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A Randomised Single Blind Placebo-Controlled Study to Evaluate the Effectiveness of *Gratiola officinalis* 200C in Improving "Quality of sleep" among College Students Aged 17-25 Years, using Excessive Mobile Appliances Through Pittsburgh Sleep Quality Scale [PSQI]

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ABSTRACT

Sleep disturbance and poor sleep quality have become increasingly common among college students due to prolonged exposure to mobile devices, particularly during night-time. Blue light emitted from screens suppresses melatonin secretion, disrupts circadian rhythm, and causes cognitive and emotional hyperarousal, resulting in a condition commonly described as digital insomnia. Despite Gratiola officinalis being traditionally documented for treating insomnia, there is insufficient scientific evidence regarding its efficacy specifically for technology-induced sleep problems Recognizing this emerging public health concern, the present study aimed to scientifically evaluate the effectiveness of Homoeopathic medicine Gratiola officinalis 200C as a therapeutic option. Sleep quality was assessed before and after intervention using the Pittsburgh Sleep Quality Index (PSQI), a validated tool for measuring subjective sleep quality. Follow-ups were conducted at regular intervals, and changes in PSQI scores were statistically analysed using the unpaired t-test. The findings demonstrated a significant improvement in sleep quality in the treatment group compared to the placebo group, as assessed by the Pittsburgh Sleep Quality Index (PSQI). Administration of Gratiola officinalis 200C resulted in better sleep initiation, improved sleep continuity, and reduced daytime drowsiness, indicating its beneficial role in managing digital insomnia.

Keywords: Quality of sleep, Gratiola officinalis, Pittsburgh Sleep Quality Index, Homoeopathy

INTRODUCTION

Sleep is a physiological state of unawareness which is regulated homeostatically.[1] Almost one-third of our lives are spent while sleeping.[2] Sleep plays an important role in cognitive and physical functions, cellular toxin removal, disease prevention and restoration of both mind and body.[3,4] A major decline in the sleep hours and its strong correlation with obesity, diabetes, and other chronic debilitating

diseases have been documented in the past 20–30 years.[4,5]

Many factors can affect sleep hygiene but the role of mobile use in causing sleep problems in adolescence has gained huge attention in the past few years.[6,7] Mobile use at bedtime (after the lights have been turned off), can cause poor sleep quality (PSQ) by various mechanisms.[8] A major factor which can contribute to PSQ is the blue light emitted by screens of mobile phones.[9] This blue light can decrease the production of melatonin, the hormone which controls the sleep/wake cycle or circadian rhythm. Reduction in melatonin makes it difficult to fall and stay asleep.[10] Some studies have found that exposure to blue light increases brain alertness [11] and can stimulate cognitive functions, which in turn can lead to PSQ.[12]

According to recent studies, excessive smartphone use can lead to a wide range of negative consequences. It became a major lifestyle issue, which can lead to anxiety, depression, stress, or poor sleep-in teenagers, as well as serious consequences including violent outbursts and somnambulism during the day. Excessive mobile phone use may drain a lot of energy and negatively impact student's ability to focus and study during the day.[13]

GRATIOLA OFFICINALIS:

Named as Hedge Hyssop. Sick headache. Insomnia [14]

Known as "The Herb of Grace". Irresistible drowsiness with yawning. Great drowsiness with frequent yawning and inclination to lie down, especially in the afternoon. Deep stupor. Headache with nausea and drowsiness. [15]

Aims and Objectives:

- To evaluate effectiveness of "Gratiola officinalis 200C" in improving sleep quality in college students aged 17-25 years using excessive mobile appliances.
- To determine the quality of sleep among college students aged 17-25 years, using excessive mobile appliances.
- To demonstrate the effectiveness of "Gratiola officinalis 200C" in improving quality of sleep among college students aged 17-25 years using excessive mobile appliances through Pittsburgh sleep quality index (PSQI).

MATERIALS & METHODS

Source of data:

MNR Homoeopathic Medical college & Hospital

Type of study:

Experimental study

Study design:

Randomized placebo-controlled trial

Study population:

College students aged between 17 to 25 years are included in the study

Sample size:

30

Selection Criteria:

Inclusion criteria:

- College students suffering with insomnia aged between 17 to 25 years are included in the study.
- Both males and females.
- Students who are willing to give written consent

Exclusion criteria:

- Students below 17 years and above 25 years are excluded from the study.
- Students suffering with systemic diseases which effects quality of sleep like thyroid disorders, Rheumatic diseases, SLE are not included in study.
- Students suffering with serious psychiatric illness like depression, anxiety, schizophrenia, PTSD are excluded.
- Students under long term medications, drug/substance abuse, excessive intake of tea and coffee around bed time are excluded.

