A Dissertation On

TO EVALUATE THE EFFICACY OF PLANTAIN LEAF BATH ON QUALITY OF SLEEP IN PRIMARY INSOMNIA PATIENTS

Submitted by

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I, **Dr.S.DHARMASHAMVARDHINI** solemnly declare that this dissertation entitled **"TO EVALUATE THE EFFICACY OF PLANTAIN LEAF BATH ON QUALITY OF SLEEP IN PRIMARY INSOMNIA PATIENTS"** is a bonafide and genuine research work carried out by me at Government Yoga and Naturopathy Medical College and Hospital, Chennai from April 2019 - February 2020 under the guidance and supervision of **Dr. N. MANAVALAN**, N.D. (OSM), M.A (G.T), M.Sc (Y&N), M. Phil, P.G.D.Y, P.G.D.H.M, P.G.D.H.H, Head of the Department - Department of Naturopathy. This dissertation is submitted to The Tamil Nadu Dr.M.G.R.Medical University, Chennai towards partial fulfillment of requirements for the award of M.D. Degree (Branch – I – Naturopathy) in Yoga and Naturopathy.

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The Institutional Ethical Committee of Government Yoga & Naturopathy Medical College and Hospital, Chennai reviewed and discussed the application for approval of "**TO EVALUATE THE EFFICACY OF PLANTAIN LEAF BATH ON QUALITY OF SLEEP IN PRIMARY INSOMNIA PATIENTS**", project work submitted by **Dr.S.DHARMASHAMVARDHINI**, 2nd year M.D. Naturopathy, Postgraduate, Government Yoga and Naturopathy Medical College and Hospital, Chennai.

The proposal is **Approved**.

The Institutional Ethical Committee expects to be informed about the progress of the study and adverse drug reactions during the study and any change in the protocol and patient information sheet / informed consent and asks to be provided a copy of the final report.

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ABSTRACT

Objective: The research work aims at evaluating the efficacy of 'Plantain leaf bath'(PLB) on the improvement of sleep quality by monitoring parameters such as blood pressure, pulse rate, heart rate, and Pittsburgh Quality of Index. The previously available literature sources reported the benefits of incorporating a plantain leaf bath, which aids in improving autonomic and cardiovascular functioning. The current study intended towards monitoring the effects, with the exposure of PLB, by determining the cardiovascular and sleep quality parameters of the study participants.

Method: 40 insomnia subjects belonging within the age group of 18-45 participated in the study. The cardiovascular parameters and Pittsburgh Quality of Index were assessed during the pre and post-intervention of PLB. The collected data were subjected to data analysis and interpretation, for determining the effectiveness and therapeutic effects of the plantain leaf bath among the study participants.

Result: The study showed significant improvement in the blood pressure and Pittsburgh Quality of Index values of the study participants. The post-intervention data showed significant improvement of cardiovascular parameters and Pittsburgh Quality of Index parameters, compared to that of the pre-intervention data.

Conclusion: The incorporation of Naturopathy mediated therapy involving PLB significantly improving cardiovascular and sleep quality, which was clearly exhibited from the observed cardiovascular parameters and Pittsburgh Quality of Index values.

Keywords: Plantain Leaf Bath, Heart Rate, Naturopathy, Heliotherapy

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1. INTRODUCTION

Sleep accounts for one-third of human life. Studies suggest that poor sleep contributes to ill health. Epidemiologic studies show that abnormal sleep patterns predict lower life expectancy and that insomnia frequently co-occurs with affective disorders, substance abuse, and other physical and psychological comorbidities. The definition of insomnia is a complaint of disturbed sleep, manifested as difficulties in sleep initiation or sleep maintenance, and/or as early awakenings[1].

Insomnia is a common clinical complaint. The predominant features are difficulty initiating or maintaining sleep or nonrestorative sleep. The sleep disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning [2].

Insomnia can also be classified based on etiology into primary and secondary subtypes. The term primary indicates that insomnia is not caused by any known physical or mental condition but is characterized by a consistent set of symptoms, a defined disease course, and general responsiveness to treatment.

Primary insomnia is commonly caused by life changes, including extended periods of stress or emotional upset [3].

In a recent trend, people are adopting complementary/alternative medicine, instead of Western medicine. Naturopathy became one of the growing trends in today's health care domain. The discipline is one of the primary intervention approach, regarded by the Ministry of health - AYUSH (Government of India) [4] and is considered as one of

the complementary medicine by the global community. Even when there are numerous forms of alternative medicine, the focal point of health care research is naturopathy.

Complementary therapies involving naturopathy and healing practices aids in reducing stress levels, anxiety, and modify the entire lifestyle patterns that are contributing to Insomnia. Naturopathy is one of the promising intervention therapies that facilitate in improving the sleep pattern much more effectively[5, 6].

For exploring, an ideal approach has led the society to turn back and investigate ancient practices such as Yoga and Naturopathy to counteracting pathological conditions. Furthermore, the emergence of psychoneuroimmunology has strengthened the scientific foundations of mind-body medicine [7].

Previous studies have shown that PLB is beneficial [8-10], but they produce different physiological cardiovascular responses in healthy subjects. To our knowledge, there is no study done with the PLB on the insomnia subjects on the parameter of PSQI. Hence the present study was designed to assess the sleep quality after the intervention of Plantain Leaf Bath on Insomnia patients.

2. AIMS AND OBJECTIVES

2.1 Aim:

To evaluate the efficacy of plantain leaf bath (PLB) on quality of sleep in primary insomnia patients.

2.2 Objectives of the study:

To evaluate the effects of PLB on improvement in sleep quality using

Pulse rate (Finger Plethysmogram)

Blood pressure (BP)

Body mass index (BMI)

The Pittsburgh Sleep Quality Index (PSQI)

3. REVIEW OF LITERATURE

3.1 Insomnia

The term insomnia is used in a variety of ways in the medical literature. Insomnia is defined by the presence of an individual's report of difficulty with sleep[11].

Insomnia disorder is characterized by dissatisfaction with sleep quantity or quality, associated with difficulty falling asleep, frequent nighttime awakenings with difficulty returning to sleep, and/or awakening earlier in the morning than desired [12, 13]. The disorder is also characterized by significant distress or impairment in functioning, and daytime symptoms including fatigue, daytime sleepiness, impairment in cognitive performance, and mood disturbances. Insomnia is differentiated from sleep deprivation by difficulty sleeping despite having an adequate opportunity to sleep.

Insomnia is more common among women, middle-aged and older adults, shift workers, and patients with medical or psychiatric disorders. Persistent insomnia can produce an important burden for the individual and society, as evidenced by reduced quality of life, impaired daytime functioning and increased absenteeism at work, and higher health-care costs. Persistent insomnia is also associated with increased risks of depression and chronic use of hypnotics [14-17].

3.1.1 Prevalence

Although the etiology of primary insomnia has yet to be clarified, recent research implicates endocrine, neurologic, and behavioral factors as contributing to its pathogenesis [18-20]. Estimates of the prevalence of insomnia are variable because the definitions and diagnostic criteria for insomnia are inconsistent.

Most epidemiologic studies indicate that women are more likely to have sleep difficulties than men [21, 22].

A study conducted by Breslau et al The lifetime prevalence of insomnia in this population was 24.6% and was slightly higher in women than men (26.7% and 21.4%, respectively).

In a study of 521 healthy middle-aged women near menopause presenting at a clinic, Owens and Matthews found a very high prevalence (42%) of self-reported sleep difficulties. Among those reporting sleep problems, the most prevalent complaint was awakening during the night (reported by 92%), followed by earlier-than-desired awakening (59%) and trouble falling asleep (49%). A cross-sectional analysis failed to identify significant associations between pre-, peri-, or postmenopausal status and general or specific sleep complaints. However, among the subset of women who were premenopausal at baseline and postmenopausal and not using hormone replacement therapy at follow-up, a higher proportion reported sleep difficulties at the postmenopausal than at the premenopausal assessment [23].

Hohagen et al conducted a study of 2,512 patients aged 18 to 65 years presenting to primary care clinics in Germany; a baseline assessment identified 18.7% with severe insomnia (DSM-III-R criteria), 12.2% with moderate insomnia (DSM-III-R criteria, without impairment of daytime functioning), and 15% with mild insomnia (occasional difficulties in initiating and maintaining sleep). Follow-up assessments were conducted in patients reporting baseline insomnia at 4 months and 2 years. At baseline, mild insomnia was more prevalent among men, but severe insomnia was more common among women by a nearly 2:1 margin (65% vs 35%). More than two-thirds of patients with severe insomnia at baseline reported a disease duration of 1 year or more [24]. The

3.5-year incidence of new insomnia among subjects with no insomnia at baseline was 14.8% for women and 10.6% for men [25].

It is estimated that among patients diagnosed with insomnia, 25% to 30% suffer from primary insomnia [26,27].

The proportion of insomnia patients who report insomnia to their physicians is quite small, and physicians may not adequately assess it [28, 29].

Both patients and physicians may not recognize the impact of poor sleep on daily functioning and the risk of serious accidents and psychological sequelae [30].

A recent review of epidemiologic studies showed that the reported prevalence of insomnia in the general population can range from 2% to 48%, depending on the definition of insomnia [31].

3.1.1 Pharmacologic Treatment

Prescribing sleep agents should be based on the severity of daytime symptoms and the likelihood that short-term insomnia, if untreated, could progress into long-term insomnia [32]. The ideal sleep agent has a quick onset of action to decrease sleep latency, a duration of action that prevents early morning awakenings, and minimal side effects [33]. The lowest effective dose of an agent should be used. Medications should be used for a short period (2 to 4 weeks) and intermittently, based on the individual patient's return to an acceptable sleep cycle [34].

Melatonin, a neurohormone secreted by the pineal gland, has been publicized as a cure for many sleep problems. Nocturnal secretion of melatonin and its suppression by bright light regulate circadian rhythms and sleep [35]. Sleep disturbances occur when

melatonin secretion is dyssynchronous from the light-dark cycle [36]. Melatonin secretion decreases with age and may be partly responsible for sleep disorders in the elderly [37]. Tobacco, alcohol, and medications, such as nonsteroidal anti-inflammatory drugs, calcium channel blockers, BDZs, fluoxetine, and steroids decrease melatonin production [38]. Melatonin is available in 0.3- to 5-mg doses. Doses of more than 1 mg will produce supraphysiologic levels. The half-life of melatonin is only 30 to 50 minutes, so there is a minimal residual effect the next morning. The main side effect is drowsiness. It is unclear whether long-term use suppresses endogenous production. Melatonin can interact with luteinizing hormone and should not be given to prepubertal or pregnant women. A recent study did not find any improvement in sleep quality or quantity with melatonin administration [39]. If given incorrectly, melatonin could exacerbate sleep disturbances. Melatonin given in the early evening will advance the circadian phase [40], so this dosing regimen could help those patients who have trouble falling asleep but then sleep late in the morning. However, elderly patients who complain of early morning awakenings may have their sleep problems worsened by a pre-bedtime dose. Conversely, early morning administration of melatonin delays the circadian phase, which might help patients who become sleepy earlier and awaken early. Valerian root is an over-the-counter herbal medicine used for insomnia. Valerian Root, Valeriana officinalis, is a perennial plant with a volatile oil found in the rhizome in the dried form. The oil contains 3 distinct compounds, present in various amounts, but all have sedative effects. Compared with BDZs, side effects are generally less common. Sedation is thought to be caused by inhibition of the breakdown of either -aminobutyric acid (GABA) or direct metabolites that have GABA-like properties, thus producing central sedation. Clinical trials using 400 mg of the aqueous extract decreased

sleep latency and increased slow-wave sleep [41]. Valerian root is classified as "generally recognized as safe" (GRAS) in the United States for food use and is officially in the European Pharmacopoeia. A recent FDA Advisory[42] has recommended against the use of kava because of liver toxicity. The most commonly used non-prescription agents are the antihistamines diphenhydramine and doxylamine. Side effects include dry mouth, constipation, and urinary retention. They are effective in inducing drowsiness when taken at bedtime; however, their half-life of up to 8 hours may cause residual daytime sedation.

3.1.3 Non-pharmacologic Treatment

Treatment of insomnia should be individualized based on the nature and severity of symptoms and should occur after other causes have been considered, diagnosed, and treated. Non-pharmacologic treatment is less expensive and has fewer side effects compared with pharmacologic treatment. Pharmacologic treatment should be used if the patient will benefit from the more rapid effect of drug therapies while pursuing the longer-lasting effects of behavior modifications. Non-pharmacologic treatments for insomnia are considered effective if they decrease sleep onset latency or increase total sleep time by 30 minutes. Most treatment studies use patient-reported sleep diaries to measure outcomes. Criteria used include total sleep time, sleep-onset latency, and the number of nocturnal awakenings. A meta-analysis of 48 individual studies of behavioral therapy found stimulus control therapy to be effective and to be superior to progressive relaxation, imagery training, and paradoxical intention. Progressive muscle relaxation is superior to a placebo. A more recent meta-analysis compared the outcomes of pharmacotherapy and behavioral therapy and found no differences between the 2 except

that behavioral therapy more significantly decreased sleep latency [43]. Stimulus control therapy, based on the premise that insomnia is a conditioned response to temporal and environmental stimuli normally associated with sleep, re-associates the bed with sleep and is especially effective for sleep-onset insomnia [44, 45].

