



Music to the Ears for a Good Night's Sleep? Wake Forest Baptist Studies New Therapy for Insomnia

WINSTON-SALEM, N.C. – Nov. 20, 2012 – If you are among the 50 percent of Americans who suffer from insomnia, then you have probably tried everything – from warm milk to melatonin pills or prescription medications to induce sleep – with varying degrees of success and side effects. But what if sleep could be achieved not by a substance, but through ‘balancing’ brain activity?

Researchers at [Wake Forest Baptist Medical Center](#) have conducted a pilot clinical study to determine whether a non-invasive approach, that uses musical tones to balance brain activity, can ‘reset’ the brain and effectively reduce insomnia.

The study, was published online in October, advance of print, in the journal *Brain and Behavior*. It was funded by a \$26,696 grant from Brain State Technologies, LLC, Scottsdale, Ariz., the company that owns the technology used in the study.

[Charles H. Tegeler, M.D.](#), professor of neurology at Wake Forest Baptist and principal investigator of the study explained how the technology works. “The human brain is made up of the left and right hemispheres that work together as parallel processors. When a person undergoes trauma or a major stressor, their autonomic survival responses kick in and the brain can become unbalanced. If those imbalances persist, symptoms such as insomnia can result. Our study looked at a new technology that is intended to facilitate greater balance and harmony in brain frequencies, which may result in improved symptoms.”

The new technology is called HIRREM, high-resolution, relational, resonance-based, electroencephalic mirroring or, as it's commercially known, [Brainwave Optimization™](#). The non-invasive procedure uses a system that is designed to reflect the brain's frequencies back to itself using musical tones. Resonance between the musical tones and the electrical energy in a person's brain can bring balance to the two hemispheres of the brain.

Study results were based on a change in the Insomnia Severity Index (ISI) which measures the severity of sleep disruption using a zero-to-28 point scale; the median ISI for study participants was between 18.7 and 18.9, which is considered moderate-to-severe insomnia. Researchers found that the HIRREM group had a 10.3 point drop in ISI, improved insomnia symptoms and, clinically moved into a category of 'no insomnia' or 'sub-threshold insomnia'. The control subjects, who continued their existing insomnia treatment without HIRREM, showed no change in ISI. However, when the crossover control group received HIRREM therapy, the results were indistinguishable from those of the original HIRREM group.

This unblinded, wait-list control, crossover study enrolled 20 participants (14 women and 6 men). Ten people were randomized to receive HIRREM sessions, plus usual care; the remaining 10 were assigned to the wait-list control group. An initial assessment determined the symmetry, or balance, in amplitude and frequencies between the brain hemispheres and data collection included a subject's ISI and other measures including blood pressure and neurocognitive function tests.

Study participants randomized to HIRREM underwent eight to 12 sessions that each lasted between 60-90 minutes. The sessions involved reclining in a zero gravity chair and placing sensors over numerous locations on both sides of the scalp. A musical tone, determined by a mathematic algorithm and based on the dominant frequency in a floating middle range of the participant's EEG frequencies, was played back to the participant through ear buds. Resonance between musical tones and oscillating brain circuits is designed to allow the brain to auto-calibrate, moving towards better balance, with associated improvement in symptoms.

The limitations of the study include the small number of study participants and the absence of a sham-placebo control group which prevented blinding. This means it is possible that the changes observed with HIRREM, could be due to a placebo effect. In addition, because HIRREM therapy involves social interaction and relaxation, there may be other non-specific mechanisms for improvement, in addition to the tonal mirroring. Although the researchers believe that the degree of improvement and length of time it persisted (for four weeks after the last session) suggests real change through HIRREM, Tegeler is planning a larger clinical trial using a sham placebo, to confirm the HIRREM effect and further explore the technology.

Co-authors in the study are [Sandhya R. Kumar, M.D.](#), Dave Conklin, MS III, Dana P. Turner, MSPH, Catherine L. Tegeler, B.S., and [Tim T. Houle, M.D.](#), of Wake Forest Baptist Medical Center, Brian C. Fidali, MS I, now of Weill Cornell Medical College of Cornell University, as well as Lee Gerdes and Sung W. Lee, M.D., of Brain State Technologies, LLC.

Disclosure: The Wake Forest faculty has no conflicts of interest, no direct financial relationships or positions with Brain State Technologies, LLC, which owns the HIRREM technology. Sung Lee, M.D., is research coordinator for Brain State Technologies, LLC and Lee. E. Gerdes is the inventor of the HIRREM technology and CEO of Brain State Technologies, LLC.

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Wake Forest Baptist Medical Center is a fully integrated academic medical center located in Winston-Salem, North Carolina. The institution comprises the medical education and research components of Wake Forest School of Medicine, the integrated clinical structure and consumer brand Wake Forest Baptist Health, which includes North Carolina Baptist Hospital and Brenner Children's Hospital, the commercialization of research discoveries through the Piedmont Triad Research Park, as well a network of affiliated community based hospitals, physician practices, outpatient services and other medical facilities. Wake Forest School of Medicine is ranked among the nation's best medicine schools and is a leading national research center in fields such as regenerative medicine, cancer, neuroscience, aging, addiction and public health sciences. Wake Forest Baptist's clinical programs are consistently ranked as among the best in the country by U.S.News & World Report for the past 20 years.