https://africanjournalofbiomedicalresearch.com/index.php/AJBR
Afr. J. Biomed. Res. Vol. 27 (October 2024); 1210 - 1216
Research Article

"A Clinical Study on The Efficacy of Homoeopathic Medicines in The Treatment of Primary Insomnia – A Pilot Study"

Dr. Udmale Prajakta[1]*, Dr. Rita Sangtani[2] ,Dr. Dharmendra Sharma[3], Dr. Mangesh Udmale[4]

*[1]*Associate Professor, PhD Scholar, Department of Anatomy, Dr. D. Y. Patil Homoeopathic Medical College and Research Centre, Dr. D. Y. Patil Vidyapeeth (Deemed to be University), Pimpri, Pune, Maharashtra, India, Email: prajakta.udmale@dpu.edu.in*
Address: Dr. D. Y. Patil Homoeopathic Medical College and Research Centre, Sant Tukaram nagar, 411018, Contact number: 9673489910
[2]Professor and HOD, PhD Guide, Department of Physiology and Biochemistry, Dr. D. Y. Patil Homoeopathic Medical College and Research Centre, Dr. D. Y. Patil Vidyapeeth (Deemed to be University), Pimpri, Pune, Maharashtra, India, Email: rita.sangtani@dpu.edu.in
[3] Principal, Professor & HOD, Department of Forensic Medicine and Toxicology, Dr. D.Y. Patil Homoeopathic Medical College & Research Centre, Dr. D.Y. Patil Vidyapeeth (Deemed to be University), Pimpri, Pune, Maharashtra, India. Email: principal.homoeopathy@dpu.edu.in
[4] Associate Professor & HOD, Department of Rognidan Evum Vikriti Vigyan, Bhimashankar Ayurved College, Pune, MUHS,Nashik, Maharashtra, India. Email: man18udmale@gmail.com

Abstract:
Purpose: This study aims to assess homeopathy's efficacy in treating primary insomnia.
Methodology:
A randomized, single-blind, placebo-controlled pilot study lasting 6 weeks was conducted. The study was carried out at the OPD (Outpatient department). The study was conducted on 30 patients split into a placebo category with 15 patients and a treatment category with 15 patients. Patients received constitutional homeopathic medicine with prescribed remedial measures every 15 days in the required potency. The placebo group received an unmedicated vehicle with remedial measures. Pittsburgh Sleep Quality Index (PSQI) scale was utilized to assess pre- and post-treatment scores.
Results: The p-value of 0.001 for treatment group and 0.02 for placebo group suggest that changes observed in treatment group are statistically more significant than in placebo category. Additionally, mean difference percentage in the experimental group is substantially higher than in placebo group, indicating a potentially more effective treatment or intervention in the experimental group.
Conclusion: The findings suggest that constitutional homeopathic medicine, when prescribed in required potency, has a positive effect on symptoms of primary insomnia. However, further prospective research studies including larger sample size are suggested to scientifically validate these results.

Keywords: Constitutional Medicine; Homoeopathy; Primary Insomnia, Pilot Study, Insomnia.

**Author for correspondence: Email: prajakta.udmale@dpu.edu.in*
Receiving Date: 22/10/2024 Acceptance Date: 25/10/2024

DOI: https://doi.org/10.53555/AJBR.v27i3.3098

Introduction

Sleep is a state of unconsciousness that can be interrupted by appropriate sensory stimuli or other triggers. It may also be described as a normal, periodic inhibition of the Reticular Activating System (RAS), which plays crucial role in regulating wakefulness and alertness. Sleep is important for overall well-being, still many individuals struggle with sleep-related issues.[1] Insomnia, characterized by disturbances in sleep patterns, is a prevailing condition influencing a noteworthy part of worldwide population.[2] According to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR), approximately 10% to 15% of adults meet the standard for Primary Insomnia, a condition where underlying cause related to sleep disturbances is unknown.[3,4]

While primary insomnia may not pose an immediate threat to life, its impact on daily functioning, including social and occupational aspects, can be profound. Traditional treatments often involve the use of antidepressants, tranquilizers, sedatives, and hypnotic drugs. However, reliance on these medications can give rise to dependency and expose individuals to potential side effects associated with strong chemical compounds.