Proposed Intervention:
Gratiola officinalis 200C

Data collection:
Data collection is done through a pre-designed case proforma along with Pittsburgh Sleep Quality Index [PSQI]

Confidentiality:
As the research is being done in the hospital attached to the college, the confidentiality of details will be maintained.

Plan of Analysis:

- Informed consent forms will be given to 30 participants, who will then be divided into two groups by simple random sampling
- 15 patients will be treated with Gratiola officinalis 200C and 15 patients with Placebo.
- Pittsburgh Sleep Quality Index [PSQI] will be given to patients before treatment and thereafter every one month to assess the change in symptoms.

Ethical Clearance:
The Proposed research project has been approved by the Institutional Ethical committee

Statistical Analysis

Table No .1 Pittsburgh Sleep Quality scores of Two groups before and after treatment

S. No	Pittsburgh Sleep Quality scores Gratiola officinalis 200C Group				Pittsburgh Sleep Quality scores Placebo Group			
	OPD NUMBER	Before	After	difference	OPD NUMBER	before	after	difference
1	G/25/1925	14	7	7	G/25/1952	13	10	3
2	G/25/1939	12	6	6	G/25/1978	12	10	2
3	G/25/1946	15	8	7	G/25/1988	16	14	2
4	G/25/1949	13	6	7	G/25/2090	11	9	2
5	G/25/1962	11	5	6	G/25/2568	15	12	3
6	G/25/1999	16	9	7	G/25/2575	10	9	1
7	G/25/2460	10	4	6	G/25/2599	16	13	3
8	G/25/2560	14	7	7	G/25/2645	13	12	1
9	G/25/2596	12	6	6	G/25/2580	12	10	2
10	G/25/2647	13	7	6	G/25/2719	14	12	2
11	G/25/2670	15	8	7	G/25/2724	13	11	2
12	G/25/2679	11	5	6	G/25/2810	15	12	3
13	G/25/2706	14	6	8	G/25/2819	13	11	2
14	G/25/2712	12	5	7	G/25/2836	14	12	2
15	G/25/2724	16	9	7	G/25/2899	16	13	3

UNPAIRED t -TEST RESULTS

P value and statistical significance:

- The two-tailed P value is less than 0.0001

By conventional criteria, this difference is considered to be statistically significant.

- Confidence interval:

The mean of Gratiola minus Placebo equals to 4.47
95% confidence interval of this difference: From 3.98 to 4.95

- Intermediate values used in calculations:

t = 18.896
df = 28
Standard error of difference = 0.236

- Review of data:

Table No 2

Group	Gratiola	Placebo
Mean	6.67	2.20
Sd	0.62	0.68
Sem	0.16	0.17
N	15	15

- Based on p value, mean and standard difference of Gratiola 200C and

Placebo: Gratiola 200C (6.67±0.62) and bismuth (2.20 ±0.68).

The above unpaired t-test results reveal that Gratiola 200C showed efficacy in comparision to placebo group in improving the quality of sleep among college students aged 17-25 years, using excessive mobile appliances.

RESULT

Table No 3. Distribution of cases according to gender

Gender	No. of cases	Percentage
Male	16	53.3%
Female	14	46.6%

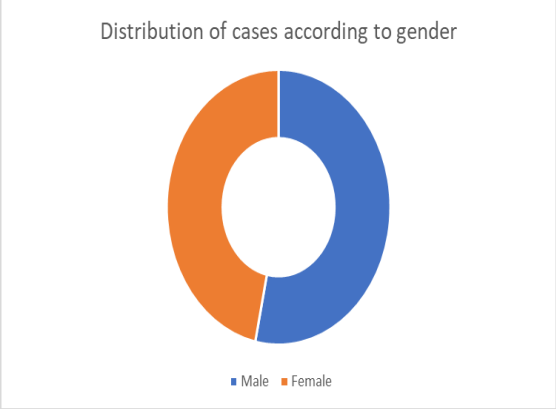

Fig no .1

Table 4. Distribution of cases according to Recurrence

Group	No. of Recurrent cases	No. of non-recurrent cases
Gratiola officinalis	2	13
Placebo	15	0

