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DEVELOPMENT OF A NON-INVASIVE SLEEP INDUCER FOR INSOMNIA TREATMENT USING FEEDBACK MONITORING SYSTEM

Amit Kumar Singh[1], A. Madhumitha[2], A. Keerthika[3], M. Pavithra[4] and S. Yazhini[5]
[1]*Department of Biomedical Engineering, Vignan's Foundation for Science, Technology and Research, India*
[2,3,4,5]*Department of Biomedical Engineering, VSB Engineering College, India*

Abstract

Sleep is vital in maintaining overall health and cognitive function. Sleep disorders, like insomnia, can significantly impact sleep quality and quantity, leading to adverse effects on humans. Around 30% of the adult population in the world has insomnia symptoms. Current treatments for insomnia include lifestyle changes, therapy, and medication, but they often have limitations and potential side effects. Non-invasive electronic methods have shown promise in addressing sleep problems, but they lack feedback on the patient's sleep condition. The study utilised a system that monitored heart rate, blood oxygen saturation, body temperature, and body movement. A microcontroller-based circuitry integrated the sensor data and provided real-time feedback. The electromagnetic coil generated a sleep-inducing electromagnetic field in the delta frequency band. The developed sleep inducer successfully monitored all the selected vital parameters. The microcontroller processed the sensor data and triggered the electromagnetic coil when deviations from specified conditions were detected. The system operated effectively to induce sleep, maintaining the coil activation for at least 5 minutes per parameter above threshold levels. We also tested the device on one volunteer for two consecutive days. The non-invasive sleep inducer demonstrated potential as an effective tool for insomnia treatment. By incorporating monitoring and feedback techniques, it addressed the limitations of existing methods and provided personalised sleep-inducing effects. The system's low cost, simplicity, and patient comfort make it a promising alternative for insomnia management. Further research and refinement are necessary to enhance the system's efficacy and ensure long-term safety due to limited testing.

Keywords:

Sleep Inducer, Non-Invasive Insomnia Treatment, Vital Sign Monitoring, Feedback Technique

1. INTRODUCTION

Sleep is an essential physiological function crucial for maintaining health and cognition. There are two kinds of sleep: rapid eye movement (REM) sleep and non-rapid eye movement (NREM) sleep [1]. These cycle through the night, lasting 90-120 minutes. NREM comprises 75-80% of total sleep. It has three stages: N1 (5-10 minutes) is light sleep transitioning from wake to sleep. Muscle activity and eye movements slow, and heart rate (HR) and temperature decrease. N2 (40-60% of total sleep) has slowed eye movements, muscle relaxation, lower temperature and HR, and unique brainwaves like spindles and K-complexes. N3 (20-25% of total sleep) is deep sleep for physical and mental recovery [2]. The body's temperature, blood pressure, and heart rate are all at their lowest points. 20 to 25 per cent of the entire amount of sleep comes in the REM sleep. High levels of mental activity and vivid dreams are marked by REMs [2]. During non-REM sleep, HR, blood pressure (BP), saturated oxygen (SpO2) [3], body temperature (BT) [4], and respiration rate (RR) decrease [5]. HR reduces by 30-50% compared to wakefulness, dropping below 50 rates per minute in some individuals. BP goes down by 10-15%, and the RR goes down by 30-50% with a pause of several seconds. In addition, there is a drop in BT by 1–2 oF. REM sleep sees a reversal of these trends with increases in HR, BP, RR and BT towards waking levels.

Sleep is critical for learning, memory consolidation and cognitive performance. Sleep problems like insomnia, sleep apnea, restless legs syndrome and circadian rhythm disorders can disrupt sleep quantity and quality, harming health and well-being [6]. According to Bhaskar et al., the prevalence of insomnia was found in 30-50 % of the world population. Insomnia is common in older adults, females, and people with medical and mental ill health [7]. Various treatments exist for sleep disorders. Insomnia treatment includes lifestyle changes, cognitive behavioural therapy, relaxation techniques, and medication. Improving sleep hygiene [8] by limiting screen time before bed, having a consistent sleep schedule, and having a dark, quiet bedroom can help with insomnia but requires time and lifestyle changes. Cognitive behavioural therapy [9] challenges negative thoughts about sleep and establishes healthy sleep habits, but needs professional guidance and time. Relaxation techniques [10] like meditation, yoga, and deep breathing reduce anxiety and promote sleep but may not work for different patients. Medications such as benzodiazepines [11], nonbenzodiazepine sedatives, and melatonin [12] can treat insomnia depending on the type, severity, preferences, and lifestyle. Lifestyle changes, therapy and medication can help in the curing of insomnia but may cause side effects and have unknown long-term effects. Hypnosis [13] can be beneficial but requires a skilled practitioner and may not work for everyone.

