Original Research (Clinical Study)

A Randomised Controlled Clinical Trial to Evaluate the Effect of *Jatamansi* and *Ashwagandha Moola Churna* in the Management of *Anidra* w. s. r. to Insomnia

Ankita Goyal[1*] Gurpreet Sama[2]

[1]Lecturer, Department of Dravyaguna Vigyan, Government Ayurvedic College, Patiala, Punjab, India 147001

[2]Post Graduate Scholar, Department of Dravyaguna Vigyan, Government Ayurvedic College, Patiala, Punjab, India 147001

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*Corresponding author:

ankita.goyal07@gmail.com

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ABSTRACT

Background: Insomnia is one of the burning problems not only in India but also all over the world. According to the statistics, 20% - 40% of adults encounter insomnia-related problems within a year. Especially 15 to 55 years old are more affected. Long-term uses of certain classes of sedatives such as benzodiazepines and newer non-benzodiazepine drugs cause physical dependence, with several side effects such as daytime fatigue. **Objectives:** To evaluate the clinical efficacy of *Jatamansi (Nardostachys jatamansi* DC.) and *Ashwagandha (Withania somnifera* Dunal) *moola churna* in *anidra* (Insomnia). **Materials and Methods:** A randomized, open-label, interventional clinical trial was conducted with 60 patients (30 in each group). Group A received *Jatamansi moola churna* (JMC) and Group B received *Ashwagandha moola churna* (AMC), both in capsule form for internal use. Treatment was administered once daily at night for 30 days. Improvement was assessed based on Ayurvedic subjective parameters: *Angmarda, Shirogaurva. Jrimbha, Jadyata, Apakti, Bhrama, Glani, Tandra, Vataj roga* and modern parameters Pittsburgh Sleep Quality Index (PSQI). **Results:** Both Groups showed statistically significant improvement ($p<0.001$). *Jatamansi moola churna* was slightly more effective, particularly in reducing *Angmarda*, *Shirogaurva. Jrimbha, Jadyata, Apakti, Glani, Tandra*, Sleep duration, Sleep disturbance, daytime dysfunction *Ashwagandha moola churna* was more effective in *Bhrama vataj roga*, sleep latency. **Conclusion:** The study concludes that both drugs *Jatamansi* and *Ashwagandha* have effective role in subsiding symptoms associated with *Anindra* (Primary insomnia). However, *Jatamansi* was found to be more effective than *Ashwagandha* upon comparison.

Keywords: *Anidra,* Insomnia, *Jatamansi, Ashwagandha,* Pittsburgh Sleep Quality Index

1. INTRODUCTION

Human life is an invaluable opportunity to achieve the prime goals of life, viz. *Dharma, Artha, Kam*a, and *Moksha*. To achieve all these things, one needs a healthy and calm life. In this competitive and stressful era, sleep has proven to be a divine gift to human beings, which refreshes and recharges an individual for further struggle for survival. However, sound sleep in a peaceful state of mind is hardly possible in this modern world. In the Ayurvedic literature, three factors, viz. *Ahara, Nidra,* and *Brahmacharya* have been compared with the three legs of a sub-pillar and have been termed the three *Upasthambhas* [1]. Approximately one-third of the adult population occasionally reports sleep problems, and 6-10% report symptoms that meet the diagnostic criteria for insomnia disorder [2]. Now it is increasing in the younger age group and the middle age group, because of lifestyle changes. Inadequate sleep not only affects the individual himself but also affects society, in turn increasing in psychic diseases. Among insomniacs, 28% receive psychotropic drugs, 14% receive benzodiazepines, and 19% receive antidepressants. Allopathic hypnotic drugs are useful for the short-term treatment of insomnia, which is due to the acute stage. Long-term use of certain classes of sedatives, such as benzodiazepines and newer non-benzodiazepine drugs cause physical dependence, which manifests in withdrawal symptoms if the drug is not carefully tapered down. Further, the benzodiazepine and non-benzodiazepine hypnotic medications also have several side effects, such as daytime fatigue [3]. Insomnia is 1.4 times more common in women than in men and affects 1 in 3 people [4]. In the present era, patients prefer readymade, cost-effective, easily palatable drugs with fewer side effects for their health problems. Hence, it is the need of the hour to formulate such a herbal formulation that can be a solution for Insomnia and can be prescribed for the long term with minimal adverse effects. From a hand search of previous research done in Ayurveda, it is found that only a few clinical trials have been done to establish the role of *Jatamansi* and *Ashwagandha* in the management of insomnia. Considering this point, a present clinical trial has been planned to evaluate the role of *Jatamansi* and *Ashwagandha mool churna (AMC)* in the management of insomnia. As both the plants have *Medya* and mind-calming properties as per textual references, an attempt is made to compare their efficacy in *Anidra*. *Jatamansi (Nardostachys jatamansi* DC.) & *Ashwagandha (Withania sommifera* Dunal) both have *Nidrajanana* and *Vatahara Karma, Jatamansi*