Left untreated or improperly managed, primary insomnia can exacerbate symptoms such as irritability, anxiety disorders, and depression, contributing to disturbances in interpersonal relationships and an increased risk of substance abuse disorders. Additionally, sleep-related fatigue can impair motivation, productivity, memory, concentration, and elevate the risk of fatigue-related accidents. [5, 6]

In the gleam of these challenges, there is an expanding need for alternative therapies which offer efficacy without the risks associated with conventional drug treatments. Homeopathy presents a promising avenue for the treatment of insomnia, providing a holistic approach which considers the individual's unique constitution and addresses underlying imbalances. [7]

Primary insomnia encompasses difficulties to fall asleep, sustaining sleep, or experiencing sleep not restoring for a duration exceeding three weeks, despite adequate opportunities for rest. Importantly, it is distinguished by its lack of attributable medical, psychiatric, or environmental causes.

Given the multifaceted impact of primary insomnia on individuals' lives, there is a compelling case for reevaluating current management strategies and exploring holistic approaches such as homeopathy to address this prevalent and often debilitating condition.

Material and methods

Study Setting: The research was carried at the OPD. The study duration spanned six weeks. Patients were included based on predetermined criteria of inclusion and exclusion. Follow-up assessments were conducted every 15 days, with the final evaluation occurring during the third follow-up, utilizing the Pittsburgh Sleep Quality Index (PSQI) assessment criteria.

Study Design: This study employed a randomized single-blind, placebo-controlled, 6-week pilot design, involving a sample of 30 cases that met the inclusion and exclusion criteria. An important aim of the study conducted was to examine and prospect the impact of constitutional homeopathic medicines in management of primary insomnia.

Participants: Thirty-five participants were initially selected using simple randomization, with five subsequently dropping out (experimental: 2, control: 3). The final sample consisted of 30 cases, meeting the predefined inclusion and exclusion criteria for primary insomnia. Participants were drawn from diverse socioeconomic backgrounds and castes, of either gender, aged between 20-45 years, exhibiting symptoms of primary insomnia.

Exclusion criteria comprised individuals with concurrent systemic illnesses, hypothyroidism, hyperthyroidism, recent surgery within the past six months, ongoing treatment for narcolepsy, sleep disorders related to breathing, circadian rhythm, or parasomnia, sleep apnea. Additionally, individuals with comorbid disorders of mind (e.g., Depressive disorder, generalized anxiety disorder, delirium) or neurological disorders, those experiencing substance-induced insomnia, alcoholism, or tobacco addiction were excluded. Diagnosis of primary insomnia (307.42) was conducted as per the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR). [8] Consent was obtained from the study participants before the commencement of the study. CTRI Registration number: CTRI/2022/09/045692

Ethical approval has been obtained from the Institutional Ethics committee

Ethics committee (Dr. D.Y.Patil Vidyapeeth, Pimpri, Pune) and reference number – DYPHMCRC/E-16/20

Intervention: Participants were grouped under two groups. Group 1 received indicated homeopathic medicine along with prescribed remedial measures, while Group 2 received placebo alongside the same remedial measures. Remedial measures included Stimulus Control Therapy (SCT) and Sleep Restriction Therapy (SRT). Stimulus Control Therapy intent to modify negative associations with sleep or the sleep environment, while Sleep Restriction Therapy regulates sleep-wake schedules to align with actual sleep duration. [9]

Case Assessment and Prescription: Detailed case histories were obtained following a standardized format. Prescription of homeopathic remedies was based on symptom similarity, referencing established materia medica texts, with potency selection guided by the principles outlined in the Organon of Medicine. Medication repetition followed established protocols tailored to individual case requirements.

Follow-up: All participants were advised to adhere to Stimulus Control Therapy and Sleep Restriction Therapy and to attend follow-up assessments every 15 days.

