WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.084
Volume 10, Issue 10, 1320-1336. Research Article ISSN 2277– 7105

CLINICAL TRIAL EVALUATION OF THE EFFECT SELECTED MEDHAYA RASAYANAS IN MENTAL DISORDER

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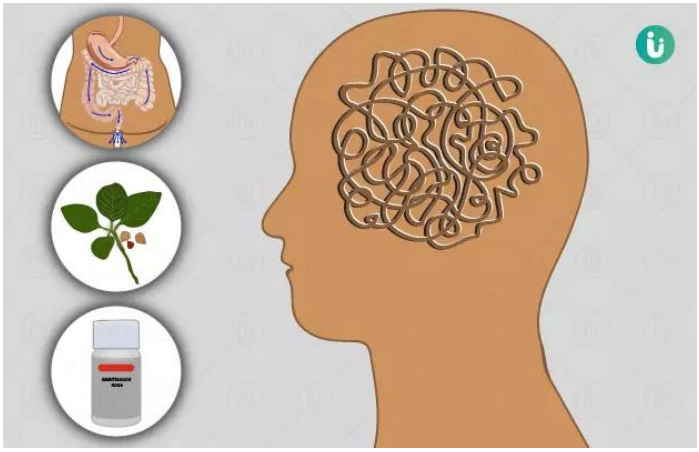

Article Received on
22 June 2021,

Revised on 12 July 2021,
Accepted on 01 August 2021

DOI: 10.20959/wjpr202110-21300

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ABSTRACT

The present study was aimed to evaluate the efficacy of Ayurvedic brain tonic medicine, a polyhedral drug, and in patients suffering from depression, Anxiety, bipolar disorder, memory loss, insomnia. This was a randomized placebo –controlled clinical trial conducted on 70 patient of either sex with clinical and neurological evidence of mental disorder. A total of 70 patient aged in between 20-75 year were registered and randomly divided into two groups as the trial and control groups. the drugs were composition for 5. The trail drugs showed improvement in memory, insomnia and in should anti-stress; anti-depressant, and anxiolytic properties. The trial group showed better results in the management compared to the control group.

KEYWORDS: ageing, Madhya Ramayana's cognitions degeneration; mental disorder.

INTRODUCTION

The definition and classification of mental disorders are key issues for researchers as well as service providers and those who may be diagnosed. For a mental state to classify as a

disorder, it generally needs to cause dysfunction. Most international clinical documents use the term mental "disorder", while "illness" is also common. It has been noted that using the term "mental" (i.e., of the mind) is not necessarily meant to imply separateness from brain or body.

According to DSM-IV, a mental disorder is a psychological syndrome or pattern which is associated with distress (e.g. via a painful symptom), disability (impairment in one or more important areas of functioning), increased risk of death, or causes a significant loss of autonomy; however it excludes normal responses such as grief from loss of a loved one, and also excludes deviant behavior for political, religious, or societal reasons not arising from a dysfunction in the individual.

DSM-IV precedes the definition with caveats, stating that, as in the case with many medical terms, *mental disorder* "lacks a consistent operational definition that covers all situations", noting that different levels of abstraction can be used for medical definitions, including pathology, symptomology, deviance from a normal range, or etiology, and that the same is true for mental disorders, so that sometimes one type of definition is appropriate, and sometimes another, depending on the situation.

In 2013, the American Psychiatric Association (APA) redefined mental disorders in the DSM-5 as "a syndrome characterized by clinically significant disturbance in an individual's cognition, emotion regulation, or behavior that reflects a dysfunction in the psychological, biological, or developmental processes underlying mental functioning.

aging has becomes a great issue for many countries due to a worldwide life prolongation. number of people over 60 years has grown rapidly to 10% of the world population. India too, in the last decade increasing population aged has been projected significantly. so it is associated with physiological changes afftecting physical, psychological, emotional and social well-being .the major consequences of the increasing number of individual in advanced age group is the increase in number of patients suffering from age –related disorders. Conservative estimation revealed that 25% of the elderly person have significant psychiatric symptoms. Though psychological disorders are common among the aged, it frequently remains undetected and untreated. it induces functional disability, disturb rehabilitation, burdens the health system and impaired the quality of life of elderly individuals.

