

The Effects of Infratonic Therapy on Levels of Stress in Adults

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The work reported in this thesis is original and carried out by me solely, except for the acknowledged direction and assistance gratefully received from colleagues and mentors.

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ABSTRACT

The Effects of Infrasound 8 Treatments on Levels of Stress in Adults

The purpose of the present study was to examine the effects of treatments using the Infrasound 8 Therapeutic Massager on levels of stress in adults. The research utilized a quasi-experimental double-blind pre-test/post-test control group design with repeated measure of the dependent variables. The 70 subjects, aged 25 to 75, were arbitrarily assigned to receive treatment from either the active Infrasound 8 Therapeutic Massager (n=38) or the inactive (control) Infrasound 8 Therapeutic Massager (n=32). Both principal investigator and participants were blinded as to which were the treatment and sham device. Intervention consisted of three twenty-minute treatments, self-administered once a week over three weeks. The treatment protocol consisted of each participant placing the massage head (transducer) of the device on the chest/heart area and turning on the power for 20 minutes. At the end of the study, participants in the control group were offered treatments using the Infrasound 8. The dependent variables included the results of the pre-test, posttest, and 4-week follow-up posttest using the State-Trait Anxiety Inventory for Adults (STAI, Y-1 and Y-2) and the Outcome Rating Scale (ORS). Results of a 2x3 mixed analysis of variance using the SPSS for the scores on the STAI indicated no significant changes in state or trait anxiety within or between treatment group and control group from pre-test to post-test or from post-test to follow-up post-test. Results on the pre-, post, and follow-up post scores on ORS showed no significant clinical change for either group. Future research considerations are discussed.

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CHAPTER 1: Review of Literature

In every culture and in every medical tradition before ours, healing was accomplished by moving energy.

—Albert Szent-Gyorgyi (1960)

Introduction

We live in a sea of sound, an ocean of vibration that keeps the universe in motion. All life is vibration. Every atom is constantly moving, connecting us to everything in the universe, including our vital life force. Energy Medicine and Vibrational Medicine have become synonymous terms. Richard Gerber, M.D. refers to Vibrational Medicine as “an evolving viewpoint of health and illness that takes into account all the many forms and frequencies of vibrating energy that contribute to the ‘multidimensional’ human energy system.”¹ In an unpublished paper written in 1990 by Edgar S. Wilson, a founding member of the International Society for the Study of Subtle Energies and Energy Medicine (ISSSEEM), one finds a succinct statement of the two-fold purpose of human energy research:

- To quantify the nature of man as a being of light, sound, and other synergistic patterns of universal unity.
- To discover the disturbances in these patterns that lead to disease and seek to provide non-invasive treatments that promote lasting healing.²

Sound is a vibrating force that affects each atom in our body. Ancient people have always known the effect sound has on body, mind, and spirit. They made use of vibratory forms of healing with rattles, drums, and chants. Infrasound is a vibrating force

of a low frequency, inaudible by the human ear.³ When infrasound is used as a healing mechanism, it is known as Infratonic Therapy.⁴ The purpose of this human energy research study is to investigate the effects of Infratonic Therapy on levels of stress in adults, using a device known as the Infrasound 8 Therapeutic Massager. It attempts to answer the question, “Will three 20-minute treatments, administered once weekly, lower levels of stress in adults as measured by the State-Trait Anxiety Inventory and the Outcome Rating Scale?”

Overview

Eight general topics are explored in this review of literature. The **Background and Statement of the Problem** discusses the effects of stress on modern day culture that provides a challenge and opportunity for complementary and alternative therapies. The next two topics explore both the **Conventional Treatments and Therapies** and the **Complementary and Alternative Therapies** for relieving stress in present day. The discussion of **Infratonic Therapy** presents a historical background of this therapy. It includes research on frequencies emitted from the hands of healers and the possible relationship of the low frequency sound to electromagnetic activity and scalar waves. The work of Richard H. Lee, president of the CHI Institute in San Clemente, CA, provides a foundation that opens the door to further research on the effects of infratonic therapy and healing. The history of **Infratonic Therapeutic Devices** begins at the National Acoustics Laboratory in Beijing, China and continues to San Clemente, CA, where Richard Lee continues to make improvements on the Infrasound 8 used in this study. The description of Infratonic Therapeutic devices includes its three signals corresponding to delta, alpha, and beta brain wave activities. **Research on Related**

Therapies includes the vast field of Qigong Therapy that is written primarily in Chinese and is not translated. The research on Infrasound is somewhat limited, with mixed results. The **Scientific Basis for Infratonic Therapy** addresses scientific foundations for this study, exploring various communications systems of the body and how possible mechanisms of Infratonic Therapy may promote healing. Finally, the **Statement of the Hypothesis** announces the purpose and possibilities of the present study.