The Pittsburgh Sleep Quality Index (PSQI) was utilized as assessment tool. [Fig 1] The PSQI formed by Buysse et al. in 1989 aims to evaluate quality of sleep over the preceding month and differentiate between individuals with poor and good sleep patterns. It encompasses several domains, including Subjective Sleep Quality, Sleep Latency, Duration of Sleep, Habitual Sleep Efficiency, Sleep Disturbances, Use of sleep medications, and Dysfunction in daytime.

The Pittsburgh Sleep Quality Index (PSQI)

Name: _____ **Date:** _____

Instructions: The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.
During the past month,

1. When have you usually gone to bed?_____

2. How long(in minutes) has it taken you to fall asleep each night?_____

3. When have you usually gotten up in the morning?_____

4. How many hours of actual sleep do you get at night? (This may be different than the number of hours you spend in bed) _

Please check the appropriate blank below.

5. During the past month, how often have you had trouble sleeping because you...		**Not during the past month (0)**	**Less than Once a week (1)**	**Once or Twice a week (2)**	**Three or More times A week (3)**
a. Cannotgettosleepwithin30minutes	**a.**				
b. Wake up in the middle of the night or early morning	**b.**				
c. Have to get up to use the bathroom	**c.**				
d. Cannot breathe comfortable	**d.**				
e. Cough or snore loudly	**e.**				
f. Feel too cold	**f.**				
g. Feel too hot	**g.**				
h. Have bad dreams	**h.**				
i. Have pain	**i.**				
j. Other reason(s),please describe, including how often you Have had trouble sleeping because of this reason(s):	**j.**				
6. During the past month, how often have you taken medicine (prescribed or" over the counter") to help you sleep?	**6.**				
7. During the past month, how often have you had trouble staying awake While driving, eating meals, or engaging in social activity?	**7.**				
8. During the past month, how much of a problem has it been for you to keep Up enthusiasm to get things done?	**8.**				
		Very good (0)	**Fairly good (1)**	**Fairly bad (2)**	**Very bad (3)**
9. During the past month, how would your ate your sleep quality overall?	**9.**				

Physician Determined Global PSQI Score: _____

Figure.1: Pittsburgh Sleep Quality Index (PSQI) Scale

A global score of PSQI exceeding 5 indicates significant sleep disturbance. Statistical analysis of pre- and post-treatment scores was conducted, comparing both groups (Group I - Homeopathy and remedial measures, and Group II - Placebo and remedial measures) regarding the treatment of Primary Insomnia. [10, 11]

At the first consultation, participants completed the PSQI, and follow-up consultations occurred at 2, 4 and 6 week, on the last follow up PSQI were collected to check and encourage participants compliance.

Results

Observations are made and final results are plotted. Data presentation is done including charts, diagrams, and tables. Age group analysis of patients is done, cases according to prescribed medicine analysis is done, and gender-wise analysis is done.

Thirty patients from the age of 20 - 45 years were included in study. Among them, 12 subjects were male, accounting for 40% of the total, while 18 patients were female, constituting 60% of the total sample. [Figure 2]