The patient is instructed to leave the bedroom if unable to fall asleep within 20 minutes. The patient then returns to bed only when very sleepy, repeating the cycle as often as needed through the night. Patients avoid sleep incompatible activities when in bed (reading or watching television). With paradoxical intention therapy, the patient confronts their fear of sleeplessness by staying awake. This decreases concern about the consequences of lack of sleep and decreases performance anxiety about falling asleep. Patients who undergo cognitive therapy do not necessarily improve their sleep parameters, but they have increased satisfaction with their sleep patterns [46]. Relaxation therapies, based on the premise that the aroused state precludes sleep, are effective, especially in young adults, but less so than stimulus control or sleep restriction [47]. Relaxation training includes progressive muscle relaxation, where patients decrease muscle tension by tensing and relaxing different muscle groups. When using imagery training to decrease cognitive arousal, patients focus on pleasant or neutral images or use thought-stopping techniques. A recent study showed cognitive behavioral therapy decreased sleep latency by 54%, compared with 16% with relaxation therapy and 12% with placebo treatment.19 Cognitive therapy addresses dysfunctional beliefs; patients may have unrealistic expectations for sleep and misconceptions about the causes and consequences of their insomnia. Cognitive therapy is as effective as pharmacologic therapy in the elderly [48]. Many insomniacs develop anxiety about

going to sleep and a fear of sleeplessness, which may perpetuate insomnia. Others nap to compensate for poor nocturnal sleep, but this aggravates insomnia.

Poor sleep hygiene may worsen mild insomnia, but improving sleep hygiene alone is unlikely to impact severe insomnia. Improving sleep hygiene involves giving patients a list of instructions facilitating a regular sleep-wake schedule [49]. Instructions include: participate in a relaxing activity until tired, go to bed only when tired, use the bedroom only for sleep and sexual activity, avoid naps, avoid caffeine, nicotine, and alcohol 4 to 6 hours before bed, avoid poor sleeping environments, decrease fluid intake before bed, avoid heavy meals, heavy exercise, stimulating late-evening activities, and eliminate bedroom clocks. Exercise, unless performed immediately before bedtime, increases sleep quality. Moderate exercise improves sleep quality, onset latency, and duration in older adults [50].

Previous studies have shown that plantain leaf baths a part of Heliotherapy is beneficial.

3.2 Sleep and Health

Sleep is a physiological and behavioral process that an individual requires to carry out his daily functions. This process is completed regularly and continuously every night. As a part of biological rhythm, the human brain has a healthy functioning by differentiating dark and day hours of the day. From controlling hormone levels to muscle tone, from regulating the pace of breathing to the contents of our thought; sleep influences all bodily and mental functions. It is not surprising that sleep can make these changes happen in the body because sleep causes significant changes in the electrical activity of the brain as a whole [51]. Sleep characterizes itself by not responding to one’s surroundings and by drifting away from perception, yet it is a reversible behavior.

During 1940–1950, physiologists believed that sleep was initiated as a result of tiredness that developed during the day and by a slowing down in the activation of the forebrain from weakening in the activation of the reticular activating system. Later, based on transection studies, brain stem was shown to be responsible for generating sleep especially studies in cats; where total sections performed on pontine tegmentum induce sleeplessness. Physiologist Nathaniel Kleitman was working at Chicago University and he discovered REM sleep together with his colleague Dement in 1959 leading to a revolution in the field of sleep medicine. Two colleagues demonstrated the nature of sleep and the relation of eye movements with sleep by recording spontaneous whole night sleep. During their observations, it was understood for the first time that sleep consisted of 90–120 minutes cycles, it first got deep and then became superficial, and that during this superficial stage rapid eye movements appeared and then sleep deepened once again. Through the same series of observations, it was found that, during the first half of the night deep sleep was more frequent and that REM sleep constituted 20–25% of the total length of the sleep [52, 53]. Sleep has an important function in an individual and sleep deprivation for a couple of days can hinder an individual's cognitive and physical performance, general productivity, and health. The vital role of sleep on homeostasis can be demonstrated by the possible death of rats who suffer from sleep deprivation for 2–3 weeks. Despite the obvious importance of sleep, we still have limited information about why it is an obligatory part of life. Sleep has two main types of physiological effects: First, its effect on the nervous system itself and second its effects on other functional systems of the body. There is no doubt that the effects on the nervous system are important. Long-lasting wakefulness generally leads to progressive impairments of thought processes and even to abnormal behavioral activities (thoughts

are blurred, as the duration of wakefulness lengthens irritability and psychosis ensues). Therefore, sleep is considered to protect the normal order of brain activity by different means and to preserve the normal "balance" between the different functions of the central nervous system [54, 55].

3.2.1 Mechanisms of wakefulness and sleep

In the regulation of wakefulness and sleep brain stem, hypothalamus, basal forebrain, and their neurotransmitters all play a role. When we analyze the neuroanatomy of wakefulness and sleep, we mainly see that neurons activating wakefulness and sleep are located at pontis oralis, mesencephalic central tegmentum, posterior hypothalamus and midline brain stem, dorsolateral medulla reticular formation and anterior hypothalamic-preoptic fields at different concentrations and different localizations. Brain stem and reticular formation are important anatomic localizations. Wakefulness is managed by the reticular activating system (RAS). RAS is localized in the pons and midbrain. RAS stimulates the cortex by ventral and dorsal tracts. The ventral tract stimulates the frontal parts of the brain through the hypothalamus and subthalamus, dorsal tract stimulates the cortex through the nucleus groups in the thalamus. During wakefulness transmission of sensory information from the thalamus is permitted through RAS control managed by the thalamus. During sleep, the activity of RAS stops and the transmission of sensory information through thalamus is blocked and the stimulation of cortex is prevented. Anatomic structures responsible for the hypothalamic control of sleep and wakefulness: for wakefulness, stimuli originating from rostral pons and caudal midbrain regions reach paramedian midbrain in the diencephalon and here the signals divide into two paths aiming to reach thalamus and hypothalamus. The main structures projecting

to the thalamus are PedunculoPontine Tegmental (PPT) and LateroDorsal Tegmental (LDT) nuclei that are cholinergic. The structure that initiates sleep is thought to be the ventrolateral preoptic nucleus (VLPO) located on the anterior part of the hypothalamus. VLPO nucleus suppresses the activities of the brain stem, pons and locus coeruleus, dorsal raphe nucleus, laterodorsal tegmental pedunculopontine tegmental nucleus via GABA and galanin neurotransmitters. Suprachiasmatic Nucleus (SCN) is known as the light-sensitive circadian pacemaker. Throughout daytime light, the stimulus is transmitted from retina to the hypothalamus through neural pathways and results in the secretion of melatonin from the pineal gland. It is an anatomical structure that has a central role in maintaining the day-night rhythm [56-58, 59]. Neurotransmitters controlling sleep and wakefulness can be listed as: "Glutamate, Acetylcholine, Histamine, Norepinephrine, and GABA". The reticular activating system stimulates the cortex by using glutamate while Ponto-mesencephalic tegmental neurons do the same job by using acetylcholine. Neurons at locus coeruleus use mostly norepinephrine, these extend from the brain stem to the cerebral cortex by including the forebrain, and they activate the stimulation of the cortex and contribute to maintaining sleep. Cholinergic neuronal network results in wakefulness in two types of cortexes:

(1) It projects to laterodorsal tegmental and pedunculopontine tegmental nuclei, midline and intralaminar thalamic nuclei, and a lesser degree to lateral hypothalamus and basal for the brain.

(2) The cholinergic neuron group starts from the basal for the brain and has a wide projection to the cortex. This ponto mesencephalic neuron group is part of the ascending reticular activating system; they not only play a part in the activation during

wakefulness but also are actively involved in paradoxical sleep. Glutamate is another excitatory neurotransmitter; it acts as the primary neurotransmitter of the ascending reticular activating system. Glutamate is found at a very high concentration at the brain stem reticular formation. This neurotransmitter plays an active role in the wakeful brain and is secreted from the cortical cells to a significant degree throughout wakefulness. During slow-wave sleep "burst discharges" appear due to the activation of special glutamate receptors. Histamine also plays an important role in wakefulness. Neurons containing histamine are found in tuberomammillary nuclei and posterior hypothalamus. Noradrenergic neurons (locus coeruleus), have diffuse projections in the brain that extend to the cortex. Histaminergic neurons are associated with cortical activation during wakefulness whereas they are shut down during REM sleep. To sleep there needs to be a shift from sympathetic regulation to parasympathetic regulation. Parasympathetic centers of significance are found in "solitary tract nucleus neurons, anterior hypothalamus, and preoptic fields". Serotonergic raphe neurons facilitate the initiation of sleep while GABA-ergic neurons inhibit the activating system. These GABA-ergic neurons are selectively activated during slow-wave sleep. As a result of this inhibition, brain stem, hypothalamus, and basal forebrain are suppressed and disfacilitation (inhibition) and hyperpolarization of the thalamocortical system takes place. Thereby from the wakeful state where we see rapid, tonic discharges on EEG, the system shifts to sleep state we start recording sleep spindles and slow-wave activity. Initiation and continuation of slow-wave sleep are made possible by lengthening and strengthening the inhibition of the activating system with the GABA-ergic system [60, 61-68] (Figure 1).

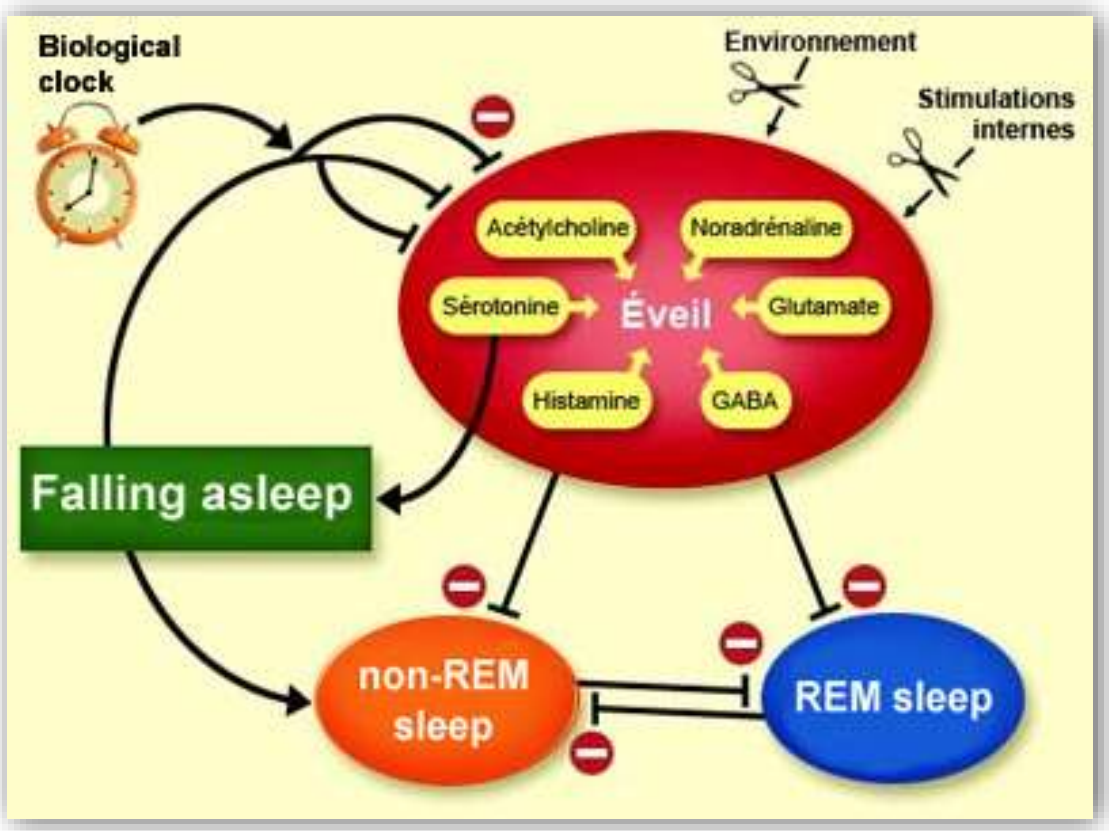

Figure 1: Mechanism of sleep

3.2.1 Normal sleep

Sleep is a complex mix of physiological and behavioral processes. Typically, sleep takes place while the individual is in a horizontal position, immobile with closed eyes, and when all other indicators point out to sleep. There are two distinct stages of sleep: The one with non-rapid eye movements (NREM) and the one with rapid eye movements (REM). These stages are differentiated from one another and wakefulness with clear margins. NREM sleep is classically divided into three stages based on EEG. EEG patterns usually consist of a mixture of synchronous sleep spindles, regular waves like K-complexes, and high voltage slow waves. Based on the depth of sleep, there are three NREM stages, during the first two stages, wake-up thresholds are generally low and

during the third stage it is at its highest or a body that can move and for a brain that can regulate, NREM sleep is a relatively inactive state going together with minimal and fragmental activity. On the other hand, during the REM stage, the body is immobile because of muscular atonia, in EEG shows activation and episodic rapid eye movements can be observed. Sleep cycle starts with NREM (calm, synchronized sleep, deep wave sleep); nearly every 90 minutes NREM and REM (mobile, desynchronized, paradoxical sleep) follow one another. Slow-wave sleep dominates the first one-third of the night and is related to the duration of wakefulness before sleep. REM sleep dominates the last one-third portion of the night and is related to the circadian rhythm. The first stage of sleep, namely NREM-1 lasts only for a couple of minutes after the initiation of sleep and it goes together with a low wake-up threshold and provides the transition from wakefulness to sleep. NREM-2 stage of sleep is identified by the presence of sleep spindles and K-complexes on EEG. To wake-up, there needs to be a more intense stimulus during NREM-2 compared to NREM-1. If stimuli given during NREM-1 are administered during NREM-2, there is no arousal; but K-complexes will appear. NREM-2 gradually progresses to high voltage slow activity and transforms into the NREM-3 stage. In a young healthy individual, the percentage of slow waves in sleep patterns should be 20–50%. NREM-REM cycles of sleep follow throughout the night by repetitions. THE First NREM-REM cycle lasts about 70–100 minutes, the second and further cycles last around 90–120 minutes. In young adults, during the first one-third of the night deep sleep is predominantly seen during the NREM stage, whereas during the last one-third portion of the night REM sleep dominates. Short wake-up periods usually happen when shifting to REM sleep [69, 70] (Figure 2).