Background and Statement of Problem

Webster defines stress as "...bodily or mental tension resulting from factors that tend to alter an existent equilibrium."⁵ Our existent equilibrium is constantly being altered since change is an integral part of life. Brian Seward defines stress as "the inability to cope with a perceived or real (or imagined) threat to one's mental, physical, emotional, and spiritual well-being which results in a series of physiological responses and adaptations."⁶ Jon Kabat-Zinn calls *stress* the popular term for "the full catastrophe,"⁷ or the enormity of our life experience, including all of its dilemmas, joys, sorrows, tragedies, and ironies.

We continually must face the necessity of adapting to pressures and pleasures we experience in living. According to a 2003 survey commissioned by the National Consumers League (NCL) in Washington, D.C., 80% of adult Americans reported significant stress in their lives.⁸ NCL president Linda Golodner reports, "Whether it's the economy, worries about personal health, or fears about international conflict, the bottom line is that the vast majority of consumers are stressed. And they're more stressed than they were a year or five years ago."⁹ Twenty years before the publication of this

survey, *Time Magazine* had a cover story labeling stress “The Epidemic of the 80’s,” and referred to it as “our leading health problem.”¹⁰

Stress occurs on many levels that interact with each other: the physiological level, psychological level, and social level.¹¹ It also originates from many sources, internal and external alike. The specific sources may change but the overall pattern of everyday stress remains constant.¹² Human beings are remarkably resilient to stress and manage to survive, persevere, cope, problem solve, and have moments of pleasure, peace, and fulfillment. However, sometimes our physiological/psychological balance can be pushed beyond its limits to respond and adapt, into dysregulation and disorder.¹³ This can result in both physical and emotional illness.

In his book, *Shamanism*, Michael Winkelman confesses that stress is a challenging construct to define and operationalize because it is based on the personal response rather than just on external circumstances. He states, “Stress involves both psychological and biological dimensions and also complex emotional, cognitive, and behavioral responses to threats, strong environmental demands, or personal loss.”¹⁴ He maintains that stress occurs as a consequence of rapid changes in major patterns of people’s lives that have important implications for their sense of self or that challenge central assumptions that people make about their world. Winkelman also reports that much stress is socially induced as the result of interpersonal interaction as well as cultural definitions of situations and expectations. Because emotions are central to stress, the emotional reactions effect changes in the autonomic nervous system linking meaning and physiological responses.¹⁵

Credit for coining and popularizing the term “stress” is given to Canadian physician Dr. Hans Selye as a result of his physiological studies in the 1950’s of what happened when animals were injured or placed under unusual or extreme conditions.¹⁶ Selye’s definition of stress is “the non-specific response of the organism to any pressure or demand,”¹⁷ Stress is identified as a major cause of disease.¹⁸ His studies provide evidence that every time we adapt to a stressor, we lower our tolerance to new stress, thus compromising our ability to adapt. The studies further maintain that maladaptation leads to the development of major stress symptoms, and eventually to physical exhaustion and illness.

Unhealthy adaptations to stress can manifest in many forms in the mental, emotional, social, and spiritual domains of health.¹⁹ Recent research indicates that psychological stress has a profound effect on health.²⁰ It is perceived that modern day people are more anxious and worried than in the past,²¹ and, as a result, stress-related conditions, including illnesses of anxiety and depression prevail in the modern world. Its symptoms range from exaggerated worry and tension to panic, insomnia, phobias, and irritability, fatigue, hot flashes and other imbalances. Charles Spielberger calls the twentieth century the “Age of Anxiety,” but maintains that concerns and fear are as old as humanity itself.²² Indeed, one can read Freud’s proposal that anxiety is the “fundamental phenomenon and the central problem of a neurosis.”²³

According to the National Institute of Mental Health, anxiety disorders affect approximately 19 million American adults.²⁴ A 2005 survey by R. C Kessler, et al. reports that 40 million adults aged 18 and older are affected by anxiety disorders in a given year.²⁵ They are the most common of all mental health problems and include