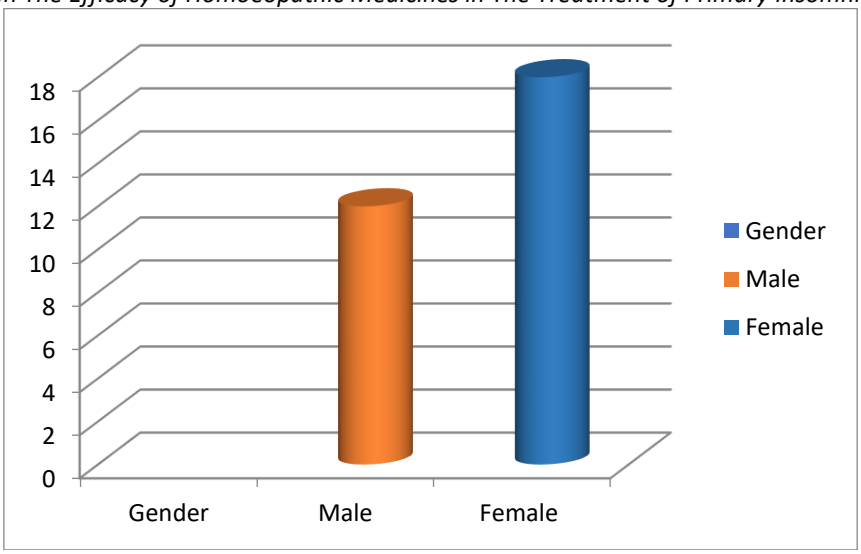

Figure 2: Total of 12 male patients, representing 40% of the sample, and 18 female patients, making up 60% of the total

The distribution of cases according to age group is as follows: 21-30 years accounted for 46.66% of the cases, 31-40 years for 33.33%, and 41-45 years for 20% [Figure 3]

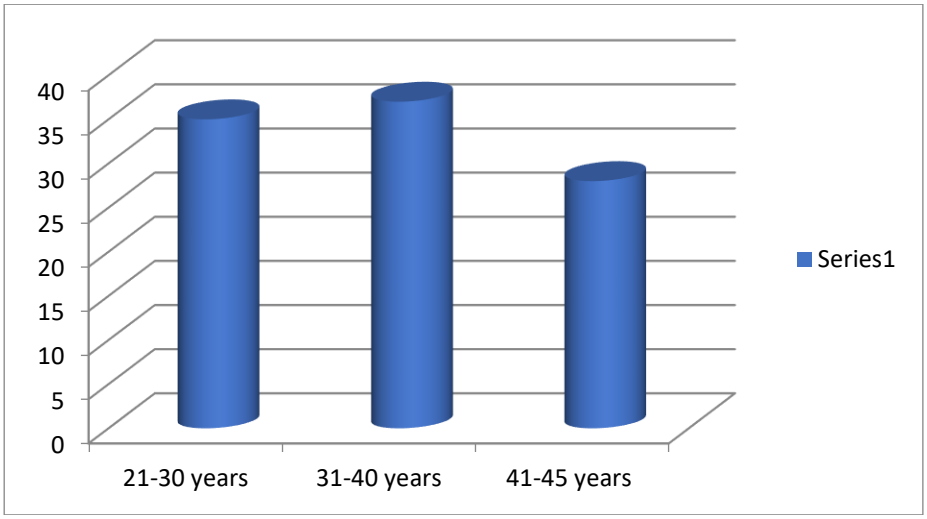

Figure 3: Distribution according to the age group

Out of 30 patients enrolled in the study, 11 were married and 19 were unmarried. Eight patients reported a family history of insomnia, while 22 did not. Nineteen patients slept alone, and 11 slept with partners. The reasons for sleep disturbance varied among the patients: climate change (1 patient, 3.33%), continuous unnecessary thoughts (1 patient, 3.33%), mobile phone use (3 patients, 10%), exam-related stress (4 patients, 13.33%), family issues (1 patient, 3.33%), job stress (1 patient, 3.33%), financial stress (3 patients, 10%), dreams (1 patient, 3.33%), no specific reason (13 patients, 43.33%), and disappointment in love (2 patients, 6.66%).

According to the PSQI scale assessment, subjective sleep quality improved remarkably in experimental category than placebo category. Sleep latency remained unchanged in placebo group but showed mild improvement in experimental category. The duration of sleep was remarkably better in experimental group than placebo category. Sleep efficiency mildly improved in the experimental group, while it remained unchanged in the placebo group. Sleep disturbance showed mild improvement in placebo category but significant improvement in the experimental category. The use of sleep medications was not applicable as patients using them were excluded from the study. Daytime dysfunction showed no change in placebo category but moderate improvement in experimental category. [Figure 4 and 5]