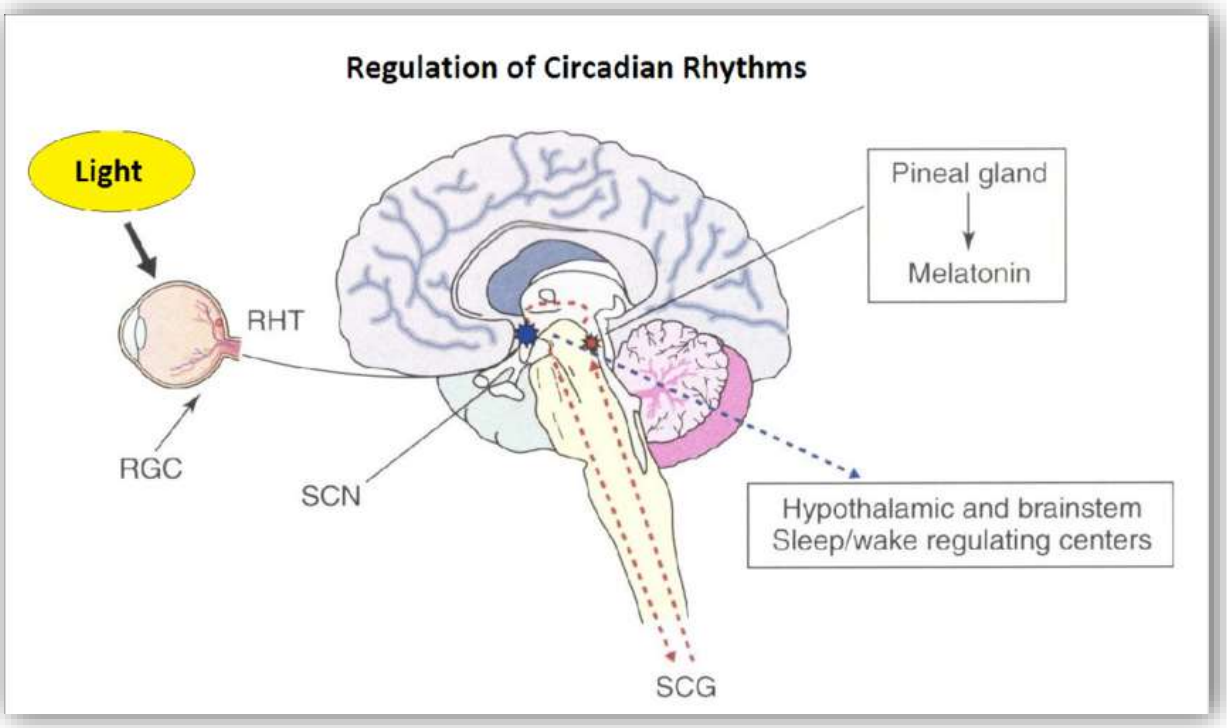

Figure 2: Regulation of circadian rhythm

3.2.3Electrophysiological signal recordings of wakefulness and sleep

During wakefulness electroencephalogram (EEG) reflects an active cerebral cortex engaged in perception and cognitive functions that shows relatively low voltage, high frequency, and rapid activity. The discharge by a single neuron or a single nerve fiber can never be recorded from the scalp surface. Only when thousands even millions of neurons or fibers are simultaneously fired, electrical potentials about a single neuron or a single fiber can be recorded as this much of an electrical potential would suffice to make such measurement from scalp surface [71]. When eyes are closed, several neurons show synchronous discharges at a frequency of 12 per second constituting alpha waves. When the eyes are opened afterward, the activity of the brain increases to a greater degree; but the synchronicity of the signals decreases which leads to the canceling out

of the brain waves. As a result of this, weak waves of higher but irregular frequency which are called beta waves appear. If the cortex does not have any connection with the thalamus, then alpha waves are not generated. Stimulation of non-specific reticular nuclei that surround thalamus and stimulation of diffuse nuclei that are located inside the thalamus result in the generation of waves in the thalamocortical system with a frequency of 8–13 per second which is the natural frequency for alpha waves. That is why alpha waves may appear from the spontaneous negative feedback impulses in the diffuse thalamocortical system that also includes the brain stem activating system. Delta waves include all the waves in EEG that have a frequency of less than 3–5 per second. They appear during very deep sleep, they also appear in the experimental animal studies where cortex has been separated from the thalamus with a subcortical section. Therefore, delta waves can appear in the cortex independent of the activities in the lower parts of the brain. Sleep spindles are produced by the thalamus. They appear as 12–15 Hz oscillations in between slow waves during NREM sleep in human EEGs. The production mechanism of these oscillations is related to the degree of hyperpolarization in thalamocortical cells. While shifting from wakefulness to sleep, the membrane potentials of thalamocortical cells are exposed to a progressive hyperpolarization, thus synaptic responsiveness decreases, and sensory information transfer is prevented. When a sufficient level of hyperpolarization is achieved, we start seeing rhythmic bursting in nucleus reticularis neurons belonging to thalamus at a frequency interval which is in correlation with sleep spindle. Furthermore, slow-wave oscillations due to membrane hyperpolarization also take place. It is accepted that sleep homeostasis is significantly affected by the size and characteristics of the sleep spindles that are formed [72-75].

3.3Sleep Architecture in Insomnia

Normal sleep consists of 2 alternating states, non-rapid eye movement (NREM) sleep, and rapid eye movement (REM) sleep [76]. The NREM-REM cycle, beginning with NREM, generally occurs 3 to 7 times per night and normally lasts 90 to 120 minutes each time [77]. The NREM sleep is composed of 4 stages (NREM1 through NREM4). Stage 1 is viewed as shallow or light sleep, having the lowest arousal threshold, and stage 2 is the transition from light sleep to deep sleep as the heart rate slows and body temperature decreases. Stages 3 and 4 are defined by high-voltage slow-wave activity, with stage 4 having a predominance of these waveforms [78]. Such high-voltage slow-wave activity is characteristic of slow-wave sleep (SWS) or deep sleep. These latter deep sleep stages have the highest arousal threshold and are believed to be required for physical restoration, while REM sleep is required for cognitive restoration [79] (Figure 3).

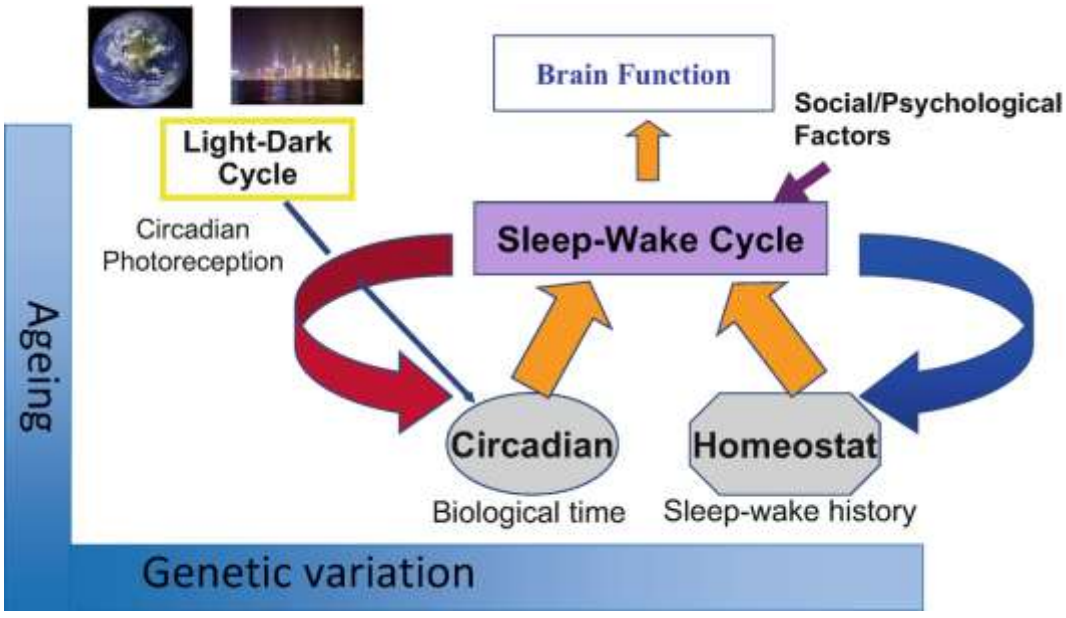

Figure 3: Pathophysiologic role of disrupted circadian

3.4 Naturopathy and Its Benefits

Naturopathy is a discipline of science that assists in the elimination of drugs without the help of external drugs. The system involves building a harmonious relationship with constructive principles on mental, physical, moral, and spiritual elements of living. It facilitates in creating a health promotive, disease preventive, and curative approach with much greater restorative potential.

According to the manifesto of the British Naturopathic Association, "Naturopathy is a system of treatment which recognizes the existence of the vital curative force within the body." Thus the interventional approach aids in determining the human system and removes the underlying factors that contribute to causing diseases and expels the toxins and unwanted waste products from the human body. These actions, in turn, facilitates in curing the diseases much more effectively [80, 81].

The method involved with practicing naturopathy majorly employs natural elements such as air, water, light, heat, food, etc., for expelling the toxins and curing the diseases thoroughly. The major aim of practicing naturopathy can be attributed to three fundamental elements:

- Removing the contributory factor that lowers a person’s vitality.
- Removal of foreign material of
- Rectifying the underlying abnormalities of the systemic circulation (blood and
- lymph)

The aim of naturopathic treatment is majorly towards improving an individual’s vitality by eliminating the accumulated waste products. This could be essentially rectified through approaches such as:

- Sauna Bath
- Steam Bath
- Therapeutic Colon Cleansing
- Therapeutic Fasting
- Heliotherapy

These intended treatments facilitate the complete elimination of toxins [82].

3.4.1Heliotherapy and Its Impact on General Health Benefits

Heliotherapy is the scientific application of the sun's rays in the treatment of disease. The living animal absorbs stored-up sun energy in the form of food, which in itself or its original form, the sun's rays, excites the living organism to greater activity accompanied by setting free stored-up energy. The sun treatment also promotes greater respiratory activity which improves the cardiac action and the general circulation. Also, heliotherapy stimulates the endocrine glands; the metabolism is increased, the appetite is improved and the digestive functions are more normal. Supporting studies, Exposure to the sun has multiple positive effects on androgen deprived prostate cancer patients and severe osteoporosis prevention [83].

Heliotherapy is the treatment of disease by exposing the body to sunlight. Heliotherapy (also called climatotherapy) makes simple use of intentional direct exposure to natural sunlight to get the therapeutic benefits of the included ultraviolet radiation. The healing effects of the sun and its benefits in many medical treatments could be traced back to ancient times. Even in modern times, during the first half of the 20thcentury saw heliotherapy to be an effective treatment and was even practiced in the western world,

in places like Europe, America, especially for the treatment of cutaneous tuberculosis [84, 85] (Figure 4).

Figure 4: Ancient practice of sunbath

3.4.1 Types of Sun Bath

3.4.1.1. General Sun Bath (Direct Sun Bath)

- Lying naked in the sun with wet compress overhead.
- Lying naked in the sun and rubbing the body with dry towel/ soft wet brush
- Massaging the body with oil while lying in the sun.

3.4.1.2. Indirect Sun Bath

Same way as General Sunbath, but in this type, the whole body should be covered within white cotton clothes and head and eye covered by the wet pack.

3.4.1. 3. Localized Sun Bath

In this type of exposure of Sun to a positive area of the body for treatment, other parts of the body covered by a wet sheet. It is effective in respiratory diseases and all joint diseases.

3.4.1.4. Plantain Leaf Bath / Banana Leaf Sun Bath

Similar to General Sun Bath, the body is covered with banana leaves and then exposed to sunlight [86].

Lindqvist et al. 2014 concluded that moderate sun exposure group had a 40%increased mortality rate and among avoiders of sun exposure the cause mortality rates doubled when compared with the highest sun exposure group [87].

Fermin et al. 2016 found in his study that Active sun exposure habits of a woman were associated with a lower mortality rate of cardiovascular cause and other non-cancer mortality, and he noted the similar magnitude of a risk factor for death of avoidance of sun exposure as like smoking [88].

Shelley Gorman et al in 2015 stated Sun produces local and systemic effects on health by its UV rays. The later potentially suppress Non Alcoholic fatty liver disease (NAFLD) through vitamin D-dependent and -independent mechanisms. vitamin D (Vit D) dependent mechanism Vitamin D derived from UV exposure preventive pathology by suppressing the potentially interacting pathways consist of hepatocyte apoptosis, liver inflammation and fibrosis, oxidative stress, the expression of protective adipokine, and changes to the composition of the gut microbiome.

