Clinical trial to assess the effect of homoeopathic nanomedicine in patients with chronic insomnia in the age group of 35- 65 years

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ABSTRACT

The corpus of research indicates that homoeopathic formulas create incredibly small particles, which are called as nanoparticles. These nanoparticles have electromagnetic or quantum properties when likened to their mass or the first structures. Hence, can be used as Homoeopathic personalised nanomedicines. As per few overviews, about 25-30% of the population suffers with insomnia in some form or another. Insomnia is a problem that can induce daytime weariness, poor focus, and irritation, according to prior study. It reduces the quality of life and increases the risk of several diseases. It influences a person's social, occupational, and general functioning. Insomnia, despite this, goes ignored and mistreated. Researchers suggest that Homoeopathy can be used to treat chronic insomnia without causing drug dependence or side effects. This study was aimed to investigate whether homoeopathic nanomedicines have effect in the treatment of patients with chronic insomnia. This study is a single-blind, non-randomized clinical trial. The improvement in sleep pattern was noted using sleep diary maintained by the patients and Insomnia Severity Index Score which was calculated before and after the study. The outcome of this study was significant improvement in chronic insomnia using homoeopathic medicines. Paired 't' test was used to analyse the result. The before treatment ISI value was 18.33 ± 2.16, after treatment ISI value reduced to 7.80 ± 3.66. This suggests that Homoeopathic nanomedicines prescribed based on totality shows significant improvement in chronic insomnia. 90% of the patients showed significant improvement in associated symptoms.

Keywords: Chronic, Homoeopathy, individualisation, Insomnia, nanomedicine.

1. Introduction

One of the most common health problems in today's environment is insomnia. It is, however, frequently neglected. The hurried and stressful lifestyles are common causes of insomnia. Poor sleeping hygiene, such as using electronic devices before bedtime and not getting enough exercise, pregnancy, and medicinal adverse effects are important factors for causing insomnia.

Consistent risk factors in researches for insomnia are found to be the increasing age, female sex, comorbid disorders along with the drugs associated, shift work, and possibly unemployment and lower socioeconomic status. [1]

Insomnia Disorder is defined as difficulty in sleep initiation or maintenance problems, adequate opportunity, and circumstances to sleep, and daytime

consequences. For duration criterion of 3 months, and a frequency criterion of at least three times per week. [2]

Insomnia in general is a very subjective matter. Enough sleep is essential for proper wear and tear of the body as well as brain and is responsible for the efficient functioning of the next day. However, patients become habituated to it and neglect the effects it produces on the body.

Research by Spielman et al [3] (1987) has suggested etiological factors of insomnia in 3P model that is Predisposing, Precipitating, and perpetuating etiology. These factors include nosological conditions like prostate enlargement, neurogenic bladder, cardiovascular conditions, Pregnancy and psychological conditions like anxiety, depression, and Personality characteristics. The factors may also be external causes like intake of caffeine, alcohol, tobacco, or side effects of any medicine taken for long duration. Insomnia is also associated with aging.

According to several studies, approximately 25-30% of the population suffers with insomnia in some form or another [4]. According to previous researches, insomnia is a disorder that can cause daytime exhaustion, poor focus, and irritation. It lowers life quality and raises the risk of different diseases. It has an impact on an individual's social, occupational, and overall functioning. In spite this fact, Insomnia, goes unnoticed and untreated.

Insomnia is often accompanied by a systemic or mental disturbance. The treatment for this comorbid condition is as equally important as treatment for insomnia.

Research by Mausami et al [5] suggested a positive association between insomnia and some medical co morbidities like hypertension, diabetes, high cholesterol, heart disease, kidney disease, thyroid disease, bronchial asthma, chronic pain and gastritis.

According to the American Association of Sleep Disorders, new guidelines [1] , insomnia symptoms affect approximately 33% to 50% of the adult population; insomnia symptoms that cause distress or impairment (i.e., general insomnia disorder) affect 10% to 15% of the population; and specific insomnia disorders affect 5% to 10% of the population.

According to D. Bhattacharya et al's research insomnia affects roughly 25-30% of the population [4].

According to Panda et al [6], insomnia was reported by 18.6% of patients in the age category of 35.1 +/- 8.7 years. Out of these, 42.6 % of the participants had hypertension.

Suri et al [7],[8] conducted a questionnaire-based study of roughly 2475 people aged 30-60 years, finding that 28.1 % of the participants had difficulty in initiation and maintenance.