There are electronic-based, non-invasive methods to help insomnia patients regarding their sleep problems. Most of the methods generate some magnetic [14], electromagnetic [15], [16], electroencephalogram (EEG) [17], and sound waves [18] to generate the sleep-inducing feature. They all require a one-time investment, and the running cost is low as it can be used daily, only requiring some electrical power for the device. Magnetic therapy [14] is low-cost, has no side effects, and does not require power, but it has a 50% success rate and no personalisation options. Sound Wave-Based Therapy [18] is low-cost, has no side effects, and allows for personalisation, but it requires power and more human testing for personalisation of the therapy. Temperature Therapy [4] is a long-standing treatment but requires high power, has high carbon dioxide levels, and is expensive. EEG Therapy [17] is low-cost, has no side effects, but requires power, is complex for personalisation, and has limited human testing along with a complicated electrode system to be placed on the head of the user. The disadvantage of most methodologies is that they provide no feedback on the patient's sleep condition. So, monitoring sleep parameters is required to increase the method's efficacy. Wearable devices can track sleep duration, periods of wakefulness during the night, and quality metrics like time in deep sleep [19]. They use motion, HR and breathing data but no brain wave measurement. A recent study demonstrated that using surface electrodes on the scalp to apply Delta rhythm electric stimulation increased power in the Delta frequency band, enhanced slow oscillations, increased slow spindle activity, improved slow wave sleep, and improved memory consolidation. A study also shows that a magnetic device operating at Delta frequencies improved sleep through brainwave entertainment [20].

Different physiological parameters are being measured to monitor deep sleep. Different low-cost smartwatches are available to monitor body parameters, including human body temperature, heart rate, body movement, and SpO2 [21]. Different sensors were used to monitor the four parameters, as mentioned by Chandel et al. [21], which uses different technologies for the health sector's compatibility and accuracy.

Hence, to monitor different vital signs of sleep and to induce the effects of the electromagnetic waves, we have developed an SI in which we monitor HR, SpO2, BT, and body movement (BM) to find the stage of sleep (provide the methods of the sensors used). The neurofeedback (EEG) method was also used to treat insomnia, but no other electronic non-invasive method uses feedback techniques to treat insomnia patients [22]. So, we also used the feedback method to help induce the sleep function, but for the electromagnetic method, The BP and the EEG waves are not included in the system as the BP uses the more complex sphygmomanometer, which too is non-continues, and EEG requires many electrodes to be placed on the head, and hence both are cumbersome and non-convenient form the patient comfort point of view. The system uses a delta frequency band to generate the electromagnetic field to induce sleep. We have chosen the sensor methodology for monitoring the body parameters based on the review provided by Chandel et al. [21].

2. METHODOLOGY

In this section we have discussed the block diagram of the developed SI, flowchart of the developed software for the SI and the procedure to use the developed SI by the user.

2.1 BLOCK DIAGRAM OF THE SI

The block diagram of the circuit used for the SI development is shown in Fig.1. The system used three sensors to monitor four vital parameters of the body. For the measurement of the BT, the thermistor sensor was used to monitor the patient's BT. The acceleration sensor was used to monitor BM, and based on the spring, it converted mechanical energy into electrical energy and was made of titanium. The HR and SpO2 levels in the blood were scanned using an optical sensor developed on IR technology. The SpO2 sensor was procured from Sunrom company [23] based on the principle of photoplethysmography. The signal conditioning circuit was there for all three sensors, which converts the sensor signal into the analogue signal, and the analogue voltages are then sent to the microcontroller's analogue-to-digital converter (ADC). The BC557 transistor provides an interface between the coil and the microcontroller. A buzzer was used to indicate audio indication. The status of the three sensors is shown on the 16*2 alphanumeric liquid crystal display.