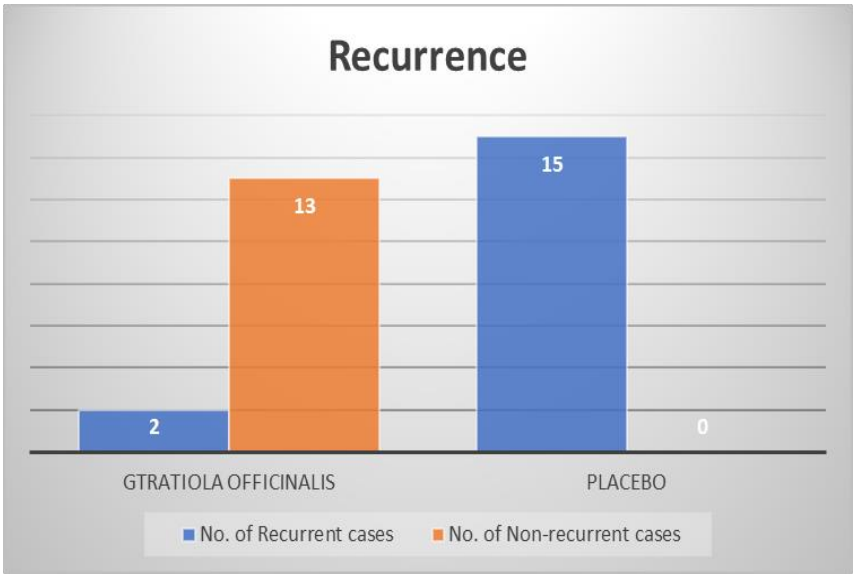

Fig no .2

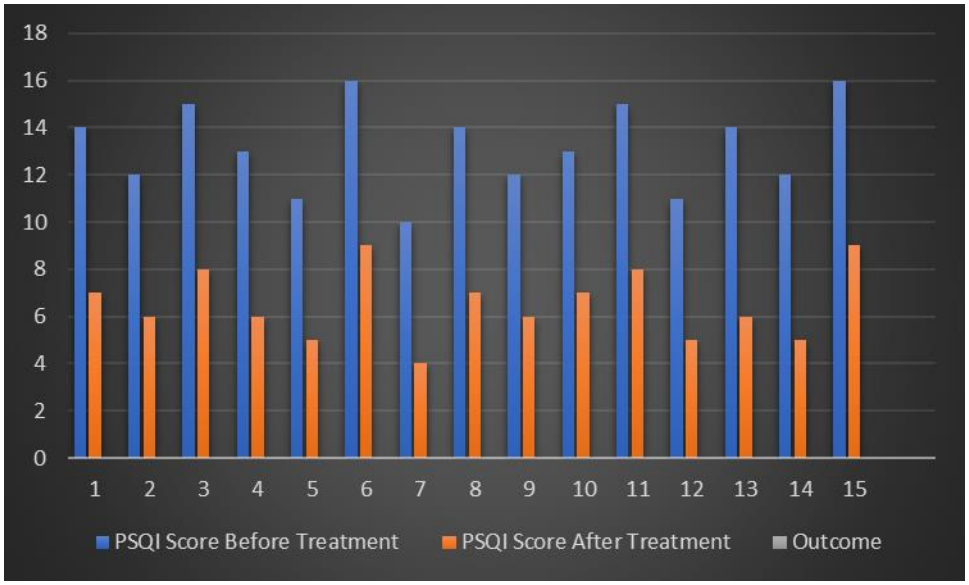

Fig no.3 Scoring of patients according to PSQI before and after using Gratiola officinalis 200C