Generalized Anxiety Disorder (GAD), Panic Disorder, Phobias, Obsessive-Compulsive Disorder (OCD), Social Anxiety Disorder, and Post-Traumatic Stress Disorder (PTSD). The *Diagnostic Manual of Mental Disorders* (DSM-IV-TR) states that the essential feature of GAD is excessive anxiety and worry and three or more of the following symptoms: restlessness, being easily fatigued, difficulty concentrating, irritability, muscle tension, and disturbed sleep.²⁶ Each anxiety disorder has its own distinct features, but they all include an excessive, irrational fear and dread.²⁷ The duration, frequency, and intensity are far out of proportion to the actual likelihood or impact of the feared events.²⁸

Depression often accompanies anxiety disorders.²⁹ A Japanese study finds significant positive correlations between the total state and trait anxiety scores on the State Trait Anxiety Inventory (STAI) and the ZUNG Self-rating Depression Scale (SDS) in normal subjects and in patients with anxiety disorders.³⁰ Candace Pert, research professor of physiology and biophysics at Georgetown University Medical Center, declares that physiology and emotions are inseparable, and when our systems get blocked, shut down, and disarrayed, we experience mood disorders.³¹ C. Norman Shealy tells us that stress diseases have replaced infections as the leading cause of morbidity and mortality since the successful use of sanitation, vaccination, and antibiotics.³²

Conventional Treatments and Therapies

Psychopharmacology

Conventional treatment for managing and lowering stress generally include psychopharmacology and/or psychotherapy. In the field of psychopharmacology, medications for stress and anxiety related symptoms are readily available and prescribed.

C. Norman Shealy states that mood-altering drugs represent at least 25% of the total pharmaceutical costs in the U. S., or over \$75 billion each year.³³ Medications such as Prozac, Zoloft, Paxil, and Celexa are selective serotonin reuptake inhibitors (SSRI), or serotonergic drugs, that are used to treat anxiety and depression alike. The number of SSRI medications has soared, with more than 142 million dispensed in 2003, up from 98 million in 2000.³⁴ However, these drugs have produced serious side effects in many users such as increased anxiety and depression, suicide, violence, arson, substance abuse, insomnia, impulsive behavior, nausea, tremors, weight loss, and exhibitionism.³⁵ These side effects have resulted in lawsuits against drug companies, like Eli Lilly.³⁶ Reports in psychiatric journals link these drugs to an overstimulation of the nervous system, known as akathisia (need to move about).³⁷ According to the National Institute of Mental Health, these medications will only reduce or control symptoms, or prevent a relapse, but will not offer a cure.³⁸ Dr. Shealy maintains that antianxiety drugs mostly block the personality and convert anxiety to depression.³⁹ He also states that complications range from damage to the liver, kidneys and heart to reduction of blood manufacturing capacity. In spite of the dangers of using prescription drugs for anxiety and depression, the medical community continues to recommend pharmacological treatment for these conditions.⁴⁰ With a 25% complication rate and 42% effectiveness rate, it becomes clear that noninvasive, alternative therapies are needed for anxiety and depression.⁴¹

Psychotherapy

Conventional counseling and psychotherapy has produced some positive results with depression and anxiety.⁴² A meta-analysis of high quality studies published from 1990-1998 on the efficacy of manualized psychotherapies for depression, panic disorder,

and GAD indicates that patients with panic improve and remain improved; that treatments for GAD produce impressive short-term effects; that most patients in treatment for GAD and depression do not improve and remain improved at clinically meaningful follow-up intervals.⁴³ Further, the meta-analysis reports that screening procedures used in many studies raise questions about generalizability, particularly in light of a systematic relation across studies between exclusion rates and outcome.⁴⁴

Complementary and Alternative Therapies

Complementary and Alternative Medicine (CAM) offers a large array of therapies for stress. A nationwide survey in 1993 of 1539 adults reveals that one in three Americans uses therapies considered unconventional.⁴⁵ A 1997 follow-up survey by the same team finds an increase in the use of alternative therapies by 25% and an increase of total visits to alternative medical practitioners by 45%.⁴⁶ This survey also indicates that people most often seek non-mainstream treatments for chronic conditions, such as back problems, anxiety, depression, and headaches.⁴⁷ In the *Illustrated Encyclopedia of Healing Remedies*, Dr. C. Norman Shealy recommends a variety of specific treatments for stress, anxiety, and depression in the fields of Ayurveda, Chinese Herbalism, Herbalism, traditional Folk and Home Remedies, Aromatherapy, Homeopathy, Flower Essences, and Vitamins and Minerals.⁴⁸