According to the sensor data, the microcontroller converts the analogue voltages from the sensors to the respective parameter values. The thermistor used in the system was calibrated against the standard mercury thermometer. The HR and the SpO2 were calibrated using the Zacurate 500C Elite Fingertip Pulse Oximeter. The manufacturer calibrated the accelerometer sensor ACC301A. The system uses a WATTNINE 12V Rechargeable Lithium battery pack whose capacity is 1200mAh. A +5V regulated voltage was produced using the 7805 IC for the rest of the electronic circuitry. The system uses the 8-bit Peripheral Interface Controller (PIC) 16F877A microcontroller from the Microchip Corporation. The microcontroller selected is ideal for our SI system since it includes 33 I/O pins, a 10-bit 8-channel ADC, a 16-bit timer, and EEPROM. The electromagnetic coil was designed in the laboratory as per the criteria mentioned in the work of Shaikh et al. [24].

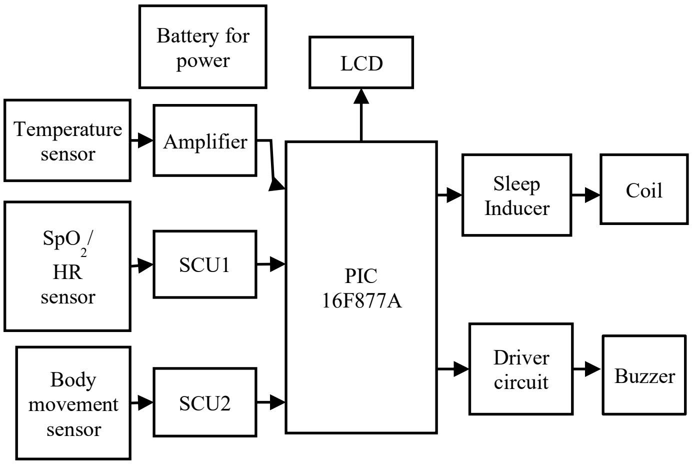

Fig.1. Block diagram of the SI

2.2 FLOWCHART OF THE SI SYSTEM

The flowchart of the SI system is shown in Fig.2. We have used the MikroC pro for the PIC compiler to write the code in C language for the SI. First, the microcontroller initialises all the input/output ports, ADC and timers. Then, the microcontroller initialises all the peripherals attached to the system, which includes the LCD and the other electronic parts of the SI system. Then, the microcontroller reads all three sensors' readings, converts them into a suitable display, and sends it to the LCD to display the patient's temperature, HR and BM. If any of the three parameters deviate from the specified condition, the SI coil program is triggered for at least 5 minutes. First, it checks the BT. If it is higher than 98.6 o F, then the patient is not sleeping else; he is asleep. Then, on the electromagnetic coil for at least 5 minutes, the device works for the user to sleep. The same loop check for HR. If an HR exceeds 80 bpm, it also ON the SI coil. It also reads the SpO2 sensor to read the third body parameter named SpO2. If the value of the SpO2 starts to decrease, then the user is going into sleep mode. If not, the SI ON the coil for 5 minutes. Then, it checks for the final parameter, which is BM. For that, it scans the acceleration sensor reading for any activity in the body. If the person moves more than an average in 15 minutes, it means the person is not sleeping and on the electromagnetic coil for 5 minutes, or it returns from the loop, and the cycle repeats.

The SI coil will be ON for at least 5 minutes for each parameter above the threshold level. If any of the two parameters are above the threshold level, the ON time for the coil would be 10 minutes. If any of the three parameters are above the threshold level, the ON time for the coil would be 15 minutes. If all four parameters are above the threshold hold level, the ON time for the coil would be 20 minutes; if all the parameters have achieved the threshold level, then OFF the electromagnetic coil till the next cycle repeats.

