

THE EFFECTS OF LIFEWAVE SILENT NIGHTS® PATCHES ON SLEEP

January 2011

LOCATION: Shealy Wellness Center
5607 S. 222nd Road
Fair Grove, MO 65648

PRINCIPAL INVESTIGATOR: C. Norman Shealy, M.D., Ph.D.

Research Associate: Robert Mueller

Investigational Review Board: Quantum IRB

INTRODUCTION:

Just over 200 years ago, most Americans slept an average of 10 hours, adjusting their wake-sleep hours to daylight. Today a huge number of individuals sleep not more than 5.5 hours per night and they do not consider that a sleep problem. In a number of surveys, 40% of individuals report that they have significant problems with insomnia.¹ There are excellent studies showing that within a month or less, insomnia leads to excessive sleepiness at work, mood disturbances, increase in errors, increase in accidents and family and social problems. Chronic insomniacs have a much higher incidence of cardiovascular disease, diabetes, obesity, gastrointestinal disease, absenteeism, disciplinary problems, separation, divorce and death. The problems and the incidence of illness, in general, are markedly increased in individuals who work anything other than a normal 8 a.m. to 5 p.m. pattern. Those who work the evening shift, roughly 4 p.m. to midnight, have increased illnesses and those who work the night shift, roughly midnight to 8 a.m. or 11 p.m. to 7 a.m., have an even greater number of illnesses. And finally, those who have swing shifts working one month one shift and the next month a different shift, have the greatest number of illnesses of all.²⁻⁸

There are a number of medications that have been used to treat insomnia. None of these is totally satisfactory and all of them carry significant potential and often “undesirable” side effects. Benzodiazepines particularly are harmful as they interfere with stage 4 sleep. Antidepressant drugs most often also have many undesirable effects when used only to treat insomnia. Finally, the drugs specifically for sleep, often lead to the feeling of a hangover or sleep walking, driving and other activities while asleep.

MATERIALS AND METHODS:

At the recommendation of a psychologist, I have studied the effect of the LifeWave Silent Nights® Patches designed specifically to enhance sleep. LifeWave® Patches are designed to stimulate acupuncture points by a mechanism that involves both acupressure and energetic principles to stimulate specific acupuncture points.

Under an Institutional Review Board approved protocol, 25 individuals suffering from insomnia were entered into the study. For this research, the Silent Nights® patch (LifeWave, La Jolla, California, USA) was used. The LifeWave Silent Nights® patch is a nontransdermal patch that does not put any chemicals or drugs into the body. The Silent Nights® patch is described as a new method improving sleep by stimulating acupuncture points on the body with a combination of pressure and infrared energy. LifeWave Silent Nights® patches reflect energy back into the body and they do not generate energy. The nontoxic materials in the patches act like frequency specific reflectors (narrow-band) as compared to the ceramic fibers found in infrared products, which are broadband reflectors. Placing a patch on the skin will allow the patch to trap and passively absorb wide-band infrared energy and reemit narrow-band infrared energy back into the body. By way of example, infrared wraps contain inorganic ceramic fibers. These inorganic fibers absorb infrared energy from the body and then reemit the energy across a

wide energy band. LifeWave Silent Nights® patches contains materials, which mirror back the energy that the body is already emitting. The difference between the LifeWave Silent Nights® patches and infrared products is that the LifeWave patches only mirror back a very narrow band of frequencies. LifeWave patches are designed to deliver infrared wavelengths to enhance the electrical conductivity of the skin and are a new method of stimulating acupuncture points.

All subjects were in reasonably good health with no major illnesses and were not on beta blockers, antidepressants or tranquilizers. None of them had an implanted electronic device. After initial evaluation which consisted of a history and physical exam, participants completed the following questionnaires:

- Symptom Index
- Total Life Stress Test
- Zung Test for Depression
- Pittsburgh Sleep Quality Index
- Leeds Sleep Evaluation Questionnaire
- Epworth-Sleepiness Scale
- Sleep Analog Scale

Individuals were instructed to place one of the patches on 1 of 5 specific acupuncture points at bedtime. The points are:

- Right Liver 3
- Right Triple Heater 23
- Right Triple Heater 17
- Governing Vessel 24.5 or
- Right Stomach 36

If individuals did not sleep adequately, they could go through each of these points until they achieved the best possible sleep and then they would continue for the duration of the study, using that particular point.