Research based on the physiological health revealed that age –associated cognitive like memory disorders and depression and insomnia high and anxiety; bipolar disorder memory loss high prevalence among the aged.

Subjective complaints from individuals with age –associated memory impairment often including difficulties in remembering names and words etc. so this condition is the result of physiological changes in the aging brain and not a specific neurological disorder.

IN AYURVEDA literature, impairment of memory is mentioned as smritibhramsha which occurs due to vitiation of rajas and tamas doshas in the mind. the appearance of jara ageing at the appropriate age is termed as kalaja jara and memory impairment appears as a clinical rupa feature of jara hence senile memory impairment can be correlated as jarajanya smritibhramsha according to Ayurveda.

Medhya rasayanas have been derived from the Sanskrit words ‘medhya ‘meaning intellect or cognition and rasayana ‘meaning rejuvenation. the medicinal plants in the ayurvedic system are classed as brain tonics or rejuvenators. earlier reports indicate that these plants are used both in herbal and conventional medicine and other benefits that [pharmaceutical drugs lack. neurological and psychiatric disorders are generally associated with loss of memory, cognitive deficits, impaired mental function etc. the medhya rasayanas are known to be benefical to improve the intellectual eg. Mandukparni swaras yashtimadhu churna with ksheer gudchi swaras and shankpushapushpi kalka.

Mental disorder

A mental disorder, also called a mental illness or psychiatric disorder is a behavioral or mental disorder is a behavioral or mental pattern that causes significant distress or impairment of personal functioning. such features may be persistent, relapsing and remitting, or occur as a single episode. Many disorders have been described, with signs and symptoms that vary widely between specific disorders. Such disorders may be diagnosed by a mental health professional.

The causes of mental disorders are often unclear. Theories may incorporate findings from a range of fields. Mental disorders are usually defined by a combination of how a person behaves, feels, perceives, or thinks. This may be associated with particular regions or functions of the brain, often in a social context. A mental disorder is one aspect of mental

health. Cultural and religious beliefs, as well as social norms, should be taken into account when making a diagnosis.

Services are based in psychiatric hospitals or in the community, and assessments are carried out by mental health professionals such as psychiatrists, psychologists, and clinical social workers, using various methods such as psychometric tests but often relying on observation and questioning. Treatments are provided by various mental health professionals. Psychotherapy and psychiatric medication are two major treatment options. Other treatments include social interventions, peer support, and self-help. In a minority of cases there might be involuntary detention or treatment. Prevention programs have been shown to reduce depression.

Common mental disorders include depression, which affects about 400 million, dementia which affects about 35 million, and schizophrenia, which affects about 21 million people globally. Stigma and discrimination can add to the suffering and disability associated with mental disorders, leading to various social movements attempting to increase understanding and challenge social exclusion.

Synonyms	Psychiatric disorder, psychological disorder, mental illness, mental disease
	
Specialty	Psychiatry, clinical psychology
Symptoms	Agitation, anxiety, depression, mania, paranoia, psychosis
Complications	Cognitive impairment, social problems, suicide
Types	Anxiety disorders, eating disorders, mood disorders, neurodevelopmental disorders, personality disorders, psychotic disorders, substance use disorders
Causes	Genetic and environmental factors
Treatment	Psychotherapy, medications
Medication	Antidepressants, antipsychotics, anxiolytics, mood stabilizers
Frequency	18% per year (United States)[1]

Herbal management of mental disorder

I have chosen these plants and herbal products to prepare my drugs name, brahmi, ashwagandha, sarpagandha, shatavari.