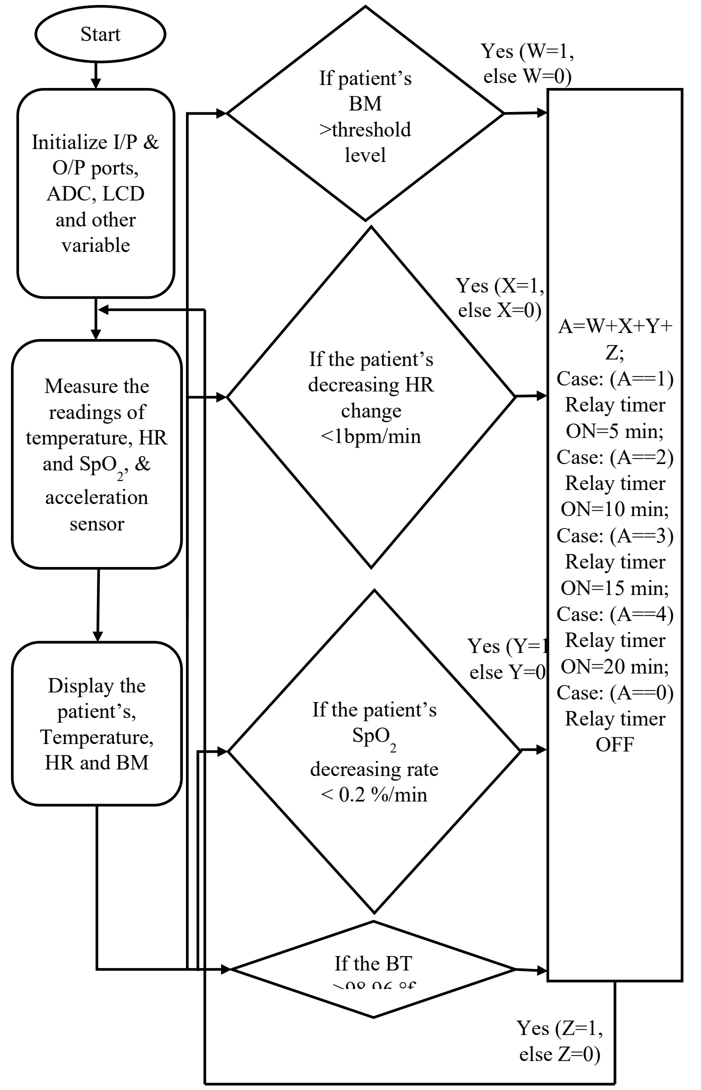

Fig.2. Flowchart of the SI system

2.3 PROCEDURE FOR THE SI

The procedure to use the developed SI is effortless and shown in Fig.3. First, all three sensors are installed on the patient's body at appropriate places. The HR/SpO2 sensor and temperature sensors are attached to the patient's finger, while the acceleration sensor is attached to the top of the blanket near the hands. Then we ON the device. After this, the microcontroller measures all four parameters and generates the required amount of electromagnetic field per the flowchart mentioned in Fig 2. The coil generates the needed strength of an electromagnetic field in the delta frequency range and helps induce sleep. The system is a closed loop as the device finds that the patient is still not going into sleep mode, which can increase the time duration of the electromagnetic field or change the frequency of the electromagnetic field. Still, after long use, if it was found that the patient was not able to sleep, say one hour from the device was ON, the system then ON the buzzer to alert the caregiver of the patient that the patient is not yet sleeping and can provide the patient other therapy like sleep medicine.

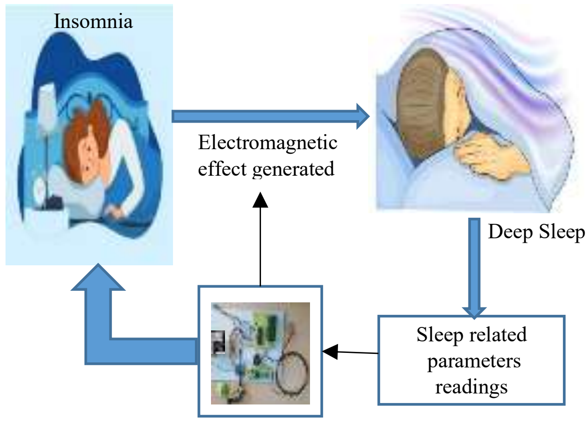

Fig.3. The procedure to use the developed SI

3. RESULTS

3.1 COIL FORMATION

The developed coil was based on the design published by Shaikh et al. [24]. In our work, we reduced the coil turn to 400 turns of 0.23 mm diameter Giapro enamelled copper wire. So, to compensate for the required field, we have increased the coil size. The size of the developed coil was 15 cm * 20 cm (nearly equal to the size of the average adult head. The frequency developed in the coil was set between 0.1 to 5 hertz using the BC557 transistor [16]. We created the coil in an oval shape to cover the whole head and create an electromagnetic field in the complete area of the patient's head.