(Nardostachys jatamansi DC.) has properties such as *Tikta, Kashaya, Madhura Rasa, Snigdha Guna, Sheeta Virya,* and has *Nidrajanan, Medhya,* and *Sangya, Sthapak Karma* [5]. *Ashwagandha (Withania sommifera* Dunal) has *Tikta, Katu, Madhura Rasa, Laghu,* and *Snigdha Guna, Ushna Veerya,* and has *Vatahara, Dhatuvardhaka, Rasayana, Swapanajana Karma* [6]. Both the *Aushadha Dravya* have anti-stress, neuroprotective, antioxidant, memory-enhancing properties, and help to relieve stress, and insomnia, and act as a rejuvenator and brain tonic.

1.2. Phytoconstituents in these drugs

Constituents are listed below:

Jatamansi root [7]	*Ashwagandha* root [8]
Jatamansone	Wathanolides
Valeranone	Somniferinine
Nardostachone	Tropine
Atchoulense	Cuscohygrine
Jatumunsin	Somniferine
Valeranal	Withananine
Alpha-patcho-ulense	Pseudo-tropine
B-sitosterol	Isopelletierine
Jatamansinol	Somnine
Nurdostachnol	Pseudo-withanine
Angelicin	3-a-gloyloxytropane
Volatile oil	Anaferine andanahydrine

1.3. Objectives of the study

To evaluate the clinical efficacy of *Jatamansi* (*Nardostachys jatamansi* DC.) and *Ashwagandha* (*Withania somnifera* Dunal) *moola churna* in *Anidra* (Insomnia).

2. MATERIALS AND METHODS

2.1. Collection of Drug

Jatamansi (*Nardostachys jatamansi* DC.) and *Ashwagandha* (*Withania somnifera* Dunal) *Moola* for the present study were procured from Herbal Health Research Consortium, Amritsar, Punjab, India and were authenticated by Government Drug Testing Lab, Patiala (Punjab).

2.2. Pharmaceutical preparation

Churna kalpna (Upkalpna of Kalka) has a longer shelf life, a low dose, and improved palatability, among the five basic *Kalpnas* (Formulations) mentioned in Ayurveda. In the present research, *Churna* (Powder), preparation of the rest of the drugs was dispensed in capsule form to overcome the hygroscopic nature of *Churna* [9].

2.3. Ethical considerations

Approval of the Institutional Ethics Committee (IAC) was obtained before the start of the research (Reference letter reference no. 4685/02-11-2022, Government Ayurvedic College, Patiala)

CTRI registration was done with, Registration No. CTRI/2023/08/057101.

Written informed consent was obtained from all the participants prior to their selection as patients and the data was kept confidential.

2.4. Clinical study: Trial design

The clinical study was designed as a randomized, double-group, open interventional trial with two Groups: Group A: JMC (Trial group) and Group B: AMC (Control group). Sixty-five patients were enrolled irrespective of caste, creed, sex, religion etc., with informed consent, following the inclusion, exclusion criteria. Thirty patients each for *Jatamansi mool churna* (Group A) and *Ashwagandha mool churna* (Group B) completed the course of trial. Five patients were dropouts. Two in-group A and three in Group B.

2.4.1. Inclusion Criteria

i. Patients who had given written consent for the study. Patients aged between 18 and 60 years were selected irrespective of sex, religion, and economic status.

ii. Patients having clinical features of *Anidra* (Insomnia) as

Angmarda (pain over body parts), *Shirogourva* (Heaviness of head), *Jrimbha* (Yawning), *Bhrama* (Hallucinations), *Glani* (Guilt), *Vat Roga* (Musculoskeletal disorders) *Tandra* (Sleepiness), *Jadyata* (Stiffness).

iii. Post CoViD19 insomnia.

iv. Patients with computer or mobile screening time less than six hours.