Herbal Remedies

Psychiatrist Harold H. Bloomfield suggests a wide variety of herbal remedies for the treatment of anxiety and depression including kava-kava, valerian, hypericum, ginseng, and Chinese herbs in his book *Healing Anxiety with Herbs*. He cites 17 pages of

references documenting studies and clinical trials using the herbs to treat anxiety and depression.⁴⁹ One randomized pilot study using valerian extract as a treatment for GAD suggests that it may have a potential anxiolytic effect on the psychic symptoms of anxiety.⁵⁰

Studies found on hypericum extract (St. John's wort) indicate that it is therapeutically equivalent to imipramine in treating mild to moderate depression, yet tolerable to patients.⁵¹ A review of 24 randomized clinical trials involving hypericum reveals it to be superior to a placebo in the treatment of mild to moderately severe depressive disorders and may offer an advantage in terms of relative safety and tolerability over traditional pharmacological medicines.⁵² The authors of one study state clearly that their research is deliberately confined to patients affected by mild forms of depression and that there is no evidence to suggest that hypericum would be of any benefit to patients suffering from more serious forms of depression.⁵³

Kava-kava is an herbal remedy in the form of a psychoactive beverage that is said to induce relaxation, improve social interaction and promote sleep. Findings in a study conducted by researchers in Berlin report that it inhibits blood platelets and may offer an important alternative in psychotropic medicines.⁵⁴

Flower Essences

Flower essences, identified by Edward Bach to have curative powers, may be used adjunctively to facilitate the resolution of mild to moderate depression.⁵⁵ Jeffrey Cram reports a successful double-blind, controlled study on various combinations of flower essences, including "Rescue Remedy," a 5-flower essence for treating stress.⁵⁶

Aromatherapy

Aromas have measurable effects on people's feelings. Torii et al. report on the psychologically stimulating effect of jasmine;⁵⁷ Manley depicts the psychologically stimulating effect of lemon, lemongrass, peppermint, and basil and the relaxing effects of bergamot, chamomile, and sandalwood;⁵⁸ and Yamaguchi discovers the relaxing aromas of rose and lavender.⁵⁹ Key findings in five studies on aromatherapy indicate improvement in mood and perceived levels of anxiety, less depression, reduced stress, and can have an effect on brainwaves.⁶⁰ The effects of aromatherapy, however, do not appear to be sustained or cumulative.⁶¹

Distant Healing

In the area of distant healing therapy, studies on Reiki provide data that supports the hypothesis that Reiki improves clients' sleep patterns, mood, and clarity of thinking;⁶² reduces state anxiety; and brings a profound relaxation, calm, and sense of inner peace.⁶³ Studies on Therapeutic Touch, another distant healing technique, show it to be an effective stress-reduction therapy.⁶⁴ In a study of breast cancer patients, those participants receiving Therapeutic Touch indicate decrease in mood disturbance over time, significant reductions in tension, confusion, and anxiety, and increased vigor.⁶⁵ A systematic review of 23 randomized trials on the efficacy of distant healing for any condition (5 examining prayer, 11 assessing non-contact Therapeutic Touch, and 7 examining other forms of distant healing), 13 (57%) yield statistically significant treatment effects.⁶⁶ The methodological limitations of several studies make it difficult to draw definitive conclusions about the efficacy of distant healing. It is not known if any of these studies addressed stress, anxiety, or depression.

Massage

Another form of healing with a practitioner is massage, and there is some indication within the literature that it also reduces anxiety and depression.⁶⁷ A review of the literature from published works, abstracts from conference proceedings, theses, and dissertations on Healing Touch evaluates outcomes and concludes that no generalizable results can be found to date, but that a foundation exists for further research to test its benefits.⁶⁸

