2] Kapha [3]

53. Kṣīṇa Mānasika Doṣa

Rajas [1] Tamas [2]

54. Stages of disease (Rogakriyā kāla)

Sañcaya [1] Prakopa [2] Sthānasaṃśraya [3]

Prasara [4] Vyakti [5] Bheda [6]

SROTAS PARĪKṢA

55. Prāṇavaha Srotas

Alpa alpa Śvāsa (Shortened Breathing)	1
Atiśrama Śvāsa (Increased respiration rate)	2
Abhīkṣṇa Śvāsa (Chyne stroke breathing)	3
Kupita Śvāsa (Vitiated breathing)	4
Saśūla Śvāsa (Dyspnoea with pain)	5

56. Udakvaha Srotas

Jivhā Śoṣa (Dryness of tongue)	1
Auṣṭha Śoṣa (Dryness of lip)	2
Tālu Śoṣa (Dryness of palate)	3
Kaṇṭha Śoṣa (Dryness of throat)	4
Kloma Śoṣa (Excessive thirst)	5
Tṛṣṇā (Thirst)	6

57. Annavaha Srotas

Anannābhilāṣa (Lack of desire for food)	1
Aruci (Anorexia)	2
Avipāka (Indigestion)	3
Chardi (Vomitting)	4

58. Rasavaha Srotas

Mukha vairaṣya (Bad taste in mouth)	1
Arasajñatā (Tastelessness)	2
Hṛllāsa (water brash)	3
Gaurava (Feeling of heaviness)	4

	Tandrā (Stupor)	5
	Aṅgamarda (Body ache)	6
	Jvara (Fever)	7
	Pāṇḍu (Anaemia)	8
	Avasāda (Depression)	9
	Klaibya (Loss of libido)	10
	Kārśya (Emaciation)	11
	Agnimāndya (Diminished appetite)	12
59.	**Raktavaha Srotas**	
	Pīḍika (Boils)	1
	Raktapitta (Bleeding from any of the orifice)	2
	Mukhapāka (Stomatitis)	3
	Vidradhī (Abscess)	4
	Carmaroga (Skin disease)	5
	Kāmalā (Jaundice)	6
60.	**Māṃsavaha Srotas**	
	Arbuda (Tumour)	1
	Alajī (Phlyctenular conjunctivitis)	2
	Gaṇḍamālā (cervical lynphadenitis)	3
	Upajivhikā (Epiglotitis)	4
	Adhimāṃsa (Protruberance of flesh/cancer/cyst)	5
	Pūtimāṃsa (decayed flesh/gangrene)	6

61. Medovaha Srotas

Malādhikya (Excess of excreta)	1
Hastapāda dāha (Burning sensation in the palm and sole)	2
Hastapāda suptatā (Numbness of the palm and sole)	3
Tandrā (Stupor)	4
Dehacikkaṇatā (Greasiness of the skin)	5
Ālasya (Lethargy)	6

62. Asthivaha Srotas

Adhyasthī (Hypertrophy of bone)	1
Adhidanta (Redundant tooth)	2
Dantaśūla (Toothache)	3
Asthiśūla (bone pain)	4
Keśa, loma, nakha, saṃśru vikāra (Any defects of hair, hair follicles, nails and mustaches)	5

63. Majjāvaha Srotas

Parvaśūla (Pain in the Interphalangeal joints)	1
Bhrama (Vertigo/Giddiness)	2
Mūrcchā (Syncope)	3
Mithyājñana (Illusion)	4

64. Śukravaha Srotas

Klaibya (Sterility/impotence)	1
Aharṣaṇa (Loss of erection)	2
Garbhapāta (Abortion)	3
Santāna vikṛti (Congenital deformity of the children)	4

65. Manovaha Srotas

Manovibraṃśa	1
Budhivibraṃśa	2
Saṃjñavibraṃśa	3
Smṛtivibraṃśa	4
Bhaktivibraṃśa	5
Śīlavibraṃśa	6
Ceṣṭāvibraṃśa	7
Ācāravibraṃśa	8

66. Ārtavavaha Srotas

Anārtava (Amenorrhoea)	1
Vandhyatva (Sterlity)	2

67. Mūtravaha Srotas

Bahumūtratā (Polyuria)	1
Atibadhatā (Urination with obstruction)	2
Prakopa mūtra (Defective Urination/Difficulty in micturition)	3
Alpa alpa (Scanty urination)	4
Abhikṣṇa (Constant/repeated urination)	5
Bahulamūtratā (Urine with prostatic secreation)	6
Saśūla mūtratā (Painful micturition)	7

68. Purīṣavaha Srotas

Alpa alpa purīṣa (Scanty defecation)	1
Saśūla purīṣa (Painful defecation)	2
Atidrava purīṣa (Diarrhoea)	3

	Atigrathit purīṣa (Scybala)	4

69. Svedavaha Srotas

	Asvedana (Loss of perspiration)	1
	Atisvedana (Profuse sweating)	2
	Pāruṣya (Roughness of the skin)	3
	Lomaharśa (Thrill)	4
	Aṅgaparidāha (Burning sensation in the body)	5

70. Investigations

Clinical assessment

71. Provisional diagnosis Final diagnosis

72. Medical management

73. Principle drug therapy

Drug	Dose	Vehicle	5

Diet

Duration of treatment

74. Summary of findings

75. Results:

Good response	1	Fair response	2	Poor response	3
No response	4	Drop out	5	LAMA	6
Death	7				

Date:

Signature of Investigator/
Medical Officer

CENTRAL COUNCIL FOR RESEARCH IN A YURVEDA AND SIDDHA CLINICAL EVALUATION OF AYURVEDIC FORMULATIONS IN THE MANAGEMENT OF *MĀNASA MANDATĀ* (MENTAL RETARDATION) INVESTIGATION RECORD

Name of the participant : .....

Address .....

Institute/Centre .....

Code No. of clinical trial .....

Participant No. .....

Group No. : Treatment ..... Control .....

Investigations	Before/ After treatment

Urine- Routine & Microscopic

Stool-Macroscopic

Haematological Investigations

HB %

T.L.C. (in thousands/Cmm)

D.L.C.

Polymorphs . . . . . %

Lymphocyte. . . . . %

Basophil. . . . . %

Eosinophil. . . . . %

E.S.R. 1 Hr ... mm 2 Hr ... m

Biochemistry:

Total proteins (gm %)

Alkaline phosphatase ... IU/L

S.G.O.T. .. lU/L

S.G.P.T. ... lU/L

Bilirubins ... mg/100 ml

Urea .....mgl100 ml

S. Creatinine ..... mg / dl

Special Tests

Urinary catecholamines

CT Scan for Head

EEG

Note: Only such investigations are to be undertaken for which facilities exist in the Institutes/ Centres/Units themselves, unless exempted.

Clinical assessment

Initial	After 180 days	After 360 days
1.	Objective tests	
	i. Binet Kamat test	
	ii. Seguin Form Board Test	
	iii. Vineland Social Maturity Scale	