Skin exposure to UVR induces several immune effector molecules, including vitamin D, NO, heme oxygenase, cis-urocanic acid, and serotonin. UVR induces the production of mediators such as NO and HO-1, which may contribute towards the protective effects of sunlight through a variety of mechanisms that suppress liver inflammation. They finally stated by their studies and suggesting that UVR has the potential to suppress Non Alcoholic fatty liver disease development through vitamin D dependent and -independent mechanisms [89].

Jacobsen et al. 2015 found that more sun exposure during the third gestational trimester of a mother was associated with a lower risk of type 1 diabetes in male children [90].

Sun exposure produces a clinical improvement of psoriasis by a rapid reduction in local and systemic inflammatory markers. It was extensively documented that UV irradiation is potentially inducing immunosuppression by significantly reducing CD4+ and CD8+ T-cells in the lesional skin of the epidermis and dermis [91].

3.5 Plantain Leaf Bath

Plantain's scientific name: *Musa paradisiaca* is one of the mono herbaceous plants belonging to the family; Musaceae. It is commonly referred to as plantain. Plantain refers in India to a coarse banana. In most of India like Assam, Madhya Pradesh,

Bihar, Gujarat, Andhra Pradesh, Karnataka, Jalgaon district in Maharashtra, West Bengal, Tamilnadu, etc. as well as in Burma, where the species is abundantly distributed. Apart from Asia, they are available densely in the regions of America, Australia, and tropical Africa [92] (Figure 5).

Figure 5. Plantain tree (*Musa paradisiaca*)

3.5.1 Benefits

Traditionally the Plant *Musa paradisiaca* was used for different purposes such as Abscess, Alopecia (female), burns, cancer, cataplasm, diabetes, diarrhea, dog bites, snakebite, dysentery, dyspepsia, fracture, gangrene, hematuria, hemiplegia, hemoptysis, hemorrhage, hypertension, lizard bites, marasmus, migraine, ringworm, shingles,

smallpox, syphilis, tuberculosis, tumor, uremia, otalgia, psoriasis, urticaria, warts, and wounds.

3.5.2 Benefits of Plantain Leaf bath as a Naturopathic Ailment

Banana leaf bath involves a different form of heliotherapy treatment, involving exposure to sunlight with the individuals covering themselves thoroughly with plantain leaves.

The treatment aids in facilitating the movement of green rays present in the sun, directly in the body. The rays were found to serve as a good antiseptic agent. This process is regarded as one of the detoxification processes involving in inducing profuse sweating [93, 94].

Asides their removal of toxin, they aid in burning the fat, effective for diabetic patients and asthma patients. Some of the major benefits of PLB include:

- Detoxifying the body and aids in weight loss, arthritis and curative for all sorts of skin diseases
- Maintain the skin’s glow and clears the acne and back heads from the skin.
- Induces to open the pores and clears the dirt away
- Excellent anti-inflammatory properties.

Plantain leaf helps in soothing the lungs as well as promotes respiratory health thus aids in treating coughs and bronchitis. Additionally, their purported use for plantain leaf includes enhanced circulation, stimulating the uterus, treating cystitis, and hay fever-reducing total cholesterol levels. Through enhanced circulation, rejuvenates the entire body and the circulatory system. This in turn assists in improving the circulatory system to a greater extent [95].

As this is the first study evaluating the effect of PLB, a previous evidence-based study was not available for literature review.

3.6 Sleep and Sunbath

Sunbathing, a simple and safe method is thought to reinforce social synchronizing factors as well as light synchronizing factors [96].

In the present case of severe mental and intellectual disabilities (SMID) accompanied by behavioral disturbance, sunbathing appeared to be effective for the treatment of insomnia [97]. Its effect included, i) improvement of the SWC; ii) reduction of the frequency of excitement; iii) reduction of the frequency of pyrexia, suggesting improvement of immune function; and iv) reduction of the frequency of epileptic seizures. MRI findings demonstrated infarction of the cerebral cortex and atrophy of the brainstem, suggesting injury of the ascending reticular formation which plays roles in determining the SWC [98].

In the case of severe mental and intellectual disabilities (SMID) accompanied by behavioral disturbance, sunbathing appeared to be effective for the treatment of insomnia. Its effect included, i) improvement of the SWC; ii) reduction of the frequency of excitement; iii) reduction of the frequency of pyrexia, suggesting improvement of immune function; and iv) reduction of the frequency of epileptic seizures.

MRI findings demonstrated infarction of the cerebral cortex and atrophy of the brainstem, suggesting injury of the ascending reticular formation which plays roles in determining the SWC [99]. This was a possible cause of sleep disturbance in the present case. During the period of sunbathing, serum levels of melatonin, an endogenous sleep-

inducer, and cortisol at time 0:00 tended to increase to normal levels, although sampling number and reproducibility were insufficient for definitive analysis.

Sunbathing, a simple and safe method is thought to reinforce social synchronizing factors as well as light synchronizing factors [100]. In the present case, similar to the effect of light therapy for insomnia in elderly persons, low melatonin levels tended normalization [101].

Generally, mentally retarded people typically exhibit poor sleep efficiency and reduced nocturnal plasma melatonin levels. This state is similar to that of the elderly, in whom a decrease in amplitude of the sleep-wake rhythm and decreased levels of melatonin secretion are observed [102]. Exposure to bright light suppresses the production of melatonin, increases nocturnal melatonin secretion, and contributes to the regulation of the circadian rhythm. The mechanism of elevation of nocturnal melatonin level in the present case remains to be explored.

Sunbathing and / or phototherapy appears to be useful for treating insomnia in individuals with brain damage including certain types of mental retardation and dementia. Melatonin, insomnia, behavioral disturbance, and sunbathing should be further studied in larger numbers of patients with mental retardation, to obtain evidence for the effectiveness of sunbathing in treating insomnia and behavioral disturbance in the mentally retarded.

Reviewer's comments incorporated from here: 1. A list of various therapies where light and /or heat is being used for therapeutic purposes may be listed are below.

3.6.1 Systematic use of Heliotherapy in the Treatment of Various Disorders

The therapeutic properties of ultra-violet light came to the attention of the medical profession during the early years of the 19th century. Dr. Niels Finsen (1860-1904), was the first physician to use sunlight in clinical practice and to investigate its effects scientifically. Finsen was awarded second Nobel Prize for Medicine in 1903 for his contribution in the treatment of tuberculosis of the skin with ultra-violet light; and he raised concentrated ultra-violet rays from specially constructed carbon-arc lamps known as “Finsen Lamps” [103].

3.6.1.1 Heliotherapy: A Therapeutic Practice Against Tuberculosis

As long ago in 1774, Faure and other French surgeons reported the cure of ulcers of the legs by exposure to the sun rays. Gauvain (1815) and Bonnet (1840), advised the same treatment for chronic articular inflammations. Until 1880 heliotherapy became a recognized therapeutic procedure for surgical tuberculosis. Ollier(1880), declared that heliotherapy was the excellent treatment for tuberculosis and arthritis. Later Poncet, exposed his students suffering from osteitis and arthritis to the sun and to allow the skin and the tissues to breathe in the pure air. Other physicians of France and the Mediterranean followed the heliotherapy practices as suggested by Poncet [104]. In 1904, Bernhard reported his 4 years experience with heliotherapy in the high altitudes of the Engadine. Rollier, a Swiss physician, influenced by the results of Bernhard, established a hospital in Leysin(Switzerland). Rollier practiced heliotherapy for ten years, and his work has attracted much attention [104]. The pioneer contributions to this series have been made by Brannan (1914) and Hinsdale (1919), Gardiner(1991), Kiebs, Pottenger, Pryor, and Twitchell recorded observations principally dealing with infections of bones, joints or with the pulmonary disease [105] (Figure 6).

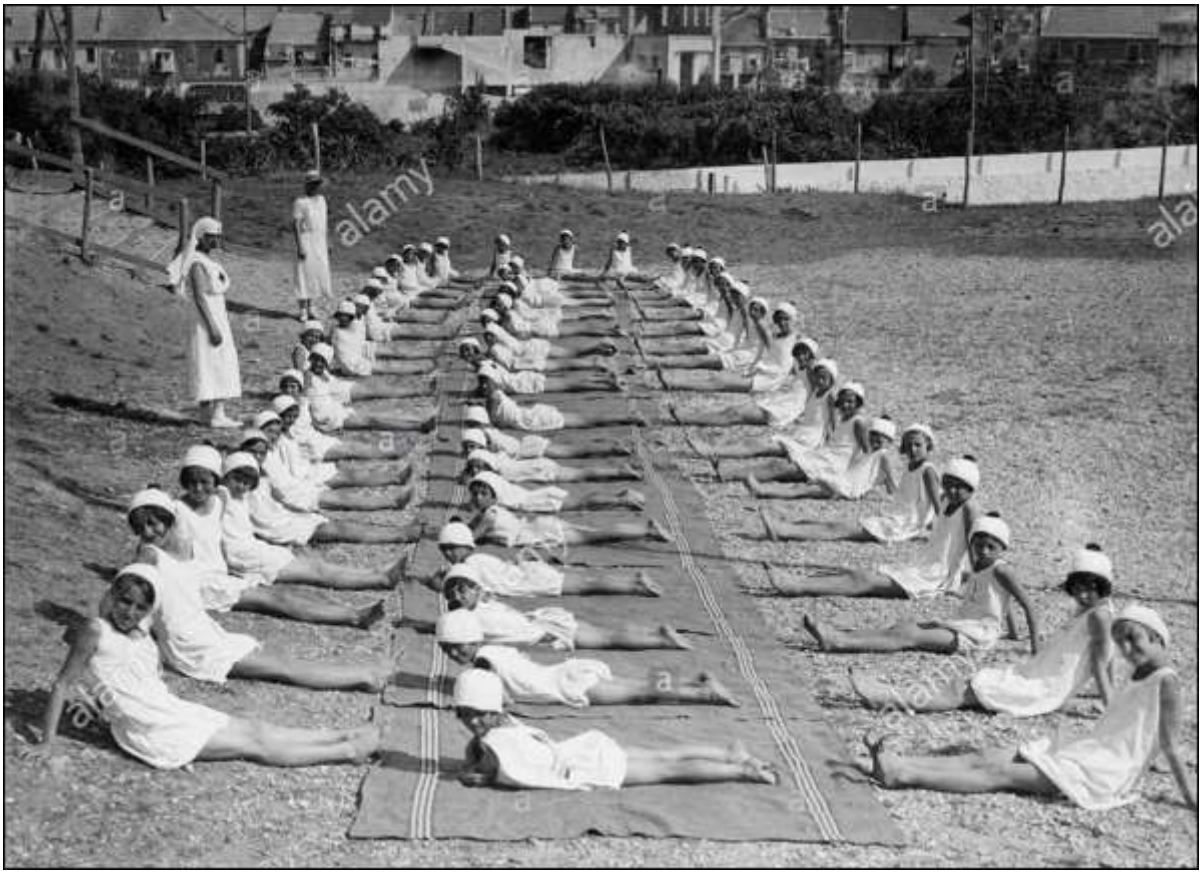

Figure 6: Heliotherapy: A Therapeutic Practice Against Tuberculosis

Heliotherapy Practice Proposed by Rollier On the first day, the exposure to the sun is five to ten minutes in three gradual intervals. This is steadily increased as pigmentation of the skin appears until finally the entire surface of the body is exposed from sunrise to sunset. With the development of pigmentation, the cure progresses until recovery is completed. Rollier noticed the pigmentation as an important element in the cure. It gives the skin a remarkable resistance, favors the cicatrization of wounds, and confers a local immunity to cutaneous microbial infections [104].

3.6.1.2 Phototherapy for Skin Diseases

Heliotherapy has long been used for the treatment of skin conditions. In ancient times, Egyptians were known to use sunlight to treat a variety of skin ailments, while other early civilizations including the Romans and Greeks also used sunlight for therapeutic purposes. More recently the sophisticated uses of phototherapy, specifically for the treatment of psoriasis, with significant development have begun in the early 20th century [106]. Psoriasis is a chronic, inflammatory, and systemic disorder that is characterized by scaling and erythematous plaques, which may be severely pruritic or painful. Psoriasis Vulgaris (or plaque psoriasis) is the most common clinical manifestation of psoriasis. Phototherapy has been proven effective for psoriasis10. Phototherapy involves exposure of patients to specific wavelengths of light, either ultraviolet A (UVA) or ultraviolet B (UVB). It has been widely used as an effective therapeutic approach for psoriasis and is considered free of the side effects associated with conventional systemic therapies. However, some undesirable side effects can be induced by phototherapy, including erythema and pruritus [107]. In 1925, Dr. William Goeckerman described the benefits of treating psoriasis using ultraviolet rays in combination with crude coal tar. In the 1950s, Dr. John Ingram developed a treatment regimen using ultraviolet B (UVB) radiation in conjunction with coal tar and anthralin paste. In the 1970s, broadband UVB was discovered to be effective in clearing mild forms of psoriasis when given in doses, while ultraviolet A (UVA) irradiation in combination with either oral or topical application of psoralen, was found to be effective in treating psoriasis. In the 1980s, a more defined wavelength of UVB was discovered by researchers to be particularly effective in treating psoriasis—and was subsequently

referred to as narrowband UVB (nbUVB)9. Phototherapy is more effective than traditional topical acne solutions such as benzoyl peroxide and salicylic acid. Acne vulgaris is one of the commonest causal agents developing 70% of adolescent's acne. Bacteria inhabit the sebaceous glands that secrete sebum, commonly known as oil, under phototherapy treatment light is used to open the pores and exfoliate the skin to allow light to penetrate below the surface of the skin. The light attacking the sebum causes a chemical reaction that can destroy the bacteria. The initial phototherapy technologies utilized for acne therapy were based on UV light, X-rays, infrared (red) light, or ultraviolet light technology. High-intensity blue light was found to be the most effective in destroying acne bacteria with phototherapy [108].