Psychological, behavioral, and pharmaceutical treatments for insomnia are already accessible, according to studies [12]. These specifically target the insomnia condition but the root cause that is the comorbid condition remains as it is. Homoeopathic similimum with individualistic approach will be helpful in the treatment of insomnia as well as in helping the comorbid condition if any [13]. The initial researches done in homoeopathy seconds it.

Objectives of this study were to assess the improvement of chronic insomnia using Insomnia severity index (ISI) [14] in patients with chronic insomnia in age group of 35-65 years with homoeopathic medicines. Along with that to assess the improvement of chronic insomnia using Sleep Diary [14], [15] in patients with chronic insomnia. The secondary objective of the study was to assess whether there is improvement in the comorbid symptoms (if any) along with improvement of insomnia with homoeopathic individualistic medicines.

2. Materials and Methods

It is a non-randomized, single blind clinical study to assess the effects of homoeopathic treatment in cases of chronic insomnia in patients in the age group of 35-60 years.

The research was carried out in the Out Patient Department of Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College and Homoeopathic Hospital, Department of Post-Graduate and Research Centre. Total 30 cases were studied who were diagnosed with Chronic Insomnia disorder based on the criterions and guidelines given by international classification of sleep disorders. [2]

Insomnia severity Index was calculated at the beginning of the study as well as at the end of the study after treatment. Appropriate Statistical tests were applied and results were obtained.

2.1 Selection of samples:

2.1.1 Sample size of 30 individuals within the age group of 35-65 years where insomnia is majorly affected were considered.

2.1.2 Patient shaving trouble sleeping, having uninterrupted sleep, getting up sooner than wanted with inability to get back to sleep. This difficulty occurs despite adequate opportunity & circumstances for sleep. (According to the case definition given by ICSD)

2.1.3 Having the following associated consequences:

1. Fatigue/Malaise
2. Attention, concentration, or memory impairment
3. Day to day activities, societal relations getting hampered
4. Mood disturbance, irritability
5. Daytime Sleepiness
6. Behavioral problems (eg. Hyperactivity, impulsivity, aggression)
7. Reduced motivation, energy, initiative
8. Proneness for errors, accidents
9. Concerns about or dissatisfaction with sleep
10. Significant discomfort or social, work related, or other important

areas of functioning getting hampered.

2.1.4 The procedure was explained to the participants and written signed consent in English as well as in the vernacular language (Marathi) was taken.

2.1.5 The cases were recorded in a standard format with detailing the symptoms of insomnia.

2.1.6 The Repertorisation of the cases was done to arrive at a group of similar remedies for individual case followed by selection of the similimum with help of Materia Medica.

2.2 Inclusion and exclusion Criteria:

2.2.1 Inclusion criteria:

Patients fulfilling the diagnostic criteria by ICSD III which is defined as Trouble sleeping, having uninterrupted sleep, getting up sooner than wanted with inability to get back to sleep. This difficulty occurs despite adequate opportunity & circumstances for sleep. For 3 months, and at least three times per week. Were considered in the study.
Patients within the range of age group of 35-65 years.
Patients with signed written consent were included in the study.

2.2.2 Exclusion criteria:

Patients having Drug induced insomnia were excluded from the study
Patients having Insomnia due to lack of opportunity and circumstances for sleep were excluded from the study.
Patients requiring mother tinctures as the form of treatment were excluded from the study.

2.3 Intervention

Intervention for the study was Individualised Homoeopathic Simlimum in the form of potentised Homoeopathic dilutions.

2.4 Preparation of the remedy

The Homoeopathic Drugs were acquired from standard Homoeopathic pharmacy and was stored as per the rules of Homoeopathic Pharmacopeia.

2.5 Selection of the remedy

The selection of the remedy was done using the individual totality and the dosage and potency were decided based on the susceptibility of the patient.

2.6 Drug Administration

The selected drug was administered through oral route.

2.7 Drug Dispensing

Drug dispensing was done in the form of globules or powders.

2.8 Follow up criteria

The patients were asked to maintain a Sleep diary every night where the details of their sleep regimen were to be entered.

The patients were followed up after every 15-20 days for total of 3 months. The improvement in the follow up was assessed based on the details of sleep diary

and score of Insomnia severity Index. The second prescription was based on the results of the follow up.

2.9 Outcome Assessment

Outcome assessment was done based on the data collected from sleep diary and score of the Insomnia Severity Index (ISI).

