

SILENT NIGHTS®

Study Report #1: Shealy N. *TREATMENT OF INSOMNIA WITH NONTRANSDERMAL ACUPUNCTURE POINT ACTIVATION (A Pilot study)*. January 5, 2011.

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- In this open label pilot study, 25 subjects used Silent Nights® patches at night for 30 days.
- These subjects had a range of self-assessed sleep difficulties and they measured changes in sleep over a 30 day period with sleep scales and questionnaires. Subjects wore the patches 5 days per week.
- Individuals were instructed to place one of the patches on 1 of 5 specific acupuncture points at bedtime.
- The acupoints tested were:
 - A. Right Liver 3
 - B. Right Triple Heater 23
 - C. Right Triple Heater 17
 - D. Governing Vessel 24.5 or
 - E. Right Stomach 36
- If individuals did not sleep adequately, on the next night they would move the Silent Nights® patch to another one of these acupuncture points until they found a placement that achieved the best possible sleep. Once they found an acupuncture point that worked for them then they would continue using the patch on that particular point on successive nights.
- Validated sleep scales and questionnaires were used and recorded as baseline prior to patch wearing and then at the end of the study period.

Efficacy of patches in this study:

- In this study, 72% percent of the individuals had normal daytime sleepiness on the Epworth Sleepiness Scale (ESS Test).
- At the end of the study, 80% noted improved quality of sleep on the Leeds Sleep Evaluation Questionnaire (LESQ Test).
- Also, 88% of participants had improved length of sleep on the Pittsburgh Sleep Quality Index (PSQ Test).
- Considering the safety and results obtained in this study of Silent Nights® patches, it is reasonable to suggest that they may well be one of the preferred potential approaches to insomnia since 72 to 88% of the subjects experienced significant improvement in sleep.

Assessment: *This study used three standard scales and questionnaires used in sleep studies. The Silent Nights® patches showed sleep improvements in all three scales.*

Study Report #2: Blake-Greenberg S, Nazeran H. *Silent Nights® Patch Improves Qualitative and Quantitative Measures of Sleep and Enhances Quantitative Markers of Organ Function*. Presented at 22nd International Conference on Electronics Communications & Computing. Feb-Mar 2012.

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- Acupoint tested:
 1. Triple Burner 23
 2. Kidney 3
- Actigraphic measurements depicting movement during sleep, Electro Interstitial Scans (EIS) of different organs reflecting physiological functional status, Leeds Sleep Evaluation Questionnaire, as well as, sleep diary data reflecting subjective self-evaluation of sleep were collected from 20 volunteers [5 males and 15 females, 20-79 years of age) over a period of 3 weeks at baseline and at the end of each week afterwards.
- Organs tested were: frontal and temporal lobes, hippocampus, hypothalamus, pituitary, thyroid, kidneys, adrenals, liver, small and large intestines.
- Baseline data were acquired from all subjects at the beginning of the study period before wearing the Silent Nights® Patch. After one week of accommodation to wearing the Actiwatches, Silent Nights® Patch was worn nightly on the right temple 1 hour before sleep for 2 weeks.

Efficacy of patches in this study:

- Actigraphic data analysis demonstrated that compared to baseline on average there was 29% reduction in activity level during sleep, 22% reduction in total awake time, 28% increase in ratio of time in bed over awake time, and 28% reduction in restlessness after wearing the Silent Nights® Patch for 2 weeks.
- The Leeds Sleep Evaluation Questionnaire and sleep diary data on average showed considerable qualitative improvements at the end of the study period in a number of sleep attributes such as: easier and quicker than usual getting to sleep, calmer with less wakeful periods than usual during sleep (better sleep quality), easier and requiring less time to waking up than usual in the mornings, feeling more alert than usual, and less disrupted balance and coordination upon awakening.
- Statistical analysis of the EIS data revealed that there was significant improvement in cellular physiologic functional status of the brain (frontal lobe, temporal lobe, hippocampus, hypothalamus), cardiac ventricles, adrenals, and thyroid gland at the end of the study period with respect to the corresponding baseline data.

Assessment: *In summary, the overall data in this study demonstrated that the Silent Nights® Patch worn on the right temple (Triple Warmer 22) and right ankle (Liver 3) nightly one (1) hour before sleep for 2 weeks produced considerable improvements in the objective and subjective measures of sleep and caused an impressive improvement in the physiologic functional status of different parts of the brain and adrenal glands with significant enhancement on the functioning of the cardiac ventricles and thyroid glands. These two studies are supportive of the claim that the Silent Nights® patches improve sleep.*

Study Report #3: Shealy N. *TREATMENT OF INSOMNIA WITH ENERGETIC ACUPUNCTURE POINT ACTIVATION – A Double-Blind Placebo Randomized Trial.* April 2012.

Safety issues:

- No adverse events were reported.

Patch instructions and study procedures:

- 50 subjects with chronic insomnia for a minimum of over three months, between ages of 18 and 80.
- Eligible subjects were randomized to receive treatment with Silent Nights® or a placebo for the first two-weeks. All subjects received Silent Nights® for an additional 4 weeks.
- Acupoints tested (subjects rotated through the following points five days per week):
 1. Right Liver 3
 2. Right Triple Heater 23
 3. Right Triple Heater 17
 4. Governing Vessel 24.5
 5. Right Stomach 36
- The aim of the study is to show that when compared to placebo, subjects with sleep issues improved their quality and length of nightly sleep and decreased their daytime sleepiness.
- Three validated sleep scales were used to measure daytime sleepiness and length of sleep at baseline and then at the end of the two week placebo period and again at the end of the study.

Efficacy of the patches:

- The results in the open label and the randomized double-blind placebo controlled study are remarkably similar, with only 8% less increase in length of sleep in the placebo-controlled study.
- Those receiving active patches entered with 3.9 hours average length of sleep. At the end of the first 2 weeks, they were sleeping an average of 6.1 hours and after another 4 weeks they were sleeping an average of 6.2 hours.
- Those who initially received placebo patches entered sleeping an average of 3.6 hours. At the end of the first two weeks, they averaged 4.6 hours and after 4 weeks using the active patches, they averaged 6 hours of sleep.

Assessment: *When we examine the placebo group's increase in numbers of hours asleep at final compared to baseline (when they were wearing active patches for the last 4 weeks) we find an increase in 64.5 hours divided by N=23 = 2.8 hours longer sleep. When we examine the active group's increase in numbers of hours asleep at final compared to baseline (when they were wearing active patches for the last 4 weeks), we find an increase in 53 hours divided by N=23 = 2.3 hours longer sleep. Taking the whole together we find that use of active LifeWave patches in all 46 people who used active patches for the last 4 weeks) means that $(2.30 + 2.80) = 5.10$ divided by 2 = 2.55 hours of longer sleep for a N=46 population of subjects who used active patches for the last 4 weeks. This is a significant number, which means sleep duration increased over 2 and one-half hours longer with use of the patches.*