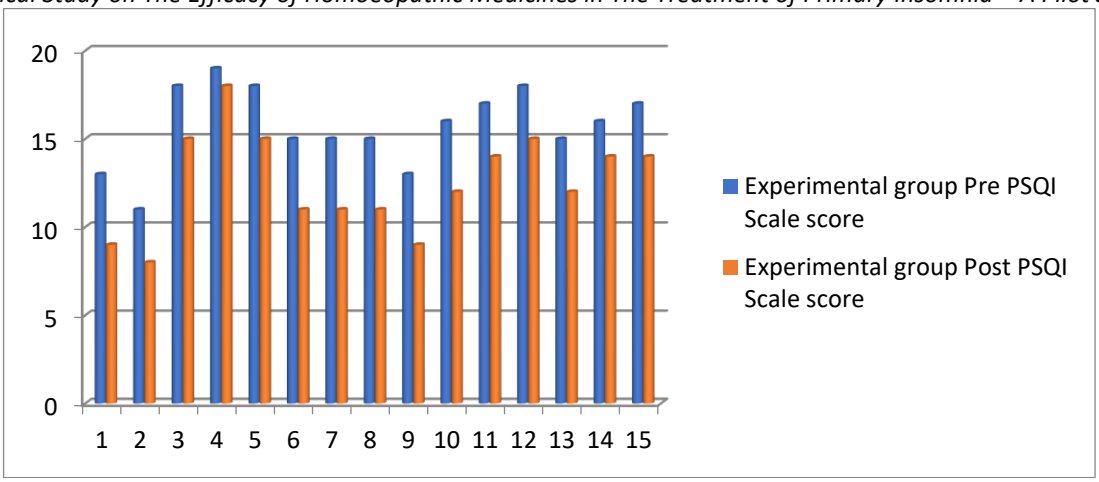

Figure 4: Distribution of Pre & Post Score of Experimental group

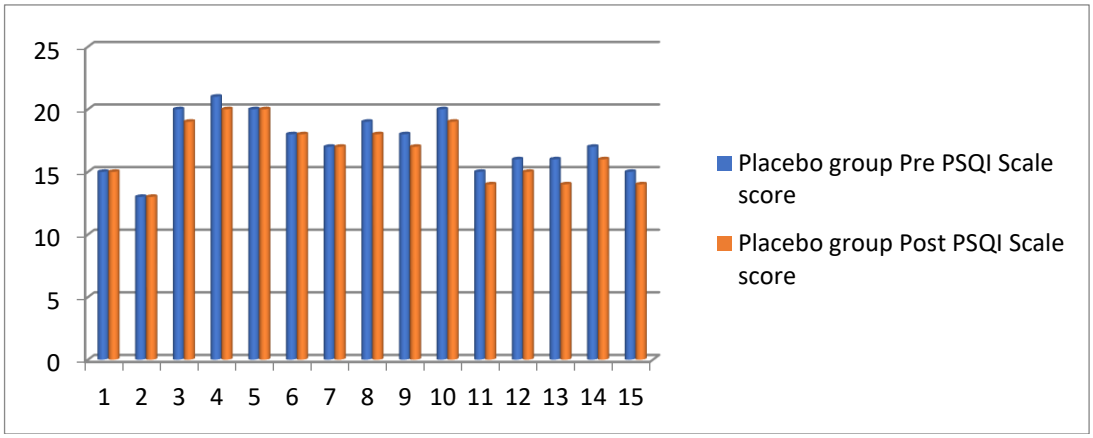

Figure 5: Distribution of Pre & Post Score of Placebo group

The most frequently prescribed medicines were Arsenicum album, Nux vomica, Kali phosphoricum, Coffea cruda, and Argentum nitricum (each prescribed to 13% of patients). Ignatia amara, Silicea, Medorrhinum, Calcarea carbonica, and Natrum muriaticum were also commonly prescribed (each to 7% of patients). Potencies used included 30C, 200C, and 1M, with significant results observed particularly with the 200C and 1M potencies in patients with primary insomnia. [Figure 6]