Relaxation Techniques

Relaxation techniques produce some studies showing positive results in reducing stress. Autogenic muscle relaxation and warming, yoga, a variety of meditation techniques, and biofeedback are just a few of the relaxation techniques. Some researchers report that muscle relaxation, yoga stretching, and imagery are capable of inducing a deep state of relaxation and should be more widely taught to patients who need help controlling stress.⁶⁹ Meditation practices, such as Transcendental Meditation, have shown significant impacts on stress reduction and positive behavioral changes for adolescents as well as adults.⁷⁰ In several studies, mindfulness meditation demonstrates decreased psychological distress, reduction in state and trait anxiety, increased empathy levels and increased spiritual experiences when used over time as a stress reduction intervention.⁷¹ Biofeedback is another form of self-regulation that has demonstrated benefits such as lower blood pressure, reduced tension and migraine headaches, and other relief from stress-related diseases.⁷²

Other Complimentary Therapies

Many other therapies prove useful and effective in stress management. There are controlled medical studies confirming that acupuncture is an excellent therapy in the treatment of depression and stress-related disorders.⁷³ Others support exercise, alone or with another intervention, as an effective intervention in the management of depression.⁷⁴ Full spectrum light is effective in treating seasonal affective disorder (SAD).⁷⁵ The Transcutaneous Electrical Nerve Stimulator (TENS) has been shown to be more effective than any antidepressant drug, having a 50% effectiveness rate when used alone and an 85% effectiveness when combined with education, photostimulation, and music.⁷⁶ Vitamins may also play an important part in stress management. Vitamin B-12 level and the probability of recovery from major depression may be positively associated.⁷⁷ It is reported that more B vitamins in general are needed during times of emotional upheaval, especially B-6, niacin, and/or vitamin C.⁷⁸

CAM therapies show promise as safe, non-invasive therapies for managing stress. Further studies on all CAM therapies are needed in the field in order to gain the respect of the medical community and to be more utilized by the general population. This study examines the effect of Infratonic Therapy, a safe, noninvasive, alternative therapy for reducing stress.

Infrasound/Infratonic Therapy

Historical Background

The historical roots of Infratonic therapy can be traced as far back as the sixth century B.C. with Pythagoras, the Greek philosopher who felt that the human mind was

capable of perceiving vibrations and tone proportions as musical notes and intervals that were reflections of a cosmic spiritual level, at times inaudible to the human ear.⁷⁹ He believed that the planets vibrated to the same frequencies and proportions as audible music (hence, the term “music of the spheres”), and that they produced a particular note according to the distance from the center of the earth. However, these sounds were considered to be inaudible to the human ear. This, perhaps, was the beginning of the concept of the relation of vibration to a universally organized mind, body, and spirit connection and the use of vibrations, sounds, and music in medicine. Pythagoras called his method of healing “musical medicine with certain melodies composed to cure the passions of the psyche, including despondency and mental anguish.”⁸⁰

Many ancient healing modalities in India, China, Africa, Tibet, Europe, South America, and Australia involved audible sound healing.⁸¹ They included the use of drums, bells, bowls, and the human voice (chanting, words, vowels) as a foundation of their spiritual practices. Infratonic therapy, however, involves extremely low frequencies of sound for healing. These frequencies, below 16 Hz, are called Infrasound because they are below the level of hearing by the human ear.

Present Day Infratonic Therapy

Infratonic Therapy is a healing technology that uses infrasound, a particular low sound frequency or set of frequencies, produced by a medical device (or the hands of a healer) to stimulate relaxation, repair of tissues, and circulation of Qi (life force or vital energy), blood, or endocrine tissues. James L. Oschman, labels these frequencies found by biomedical researchers to stimulate the repair of one or more tissues “frequency windows of specificity.”⁸² Oschman quotes an example of low frequency electrical

signals recorded by Dr. John Zimmerman from the hand of a practitioner of Therapeutic Touch. These frequencies varied from 0.3 to 30 Hz, with most of the activity in the range of 7-8 Hz.⁸³ Howard Wachtel's study of the effects of electromagnetic fields on cellular tissue compared endogenous currents in and around cells with those induced by exogenous extremely low frequency magnetic fields.⁸⁴ He found that weak signals, generated in living tissues by external magnetic fields, could be detected and responded to in the presence of much stronger endogenous electrical activity. C. Bassett's findings suggest that the use of pulsed electromagnetic fields at an extremely low frequency range promoted healing of an injured area on a patient.⁸⁵