2.4.2. Exclusion Criteria

i. Persons who did not agree to give written consent for the study.

ii. Patients below the age of 18 and above the age of 60 years.

iii. Pregnant and lactating mothers.

iv. Patients having a history of any serious systemic illness, such as hypotension, psychological disorder (Schizophrenia or bipolar disorders).

v. Patients taking medications like antidepressants and sleeping pills.

vi. Patients with computer or mobile screening time more than six hours.

2.4.3. Site of study

Department of *Kaya Chikitsa*, Government Ayurvedic Hospital,

Patiala, from September 2023 to January 2024.

2.5. Intervention

- Dosage form: *Jatamansi mool churna* and *Ashwagandha mool churna* in Capsule form.
- Dose and frequency: 2gm (4 Capsules of 500mg each) at bedtime with lukewarm water for 30 days.
- Duration: 30 days of intervention and 7 days after treatment, stopping the medicine.
- Follow up On Day 1, Day 15, Day 30, and Day 37 (7days after stopping the medicine).

2.6. Outcomes

2.6.1. Primary outcomes

Patients were assessed for *Anidra* (Insomnia) at Day 1 for Ayurvedic parameters *Angmarda, Shirogaurva, Jrimbha, Jadyata, Glani, Bhrama, Tandra, Vataj Roga* subjectively and using PSQI index for Sleep latency, Sleep duration, Sleep disturbance, Sleep quality, Sleep medication, Day time dysfunction, Habitual sleep efficiency. A general follow up was done on Day 15, Day 30 with intervention and Day 37 after stopping the intervention. These were considered as a statistical outcome measures for the present study.

2.6.2. Secondary outcomes

The other day-to-day activities that might hamper sleep were also assessed, like usual bedtime, time taken to usually fall asleep each night, other factors that may affect sleep, like snoring, anxiety, etc., using PSQI. Objective parameters like Hb, TLC, DLC, ESR, LFT, RFT were done before treatment and after treatment to see any changes in the parameters. These were not considered as a statistical outcome measures in the study.

2.6.3. Sample size and randomization

A convenient sample of 65 patients, 30 in each group, was randomized with simple random technique based on footfalls in the clinical OPD at Department of Kaya-chikitsa. Alteration of the patients to each group was done. The estimated duration of the trial was for one year. Trial completed within 6 months with efficient procurement of required resources. There were five dropouts. Two in-group A and three in-group B. The template for Consort flow diagram is as shown in Fig1.

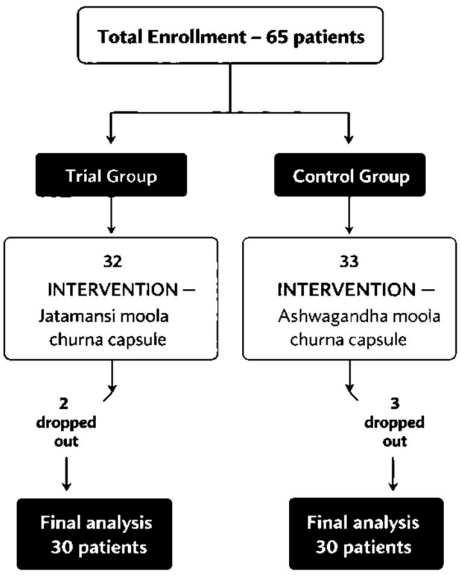

Fig.1. Consort flow diagram

2.6.4. Outcomes and estimation

The results evaluated using subjective and objective variables were classified under five groups in subjective and objective parameters as

- Complete relief : 76-100%
- Marked improvement: 51-75%
- Moderate relief: 26-50%
- Mild relief: 10-25%
- No relief : less than 10%

3. RESULTS

The selected patients were statistically evaluated by applying Wilcoxon Signed Rank test on subjective criteria.

53.4 % of the patients had *Angmarda* in the Grade of three before treatment, which was reduced to Grade 1 after treatment, with 63.4 % of patients in Group A and 43.3 % of the patients had *Angmarda* in the range of 3 before treatment which was reduced to Grade 1 after treatment, with 46.46 % of patients in Group B.

56.7 % of the patients had *Shirogaurav* in the range of 4, before treatment which was reduced to Grade 1 where 70% of patients were relieved after treatment in Group A and 50% of the patients had *Shirogaurav* with Grade 3, before treatment which was reduced to Grade 0 where 33.3% of patients were relieved after treatment and there is no *Shirogaurav* in Group B.