1. Brahmi

Bacopa monnieri (**waterhyssop**, **brahmi**, **thyme-leafed gratiola**, **water hyssop**, **herb of grace Indian pennywort** is a perennial, creeping herb native to the wetlands of southern and Eastern India, Australia, Europe, Africa, Asia, and North and South America. Bacopa is a medicinal herb used in Ayurveda, where it is also known as "Brahmi", after Brahmā, the creator God of the Hindu pantheon. It is a non-aromatic herb. The leaves of this plant are succulent, oblong and 4–6 mm (0.16–0.24 in) thick. Leaves are oblanceolate and are arranged oppositely (opposite deccusate) on the stem. The flowers are small, actinomorphic and white, with four to five petals. Its ability to grow in water makes it a popular aquarium plant. It can even grow in slightly brackish conditions. Propagation is often achieved through cuttings.

Brahmi is a therapeutic herb commonly **used** as a memory enhancer, aphrodisiac and a **health** tonic. ... **Brahmi** reduces stress and anxiety as it decreases the levels of cortisol, which is known as the stress hormone. **Brahmi** counteracts the effects of stress by regulating hormones involved with the stress response.

- Brahmi reduces stress and anxiety as it decreases the levels of cortisol, which is known as the stress hormone. Brahmi counteracts the effects of stress by regulating hormones involved with the stress response.

- Brahmi is known to help ease the symptoms of Alzheimer’s disease due to the presence of the amyloid compound in the neuron that is responsible for damaging the brain. The bio-chemical known as bacosides in Brahmi helps in re-building brain tissues by influencing the brain cells.

- As suggested by Dr. Sharma, Brahmi helps in boosting your memory. It has a positive effect on the hippocampus part of the brain that is responsible for intelligence, concentration and memory. Interestingly, the leaf of the Brahmi herb has a similar shape like that of the cerebellum - part of the brain which helps in controlling concentration and memory.

Brahmi leaves (fresh or dry) can be used to make tea that helps calming you down and relieves anxiety and stress. There are Brahmi supplements available in the markets as pills or in powdered form, but it is advisable to take these supplements only after consulting a doctor or a health expert.

2. Ashwagandha

Ashwagandha is a herb rich in antioxidants that can lower cortisol levels by 28%, fight cell damage caused by free radicals, and promote restorative sleep. That way, it cures chronic stress, improves insomnia, and reduces depression and anxiety. It also clears protein plaques, raises dopamine levels, reconstructs nerve networks and synapses, and improves muscle control and balance, thus helping patients with Alzheimer's and Parkinson's.

Ashwagandha (Withania somnifera), a subtropical undershrub, is highly esteemed as a potent herb in Ayurveda. It exerts a positive influence on the central nervous system by combating mental and emotional stress. Ashwagandha prevents and repairs brain cell damage; reconstructs nerve networks and synapses; improves memory, muscle control, body movements, and balance; regulates sleep-wake cycles; reduces stress; improves vitality; and stabilizes mood. Ashwagandha has been shown to increase levels of key antioxidant enzymes, clear protein plaques, increase dopamine levels, and reconstruct nerve networks and synapses. It prevents, repairs, and heals brain cell damage and helps improve muscle control,

movement, balance, and memory – all of which are beneficial for Parkinson's and Alzheimer's patients.

Insomnia occurs when the body cannot regulate its sleep-wake cycles typically because of chronic stress and deterioration in immunity, metabolism, and hormonal balance. Ashwagandha does not act as a sedative; instead, it reduces stress, improves vitality, and makes the body more robust and active, thereby helping restore the body's natural mechanisms to regulate sleep. About 2 tsps a day is both effective and safe. Ashwagandha is a direct cure for chronic stress as it can reduce cortisol levels by 28% and promote restorative sleep. By lowering blood pressure and blood glucose, it treats hypertension and diabetes, which are both causes and effects of stress. It cures depression and anxiety and can even cure Alzheimer's by repairing damaged brain cells and reconstructing nerve cell networks. It also cures premature aging induced by stress.

