Case study

Effectiveness of Kasa Kasa Kudineer in treating Insomnia patients attending OPD at AAGHIM, Chennai – A Case Series

ABSTRACT

Aims: The aim of the study is to evaluate the effectiveness of Siddha medicine *Kasa Kasa Kudineer* (KKK), in treating insomnia patients, attending OPD at AAGHIM, Chennai.
Study design:
Place of Study: The study was conducted at Arignar Anna Government Hospital of Indian Medicine and Homeopathy, attached with Government Siddha Medical College (AAGHIM attached with GSMC), Chennai- 106.
Methodology: The study was conducted at the Arignar Anna Govt. Hospital of Indian Medicine (AAGHIM), attached with Govt. Siddha Medical College, Chennai 106, with a sample size of 20. The study protocol and informed consent were reviewed and approved by IEC (with a waiver from IEC). Patients attending the OPD of AAGHIM with complaints of sleep disturbances were chosen for enrollment based on their insomnia severity index score of more than 15. Observations were made before and after the treatment.
Results: Results were analyzed. Descriptive statistics, Paired t- test were analyzed using SPSS trial version 25, and out of 20 patients, 17 patients shown significant improvement in their sleep pattern and the score were also moved to no clinically significant category of Insomnia severity index score. All parameters whose p value is less than 0.05 reject the null hypothesis. Results were encouraging, as it shown considerable improvement by the end of the study.
Conclusion: This study reveals the significant effectiveness of treating Clinically significant insomnia patients, attending OPD at AAGHIM, Chennai with *Kasa Kasa Kudineer* (KKK), which may ignite a new Siddha medicine for a better quality of life.

Keywords: Sleep, Insomnia, Insomnia severity index score, Kasa Kasa, Siddha

1. INTRODUCTION

As per the saying of Benjamin Franklin "Early to bed and early to rise make a man healthy, wealthy, and wise." The ancient Siddhars spelled these pearls of wisdom earlier than this. Since the Siddha System of Medicine is convergent with health, i.e., both cure and prevention, as well as wealth, wisdom, and eternity, The word "insomnia" has become the most common terminology to search for nowadays. Insomnia is defined by the presence of an individual's report of difficulty sleeping. Long sleep latency, multiple nocturnal awakenings, an extended period of wakefulness throughout the sleep phase, or even a lot of brief awakenings are considered signs of insomnia [1]. The diagnosis is based on difficulty falling asleep, difficulty staying asleep, problems waking up too early, and subsequent

impairment in quality of life. Various studies worldwide have shown the prevalence of insomnia in 10%–30% of the population, some even as high as 50%–60%. Older people, women, and those with physical and mental illness are more likely to experience it. 33% of people reported chronic sleeplessness. Insomnia was substantially correlated with advancing age and diabetes, but not with other socioeconomic characteristics or co-morbidities [2]. A 2012 study from the National Institute of Mental Health and Neuroscience says about the prevalence of sleep-related disorders in south India, including 1050 participants from Tamil Nadu, Karnataka, Andhra Pradesh, and Kerala, that compared to hypersomnia, insomnia was noted in greater proportions [48 (4.6%) vs. 195 (18.6%).

Difficulties in sleep initiation and maintenance were observed in 18% of patients, and 7.9% had early morning awakenings. No significant gender bias was noted. Insomnia was attributed to depression in 123 subjects (11.7%) and anxiety in 26 (2.5%). A female preponderance was noted in insomniacs with depression (74.1%: 47.1%) and anxiety (17.6%: 8%) [3] which depicts that it is a significant health condition that needs to be taken into consideration for its consequences. In Siddha literature, insomnia is correlated with *Thookaminmai*, and in classic literature, *Patharthaguna Sindhamani* talks about criteria for good sleep and says health impairment due to lack of sleep as *Nithirai inmai* and *Nithirai bandham* depicting it as V*ettai nai kavvuvadhai pol peedikum*, meaning due to impaired sleep, diseases catch like a hunting dog [4,5]. On that note, when you're constantly losing sleep because of insomnia, your brain doesn't get the time it needs to perform its important tasks. Hence, insomnia is a serious health problem because of its high prevalence and management challenges. Siddha has effective, easily available somniac medicines and external treatment procedures for insomnia. This study depicts a case series of one such internal medicine named *Kasa Kasa Kudineer* (KKK), which is a decoction-based preparation but highly effective for insomnia as its ingredients show hypnotic and sedative action.