2.9.1. Sleep Diary:

The patients were counselled to maintain a sleep diary every night. Sleep diary consists of the details to be filled by the patient every day from starting of the treatment which includes:

i. Timing of retiring to bed and timing of arising in morning.
ii. Total hours spent in bed
iii. Number and duration of episodes of waking up in night
iv. Sleep efficiency
v. Total sleep time in hours
vi. Total minutes and Number of Daytime naps

2.9.2. Insomnia Severity Index:

The Insomnia Severity Index is designed to assess the nature, severity, and impact of insomnia and monitor treatment response in adults. The index has seven questions. The seven answers are added up to get a total score. The total score is used to interpret based on the given guidelines to see where the sleep difficulty fits.

2.10 Data Collection

Data collection that is the information required for the clinical trial was collected from various tools like patient interviews, Sleep diary evaluation and Insomnia Severity Index.

3. Results

In the study, patient in the age group of 45-55 years were found to be having complaints of insomnia more. The distribution of age was as given in Figure 1.

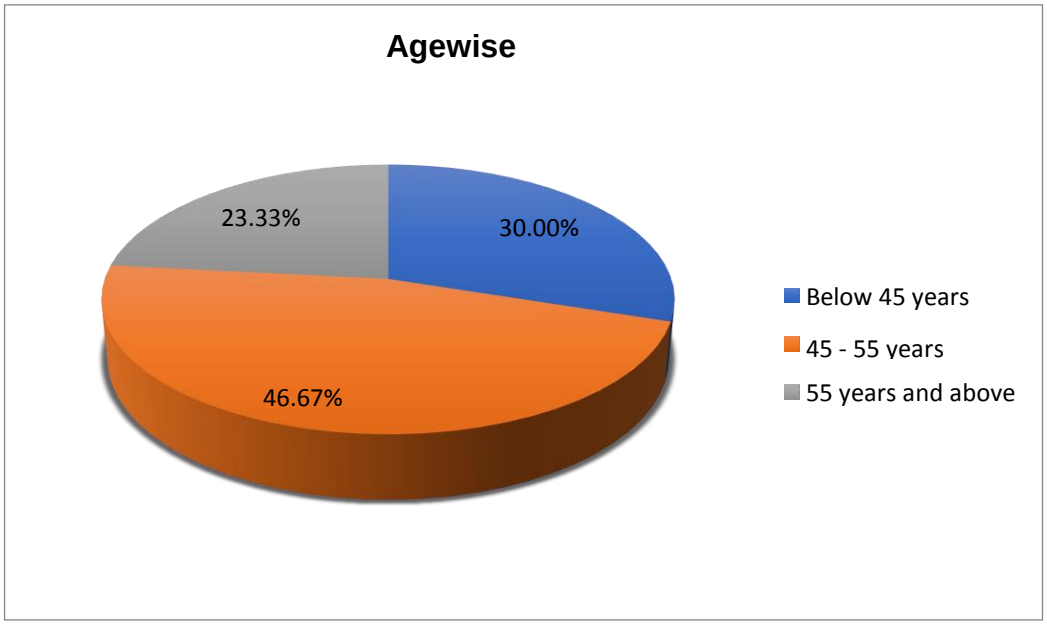

Fig. 1. Pie chart of age wise distribution of patients

The distribution of patients according to the occupation suggests that those having jobs are affected more (56.67%) than those with business (33.33) and household work (10.0%).

The Distribution of patients according to Insomnia Complaint, i.e., difficulty falling asleep, Difficulty maintaining the sleep or both was found equal (33.33% each). The remedy distribution for the 30 patients is given in Figure 2.