Taken daily, ashwagandha can mitigate chronic stress, which is a key driver of anxiety and depression. It also curbs calcium excitation, a probable cause of many psychiatric conditions, like anxiety. It trumps standard anti-anxiety and antidepressant drugs as it stabilizes mood, relieves insomnia, and revitalizes the body sans side effects or withdrawal symptoms.

3. Sarpagandha

Sarpagandha has been known for its medicinal value and has several medicinal value and has several health benefits, such as; Treatment of snake and spider bites, reduces high blood pressure, suitable remedy for insomnia, aids to mental disorders, regularizes menstruation, controls dysentery, provides relief from uterine pain due to or after miscarriage. Sarpagandha is a species of flower from the family Apocynaceae. It is an evergreen, erect, perennial herbs. Roots of this herb are tuberous with a cork of pale brown colour, leaves are of bright green colour and found in whorl of three. The flowers are mostly white in colour, sometimes violet. Drupes of this plants are slightly connate, ovoid, and purplish black in colour. Fruits are oval and fleshy, turns shiny purple – black on ripening. Sarpagandha has hypnotic action, which helps to induce sleep. Its root powder can be used for this purpose along with Rose Distillate, just 2 hours before sleep. For the best results, Sarpagandha powder along with 1 part of khurasani ajwain combined with 2 parts of misery can be taken before sleep. Sarpagandha has hypnotic, antipsychotic (neuroleptic), sedative and anti-anxiety actions. Therefore, it helps to treat several types of mental disorders with aggression, crying, running, beating and sleeplessness. In such cases, 1 part of Sarpagandha

powder mixed with 2 parts of Jatamansi Root Powder, should be taken twice daily with cow's milk.

4. Shatavari

This lovely herb comes to us via India and Ayurvedic medicine and is one of the most common herbs given for women's health. shatavari promotes breast milk production, strengthens women,s reproductive system, improve hormonal balance and strengthens fertility.

Shatavari also improve digestion and elimination, cooling bronchial and digestive inflammation, strengthens the immune system and has a nice gentle quality for reducing stress and tension in the system. This is an herb that is especially useful for women who tend to run dry and hot, appear exhausted and overwhelmed with associated digestive and reproductive inflammation.

5. Shankhpushpi

Shankhpushpi convolvulus pluricaulis is an herb found in India and Burma that is used in Ayurveda. The Ayurveda preparation shankapushpi is, according to most sources, identical with convolvulus pluricaulis, but some say shankpushpi is clitoria ternatea.

Properties: nootropic anxiolytic nervous system tonic anti-inflammatory, analgesic expectorant, diuretic, hypotensive.

Action: long used in ayurvedic medicine, shankhpushpi is primarily offered to improve memory, concentration, cognitive acuity and to reduce anxiety, sleeplessness and melancholy. shankhpushpi is a nervous system tonic, stimulates blood circulation, reduces blood pressure and alleviates pain such as depression and neuralgia. Ayurvedic practitioners offer it in formulas for dementia, insomnia, anxiety hypertension and to improve sperm production.

Dose given for clinical trial

Ashwagandha – 1 gm

Supportive drugs:

Bramhi -2gm

Shankhpushpi 500-mg

Shatavari -1gm

Sarpagandha-500mg

Dose to be taken

Each sample of medicine by name of "AYURVEDIC BRAIN TONE MEDICINE" contains 100 gm of medications as mentioned above.

Patient was advised to take the medicine as follows:

1. For old age group: one tea spoon twice a day.
2. For adult : one tea spoon twice a day
3. For adolescent: half tea spoon twice a day.

Note: one tea spoon contains nearly 5 gm of medication.

Picture of the drug sample used for trail

MATERIAL AND METHODS

Selection of the patients

Total 70 patients having symptoms of memory impairment attending O.P.D AND I.PD.OF Department of kayachikitsa faculty of Ayurveda institute of medical sciences Banaras Hindu university Varanasi [up] India were selected for the present study. A purposive sampling technique brain power machine was adopted irrespective of their sex, religion, occupation, educational status etc.