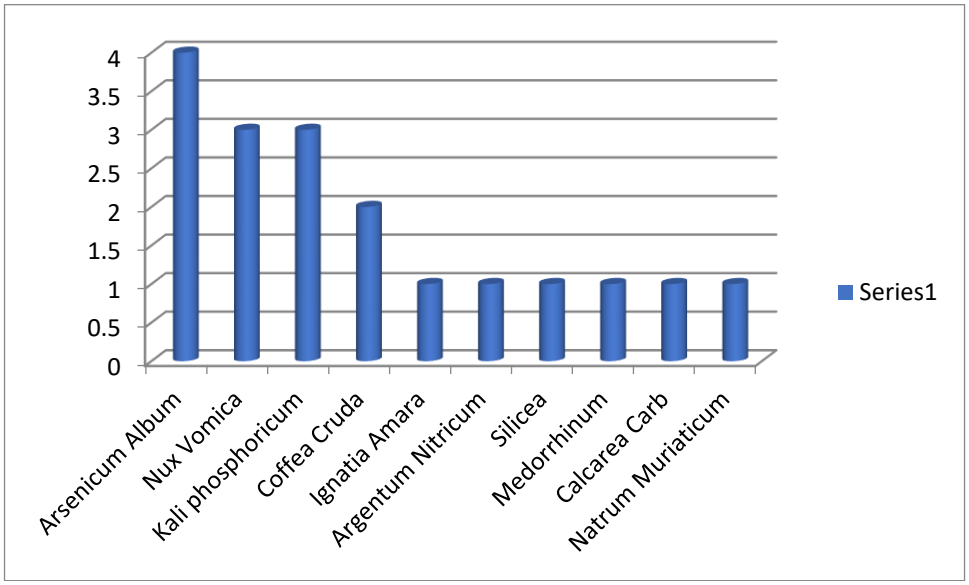

Figure 6: Distribution according to constitutional remedies

Statistical analysis:

Paired t-test was utilized for the statistical analysis for comparisons within the same group, and the unpaired t-test for comparisons between different groups.

Following statistical analysis of the data, the mean difference between pre and post - treatment in the placebo group is 0.3125. However, this difference is non- significant statistically at conventional significance level of 0.05 (p-value = 0.02). A p-value of 0.02 indicates a 2% chance of observing such a result if there were no true differences between the pre- and post-treatment means (assuming the null hypothesis is true).

In contrast, the mean difference between pre and post-treatment in the experimental group is 2.9333, showing notably larger difference than the placebo group. The p-value is 0.001, representing major statistical significance. Percentage mean difference of 17.1206% in the experimental group suggests a substantial change from pre- to post-treatment.

The p-values of 0.001 for experimental group and 0.02 for placebo group suggest that the changes observed in experimental group are statistically more significant than placebo group. Additionally, the mean difference percentage in experimental group is substantially high than in placebo group, indicating a potentially more effective treatment or intervention in the experimental group.

Based on the statistical analysis conducted at a 95% confidence interval with a degree of freedom of 29, the results indicate a significant difference ($p < 0.0001$) between groups. Therefore, null hypothesis is rejected. Consequently, the statistical findings suggest that constitutional homeopathic medicines are effective in managing primary insomnia. This implies that the treatment intervention had a noticeable impact on improving sleep quality or reducing insomnia symptoms in the study population. [Table no: 1]

Table No: 1 Statistical analysis of result

Paired Samples Statistics								
		Mean	**Mean diff**	**Mean diff %**	**N**	**Std. deviation**	**Std. Error Mean**	**P Value**
Placebo	Pre	17.1875	0.3125	1.8182	16	4.51986	1.12997	
	Post	16.8750			16	4.39507	1.09877	0.02
Experimental	Pre	17.1333	2.9333	17.1206	15	4.05087	1.04593	
	Post	14.2000			15	2.54109	0.65611	0.001