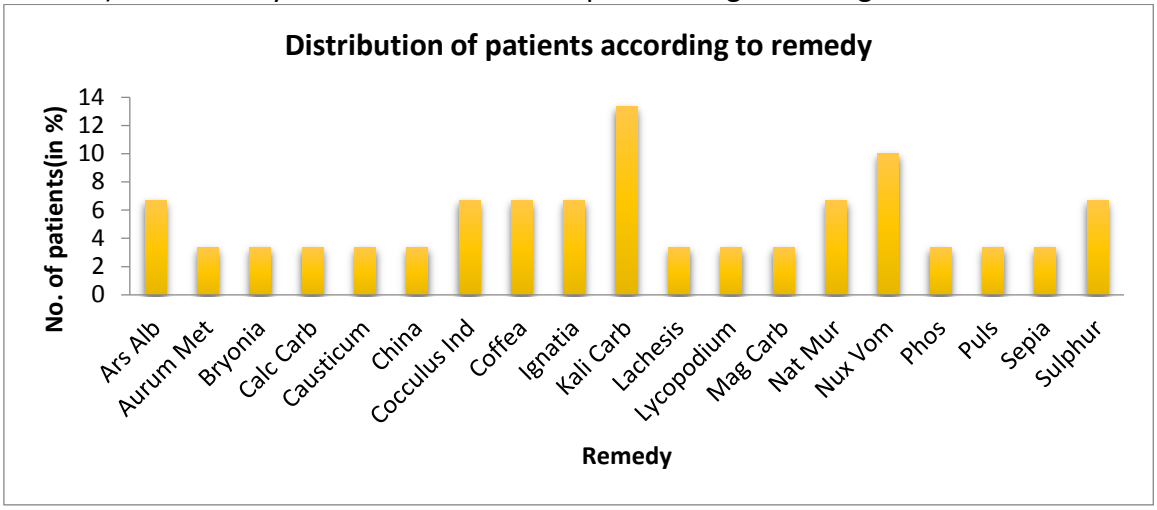

Fig. 2. Distribution of patients according to remedy

The graph shows medicines used to treat chronic insomnia depending on the totality of symptoms. *Kali carb* was most used remedy (13.33%) followed by *Nux vom* (10%).

The data collected using insomnia severity index score to assess severity of insomnia before and after the treatment suggested that before the treatment 80% patients were having moderate clinical insomnia, 16.67% patients were having severe clinical insomnia and 3.33% patients were having subthreshold insomnia. After the treatment, 50% patients were having subthreshold insomnia, 43.33% patients were having no clinically significant insomnia. 6.67% patients were having moderate clinical insomnia. Figure 3.

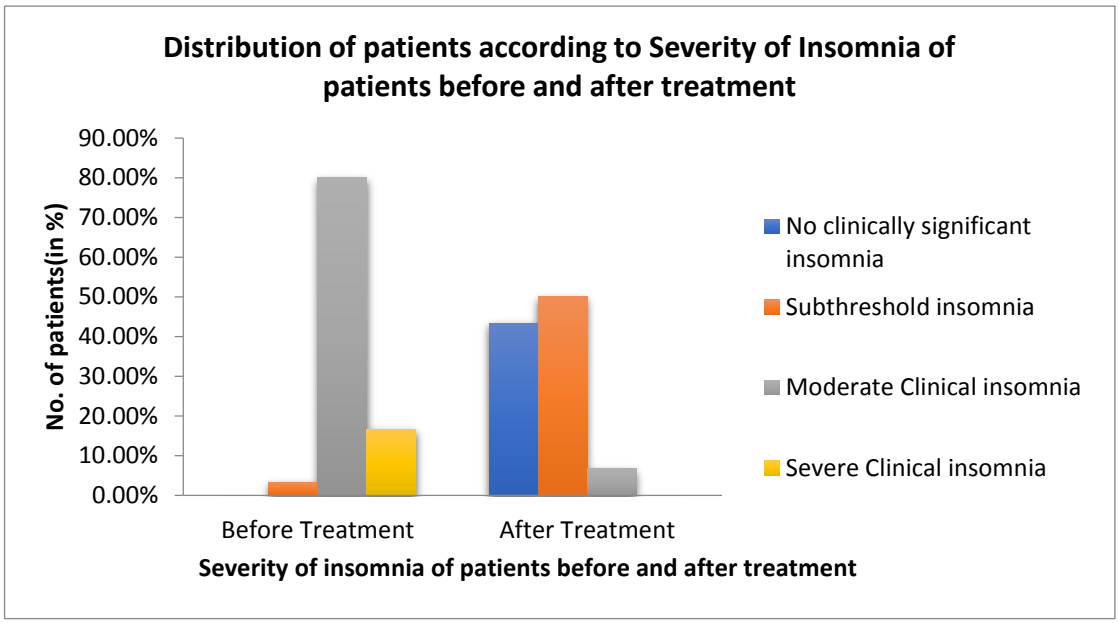

Fig. 3. Distribution of patients according to Severity of Insomnia of patients before and after treatment

The data collected from this study was assessed to check the effectiveness of treatment using paired t-test. The data showed that the before treatment ISI value, was 18.33 ± 2.16, and after treatment ISI value, reduced to 7.80 ± 3.66. Test statistic value is 14.16 and p-value (0.000) is very small, it suggests that, Homoeopathic Individualized medicine helps in relieving chronic insomnia in patients. TABLE 1.

TABLE 1. Descriptive statistics of Insomnia Severity Index (ISI) before and after intervention. Test used: Paired t-test, **: Highly Significant Difference, T-value: Test Statistic value.