STUDY DESIGN

The Shealy Wellness Center enrolled 25 candidates ranging in age from 18 to 80 years. The primary complaint was of poor or inadequate sleep. Testing consisted of:

- History and Physical Exam
- Symptom Index
- Total Life Stress Test
- Zung test for depression
- Pittsburgh Sleep Quality Index
- Leeds Sleep Evaluation Questionnaire
- Epworth –Sleepiness-Scale

After the primary data collection portion of the study, each subject will be phoned after one week to be certain there are no problems, given instructions to phone us if any develop, and were scheduled to return for repeat tests at the end of 30 days.

I. SUBJECT POPULATION

This study enrolled a minimum of 25 subjects. Once the one-month follow-up has been completed on this group of subjects, assuming results are sufficiently effective, an additional 25 subjects may be recruited, if the sponsor wishes us to pursue that.

II. INCLUSION CRITERIA

- a. Participants will be willing to participate by signing a voluntary informed consent.
- b. They will have the ability and willingness to follow the instructions of the Principal Investigator (PI) and the research staff.
- c. They will be in reasonably good health and not have any major illness, not be on any beta blockers, antidepressants or tranquilizers.

III. EXCLUSION CRITERIA

- a. Individuals with an implanted electronic device.
- b. Individuals with major medical illnesses.
- c. Individuals on beta blockers, tranquilizers or antidepressants.
- d. Not more than 10 of the 50 potential subjects will be smokers

e. Pregnancy

STUDY RESULTS:

One individual dropped out of the study and could not be contacted for further evaluation.

There were no negative reports. Seventy-two percent of the individuals had normal daytime sleeping (ESS Test), 80% noted improved quality of sleep (LESQ Test) and 88% had improved length of sleep (PSQ Test). In general, the PSQ Test and the Sleep Analog yielded equal results.

- 13 of 25 initially had a Zung score 50 or above (clinical depression)
- After a month, 8 still 50 or above
- Not a useful test for these people

- 15 initially had Total Life Symptoms of 50 or above (high stress)
- After one month, no change in total with 50 or above
- Not a useful test for these people

- 8 initially had 20 or more total symptoms
- After one month, only 5 had 20 or more symptoms
- Not a useful test for these people

The ESS Test (daytime sleepiness) 10 or less is "normal"

- 9 had a score of 11 or above
- After one month, 7 had a score 11 or above
- Thus 72% had normal daytime sleepiness

The LSEQ Test (quality of sleep)

- 16 had a score 28 or less
- After one month, 5 had a score or 28 or less
- 80% had good quality of sleep

PSQTest (length of sleep)

- 22 had an initial score of less than 6.5
- After one month, 3 had a score of less than 6.5.
- After one month, 22 of 25 had improved their sleep on this test
- 88% had improved length of sleep

On the Sleep Analog scale

- 18 were sleeping longer than initially
- 72% had improved length of sleep

SUMMARY:

- LifeWave Silent Nights improved quality of sleep, length of sleep and decreased daytime sleepiness in 72% or more of these 25 individuals.

DISCUSSION:

Although this study did not include a control or placebo group, the percentage of success is quite significantly higher than the average placebo study. There are several other studies of LifeWave® technology including one which showed marked improvement in heart rate variability signals with LifeWave Energy® Patches during rest and exercise in 20 young and healthy volunteers.⁹

Another study done by Tamara Austin and Homer Nazeran under the auspices of the Engineering Department at the University of Texas at El Paso, demonstrated a highly significant reduction in quantitative and qualitative measures of pain with an average statistical power of at least 94% and significant at the greater than 0.001 level.

Of the 25 individuals who entered the study, 9 had a Zung score of 50 or above which suggests clinical depression. Seven of those had reductions in their depressive score. Thirteen had decreases in the Total Life Stress Test.¹⁰ On the Symptom Index, 9 of the individuals had decreases in the total number of symptoms. For this particular study, it would appear that depression, total life stress and symptomatology were not affected nearly as much as the sleep studies themselves.

Considering the safety and results obtained in this study of LifeWave Silent Nights® Patches, it is reasonable to suggest that they may well be one of the preferred potential approaches to insomnia.

DISCLOSURE STATEMENT:

No competing financial interests exist.