40% of patients had *Jrimbha* with Grade 2, before treatment which was reduced to Grade 1 where 70% of patients were relieved after treatment in Group A and 50% of the patients had *Jrimbha* with Grade 4, before treatment which was reduced to Grade 2 where 33.4 % of patients had relieved after treatment and there is no *Jrimbha* in Group B.

56.7% of the patients had *Jadyata* with Grade 4, before treatment, which was reduced to Grade 1 where 63.4 % of patients were relieved after treatment in Group A and 40% of patients had *Jadyata* with Grade 3, before treatment, which was reduced to Grade 1 where 36.7% of patients were relieved after treatment in Group B.

46.7% of patients had *Apakti* with grade 3, before treatment, which was reduced to Grade 1 where 43.3% of patients were relieved after treatment in Group A and 56.7% of patients had *Apakti* with grade 4, before treatment, which was reduced to Grade 3 where 36.7% of patients were relieved after treatment in Group B.

36.7% of patients had *Bhram* with grade 0, before treatment, which was reduced to Grade 0 where 53.3% of patients were relieved after treatment in Group A and 46.7% of patients had *Bhram* with grade 2, before treatment, which was reduced to Grade 1 where 60% of patients were relieved after treatment in Group B. 63.3% of patients had *Glani* with grade 3, before treatment, which was reduced to Grade 1 where 63.3% of patients were relieved after treatment in Group A and 33.3% of patients had *Glani* with grade 2, before treatment, which was reduced to Grade 1 where 53.3% of patients were relieved after treatment in Group B.

30 % of the patients had *Tandra* with grade 2 and 3 before treatment, which was reduced to Grade 1 where 36.6 % of patients were relieved after treatment. This implies that most of the patients were relieved of *Tandra*'s symptoms in Group A. whereas 40 % of the patients had *Tandra* with grade 4 before treatment, which was reduced to Grade 1 where 66.7 % of patients were relieved after treatment in Group B.

43.3% of the patients had *Vat Roga* before treatment, which was reduced to Grade 1 whereas 43.3 % of patients were relieved after treatment in-group A whereas 40% of the patients had *Vat Roga* before treatment which was reduced to Grade 0 where 40% of patients were relieved after treatment.

Out of 60 patients enrolled in the study, In Group A the maximum number (60%) of patients were between the age group 51-60 years, the Minimum (3.3%) belonged to the age group of 21-30 years and the rest of the patients were between the age group 31-50 years. In Group B the maximum number (53.4%) of patients were between the age group 51-60 years, the minimum (3.3%) belonged to the age group of 18-20 years and the rest of the patients were between the age group 21-50 years.

Among 60 patients, In Group A 29 enrolled patients were married and 1 was unmarried, 15 male and 15 female, and in group B, 27 patients were married and 3 were unmarried, 17 male and 13 female were present.

Baseline data for etiological factors indicated that 36.7% of patients in Group A and 46.7% in Group B were Non-vegetarian. 56.7% of patients had no

addiction, 23.3% were addicted to alcohol, 16.7% were addicted to tea and the rest had cigarette addiction in Group A and 80% of patients had no addiction, 20% were addicted to alcohol and no patient was addicted to tea and cigarette addiction in Group B. 86.7% of patients had *Manda Agni* (Slow digestion) whereas 13.3 % had *Sama Agni* (Normal digestion) and in Group A, 96.7% patients had *Manda Agni* whereas 3.3 % had Sama *Agni* in Group B. 86.7% of patients were of *Vata-Pittaj Prakriti* and the rest 13.3% were of *Vata-Kaphaj Prakriti* in Group A and 93.3% of patients were of *Vata-Pittaj Prakriti* and the rest 6.7% were of *Vata-Kaphaj Prakriti* in Group B. In terms of physical activity, 40% of patients in Group A and 30% in Group B were not in the habit of exercising.

3.1. Results based on Pittsburgh Sleep Quality Index (PSQI)

66.7% of the patients had difficulty in falling asleep with grade 2 before treatment which was reduced to Grade 1 where 40% of patients were relieved with improvement in Sleep latency after treatment in Group A and about 50% of the patients had Sleep latency problem with grade 1 before treatment which was reduced to Grade 1 where 60% of patients were relieved with improvement in Sleep latency after treatment in Group B.

56.7% of the patients had lesser sleep duration before treatment which was reduced to Grade 1 where 46.7 % of patients felt increased Sleep duration after treatment in Group A and 70% of the patients had lesser sleep duration with grade 2 before treatment which was reduced to Grade 1 where 76.7% of patients were felt increased Sleep duration after treatment in Group B.