Fig.4. The developed coil photos (a) Close view of the designed coil (b) Close view of the copper wire used in the coil

The system uses the 16-bit inbuilt timer of the PIC16f877A to generate the required frequency with a 50% duty cycle to generate the electromagnetic wave through the coil. To increase or decrease the overall dose for the patient, the system's duty cycle can be changed while maintaining the same frequency. A coil generates an electromagnetic field around the head when current passes through it. The photo of the developed coil is shown in the Fig.4. The coil was covered with transparent cello tape to provide the patient with electrical isolation from the coil. The coil's power consumption was between 25 µW to 200 µwatt. The electromagnetic radiation was confirmed using a galvanometer. The generated electromagnetic wave was too small to be detected and hence did not reach the electromagnetic hazard range for humans.

3.2 DEVELOPED PROTOTYPE

The photo of the developed SI prototype is shown in Fig.5. The system consists of all three sensors, a buzzer, LCD, microcontroller, signal conditioning circuits and the battery to power the electronic part. All the electronic parts were mounted on the class-2 type printed circuit board (PCB) we had developed. First, three different PCB designs were made: one for the microcontroller board, another for the power supply and the third for the coil driver circuit. Then, the sensor and signal conditioning circuits were purchased readymade from Sunrom Technologies [23] and other commercial websites. Next, the device was assembled, and the PIC16F877A microcontroller program was written in Mikroc Pro for the PIC compiler. Then, all the SI sensors were calibrated, and the readings were verified. After that, the electromagnetic coil generation circuit was also tested and verified.

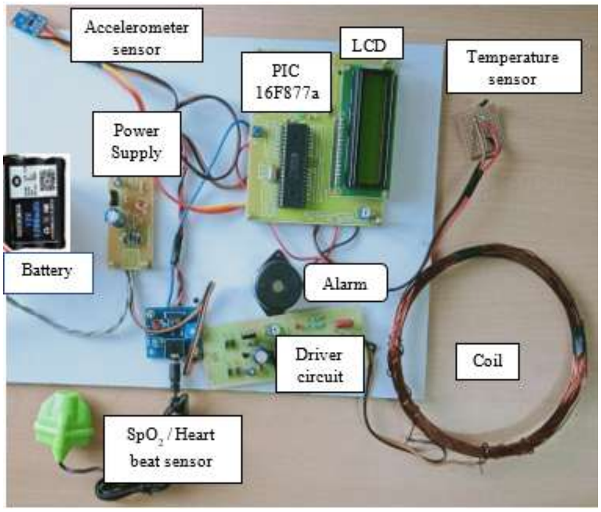

Fig.5. Photo of the developed non-invasive SI prototype

The generated electromagnetic waveform was tested on the Tektronix DSO in the laboratory. The device was tested for 0.1 to 5 Htz frequencies, respectively. The voltage amplitude of the wave was around 500 mV. The device's battery backup was also tested, and it found that the battery works for 24 hours in one recharge. Therefore, the developed system can be used for two nights on a single recharge. The rechargeable battery helps recharge the battery for reuse. Then, the device was tested on the volunteer subject to detect the vital parameters reading. The photo of the volunteer using the SI device is shown in Fig.6. The essential parameters recorded on the LCD screen and stored in the EEPROM of the PIC16f877A of the SI were noted/read and shown in Table.1. From Table.1, the data shows that as the subject starts to come in the rest position, the SpO2 level starts to decrease, the HR also starts to fall, and the temperature drops, but not at the expected rate. The volunteer continuously moves, so the acceleration sensor shows the YES condition for the BM column in Table.1 for the last fifteen minutes. So, the coil was in an ON state for one hour during real-time data testing of the volunteer.