Insomnia Severity Index	Mean ± SD	T-value	p-value	Decision
Before treatment	18.33 ± 2.16	14.16	0.000**	Reject H0
After treatment	7.80 ± 3.66			
Difference	10.53 ± 4.08	**Difference is Highly Significant**		

The distribution of the data of associated complaints suggested that there was significant improvement (90%) in the associated symptoms along with the symptoms of insomnia. Figure 4. Acidity was the most common associated symptom which was found in 50% of the patients.

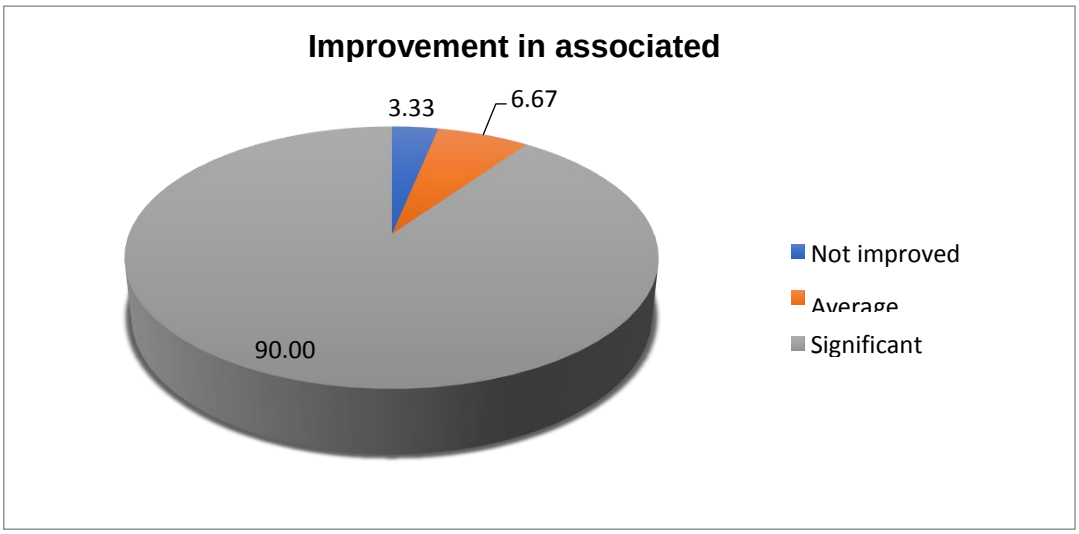

Fig. 4: Pie chart of improvement in associated complaints of insomnia

4. Discussion

Chronic insomnia is one of the most common conditions hampering daily functioning. Yet most of the times it goes unnoticed till the patient suffers from

serious consequences.

Around 25-30 % of the population suffer from insomnia. The exact cause of insomnia is still unknown. Current treatments include Behavioral modifications along with medicines. There are some serious side effects and drug dependence caused by these medications.[13] Hence, scope for homoeopathic medicines is much seen in Chronic insomnia. However more evidence-based data need to be collected through researches for strengthening the role of homoeopathy in cases of insomnia.

This study was primarily aimed to investigate whether homoeopathic medicines have any effect in the treatment of patients with chronic insomnia. For this study, 33 patients were registered belonging to the age group of 35 – 60 years, of both sexes. Out of these 33, 3 patients dropped out. 13 patients were male and 17 patients were female out of the 30 patients.

Difficulty falling asleep, difficulty maintaining sleep or both are considered as having chronic insomnia if the complaints are persistent for 3 months. Out of the 30 registered patients, 10 patients were having difficulty falling asleep, difficulty maintaining sleep and 10 having both the complaints.

The prescription was done based on totality of symptoms [18]. The most common remedies prescribed in the first prescription were *Kali Carb, Nux vom, Cocculus ind, Coffea, Sulphur, Ars Alb, Nat Mur, Ignatia* etc [19, 20, 21]. As the sample size was small, Students paired 't' test was used. It was found out that the results were positive.

There was overall improvement in the patients of chronic insomnia. The comorbid and associated symptoms also showed significant improvement with given homoeopathic treatment in most of the cases.

The Insomnia Severity Index Score was calculated before and after the treatment. Which suggested significant improvement in most of the cases. The sleep diary maintained by the patients gave the gradual changes in the sleep pattern with medicine.

5. Conclusion

From the above observations, it can be concluded that homeopathic medicines are effective in the treatment of patients with chronic insomnia. Homeopathic medicines can be used to treat chronic insomnia. It can also be concluded that as homoeopathy uses individualized medicines the comorbid conditions and associated complaints can also be taken care of along with the chronic insomnia. However, since it is a small sample study over a shorter period, further extensive researches need to be done in the future considering large sample size & extending the duration of the study.

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