2. MATERIAL AND METHODS

2.1 Medicine preparation

Kasa Kasa Kudineer (KKK) is a tri-herbal decoction consisting of *Kasa Kasa* (*Papaver somniferum*) (0.015 gm), *Elarisi* (*Elettaria cardamomum Maton) (*0.002 gm), and *Kurosani Omam* (*Hyoscyamus niger*) (0.003 gm) from the reference book, Pharmacopoeia of the Hospital of Indian Medicine, Part II [6]. Purified *Kasa Kasa* (*Papaver somniferum*), *Elarisi* (*Elettaria cardamomum Maton.), and Kurosani Omam* (*Hyoscyamus niger*) were taken in the above-mentioned ratio, made into a coarse powder individually, and mixed. Patients were given single-dose packets (2 gram) and advised to prepare decoction on their own. Decoction was prepared by adding eight parts of water (240 ml) to a single packet, boiling and reducing it to one eighth of the water (30 ml), filtering, and being advised to consume at bedtime.

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2.2 Eligibility criteria

2.2.1. Inclusion criteria

1. All gender 25 – 40 years
2. Presence of chronic insomnia defined as self-reported difficulty initiating (latency to persistent sleep >30 min) and/or maintaining sleep (>30 mins awake, or waking >30 mins before desired waking time)) on three or more nights per week) for at least 3 months
3. Insomnia Severity Index score >15

2.2.2 Exclusion criteria

1. Untreated cardiovascular disease, arrhythmias, hypertension or severe heart failure.
2. History of allergies particularly to plant-based products containing terpenes, Ie. flavours and aromatic natural oils for example citrus, mango, lavender, thyme, cedarwood and pine products
3. Currently regularly using psychotropic or CNS-active drugs (including cannabis, opioids, benzodiazepines)
4. Inability to refrain from use of psychotropic or CNS-active drugs for at least one week prior to and duration of study
5. Inability to refrain from use of Cytochrome P450 inhibitors for at least one week prior to and duration of study.
6. Untreated metabolic disorders such as diabetes
7. Presence of severe depression, severe anxiety or other severe psychopathologic conditions.
8. History of suicide attempt or current suicide ideation.
9. History of seizures or epilepsy
10. History of drug or alcohol abuse
11. Insomnia associated with sleep apnea
12. Are currently participating in a formal behavioral therapy program to facilitate sleep
13. Pregnancy or lactation
14. Inability to refrain from greater than 2 standard drinks/day of alcohol consumption for study duration
15. Inability to refrain from greater than 400mg/day of caffeine consumption for study duration
16. Any person required to drive within 10 hours of dose, or those with a self-reported history of falling asleep while driving
17. Current delayed sleep phase syndrome where wakes up time is regularly later than 8.00 am [7].

2.2.3 Withdrawal criteria

1. Intolerance to the drug and development of any serious adverse effect during trial.
2. If ADR is reported, patients will be referred to Pharmacovigilance Centre of G.S.M.C.
3. Poor complaints leading to any adverse events.
4. Any other acute illness during course.

2.3 Outcome

The outcome is mainly assessed by a reduction in clinical symptoms measured by the **insomnia severity index [8].** The Insomnia Severity Index has seven questions. The seven answers, ranging from 0 to 4, are added up to get a total score. The included questions were mentioned below:

Table 1. Questions 1 – 3 from insomnia severity index score

Insomnia Problem	None	Mild	Moderate	Severe	Very Severe
1. Difficulty falling asleep	0	1	2	3	4
2. Difficulty staying asleep	0	1	2	3	4
3. Problems waking up too early	0	1	2	3	4

4. How SATISFIED/DISSATISFIED are you with your CURRENT sleep pattern?
5. How NOTICEABLE to others do you think your sleep problem is in terms of impairing the quality of your life?

6. How WORRIED/DISTRESSED are you about your sleep?

7. To what extent do you consider your sleep problem to INTERFERE with your daily functioning (e.g., daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.) CURRENTLY?