66.7% of the patients had sleep disturbance before treatment with grade 3 which was reduced to grade 1 after treatment where 56.7% of patients were relieved with reduced sleep disturbance in Group A and 56.7% of the patients had sleep disturbance before treatment with grade 3 which was reduced to grade 2 after treatment where 43.4% of patients were relieved with reduced sleep disturbance in Group B.

43.3% of the patients had poor Sleep quality with grade 3 before treatment which improved to Grade 1 with 50% of patients felt better sleep quality after treatment in Group A and 46.7% of the patients had poor Sleep quality before treatment with grade 2 which improved to Grade 0 where 53.3% of patients were patients felt better sleep quality after treatment in Group B. 43.3 % of the patients were on Sleep medication with grade 3, before treatment which was

reduced to Grade1 where 63.3 % of patients reduced taking Sleep medication after treatment in Group A and 56.7% of the patients were on Sleep medication with grade 3, before treatment which was reduced to Grade1 where 46.7% of patients reduced taking medication after treatment in Group B.

and 56.7% of patients were suffering with day time dysfunctioning with grade 2 before treatment which was reduced to grade 1with 56.7% of patients in Group B.

50% of patients were having poor Sleep efficiency with grade 1 which improved to grade 0 with 56.7% of patients in Group A

Ayurvedic parameters	**Comparison**
Angamarda	Upon comparison of both Groups, it is inferred that Group A is better relieved than Group B.
Shirogaurava	Upon comparison of both Groups, it is inferred that Group A is better relieved than Group B.
Jrimbha	Upon comparison of both Groups, it is inferred that the Group A is better relieve than Group B.
Jadyata	Upon comparison of both Groups, it is inferred that Group A is better relieved than Group B.
Apakti	Upon comparison of both Groups, it is inferred that Group A is better relieved than Group B.
Bhrama	Upon comparison of both Groups, it is inferred that Group B is better relieved than Group A.
Glani	Upon comparison of both Groups, it is inferred that Group A is better relieved than Group B.
Tandra	Upon comparison of both Groups, it is inferred that Group A is better relieved than Group B.
Vat Roga	Upon comparison of both Groups, it is inferred that Group B is better relieved than Group A.
Modern Parameters	
Sleep Latency	Upon comparison of both Groups, it is inferred that Group B is better relieved than Group A.

33.4% of patients were suffering with daytime dysfunctioning with grade 2 before treatment which was reduced to grade 0 with 50% of patients in Group B.

and 46.7 % of patients were having poor sleep efficiency with grade 2 which improved to grade 1 with 40% of patients in Group B.

Sleep duration	Upon comparison of both Groups, it is inferred that Group A is better relieved than Group B.
Sleep disturbance	Upon comparison of both Groups, it is inferred that Group A is better relieved than Group B.
Sleep quality	Upon comparison of both Groups, it is inferred that both the Groups relieved equaly.
Sleep medication	Upon comparison of both Groups, it is inferred that both the Groups relieved equaly.
Day time dysfunction	Upon comparison of both Groups, it is inferred that Group A is better relieved than Group B.
Habitual sleep efficiency	Upon comparison of both Groups, it is inferred that both the Groups relieved equally.

4. DISCUSSION

4.1. Probable mode of action of Jatamamsi

In *Anidra* both *Vata Dosha* and *Manas* (Mind) play an important and interdependent role, if one is vitiated it also affects other adversely. *Jatamansi* is quoted as *Soumanasyajanana*, in Ayurveda as it acts on *Manas* and there by leading to *Mana Prasadana* and inducing, the sound sleep.

Due to *Tikta, Kashaya Rasa* both the drugs *Jatamansi* help to open up the blocked *Manovahi-srotas*.

At *Mahabhoot* (five elements) level *Vayu*, *Agni* and *Akash* help to improve *Agni* and open the channels. Due to *Snigdha Guna*, *Kapha* is increased in body leading to increase in *Tamodosha*, as both *Kapha* and *Tamoguna* are imminent factors to induce sleep. *Snigdha Guna* is *Jala Mahabhoot* dominant same as *Kapha* thus according to *Smanya Sidhant* it helps to increase *Kapha Dosha* and induces sleep.