Table.1. The volunteer subjects' four crucial parameters (SpO2, HR, Temperature, and BM) during sleep for two consecutive days were stored in the EEPROM of the PIC16F877A microcontroller.

Subject Day No.	SpO_2 (%)	HR (bpm)	Temperature (°F)	BM (In the last 15 min)	Coil (ON /OFF)	Time (AM/PM)
1	96	120	98.96	Yes	ON	10:00 PM
	95	115	98.96	Yes	ON	10:15 PM
	94	110	98.78	Yes	ON	10:30 PM
	93	105	98.78	Yes	ON	10:45 PM
	92	100	98.6	Yes	ON	11:00 PM
2	97	116	98.40	Yes	ON	10:00 PM
	96	114	98.30	Yes	ON	10:15 PM
	93	113	98.20	Yes	ON	10:30 PM
	92	110	98.10	Yes	ON	10:45 PM
	92	107	98.00	Yes	ON	11:00 PM

4. DISCUSSIONS

In this work, we developed the oval-shaped coil to cover the maximum part of the patient's head to increase the desired electromagnetic effect on the patient's mind.

Fig.6. Volunteer subject showing the use of developed ASI in the sleeping posture on the bed. The subject shows the coil wearing on his head, an HR/ SpO2 sensor on his right-hand index finger, the temperature sensor and the accelerometer sensor on his hand.

We have also tested the device on a healthy person. The Table.1 shows the permanent variations of the subject for two consecutive days. The device was tested for the subject till it slept. The results show decreasing trends in SpO2, HR, and temperature parameters. The BM sensor shows that the subject is moving during the test. The results of the test parameters are in accordance with the other authors who had worked on the electromagnetic method [25]. Table 1 also shows that the feedback-based method is used in conjunction with the neuro-feedback-based method [22]. As the developed system uses the feedback mechanism for the sleeping stage, the device can reduce the electromagnetic field time, thereby reducing the consumed power (the wattage of the coil peak load shows it in the range of microwatts.) and thus generating the shallow level of electromagnetic radiation. The patient can sleep on their own once they sleep, providing direct benefit compared to sleeping pills as the patient will take the dose daily even if it improves from the sleeping disorder. In addition, the developed SI has some good features, which are as follows:

1. Real-time monitoring and alarm: The device can monitor the user's sleep patterns, adjust the SI accordingly, and provide an audio alarm.
2. Biometric sensors: The device can use the four sensors to track the user's HR, SpO2, BT, and BM during normal sleep and then feed the exact data for the feedback algorithm to one of the coils and optimise their sleep quality.
3. Low cost and hence affordable for developing countries as the hardware components used in the system cost only around 50 $ which is more comparable to the other existing solutions [22].

5. CONCLUSION

Thus, developing an SI system using electromagnetic fields holds promise for treating insomnia and other sleep disorders non-invasively. By carefully controlling the electromagnetic field's frequency, intensity, and waveform, it is possible to gently entrain brain waves and create a relaxed mental state conducive to sleep. While electromagnetic sleep induction is still in the early research stages due to the limited number of field trials, it has several attractive qualities as a potential treatment for insomnia, chronic pain, anxiety, or depression, all of which can disrupt sleep. The developed method uses a closed-loop, non-invasive method. It is drug-free, eliminating sleeping pills' side effects and long-term issues. It can also be finely tuned to a person's unique brain wave patterns [24] and adjusted as their conditions change. It does not emit ionising radiation like other medical technologies. Different sensors in the system allow for enhanced monitoring capabilities, such as tracking HR, BT, SpO2, and body mobility, which can provide valuable information for diagnosing and treating sleep disorders for the specific patient. The developed closed-loop system with the feedback monitoring of the important patient parameters helps in better sleep-inducing effects at different stages of the sleep cycle. The overall cost of the system is around 50$, which makes it a cost-effective solution, especially for developing countries. That will lead to wider availability and accessibility of this technology for patients suffering from sleep disorders. More clinical trials are needed to understand better the effects of SI methodology on sleep architecture and sleep quality for insomnia patients and other sleep disorders. With continued advancement in brain wave sensing and electromagnetic field generation, systems can become more portable, automated, and optimised for individual users. The future of electromagnetic sleep induction is bright, even if people using the technology will be fast asleep.

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