According to 'Guidelines for Scoring/Interpretation', insomnia patients were categorized as below

Table 2. Scoring of insomnia severity index score

Scoring	Category
0 - 7	No clinically significant insomnia
8 – 14	Subthreshold insomnia
15 – 21	Clinical insomnia (moderate severity)
22 - 28	Clinical insomnia (severe)

Observations were made before and after treatment for 2 weeks and results were analyzed. Statistical analysis - Descriptive statistics, Paired t- test were analyzed using SPSS trial version 25

3. RESULTS

Results were shown in figures from 1 to 6. Out of 20 patients selected, 50% were female and 50% were males and their age group falls like 11 under 25 to 30 years, 5 under 31 to 35 years, and 4 of them under 36 to 40 years. They were randomly selected whose insomnia severity index score greater than 15. Difficulty falling asleep, difficulty staying asleep was the important symptom of concern. They significantly shown improvement in their sleep pattern, after the treatment, thereby the graph shown the significance from clinical insomnia to no clinically significant category.

Fig.1: Participants age group

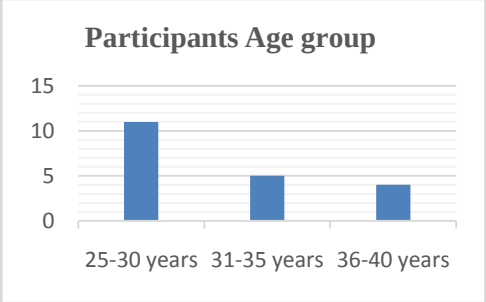


Fig.2: Participants gender

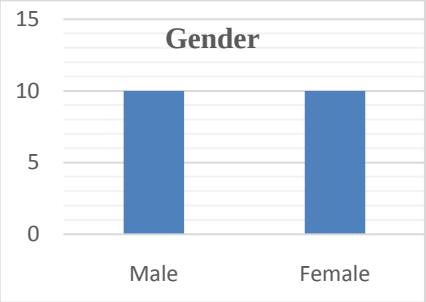
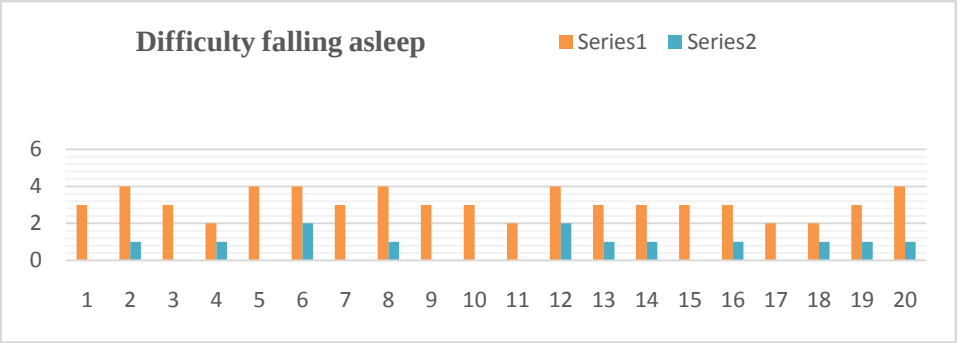
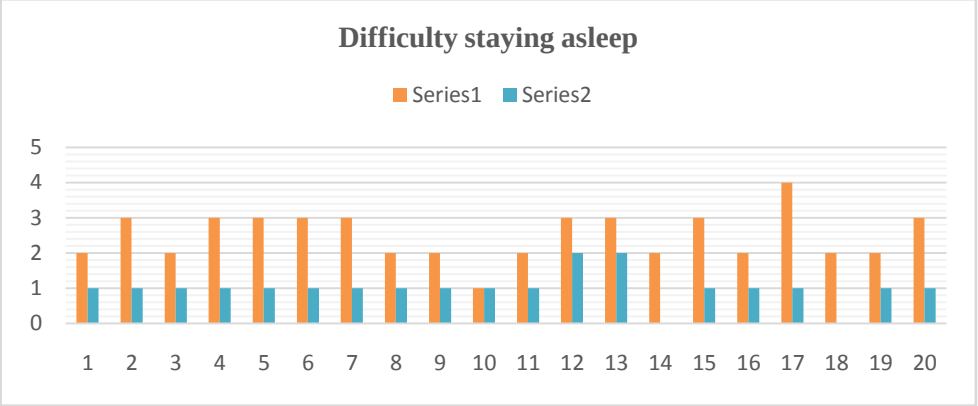