3.6.1.3 Phototherapy for the Treatment of Vitiligo

Phototherapy is used as an alternative skincare treatment for several alignments such as hyperpigmentation, eczema, rosacea, and acne. Ultra Violet light, or Phototherapy, can help to promote re-pigmentation of vitiligo. Vitiligo is characterized by loss of pigment in patches of the body. Phototherapy vitiligo treatment may continue twice a week for a year or more [109]. Finsen developed a quick and better method for the treatment and cure of Lupus vulgaris. He discovered light rays passing through quartz, and, simultaneously blocking the painful, blistering burns of the germ-killing, stimulating chemical rays with running cold water [110] (Figure 7).

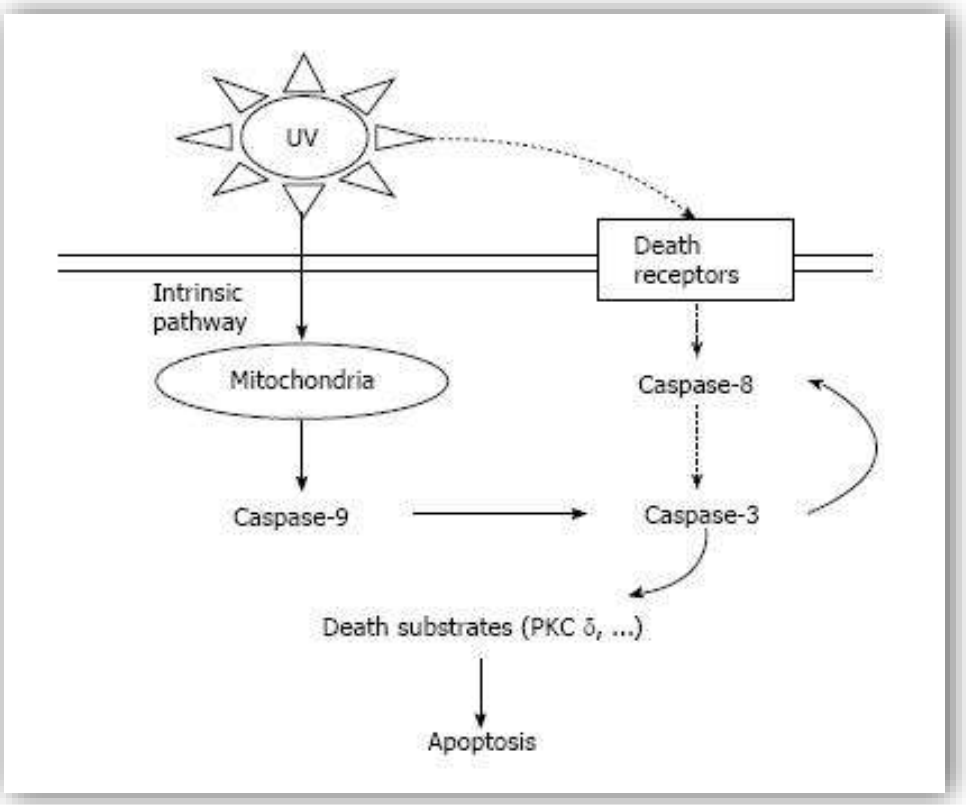

Figure 7: Narrowband ultraviolet B radiation in vitiligo

3.6.1.4 Neonatal Jaundice

Phototherapy has been used for the treatment of neonatal jaundice for more than 4 decades, the most efficacious phototherapy method with the least side effects has not been developed yet. Its efficacy is dependent on the color (wavelength) and intensity (irradiance) of the light emitted during phototherapy, the exposed body surface area, and the duration of exposure [111] (Figure 8).

Figure 8: Neonatal jaundice phototherapy exposure

3.6.1.4 Phototherapy for Sun Deprivation Disorder Rickets

Rickets, a sun-deprivation disorder, most likely affected early residents of the world's temperate Climates. For the first time Soranus of Ephesus, a famous physician of the Greco-Roman Era observed bony deformities suggestive of rickets among infants residing in Rome [112]. In 1919, Huldschinsky reported the cure of rickets by the ultraviolet rays. Following repeated exposure to X-ray, increased deposits of lime salts at the ends of the long bones, and the symptoms of the disease disappeared within two months. Park, Howland, Hess, and other observers have investigated the exact chemical nature of these changes in the phosphorus and calcium metabolism [113].

3.6.1.5 Bactericidal and Fungicidal Effect of Sunlight

The investigation on light and its relation with living system date from the time of Downes and Blount (1877), who reported that exposure to light retarded the growth of bacteria. The bactericidal action of ultraviolet light has been led by Bayne-Jones and Van der Lingen. They described the visible rays of the spectrum have little influence on bacterial growth, but the light with shorter wavelengths is absorbed by the bacteria [113].

3.6.1.6 Radiation Therapy for Cancer

Radiation therapy involves X-rays, γ-rays, and high-energy radiation to shrink tumor cells. In systemic radiation therapy, a patient receives an injection of a radioactive substance, such as radioactive iodine (131I) bound to a monoclonal antibody, which helps to target the radioactive substance to the right place. A variety of drugs has been approved by the FDA (Food and Drug Administration), such as Ibritumomab Tiuxetan (trade name Zevalin®) for the treatment of certain types of B-cell non-Hodgkin lymphoma (NHL). The antibody part of this drug recognizes and binds to a protein found on the surface of B lymphocytes [114]. Many other methods of external-beam radiation therapies are currently being used in cancer treatment. For some cancers, radiation therapy alone is an effective treatment. However, other types of cancer respond best to combination treatments. This may include radiation, surgery, chemotherapy, or immunotherapy (Figure 9).

Figure 9: External beam of radiation therapy for cancer

3.6.1.7 Sundial: An Ancient Time Machine

A sundial, in its broadest sense, is a device used to interpret the appropriate time by the apparent position of the Sun in the sky. It consists of a flat plate, the dial, and a gnomon (projecting piece) which throws a shadow onto the surface; lines marked onto the surface indicate the time of day [115]. The first record of the sundial is not clearly defined, about 1500BC the Egyptians constructed step Sundials monument called the Stonehenge on Salisbury plains, which traces the movement of the sun over a year. Jantar Mantar, an astronomical observatory was built in the city of Jaipur, India by the Rajput king Sawai Jai Singh in 1728, it features the world's largest stone sundial, and is a UNESCO World Heritage site [116].

3.6.1.8 Medical Sundial (MSD)

The MSD tracks the internal biological clock or the circadian cycles, which indicate the time of peak energy flow of the different organs. Considering that the heart, lungs, spleen, pancreas, liver, and kidneys are (right) organs and the intestine, stomach, gall bladder are (left) organs. The body shifts from right to the left position at 4h intervals and the circulatory and digestive systems are functional at optimum levels during the high energy periods of daylight hours while the respiratory system functions best during the low energy period that is night. In different seasons of the year when the heat of sunlight is contradicted to the biological clock, may result in various disorders [117]. Solar Power and Enlightening World Solar power is the cleanest and most reliable form of renewable energy. A solar system converts the sunlight into electricity, either directly using photovoltaics (PV), or indirectly using concentrated solar power. An estimate of the International Energy Agency proposed in 2014 stated that by 2050, solar photovoltaics and concentrated solar power would contribute about 16% and 11% respectively, of the worldwide electricity consumption, and solar energy would be the largest source of electricity worldwide. The first solar cell was developed by Charles Fritts in the 1880s and Ernst Werner; a German industrialist recognized the importance of this discovery. The first commercial concentrated solar power plant was first developed in the 1980s. The largest solar power plant Ivanpah, located in the Mojave Desert of California harnessed 392 MW electricity [118].

Heliotherapy, solar theology, sun calendars, solar calculations, and phototherapy constitute an instructive and fascinating episode in the history of medicine, also historical overview, that sun worship, inspired by nature, dominated in ancient

civilizations and cults as well. Light therapy has a crucial role in the treatment of various disorders and malignant diseases. In recent years, the efficacy of light therapy has been improved by new techniques and novel approaches that combine radiation therapy with molecule-based targeting of cancer like diseases and revealed promising results.

4. MATERIALS AND METHODOLOGY

4.1 Subjects

A total of 40 subjects of both gender with ages ranging between 18-45 years participated in the study.

4.1.1 Description of the subjects including the selection of samples

The study subjects were recruited from the Government Yoga & Naturopathy Medical College and Hospital, Arumbakkam, Chennai of Tamil Nadu State in India. The Subjects were recruited from the above-mentioned hospital through screening done to assess diagnostic criteria, inclusion, and exclusion criteria. Forty participants were screened through a routine medical check-up and those satisfying the Diagnostic criteria for Insomnia were recruited for the study.

4.2 Demographics

Table 1: Describes the demographic details of the subjects

PARAMETERS	MEAN ± SD	MEDIAN
Age	32.38± 9.145	34
Height (cm)	157.92± 8.914	158
Weight (Kg)	60.72± 6.089	60
BMI	24.173± 2.6275	24
PR (bpm)	71.90± 1.105	72

4.3. Ethical Considerations

4.3.1 Ethical clearance

Ethical clearance was sought from the Institutional Ethics Committee before the start of the study and the approval for the same was granted.

4.3.2 Written Informed Consent

Subjects who fulfilled inclusion criteria were appraised about the purpose of the study and their rights as research subjects. The informed consent form was administered in English. As all the subjects understood spoke English, there was no requirement of translating the signed informed consent form into native language i.e., Tamil. Adequate time was given to each patient to go through the information sheet and their queries were answered. Their right to withdraw anytime from the study and the need for a willingness to participate voluntarily in the study was explained. All the subjects expressed their willingness to participate in the study by giving a signed informed consent.

(A sample information sheet and consent form is enclosed as **Annexure 1**)

4.4 Study Design

The study employed Pre and post-study. This intended study is entailed on evaluating the efficacy of Plantain Leaf Bath (PLB) in improving the quality of sleep pattern parameters.

4.5 Screening of Subjects

4.5.1 Criteria for Diagnosis

4.5.1.1 The Athens Insomnia Scale

The Athens Insomnia Scale (AIS) may be one of the useful measures because it assesses all major insomnia symptoms (difficulties in initiating sleep [DIS], difficulties in maintaining sleep [DMS], and early morning awakening [EMA]) and important sleep domains (sleep quality and quantity as well as daytime functioning) [119].

4.5.1.2Pittsburgh Sleep Quality Index (PSQI)

The PSQI is the most widely used sleep health assessment tool in both clinical and non-clinical populations. Of the many psychometric studies carried out on the PSQI, 75% have reported an

internal consistency in the ideal range for within- and between-group comparisons but not for comparisons made between questionnaires for individual patients [120].

4.4.2Inclusion and Exclusion Criteria

4.4.2.1 Inclusion Criteria

The following inclusion criterion was adopted for recruiting the subjects:

- Aged within 18 to 45 years
- Both gender
- Primary insomnia patients – diagnosed by the Athens Insomnia Scale
- People ready to give their consent

4.4.2.1 Exclusion Criteria

Subjects with a history of systemic and /or psychological, regular use of any medications, recently hospitalized, regular smoking, alcohol consumption, people who are pregnant, lactating, menstruating.

4.4.2.2 Withdrawal Criteria

All subjects are free to withdraw from participation in the study at any time, for any reason, specified or unspecified, and without prejudice to further PLB. Subjects who are withdrawn from the study will not be replaced.

4.4.2.3 Allocation of patients into study & control groups

The patients were allocated to the Study group. Forty subjects were initially screened and recruited and assigned to the study group (n = 40).

4.4.3 Data Points

The data collection was done before and after the interventions. The effect of the intervention was also taken after the intervention.

4.4.5 Trial Profile

The trail profile of the study is presented as Figure 10which illustrates the study plan; the flow of patients across data points and reasons for the dropout.