Criteria of inclusion

1. Patient aged 20 and above up to 55 years of age.
2. Complaints of memory impaired on the basic of shorts term and long term.

Case history: patients with major depressive disorder may not initially present with a complaint of low mood, anhedonia, or other typical symptoms in the primary care setting, where many of these patients first seek treatment, the presenting complaints often can be somatic(eg fatigue, headache, abdominal distess, or change in Wight). Patients may complain more of irritability or difficulty concentrating than of sadness or low mood. Dysphonic mood state may be expressed by patients as sadness, heaviness, numbness, or sometimes irritability and mood swings. They often report a loss of interest or pleasure in

their usual activities, difficulty and motivation. their thinking is often negative, frequently with feeling of worthlessness, hopelessness or helplessness.

Psychosis: patients with major depressive disorder commonly show ruminative thinking. nevertheless, it is important to evaluate each patient for evidence of psychotic symptoms, because this affects initial management.

Short term e.g. misplacing objects, difficulty in remembering multiple items to be purchased, difficulty in recalling information quickly, problems in remembering name and place telephone numbers.

Long term: eg difficulty in recall of special event of personal life, difficulty in recall of special events of personal life, difficulty in recall of pervious histories of life and recognition.

Patient suffering from depression, bipolar disorder, insomnia,

Criteria of exclusion

1. Patient below 55 years and above 75year of age.
2. Patient with evidence of delirium, confusion or other disturbances of consciousness, Parkinson s disease, stroke, intracranial hemorrhage, brain tumors, history of alcoholism or drug dependence, use of any psychotropic drug, Alzheimer,s disease, diabetes mellitus, etc.

Investigation: routine hematological and biochemical test were carried out before and after the treatment. Among the biochemical tests, serum Acetylcholine Esterase [AchE] estimation, as a biomarker of senile memory impairment was carried out.

Plan of the study

Patient fulfilling the inclusion criterion were grouped in to two after obtaining written consent.

Subjective criteria: assessments on improvement in signs and symptoms were carried out using appropriately designed scoring method, with the scores ranging from 0 to 4. cognitive state was assessed by mini mental state examination .and psychological health of the patient was evaluated with Hamilton rating scales for depression and anxiety.

Objective Criteria: serum ache estimation was carried out as a biomarker of senile memory impairment.

OBSERVATION AND RESULTS

In this study, various ethological factor were identified. maximum number of patients reported chinta (thoughts; 92%) followed by krodha (anger; 83.3%), (worries; 70%), chgittodvega (anxiety; 64.4%) Bhaya (fear; 51.4%) Ruksha ahara (dried food; 55.7%), rattri jagarana (awaking at night; 87%), etc.

Place for conduction of clinical trail

The trail was conducted in Outpatient department of kayachikitsha, in psychiatry OPD, Faculty of Ayurveda, Sir sunderlaal hospital, Banaras Hindu University under the super vision of Professor Dr. J. S. Tripathi for a total duration of 6 months.