Fig.3: Difficulty falling asleep



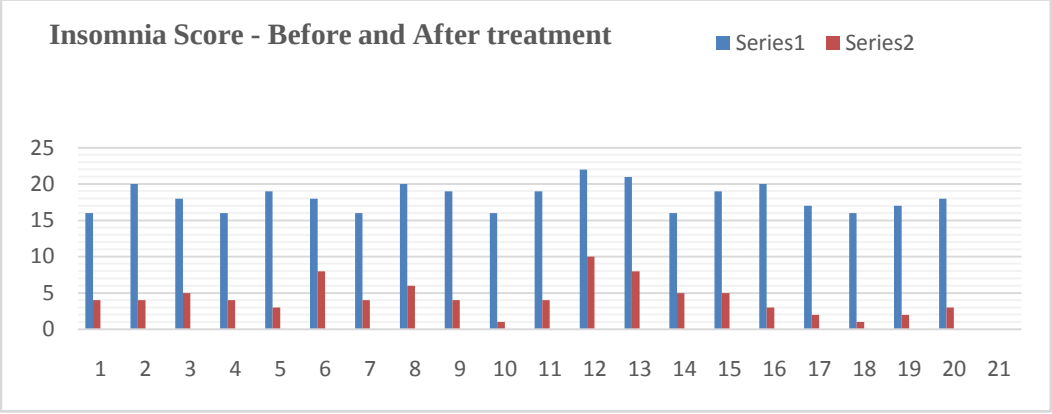
*Series 1: Before treatment, Series 2: After treatment

Fig.4: Difficulty staying asleep



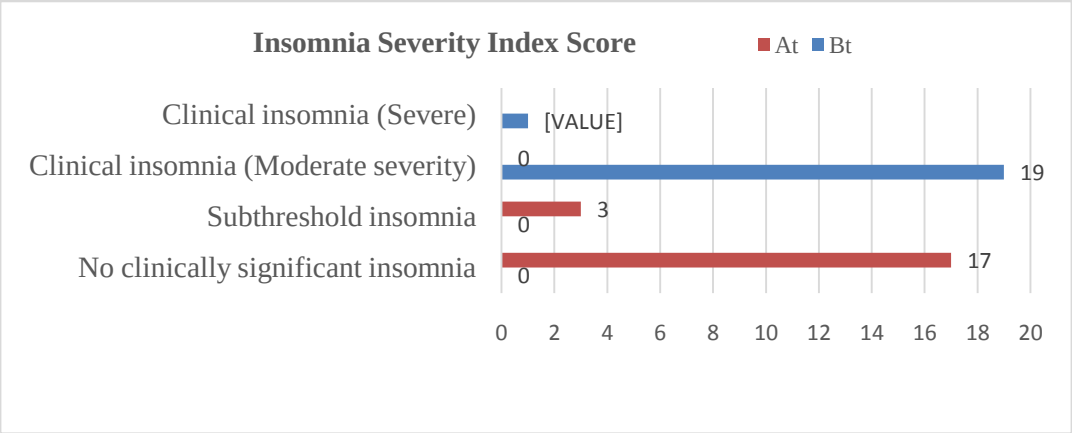
*Series 1: Before treatment, Series 2: After treatment

Fig.5: Insomnia severity index score before and after treatment



*Series 1: Before treatment, Series 2: After treatment

Fig.6: Scoring interpretation



All parameters whose *P* value is $P < 0.05$ reject the null hypothesis. That is, there is a statistically significant difference between the treatment methods in these parameters. After the administration of the intervention, the mean value before and after the intervention has been reduced, which shows a positively significant prognosis for the disease. The study showed significant improvement in the majority of patients by reducing the score from clinical insomnia to no clinically significant insomnia.