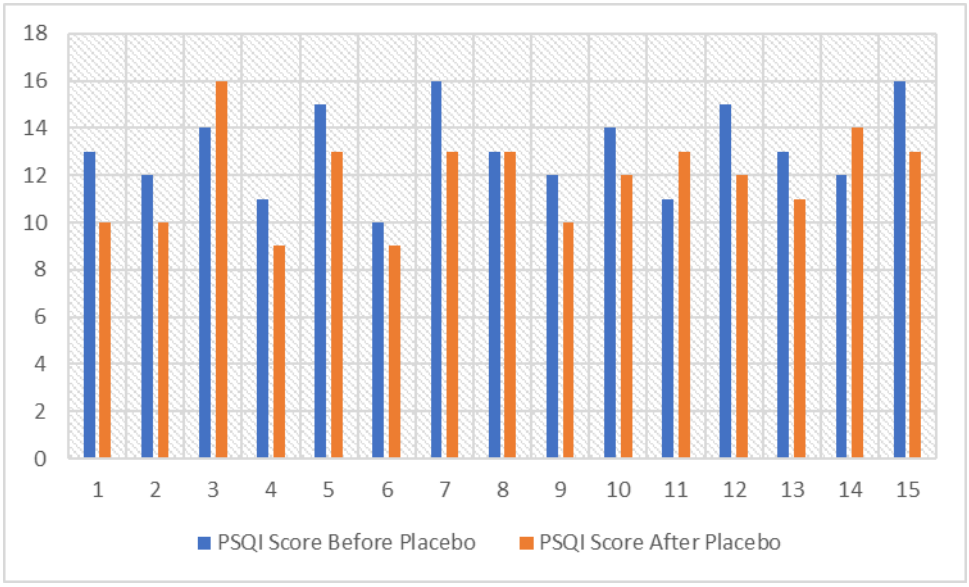

Fig no.4 Scoring of patients according to PSQI before and after using Placebo

DISCUSSION

The present study was conducted to evaluate the effectiveness of Gratiola officinalis 200C in improving the quality of sleep among college students aged 17-25 years who excessively use mobile appliances. Sleep disturbance due to prolonged mobile usage, especially during night hours, has emerged as a significant health concern among young adults, affecting their academic performance, mental health, and overall quality of life.

In this study, sleep quality was assessed using the Pittsburgh Sleep Quality Index (PSQI), which is a validated and widely used subjective tool for evaluating sleep disturbances. Prior to treatment, participants in both the treatment group (Group A) and the placebo group (Group B) showed poor sleep quality, indicating that excessive mobile usage had a negative impact on their sleep patterns.

After the intervention, a marked improvement in PSQI scores was observed in Group A, which received Gratiola officinalis 200C, when compared to Group B. Participants treated with Gratiola officinalis reported improvement in sleep

initiation, reduction in nocturnal awakenings, better sleep continuity, and improved daytime alertness. In contrast, the placebo group showed minimal or no significant improvement in sleep quality.

The findings of this study reveal that Gratiola officinalis 200C is effective in improving sleep quality among college students using excessive mobile appliances. The results are in accordance with homoeopathic literature, where Gratiola officinalis is described as useful in conditions associated with drowsiness, disturbed sleep, nervous debility, and exhaustion. The remedy appears to act by restoring balance in the nervous system and improving overall vitality, rather than merely inducing sleep.

The improvement observed in the treatment group may also be attributed to the holistic approach of homoeopathy, where individual symptoms, lifestyle factors, and exciting causes such as excessive screen exposure are considered. Additionally, general sleep hygiene advice given to participants may have supported the therapeutic effect, although the significant difference between the treatment and placebo groups suggests a specific role of the remedy.

CONCLUSION

College students often struggle with sleep due to late-night mobile use. Blue light from screens affects melatonin production, messes with their sleep-wake cycle, and keeps their brain too active, leading to what's known as digital insomnia. The present study concludes that Gratiola officinalis 200C is effective in improving the quality of sleep among college students aged 17–25 years who use mobile appliances excessively. The findings demonstrated a significant improvement in sleep quality in the treatment group compared to the placebo group, as assessed by the Pittsburgh Sleep Quality Index (PSQI). Administration of Gratiola officinalis 200C resulted in better sleep initiation, improved sleep continuity, and reduced daytime drowsiness, indicating its beneficial role in managing digital insomnia.

The study supports the research hypothesis and suggests that Gratiola officinalis 200C can be considered a safe, effective, and non-pharmacological homoeopathic remedy for sleep disturbances related to modern lifestyle habits. However, further studies with larger sample sizes, longer follow-up periods, and objective sleep assessment tools are recommended to strengthen and validate these findings.

Declaration by Authors

Ethical Approval: Approved

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Conflict of Interest: The authors declare no conflict of interest.

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