Discussion

The age distribution in study suggests that primary insomnia affects a broadly adults, remarkably in the 31-40 years of group of age. This might represent that patients of this age range are more inclined seek treatment, possibly due to lifestyle stressors or responsibilities that impact sleep. The slightly higher proportion of female patients (60%) compared to males (40%) could reflect a greater prevalence of insomnia among women or a higher tendency for women to seek alternative treatments. The marital status of patients, with a majority being unmarried, may also offer insights into social and psychological factors affecting insomnia. The study highlights various factors contributing to sleep disturbances, with a significant portion of patients (43.33%) reporting no clear reason for their insomnia. This suggests that idiopathic insomnia is a common issue, where no specific cause can be identified. Other factors like financial stress, exam-related stress, and mobile phone usage also play a role, indicating the need to address these stressors in treatment plans. The use of the Pittsburgh Sleep Quality Index (PSQI) is a robust method for assessing sleep quality and disturbances. Findings from the PSQI indicate that homeopathic treatment led to marked progress in the experimental category than the placebo category in Subjective Sleep Quality, Mild improvement in the experimental category and no change in the placebo group in Sleep Latency**,** remarkable progress in an experimental category in the duration of sleep**,** Mild improvement in the experimental category in Efficiency of sleep, Significant reduction in an experimental category in Sleep Disturbances, Moderate progress in an experimental category in Daytime Dysfunction. These results suggest that homeopathic treatment has a positive impact on various aspects of sleep quality, particularly in reducing sleep disturbances and improving overall sleep quality. The study highlights that Argentum Nitricum, Coffea Cruda, and Natrum Muriaticum in 200C potency were frequently used. These remedies are chosen based on individual patient symptoms and characteristics, reflecting a individualized approach to homeopathy. The use of different potencies (30C and 1M) in some cases suggests that treatment is regulated as per the response of patient. The promising results for homeopathic treatment in this study add to the growing evidences suggesting its potential benefits for primary insomnia. However, it's important to consider that homeopathic remedies might be more effective for some patients than others, and results can vary. While the study shows positive outcomes, the sample size (30 patients) is relatively small. More researches with bigger sample size and control groups is required to verify these results and establish a broader understanding of efficacy of homeopathic treatments for primary insomnia. The study underscores the requirement for more awareness and education about primary insomnia and its treatment options. Many individuals might be unaware of the available alternatives to conventional treatments, and further research can help inform both patients and healthcare providers about effective strategies for managing primary insomnia.

Conclusion

This single blind, randomized, prospective, placebo controlled clinical trial, including 30 subjects afflicted suffering from primary insomnia, demonstrates efficacy of constitutional homeopathic medicines in managing primary insomnia and its associated symptoms. The utilization of both 200C and 1M

potencies yielded beneficial outcomes for patients. The study established significance with a p-value of less than 0.0001.

Statistically significant dissimilarities were observed for sleep efficiency, overall sleep timing, spent time in bed, all in favor of homeopathy over placebo, ranging from moderate to large effect sizes. Conversely, group differences were insignificant for other outcomes, such as sleep latency, total minutes when stays awake in the middle of sleep, and time in minutes when wakes up too early. Notably, individualized homeopathy demonstrated important and significantly superior effects than that of the placebo.

This study highlights the potential of homeopathy as a viable option of treatment for primary insomnia. However, further independent studies on the same and appropriately powered trials are warranted to corroborate these findings.

Acknowledgments

I would like to express my gratitude to Dr.D.B.Sharma sir, Principal, Dr.D.Y.Patil Homoeopathic Medical College and Research Centre, Pimpri, Pune (Deemed to be University) for his support and resources. I would also like to extend gratitude to Dr. Parth Aphale, Research Co-ordinator, Dr.D.Y.Patil Homoeopathic Medical College and Research Centre, Pimpri, Pune

I would like to thank my guide Dr.Rita Sangtani, Professor, Department of Physiology, Dr.D.Y.Patil Homoeopathic Medical College and Research Centre, Pimpri, Pune for the invaluable insights and guidance throughout the study.

Disclosure

No conflicts of interest in this work.

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