4. DISCUSSION

Insomnia, being a major concern, among non-communicable diseases, according to WHO. In my study, most of the participants fall between the age group 25 - 30 years. A recent study about prevalence of insomnia in COVID 19 pandemic says that young adults between 19 to 40 years were markedly had the symptoms of insomnia, nearly half of the responders, according to the study [9]. This could also represents due to lifestyle changes after COVID pandemic. The present study assessed *Kasa Kasa Kudineer* which reduced the symptoms of clinical insomnia in a significant way. Along with the *Kasa Kasa Kudineer*, suggested the patients to do those practice of taking Oil bath twice in a week with gingelly oil (*nallennai*), or any other medicated oils, which is good for sleep and body, as it generally prevents the occurring of diseases and promote healthy life and also insisted the participants to avoid taking coffee or beverages after 5pm.

An article published in 2015 entitled Sleep in ancient Egypt says that the Early sleep disorders and their treatment could be found in the few survived papyri dealing with the ancient Egyptian medicine and the first hypnotic medication in history was prescribed by the Egyptians, who used poppy seeds (opium) to treat insomnia, headache, and as an anesthetic [10]. A study from American medical journal in 2011 titled as Nutritional Supplements and its Effect on Quality of Life and Sleep represents that the maximum improvement in insomnia was found with poppy seed drink (63.6%) [11]. Another investigation, Poppies as a Sleep Aid for Newborns, was published in the journal Toxicological Reports in 2021. According to the study,"Hypnos" remedy of Cretan folk medicine, opium poppies have been used for medicinal and religious purposes, primarily as hypnotic and pain-relieving agents, since antiquity. However, until the early 20th century, Cretan folk medicine prescribed them with other poppies to induce sedation in children, hence the name "Hypnos," which means sleep [12].

Also, according to Unani literature, action of seeds of *Papaver somniferum* were mentioned as *Munawwim* (Sedative/Hypnotics), *Musakkin alam* (Antianalgesic), *Mukhaddir* (Anaesthetic) and therapeutic use of seeds for *Sahar* (Insomnia), says an article published by the journal, Journal of drug delivery and therapeutics in the year 2018 [13]. Rat model Studies related to *Elam* include, the control group Imipramine group (standard drug) and

Elettaria cardamom extract groups when compared for their effects on the behavior exhibited by the rats on the forced swim apparatus shows that the herbal drug *Elettaria cardamom* proved to be significantly effective in relieving rats from the depression and this effect may be due to the linalool which interacts with the monoaminergic system including serotonergic and nonadrenergic system. The decrease in the immobility time period is the indication of the antidepressant effect of the drug [14] and another rat model study of methanolic extract of *E. cardamomum* on anxiety-like behavior in a rat model of post-traumatic stress disorder (PTSD) says, particularly at the dose of 400 mg/kg, significantly ($P < 0.05$) improved anxiety-like behavior in a rat model of PTSD, as examined by the open field, elevated plus-maze, and rotarod tests [15].

Seeds of *E. cardamomum* were evaluated for toxicological activity in NMRI male mice. No mortalities were observed up to the doses of 2 g/kg and 0.75 ml/kg for the extract and essential oil. Crude extract from fruit did not cause any mortality up to the dose of 10 g/kg when evaluated for toxicological activity in Swiss albino mice [16]. Also, study of *Kurosani omam* says that *Hyoscyamus niger* extract has antidepressant like activity in FST and TST in mice, a valid animal model to screen antidepressant drugs by the journal of Innovations in Pharmaceuticals and Pharmacotherapy [17].

According to various research works, related to the study ingredients, all the ingredients having the effects related to improving sleep, which overall contributed to the outcome of the present study. Though, *Kasa Kasa* administrated as home remedy in clinical practise to sleep disturbed patients and indications given in literature for good sleep, clinical trial research papers are not sufficiently available about *kasa kasa* in administrating for insomnia, whereas research papers related to pharmacological action, sleep, stress, anxiety papers and ancient literature available.

5. CONCLUSION

Based on the findings of this study, the significant effectiveness of treating clinically significant insomnia patients was observed within 2 weeks on a small scale. Though the sample size is very small, the symptoms were well reduced in all the cases. If it is larger, the positive result may be even higher. This will give a deeper structure for treating and evaluating the study medicine through further research and subsequently effective medicine from Siddha system for insomnia will arise in clinical practice and also with a scientific approach as well. It will also improves the quality of life for sufferers.

CONSENT

Authors declare that informed consent was obtained from the patients.

ETHICAL APPROVAL

Authors hereby declare that the study protocol and informed consent were reviewed and approved by the Institutional ethics committee (with a waiver from IEC).

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