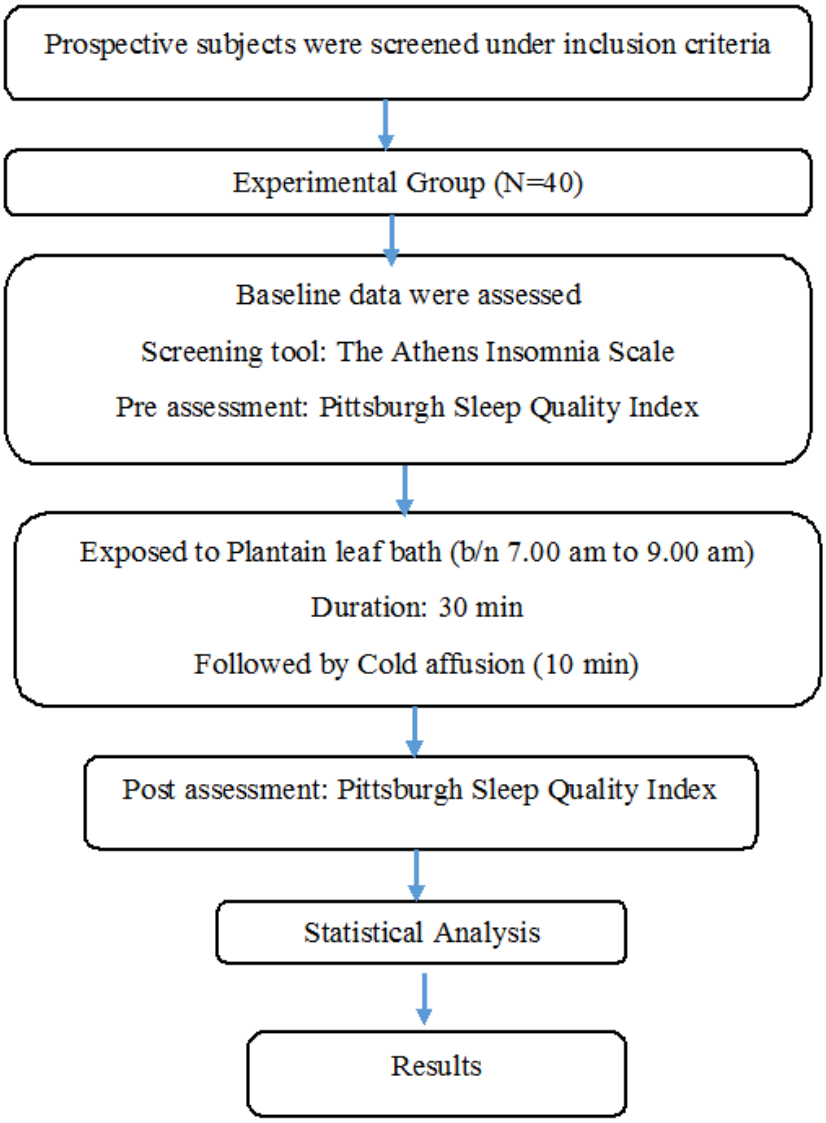

Figure 10: Trail Profile

4.5 Assessments

The baseline and post-intervention assessments consisted of:

Table 2: List of Primary and Secondary outcome variables

PRIMARY OUTCOME VARIABLES	SECONDARY OUTCOME VARIABLES
Heart rate (HR)	Blood Pressure (BP)
Pulse Rate (PR)	Body Mass Index (BMI)
Height (cm); Weight (kg)	Pittsburgh Sleep Quality Index (PSQI)

4.5.1 Primary outcome variables

4.5.1.2 Heart rate

The R waves from the electrocardiogram are detected, to obtain a point event series of successive R-R intervals, from which the beat to beat heart rate series are computed. The heart rate is obtained based on the R-R inter-beat interval analysis. The heart rate in beats per minute (bpm) was obtained by continuously counting the QRS complexes in successive 60 s periods.

4.5.1.4 Blood pressure

Blood pressure was recorded before and after the cold spinal bath by using a standard mercury sphygmomanometer, auscultating over the right brachial artery. The systolic pressure was noted as the first clear tapping sound (korotkoff sounds) and diastolic pressure was noted as the reading at which the korotkoff sounds appeared muffled.

4.6 Intervention

4.6.1 Procedure of Test Intervention

- PLB (Plantain Leaf bath) was performed among the study participants in morning sessions between 7.00 am to 9.00 am.
- The Subjects were instructed to wear a minimum dress during PLB.

- Subjects were made to lie supine over the plantain leaves spread on a mat.
- The subjects were wrapped with the plantain leaves and tied with 4 to 6 ropes which were laid between the mat and the plantain leaves at fixed intervals.
- The anterior (ventral) portion of the subjects should be covered with plantain leaves and tied with the rope underneath. This ensures in preventing the entry of air inside.
- The full body was completely wrapped with plantain leaves, with a small slit on the leaves above the nostrils to facilitate breathing. The maximum duration of the bath will be 30 minutes.
- Subsequently, on completion of the above procedure, the subjects were instructed to take cold affusion for a minute.

Figure 11 represents a study participant/subject, who was employed with PLB:

Figure 11: Plantain Leaf Bath

4.7 Data extraction & analysis

4.7.1 Data Extraction

The data was collected as self-reported observations using primary outcomes and secondary outcome variables. The assessments were done on the first day (baseline data) and end of the intervention (post data). The data was organized in Microsoft Excel Sheets (Version 2010).

4.6.2 Data Analysis

Data were analyzed using IBM SPSS 16.0. The data were checked for normality by the Shapiro-Wilk test, Non-parametric Variables are analyzed through the Wilcoxon Signed Rank test employed to compare means between the two groups. For all the analyses, we present 95% confidence intervals and considered $p < 0.05$ as significant.

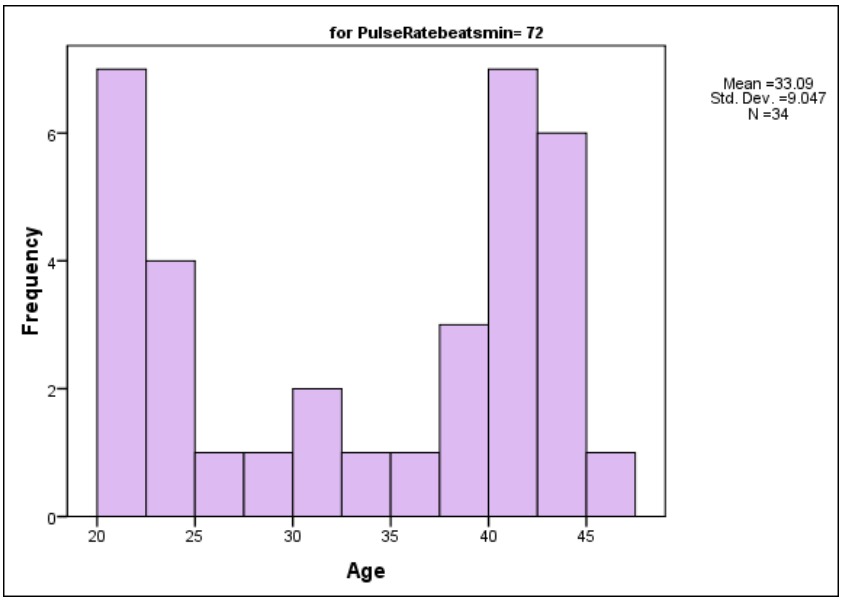

Figure 12: Normality of Data distribution

5. RESULTS

The present study was conducted to evaluate whether the intervention of PLB had any influence in any of the outcome variables viz., Heart Rate Variability, Respiratory Rate, Pulse rate, Blood Pressure, Body Mass Index in insomnia individuals. Results were compared within the group, wherein data was extracted at both baseline and post-intervention.

The results showed the significant differences in the Mean Heart Rate ($p<0.03$), Pulse rate ($p<0.02$), Systolic Blood Pressure ($p<0.003$), Diastolic Blood Pressure ($p<0.0001$), Body Weight ($p<0.0001$), Body Mass Index ($p<0.0001$), and in Respiratory Rate ($p<0.77$) (Table 3).

Table 3: Pre-post comparison mean variables in blood pressure and PSQI

PARAMETERS	**N**	**Mean ± SD**	**P-value**
PRE_SBP	40	113.75 ± 13.337	0.011
POST_SBP	40	144.50 ± 176.388	
PRE_DBP	40	77.50 ± 8.987	0.023
POST_DBP	40	80.50 ± 8.149	
PRE-PSQI	40	10.22 ± 1.423	0.000
POST-PSQI	40	6.68 ± 1.474	

Figure 13 shows the Pre-post comparison mean variables of PSQI which shows significant change after the intervention of PLB.

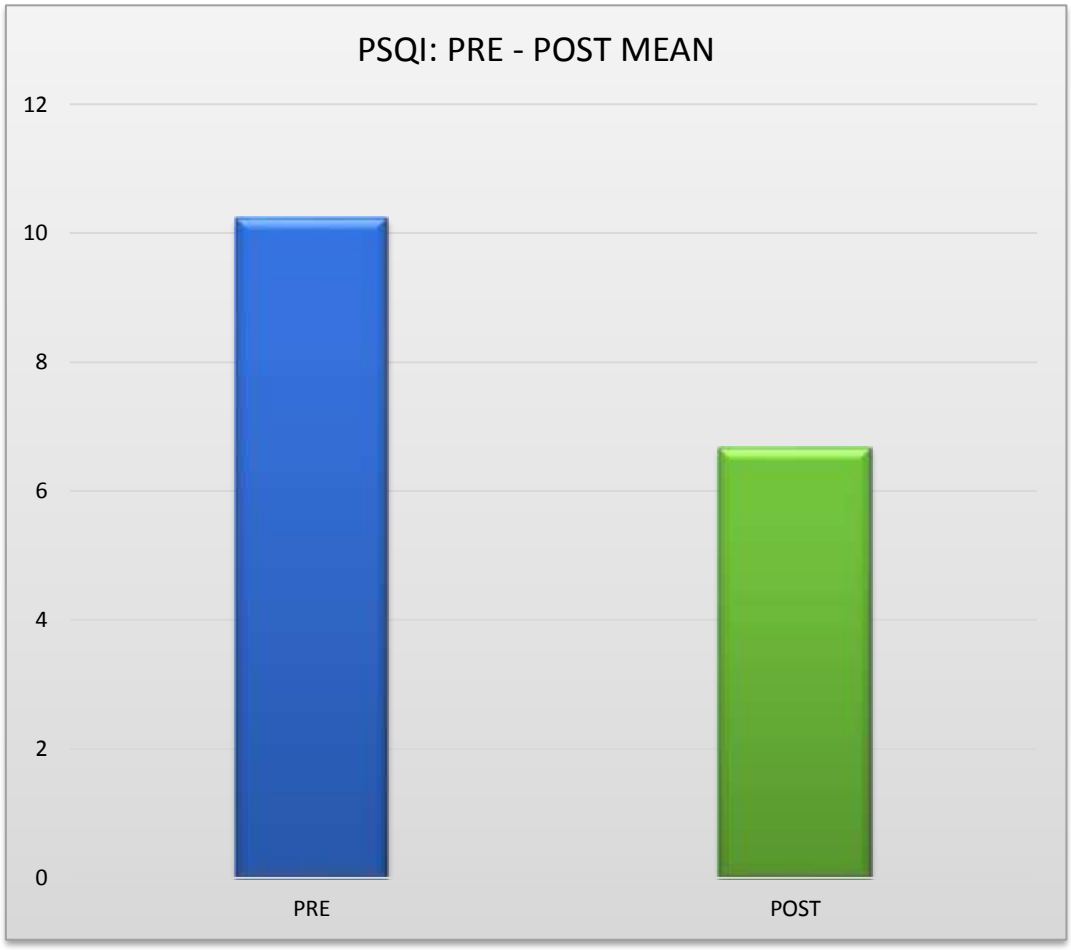

Figure 13: Pre-post comparison mean variables of PSQI

6. DISCUSSION

Heliotherapy mediated with PLB could facilitate in improving the systemic circulation, quite effectively but there are not enough literature studies that have focused on PLB and its impact on CVS. Current public health advice advocates avoidance of direct sunlight regarding skin cancer. The main aim of this study was to encourage the protective sunbath as a plantain leaf bath and the evaluation of its physiological effect on circadian rhythm and autonomic functions by measuring blood pressure, pulse rate, and heart rate.

The result of this study revealed that an intervention of Plantain Leaf Bath (PLB) decreased the Heart Rate and Pulse rate in the experimental group. In this study, there is a significant difference *($p<0.05$)* within the experimental group in the Mean Heart Rate, Pulse rate, Systolic Blood Pressure, Diastolic Blood Pressure, and Body Mass Index at the end of the intervention in comparison to the baseline data.

In this study, results show a significant decrease in the PSQI score. This shows that parasympathetic activity is dominant. The geographical difference, diurnal variation, and repeated exposure had a role in blood pressure reduction in the previous studies. The mechanism might be due to vasodilatation in response to the release of nitric oxide from the skin to the systemic circulation. In the current study blood pressure values were increased, this increase in blood pressure effect might be the result of increased peripheral resistance related to Vit D. In a previous study Vit D3 supplementation with a daily dose of 2000 IU significantly reduced the vascular stiffness [121]. The reduction of vascular resistance can be obtained by increasing the Vit D3 by taking PLB for a due period. In this study, the increased blood pressure value was under normal range. The result has shown that PLB has a stabilizing effect on blood pressure which has to be evaluated in a future study with proper study design.

6.1 Limitations

a. The sample size is relatively smaller. Hence, generalizing the study outcomes to a larger population would not be conclusive.

b. The duration of the practice is limited; longer exposure to the practice is needed.

c. The room temperature was not maintained during the assessment.

d. Diurnal variations might have influenced the results.

e. Other naturopathic treatments acted as confounding factors during the study.

7. CONCLUSION

To our knowledge, there is no study done with the intervention of PLB on the insomnia subjects on these parameters. Hence the present study was designed to assess the change in HR, BMI, and PSQI after the intervention. The present study showed that there is a significant change in resting cardiovascular parameters and PSQI among the insomnia participants immediately after plantain leaf bath intervention.

The significant reduction of resting cardiovascular parameters reflected the status of parasympathetic domination immediately after plantain leaf bath intervention.

SUMMARY

Objective: The research work aims at evaluating the efficacy of 'Plantain leaf bath'(PLB) on the improvement of sleep quality by monitoring parameters such as blood pressure, pulse rate, heart rate, and Pittsburgh Quality of Index. The previously available literature sources reported the benefits of incorporating a plantain leaf bath, which aids in improving sleep quality and cardiovascular functioning. The current study intended towards monitoring the effects, with the exposure of PLB, by determining the cardiovascular and sleep quality parameters of the study participants.

Method: 40 insomnia subjects belonging within the age group of 18-45 participated in the study. The cardiovascular parameters and Pittsburgh Quality of Index were assessed during the pre and post-intervention of PLB. The collected data were subjected to data analysis and interpretation, for determining the effectiveness and therapeutic effects of the plantain leaf bath among the study participants.