RESULTS

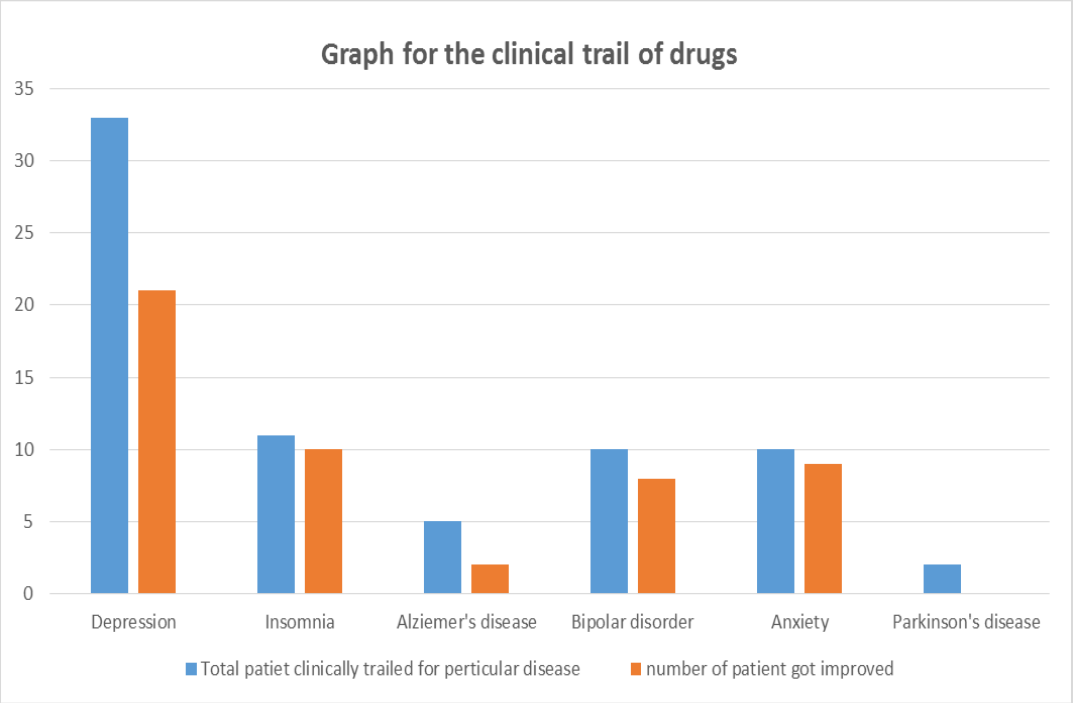
Total number of patient -70

Disease	Total patient clinically trailed for particular disease	number of patient got improved
Depression	33	21
Insomnia	11	10
Alziemer's disease	5	2
Bipolar disorder	10	8
Anxiety	10	9
Parkinson's disease	2	0

Response of patient towards medicine:

Till now I have tried this medication on 70 patient out of which 50 showed nice improvement as follows;

- 63% patient gave positive response depression
- 90.9% patient gave positive response insomnia
- 40% patient gave positive response Alzheimer’s disorder.
- 80% patient gave positive response Bipolar disorder.
- 90% patient gave positive response Anxiety
- And patient of Parkinson’s disease are still under the trial.



1. I have taken 33 patients suffering from depression and from that 21 patients got improved by medicine.
2. I have taken 11 patients suffering from insomnia and from that 10 patients got improved by medicine.
3. I have taken 5 patients suffering from Alzheimer, disease and from that 2 patients got improved by medicine.
4. I have taken 10 patients suffering from bipolar disorder and from those 8 patients got improved by medicine.
5. I have taken 10 patient suffering from anxiety and from that 9 patients got improved.
6. I have taken 2 patient from Parkinson's disease and those patients are still under the trail, the result is not declared till now.

DISCUSSION

It has been mentioned in text that GMR contributes to enhance the memory power within a short period on the basic of nootropic drug the pharmacotherapeutic properties reveal that it contain ashwagandha(withania somnifera) GABA-like activity, owing to its anxiolytic effect increase in the level of three natural antioxidants superoxide dismutase, catalase and glutathione peroxidase. sarpagandha has been known for its medicinal value and has several medicinal value and has several health benefits, such as; Treatment of snake and spider bites, reduces high blood pressure, suitable remedy for insomnia, aids to mental disorders,