Katu Vipak of *Jatamansi* helps to open up blocked *Manovahi Srotas* in Anidra, leading to normalize sleep. *Sheet Virya* of *Jatamansi* results in *Brhinghan Karam*, which help to calm the mind and induce sleep. *Jatamansi* also improves sleep tendency by its *Manodoshhara Prabhav*, which helps to relieve stress that induces sleep. According to Ayurvedic Pharmacopoeia of India *Jatamansi* is having the properties like *Tridoshanut* and *Nidrajanana*. In addition, it is having therapeutic uses in *Manasaroga, Anidra.* *Jatamansi* contains a variety of chemical constituents, mainly Jatamansic acid, Nardostachone, Jatamansinol, Valepotriates and Valeranone are responsible for the chief effect of *Jatamansi* as a potent sedative and brain tonic. It inhibits enzyme- induced breakdown of GABA in the brain resulting sedation and induces good sleep.

4.2. Probable mode of action of *Ashwagandha*

Due to *Tikta, Kashaya Rasa* the drug *Ashwagandha* helps to open up the blocked *Manovahisarotas*. In addition, *Madhur Rasa* of *Aswagandha* is *Vatashamaka* and *Kaphavardhak* thus induces sleep by pacifying *Vata Dosha*.

Due to *Tikta, Kashaye Rasa, Ashwagandha* helps to open up the blocked *Manovahisarotas*. *Madhur Rasa* present in *Ashwagandha* also performs *Manoprasadana karma* thus calming the brain and induces sleep. *Vayu, Agni* and *Akash Mahabhut* present in *Ashwagandha* improve *Agni* and thus it opens the channels. Due to *Snigdha Guna, Kapha* is increased in body leading to increase in *Tamodosha*, as both *Kapha* and *Tamoguna* are imminent factors to induce sleep. *Snigadha Guna* has *Jala Mahabhut* predominance so according to *Smanya Sidhant* it helps to increase *Kapha Dosha*.

Madhur Vipaka of *Ashwagandha* helps in nourishment of body at cellular level including brain cells thus relieving stress and induces sleep.

Ushna Virya keeps in check the blockage of channels leading to proper nourishment of brain cells. Thus calming the brain.

According to Ayurvedic texts *Ashwagandha* is having *Vatahara* property. Thus pacifying the *Vata Dosha*, which is main *dosa* responsible for *Anidra.* It also has properties like Anti-stress, Anticonvulsant; Sleep inducing, Anti-Parkinson's. So it relaxes brain cells and improves their function. *Ashwagandha* contains a variety of chemical constituents, mainly Withananine, Withanolides, Somnine, Somniferine and Tropine that are responsible for the chief effect of *Ashwagandha* as a potent substitute for sleep medications.

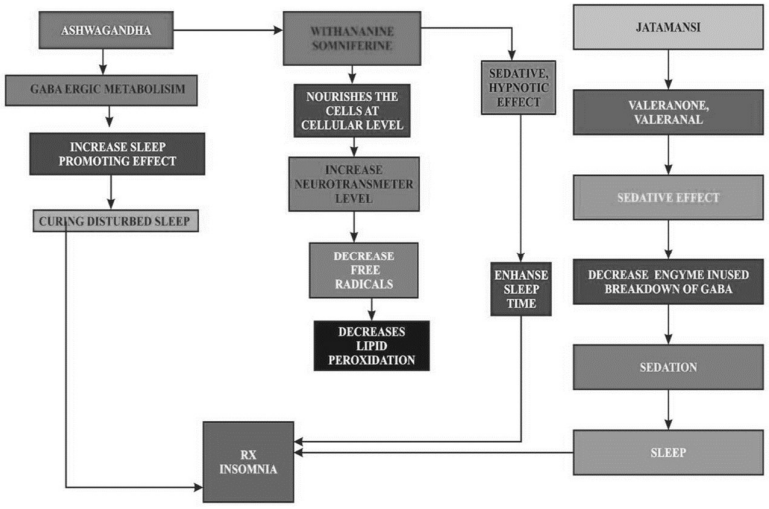

Fig. 2: Diagrammatic representation of probable mode of action of phytochemicals of *Jatamansi and Ashwagandha* on insomnia.

5. CONCLUSION

The study concludes that both drugs *Jatamansi* and *Ashwagandha* have effective role in subsiding symptoms associated with *Anindra* (Primary insomnia). However, *Jatamansi* was found to be more effective than *Ashwagandha* upon comparison. *Jatamansi Moola* showed excessive urination problems in some patients. *Ashwagandha* Moola showed bloating in some patients.

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