Result: The study showed significant improvement in the blood pressure and Pittsburgh Quality of Index values of the study participants. The post-intervention data showed significant improvement of cardiovascular parameters and Pittsburgh Quality of Index parameters, compared to that of the pre-intervention data.

Conclusion: The incorporation of Naturopathy mediated therapy involving PLB significantly improving the cardiovascular and sleep quality, which was exhibited from the observed cardiovascular parameters and Pittsburgh Quality of Index values.

REFERENCES

1. Doghramji K. The epidemiology and diagnosis of insomnia. American Journal of Managed Care. 2006 May 1;12(8): S214.
2. The American Psychiatric Association, Quick Reference to the Diagnostic Criteria from DSM-IV-TR. The American Psychiatric Publishing, 1st edition, 2000
3. National Heart, Lung, and Blood Institute and the NIH. Insomnia: key points. www.nhlbi.nih.gov/health/dci/Diseases/inso/inso_summary. HTML. Accessed May 2009
4. Ministry of AYUSH | GOI. About The Systems | Ministry of AYUSH GOI. Cited February 27, 2018. Available from: http://ayush.gov.in/about-thesystems/naturopathy/definition-naturopathy
5. Seely D, Szczurko O, Cooley K, Fritz H, Aberdour S, Herrington C, Herman P, Rouchotas P, Lescheid D, Bradley R, Gignac T. Naturopathic medicine for the prevention of cardiovascular disease: a randomized clinical trial. Cmaj. 2013 Jun 11;185(9): E409-16.
6. Yeh GY, Davis RB, Phillips RS. Use of complementary therapies in patients with cardiovascular disease. The American journal of cardiology. 2006 Sep 1;98(5):673-80.
7. Kiecolt-Glaser JK, McGuire L, Robles TF, Glaser R. Emotions, morbidity, and mortality: new perspectives from psychoneuroimmunology. Annual review of psychology. 2002 Feb;53(1):83-107.
8. Perk J, De Backer G, Gohlke H, Graham I, Reiner E, Verschuren M, Albus C, Benlian P, Boysen G, Cifkova R, Deaton C. [InlineMediaObject not available:

see full text.] European Guidelines on Cardiovascular Disease Prevention in Clinical Practice (Version 2012). International Journal of Behavioral Medicine. 2012 Dec 1;19(4):403.

9. Mancia G, Grassi G, Pomidossi G, Gregorini L, Bertinieri G, Parati G, Ferrari A, Zanchetti A. Effects of blood-pressure measurement by the doctor on patient's blood pressure and heart rate. The Lancet. 1983 Sep 24;322(8352):695-8.
10. Schutte-Rodin S, Broch L, Buysse D, Dorsey C, Sateia M. Clinical guideline for the evaluation and management of chronic insomnia in adults. Journal of clinical sleep medicine. 2008 Oct 15;4(5):487-504.
11. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. 5th ed. Arlington, VA: American Psychiatric Association; 2013.
12. HauriPJ, Sateia MJ, eds. International Classification of Sleep Disorders: Diagnostic and Coding Manual. 2nd ed. Darien, IL: American Academy of Sleep Medicine; 2005.
13. Breslau N, Roth T, Rosenthal L, Andreski P. Sleep disturbance and psychiatric disorders: a longitudinal epidemiological study of young adults. Biological psychiatry. 1996 Mar 15;39(6):411-8.
14. Ford DE, Kamerow DB. Epidemiologic study of sleep disturbances and psychiatric disorders: an opportunity for prevention?. Jama. 1989 Sep 15;262(11):1479-84.
15. Simon GE, VonKorff M. Prevalence, burden, and treatment of insomnia in primary care. American journal of psychiatry. 1997 Oct 1;154(10):1417-23.

16. Walsh JK. Clinical and socioeconomic correlates of insomnia. The Journal of clinical psychiatry. 2004.
17. Prasad K. Blood pressure and its control mechanism. In Textbook of Angiology 2000(pp. 46-54). Springer, New York, NY.
18. Richardson GS, Roth T. Future directions in the management of insomnia. The Journal of clinical psychiatry. 2001;62:39-45.
19. Drake CL, Roehrs T, Roth T. Insomnia causes, consequences, and therapeutics: an overview. Depression and anxiety. 2003 Dec;18(4):163-76.
20. Niemcewicz S, Szelenberger W, Skalski M, Androsiuk W, Piotrowski T, Myszka DM, Moskwa M. Psychophysiological correlates of primary insomnia. Psychiatriapolska. 2001;35(4):583-91.
21. Newman AB, Enright PL, Manolio TA, Haponik EF, Wahl PW, Cardiovascular Health Study Research Group. Sleep disturbance, psychosocial correlates, and cardiovascular disease in 5201 older adults: the Cardiovascular Health Study. Journal of the American Geriatrics Society. 1997 Jan;45(1):1-7.
22. Morgan K, Dallosso H, Ebrahim S, Arie T, Fentem PH. Characteristics of subjective insomnia in the elderly living at home. Age Ageing. 1988;17:1-7.
23. Owens JF, Matthews KA. Sleep disturbances in healthy middle-aged women. Maturitas. 1998;30:41-50.
24. Hohagen F, Rink K, Käppler C, Schramm E, Riemann D, Weyerer S, Berger M. Prevalence and treatment of insomnia in general practice. European archives of psychiatry and clinical neuroscience. 1993 May 1;242(6):329-36.

25. Breslau N, Roth T, Rosenthal L, Andreski P. Sleep disturbance and psychiatric disorders: a longitudinal epidemiological study of young adults. Biol Psychiatry. 1996;39:411-18.
26. American Psychiatric Association. Sleep disorders. In: Diagnostic and Statistical Manual of Mental Disorders: Diagnostic Criteria for Primary Insomnia, Fourth Edition, Text Revision. Washington, DC: American Psychiatric Association; 2000:597-61.
27. Roth T, Roehrs T. Insomnia: epidemiology, characteristics, and consequences. Clin Cornerstone. 2003;5:5-15.
28. Breslau N, Roth T, Rosenthal L, Andreski P. Sleep disturbance and psychiatric disorders: a longitudinal epidemiological study of young adults. Biol Psychiatry. 1996;39:411-18.
29. The Gallup Organization for the National Sleep Foundation. Sleep in America: 1995. Princeton, NJ: The Gallup Organization;1995.
30. National Institutes of Health. State-of-the-Science Conference Statement on Manifestations and Management of Chronic Insomnia in Adults; June 13-15, 2005. Sleep. 2005;28:1049-1057.
31. Buysse DJ, Ancoli-Israel S, Edinger JD, Lichstein KL, Morin CM. Recommendations for a standard research assessment of insomnia. Sleep. 2006 Sep 1;29(9):1155-73.
32. Ancoli-Israel S. Insomnia in the elderly: a review for the primary care practitioner. Sleep. 2000 Feb;23:S23-30.
33. Ancoli-Israel S. Insomnia in the elderly: a review for the primary care practitioner. Sleep. 2000 Feb;23:S23-38.

34. National Institutes of Health. State-of-the-Science Conference Statement on Manifestations and Management of Chronic Insomnia in Adults; June 13-15, 2005. Sleep. 2005;28:1049-1057.
35. Buysse DJ, Ancoli-Israel S, Edinger JD, Lichstein KL, Morin CM. Recommendations for a standard research assessment of insomnia. Sleep. 2006 Sep 1;29(9):1155-73.
36. Ancoli-Israel S. Insomnia in the elderly: a review for the primary care practitioner. Sleep. 2000 Feb;23:S23-38.
37. Ancoli-Israel S. Insomnia in the elderly: a review for the primary care practitioner. Sleep. 2000 Feb;23:S23-38.
38. Einstein, A., B. Podolsky, and N. Rosen, 1935, "Can quantum-mechanical description of physical reality be considered complete?", Phys. Rev. **47**, 777-780.
39. Avery D, Lenz M, Landis C. Guidelines for prescribing melatonin. Annals of medicine. 1998 Jan 1;30(1):122-30.
40. Skocbat T, Haimov I, Lavie P. Melatonin-the the key to the gate of sleep. Annals of medicine. 1998 Jan 1;30(1):109-14.
41. Arendt J, Deacon S. Treatment of circadian rhythm disorders–melatonin. Chronobiology international. 1997 Jan 1;14(2):185-204.
42. Skocbat T, Haimov I, Lavie P. Melatonin-the the key to the gate of sleep. Annals of medicine. 1998 Jan 1;30(1):109-14.
43. Zhdanova IV, Wurtman RJ, Regan MM, Taylor JA, Shi JP, Leclair OU. Melatonin treatment for age-related insomnia. The Journal of Clinical Endocrinology & Metabolism. 2001 Oct 1;86(10):4727-30.

44. Arendt J, Deacon S. Treatment of circadian rhythm disorders–melatonin. Chronobiology international. 1997 Jan 1;14(2):185-204.
45. Snitker JA, Bell WL, Schweain SL, Short RM, Burnham TH. Valerian. The review of natural products. St. Louis: Facts and Comparisons; 1999. p. 1–2.
46. Consumer advisory: Kava-containing dietary supplements may be associated with severe liver injury. Rockville (MD): Center for Food Safety and Applied Nutrition, US Food and Drug Administration; 2002 [cited 2003 Oct 28]. Available from http://www.cfsan.fda.gov/%7Edms/addskava.html.
47. Smith M, Perlis M, Park A, et al. Comparative meta-analysis of pharmacotherapy and behavior therapy for persistent insomnia. Am J Psychiatry 2002;159:5– 11.
48. Simon G, VonKorff M. Prevalence, burden, and treatment of insomnia in primary care. Am J Psychiatry 1997;154:1167–23.
49. Edinger J, Wohlgemuth W, Radtke R, Marsh G, Quillian R. Cognitive-behavioral therapy for the treatment of chronic primary insomnia. JAMA 2001;285: 1856 – 64.
50. Simon G, VonKorff M. Prevalence, burden, and treatment of insomnia in primary care. Am J Psychiatry 1997;154:1167–23.
51. Simon G, VonKorff M. Prevalence, burden, and treatment of insomnia in primary care. Am J Psychiatry 1997;154:1167–23.
52. Morin C, Colecchi C, Stone J, Sood R, Brink D. Behavioral, and pharmacological therapies for late-life insomnia. JAMA 1999;284:991–9.
53. Diagnostic Classification Steering Committee of the America Sleep Disorders Association. International classification of sleep disorders— diagnostic and coding manual. Rochester (MN): American Sleep Disorders Association; 1990.

54. King A, Oman R, Brassington G, Bliswise D, Haskell W. Moderate-intensity exercise and self-rated quality of sleep in older adults: a randomized controlled trial. JAMA 1997;277:32–7.
55. Kandel ER, Schwartz JH, Jessell TM, Siegelbaum SA, Hudspeth AJ. Principles of neural science. In: Sleep and Dreaming. 5th ed. London and New York: McGraw-Hill; 2013. pp. 1140-1146. ISBN 978-0-07-139011-8.
56. Kryger MH, Roth T, William CD. Normal sleep and its variations: History of sleep physiology medicine. In: Kryger MH, Roth T, William CD, editors. Principles and Practice of Sleep Medicine. 5th ed. St. Louis, Missouri: Elsevier Saunders; 2011. pp. 3-16.
57. Kryger MH, Roth T, William CD. Normal sleep and its variations: Normal human sleep. In: Kryger MH, Roth T, William CD, editors. Principles and Practice of Sleep Medicine. 5th ed. St. Louis, Missouri: Elsevier Saunders; 2011. pp. 16-26.
58. Guyton AC, Hall JE. Behavioral and motivational mechanisms of the brain-the limbic system and the hypothalamus. In: Textbook of Medical Physiology. 13th ed. Mississippi: Elsevier Saunders; 2011. pp. 751-761.
59. Guyton AC, Hall JE. States of brain activity-sleep, brain waves, epilepsy, psychoses. In: Textbook of Medical Physiology. 13th ed. Mississippi: Elsevier Saunders; 2011. pp. 763-72.
60. Kryger MH, Roth T, William CD. Normal sleep and its variations: Normal human sleep. In: Kryger MH, Roth T, William CD, editors. Principles and Practice of Sleep Medicine. 5th ed. St. Louis, Missouri: Elsevier Saunders; 2011. pp. 16-26.

61. Guyton AC, Hall JE. Behavioral and motivational mechanisms of the brain-the limbic system and the hypothalamus. In: Textbook of Medical Physiology. 13th ed. Mississippi: Elsevier Saunders; 2011. pp. 751-61.
62. Villablanca JR. Counterpointing the functional role of the forebrain and the brain stem in the control of the sleep-waking system. Journal of Sleep Research. 2004;13:179-208.
63. Kryger MH, Roth T, William CD. Sleep mechanisms and phylogeny: Neural control of sleep in mammals: Normal human sleep. In: Kryger MH, Roth T, William CD, editors. Principles and Practice of Sleep Medicine. 5th ed. Elsevier Saunders; 2011. pp. 76-80.
64. Kandel ER, Schwartz JH, Jessell TM, Siegelbaum SA, Hudspeth AJ. Principles of neural science. In: Sleep and Dreaming. 5th ed. London and New York: McGraw-Hill; 2013. pp. 1140-1146. ISBN 978-0-07-139011-8.
65. Guyton AC, Hall JE. Behavioral and motivational mechanisms of the brain-the limbic system and the hypothalamus. In: Textbook of Medical Physiology. 13th ed. Mississippi: Elsevier Saunders; 2011. pp. 751-761.
66. Villablanca JR. Counterpointing the functional role of the forebrain and the brain stem in the control of the sleep-waking system. Journal of Sleep Research. 2004;13:179-208.
67. Berridge CW. Noradrenergic modulation of arousal. Brain Research Reviews. 2008;58:1-7.
68. Ursin R. Seratonin and sleep. Sleep Medicine Reviews. 2002;6:57-69.
69. Jones BE. Arousal systems. Frontiers in Bioscience. 2003;8:438-451.