regularizes menstruation, controls dysentery, provides relief from uterine pain due to or after miscarriage. Sarpagandha is a species of flower from the family Apocynaceae. It is an evergreen, erect, perennial herbs. Roots of this herb are tuberous with a cork of pale brown colour, leaves are of bright green colour and found in whorl of three. The flowers are mostly white in colour, sometimes violet. Drupes of this plants are slightly connate, ovoid, and purplish black in colour. Fruits are oval and fleshy, turns shiny purple – black on ripening. Sarpagandha has hypnotic action, which helps to induce sleep. Its root powder can be used for this purpose along with Rose Distillate, just 2 hours before sleep. For the best results, Sarpagandha powder along with 1 part of khurasani ajwain combined with 2 parts of misery can be taken before sleep. Sarpagandha has hypnotic, antipsychotic (neuroleptic), sedative and anti-anxiety actions. Therefore, it helps to treat several types of mental disorders with aggression, crying, running, beating and sleeplessness. In such cases, 1 part of Sarpagandha powder mixed with 2 parts of Jatamansi Root Powder, should be taken twice daily with cow's milk. Shatavari also improve digestion and elimination, cooling bronchial and digestive inflammation, strengthens the immune system and has a nice gentle quality for reducing stress and tension in the system. This is an herb that is especially useful for women who tend to run dry and hot, appear exhausted and overwhelmed with associated digestive and reproductive inflammation. **Brahmi** is a therapeutic herb commonly **used** as a memory enhancer, aphrodisiac and a **health** tonic. ... **Brahmi** reduces stress and anxiety as it decreases the levels of cortisol, which is known as the stress hormone. **Brahmi** counteracts the effects of stress by regulating hormones involved with the stress response. Till now I have trailed this medication on 70 patient out of which 50 showed nice improvement in condition of. These observations reveal that the drug might have counteracted or pacified *Raja* and *Tamo Doshas*, so *Avarana* of mind was removed and the disease was subsided or controlled. Further pharmacological studies have proven that *Vaca* (*Acorus calemus* Linn.) and *Shankhapushpi* (*Convolvulus pluricaulis* Chois) have anxiolytic, memory enhancing, anti-stress, antidepressant, tranquilizing and sedative activities. Further, it was found that there was a significant improvement by 14.84% on the total score of the Mini Mental State Examination.

CONCLUSIONS

Senile Memory Impairment can be correlated to *Jarajanya Smritibhramsha* according to Ayurveda, and imbalance of *Trigunas* through aggravation of *Rajas* and *Tamas Doshas* in the mind leads to development of Senile Memory Impairment among elders. Modern literature

reveals that Senile Memory Impairment is closely associated with cognitive decline during aging. All the patients of Senile Memory Impairment were having features of impairment of short memory and long memory in this study. *Manasika Nidana* (psychic factors), *Aharaja* (dietary) and *Viharaja* (behavioral) factors, which were reported by the patients, play a major role in the pathogenesis of Senile Memory Impairment by vitiating *Rajas* and *Tamas Doshas* in the mind. Those factors were *Chinta* (thoughts), *Krodha* (anger), *Shoka* (worries), *Chittodvega* (anxiety), *Bhaya* (fear), *Moha* (illusions), *Ruksha Ahara* (dried food), *Ratri Jagarana* (awaking at night), etc. GMR has shown statistically highly significant improvement on short memory impairment as well as long memory impairment in Senile Memory Impairment, Reduction of AChE showed enhancement of memory functions due to improvement of cholinergic actions in the human brain in the trial group (Group A). GMR has shown memory enhancing, Antidepressant, anti-stress, and anxiolytic potential. Hence, *Madhya Ramayana* and nootropic drug therapy has proved so as to provide better improvement in comparison to the control. Mental disorder, also called a mental illness or psychiatric disorder is a behavioral or mental disorder is a behavioral or mental pattern that causes significant distress or impairment of personal functioning. such features may be persistent, relapsing and remitting, or occur as a single episode. Many disorders have been described, with signs and symptoms that vary widely between specific disorders. Such disorders may be diagnosed by a mental health professional.

Out of 70 patient, 50 patient of various psychotic and neurological disorder which counts nearly 70 percent showed positive response to the medicine which is quite clearly presented in the above Graph.

Response of patient towards medicine:

Till now I have tried this medication on 70 patient out of which 50 showed nice improvement as follows;

- 63% patient gave positive response depression
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