70. Jones BE. The organization of central cholinergic systems and their functional importance in sleep-waking states. Progress in Brain Research. 1993;98:61-71.
71. Kryger MH, Roth T, William CD. Sleep mechanisms and phylogeny: Neural control of sleep in mammals: Normal human sleep. In: Kryger MH, Roth T, William CD, editors. Principles and Practice of Sleep Medicine. 5th ed. Elsevier Saunders; 2011. pp. 76-80.
72. Vanini G, Torterola P, McGregor R, et al. GABAergic processes in the mesencephalic tegmentum modulate the occurrence of active (rapid eye movement) sleep in guinea pigs. Neuroscience. 2007;145:1157-167.
73. Kryger MH, Roth T, William CD. Sleep mechanisms and phylogeny: Neural control of sleep in mammals: Normal human sleep. In: Kryger MH, Roth T, William CD, editors. Principles and Practice of Sleep Medicine. 5th ed. Elsevier Saunders; 2011. pp. 76-80.
74. Vanini G, Torterola P, McGregor R, et al. GABAergic processes in the mesencephalic tegmentum modulate the occurrence of active (rapid eye movement) sleep in guinea pigs. Neuroscience. 2007;145:1157-167.
75. [1Kandel ER, Schwartz JH, Jessell TM, Siegelbaum SA, Hudspeth AJ. Principles of neural science. In: Sleep and Dreaming. 5th ed. London and New York: McGraw-Hill; 2013. pp. 1140-1146. ISBN 978-0-07-139011-8.
76. Vanini G, Torterola P, McGregor R, et al. GABAergic processes in the mesencephalic tegmentum modulate the occurrence of active (rapid eye movement) sleep in guinea pigs. Neuroscience. 2007;145:1157-167.
77. Steriade M, Amzica F. Coalescence of sleep rhythms and their chronology in corticothalamic networks. Sleep Research Online. 1998;1(1):1-10.

78. Knoublach V, Martens WL, WirzJustice A, Cajochen C. Human sleep spindle characteristics after sleep deprivation. Clinical Neurophysiology. 2003;114(12):2258-267.
79. Guyton AC, Hall JE. States of brain activity-sleep, brain waves, epilepsy, psychoses. In: Textbook of Medical Physiology. 13th ed. Mississippi: Elsevier Saunders; 2011. pp. 763-72.
80. Fuller PM, Gooley JJ, Saper CB. Neurobiology of the sleep-wake cycle: sleep architecture, circadian regulation, and regulatory feedback. J Biol Rhythms. 2006;21(6):482-493.
81. Markov D, Goldman M. Normal sleep and circadian rhythms: neurobiological mechanisms underlying sleep and wakefulness. Psychiatr Clin North Am. 2006;29(4):841-853, abstract vii.
82. Carskadon MA, Rechtschaffen A. Monitoring and staging human sleep. In: Kryger MH, Roth T, Dement WC, eds. Principles and Practice of Sleep Medicine. 4th ed. Philadelphia, PA: Saunders; 2005.
83. Roth T. Measuring treatment efficacy in insomnia. J Clin Psychiatry. 2004;65(suppl 8):8-12.
84. Carskadon MA. Sleep and circadian rhythms in children and adolescents: relevance for athletic performance of young people. Clin Sports Med. 2005;24(2):319-328, x.
85. Sathyaprabha TN, Murthy H, Murthy BT. Efficacy of naturopathy and yoga in bronchial asthma--a self-controlled matched scientific study. Indian journal of physiology and pharmacology. 2001 Jan;45(1):80-86.

86. Debas HT, Laxminarayan R, Straus SE. Complementary and alternative medicine. Disease control priorities in developing countries. 2006;2.
87. Ministry of AYUSH | GOI. Naturopathy | Ministry of AYUSH GoI. April 27, 2018. Available from: http://ayush.gov.in/aboutthe-systems/naturopathy(Josip Spanjol et al, 2008.
88. Nature-food. ACUPRESSURE. January 01, 1970. Available from: http://naturefood-cure.blogspot.in/2010/08/banana-leaf-bath.html.
89. Natural Health Cure RSS. Natural Health Cure. April 27, 2018. http://www.naturalhealthcure.org/therapies/helio-therapy-benefits-of-sunexposure.html.
90. Banana leaf bath. Naturopathy. January 01, 1970. Available from. http://naturopathyforhealth.blogspot.com/2013/03/banana-leaf-bath.html.
91. Lindqvist PG, Epstein E, Landin-Olsson M, Ingvar C, Nielsen K, Stenbeck M, Olsson H. Avoidance of sun exposure is a risk factor for all-cause mortality: results from the Melanoma in Southern Sweden cohort. Journal of internal medicine. 2014 Jul;276(1):77-86.
92. Fermini B, Hancox JC, Abi-Gerges N, Bridgland-Taylor M, Chaudhary KW, Colatsky T, Correll K, Crumb W, Damiano B, Erdemli G, Gintant G. A new perspective in the field of cardiac safety testing through the comprehensive in vitro proarrhythmia assay paradigm. Journal of biomolecular screening. 2016 Jan;21(1):1-1.
93. Schuh A. Climatotherapy. Experientia. 1993 Nov 1;49(11):947-56.
94. Cannon TD, Chung Y, He G, Sun D, Jacobson A, Van Erp TG, McEwen S, Addington J, Bearden CE, Cadenhead K, Cornblatt B. Progressive reduction in

cortical thickness as psychosis develops a multisite longitudinal neuroimaging study of youth at elevated clinical risk. Biological psychiatry. 2015 Jan 15;77(2):147-57.

95. Schuh A. Climatotherapy. Experientia. 1993 Nov 1;49(11):947-56.

96. Wikipedia: the free encyclopedia [Internet]. St. Petersburg (FL): Wikimedia Foundation, Inc. 2001 - Musa × paradisiacal; cited 2018 April 26. Available from: https://en.wikipedia.org/wiki/Musa_%C3%97_paradisiaca

97. Schuh A. Climatotherapy. Experientia. 1993 Nov 1;49(11):947-56.

98. Grossman E. Blood pressure: the lower, the better: the con side. Diabetes Care. 2011 May 1;34(Supplement 2):S308-12.

99. LIVESTRONG.COM. The Health Benefits of the Plantain Leaf. Published on October 03, 2017. Cited 2018, April 20. https://www.livestrong.com/article/430791-the-health-benefits-of-the-plantain-leaf/.

100. Okawa M, Nanami T, Wada S, Shimizu T, Hishikawa Y, Sasaki H, Nagamine H, Takahashi K. Four congenitally blind children with circadian sleep-wake rhythm disorder. Sleep. 1987 Mar 1;10(2):101-10.

101. Ikemoto K. Effects of Sunbathing on Insomnia, Behavioural Disturbance, and Serum Melatonin Level. MELATONIN, SLEEP, AND INSOMNIA:329.

102. Magoun, H.W. The waking brain, 2nd ed. Illinois: Charles C Thomas Springfield, 1963

103. Niederhofer H, Staffen W, Pittschieler K, Mair A. Brief report: melatonin facilitates sleep in individuals with mental retardation and insomnia. Journal of Autism & Developmental Disorders. 2003 Aug 1;33(4).

104. Dodd A, Hare DJ, Arshad P. The use of melatonin to treat sleep disorder in adults with intellectual disabilities in community settings–the evaluation of three cases using actigraphy. Journal of Intellectual Disability Research. 2008 Jun;52(6):547-53.

105. Braam W, Didden R, Smits M, Curfs L. Melatonin treatment in individuals with intellectual disability and chronic insomnia: a randomized placebo-controlled study. Journal of Intellectual Disability Research. 2008 Mar;52(3):256-64.

106. Hobday RA. Sunlight therapy and solar architecture. Medical history. 1997 Oct;41(4):455-72.

107. J.W. Brannan. Trans Am ClimatolClin Assoc. 30, 149–164 (1914).

108. J.H. Elliott. Trans Am ClimatolClin Assoc. 32, 221–227 (1916).

109. T. Wong, L. Hsu, and W. Liao. J Cutan Med Surg. 17, 6-12 (2013).

110. J. J. Yu, C. S. Zhang, A. L. Zhang, B. May, C. C. Xue, and C. Lu. Evid Based Complement Alternat Med. (2013). Retrieved http://dx.doi.org/10.1155/2013/673078

111. P. Papageorgiou, A. Katsambas, and A. Chu. Br J Dermatol. 142, 973-978 (2000).

112. National Biological: Phototherapy Patient Information: Vitiligo and Phototherapy. Retrieved January 23, (2016). https:// www.natbiocorp.com/

113. H. Bloch. J Natl Med Assoc. 82, 517–521 (1990). 14. Y. S. Chang, J. H. Hwang, H. N. Kwon, C. W. Choi, S. Y. Ko, W. S. Park, S. M. Shin, and M. Lee. (2005). J Korean Med Sci. 20, 61-64 (2005).

114. K. Rajakumar, S. L. Greenspan, S. B. Thomas, and M. F. Holick. Am J Public Health. 97, 1746-1754 (2007).

115. R.J. Wurtman. Sci Am. 233, 69-77(1975). 17. National Cancer Institute: Radiation Therapy for Cancer. Retrieved January 23, 2016. http://www.cancer.gov/about-cancer/ treatment/types/radiation therapy/radiation-fact-sheet

116. Wikipedia: Sundial. Retrieved January 23, 2016 https:// en.wikipedia.org/wiki/Sundial.

117. Colors of India: Sundial. Retrieved January 23, 2016. HTTP:// colorsofindia.com/sundial/history.html

118. Barbara E. Bryden. Sundial: Theoretical Relationships Between Psychological Type, Talent, and Disease. Center for applications of psychological type(CAPT), Gainesville, Florida. p.178 (2005).

119. International Energy Agency. Technology Roadmap: Solar Photovoltaic Energy (2014). http://www.iea.org

120. Enomoto K, Adachi T, Yamada K, Inoue D, Nakanishi M, Nishigami T, Shibata M. Reliability and validity of the Athens Insomnia Scale in chronic pain patients. Journal of Pain Research. 2018;11:793.

121. Manzar MD, BaHammam AS, Hameed UA, Spence DW, Pandi-Perumal SR, Moscovitch A, Streiner DL. Dimensionality of the Pittsburgh Sleep Quality

Index: a systematic review. Health and quality of life outcomes. 2018 Dec 1;16(1):89.

122. Dong Y, Pollock N, Stallmann-Jorgensen IS, Gutin B, Lan L, Chen TC, Keeton D, Petty K, Holick MF, Zhu H. Low 25-hydroxyvitamin D levels in adolescents: race, season, adiposity, physical activity, and fitness. Pediatrics. 2010 Jun 1;125(6):1104-11.

9.0 ANNEXURE

9.1 INFORMATION SHEET

We are conducting a study on "Efficacy of plantain leaf bath on cardiovascular and sleep quality parameters in insomnia patients" at Government Yoga and Naturopathy Medical College Hospital, Chennai, and for that, we need your participation which is valuable to us.

The purpose of the study is to evaluate the effectiveness of the plantain leaf bath on cardiovascular and sleep quality parameters.

The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.

The results of the special study may be intimated to you at the end of the study period.

Signature of investigator: Signature of participant:

Date:

9.2 INFORMED CONSENT FORM

Title of the study: Efficacy of plantain leaf bath on cardiovascular and sleep quality parameters in insomnia patients

Name of the Participant:

Name of the Principal Investigator: Dr.S. Dharmasamvarddhini

Name of the Institution: Government Yoga & Naturopathy Medical College, Chennai –

600 106

Documentation of the informed consent

I _____ have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in "Efficacy of plantain leaf bath on cardiovascular and Sleep quality parameters in insomnia patients"

1. I have read and understood this consent form and the information provided to me.

2. I have had the consent document explained to me.

3. I have been explained the nature of the study.

4. I have been explained my rights and responsibilities by the investigator.

5. I have been informed the investigator of all the treatments I am taking or have taken in the past _____ months including any native (alternative) treatment.

6. I have been advised about the risks associated with my participation in this study.

7. I agree to cooperate with the investigator and I will inform him/her immediately if Isufferunusual symptoms.

8. I have not participated in any research study within the past _____month(s).

9. I am aware of the fact that I can opt-out of the study at any time without having to give any reason and this will not affect my future treatment in this hospital.

10. I am also aware that the investigator may terminate my participation in the study at any time, for any reason, without my consent.

11. I hereby permit the investigators to release the information obtained from me as a result of participation in this study to the sponsors, regulatory authorities, Govt. agencies, and IEC. I understand that they are publicly presented.

12. I have understood that my identity will be kept confidential if my data are publicly presented.

13. I have had my questions answered to my satisfaction.

14. I have decided to be in the research study.

I am aware that if I have any questions during this study, I should contact the investigator.

By signing this consent form, I attest that the information given in this document has been clearly explained to me and understood by me, I will be given a copy of this consent document.

For adult participants:

Name and signature / thumb impression of the participant (or legal representative if participant incompetent)

Name _____ Signature_____

Date_____

Name and Signature of impartial witness (required for illiterate patients):

Name _____ Signature_____