In addition to low frequency electromagnetic fields, low frequency sound waves (infrasound) can be used in healing. Healers have been known to emit low frequency sound vibrations in addition to electromagnetic frequencies. Professor Lu Yan Fang, an acoustics scientist at the National Electroacoustics Laboratory in Beijing, China, tested the hands of a Qigong healer and discovered that he emitted a very strong sound wave signal in the infrasonic range.⁸⁶ A Qigong healer is a seasoned practitioner in the ancient Chinese "science" of movement, breathing, and meditation and who is trained to direct external Qi, or healing energy, to others. Prof. Lu tested more than 70 Qigong masters on the nature of Qi emitted from their hands and found that low frequency sound is an important energy source that fuels the human body. At the Third International Symposium of Qigong, other Chinese researchers presented studies demonstrating the infrasonic frequency vibration of qigong external qi.⁸⁷

Motivated by the pioneering research of Prof. Lu, Dr. Liu Guo-long, a medical technology specialist assigned to the research department of the Beijing College of

Traditional Chinese Medicine, studied the relationship of infrasonic waves to emitted Qi. The Dr. Liu's research confirmed that humans have a high degree of acoustic activity in the subsonic range below 20 Hz (infrasonic), similar to the alpha rhythm of EEG.⁸⁸ Dr. Liu found that people with chronic illnesses had a much lower level (or dB) of infrasonic activity in general, while Qigong masters had a much higher level of output when they were emitting Qi. The study also showed that the Qigong masters could, without touch, voice, eye contact or any other traditional communication means, induce a clear, strong, and highly measurable change in a subject's brain functioning, using EEG measurements.

A study by Niu Xin, et. al., at the Beijing College of Traditional Medicine showed that most Qigong healers emit sound in the range of 8 to 13.5 Hz. and that their energy was over 100 times higher, or amplified, than that of ordinary persons (45 to 76 dB).⁸⁹ The test was performed by an infrasonic testing system made in Denmark, conducted in a noise-proof room with a microphone hanging 2 cm. over the palm of a Qigong master.

It appears that Infrasonic Therapy also includes electromagnetic activity and/or other subtle energies.⁹⁰ Siskin and Walker of the University of Kentucky report their research that demonstrates that noninvasive electromagnetic field therapy may offer a viable alternative to surgery for the healing of soft-tissue injuries, just as the application of electromagnetic fields have been used by clinicians to promote the healing of hard tissue (bone).⁹¹ Oschman (2004) uses information gleaned from Siskin and Walker to demonstrate the healing effects of specific frequencies, most of which are less than 20 HZ.⁹² Qigong masters have been shown to produce magnetic fields from their palms in characteristic low frequency bands as tested in Beijing with a flux-gate magnetometer (designed to measure small fluxuations in magnetic fields).⁹³

While there are studies that refute the effectiveness of Kirlian photography, or gas discharge visualization (GDV), as a diagnostic technique,⁹⁴ there are others that indicate its usefulness in demonstrating fundamentals of electromagnetic fields and bioenergetic and psychosomatic medicine.⁹⁵ Lee used Kirlian images of the fingertips of test subjects to demonstrate that they have been altered with emitted Qi from Qigong practitioners and other non-contact therapeutic methods.⁹⁶ The image from the finger of a normal person shows a pattern of images resembling balls and streamers. The balls indicate electrons going out in a pooling effect, and the streamers are like lightning going into the finger. After receiving emitted Qi from a practitioner, the Kirlian image around the fingertip is smooth, possibly indicating some kind of non-ionizing effect.

Scalar waves may play an important part in Richard Lee's experiments with infratonic therapy. Oschman explains the concept of scalar waves:

“The introduction of relativity and quantum mechanics shortly after the beginning of the 20th century required that fields be expressed in terms of a more fundamental entity, called potentials. Whittaker recognized this, and Tesla generated potential waves and called them ‘non-Hertzian waves.’ When we say that a magnetic field induces a current flow in a conductor, such as a wire or a living tissue, it is actually the potential component of the field, and not the field itself that underlies the effect. The potentials are of two kinds, called electric scalar potentials and magnetic vector potentials.”⁹⁷

Aharonov and Bohm demonstrated through some experiments that the potentials must have a physical reality.⁹⁸ Known as the Aharonov-Bohm effect, the potentials have been showed to affect regions where no magnetic or electric field exists, and they have found their way into electronic applications such as a communication systems and a device for locating humans and other animals during rescue-search operations.⁹⁹ Scalar waves appear to propagate instantaneously everywhere in space, undiminished by distance, and appear to be intimately involved in healing.¹⁰⁰ Oschman posits that each bioelectric and

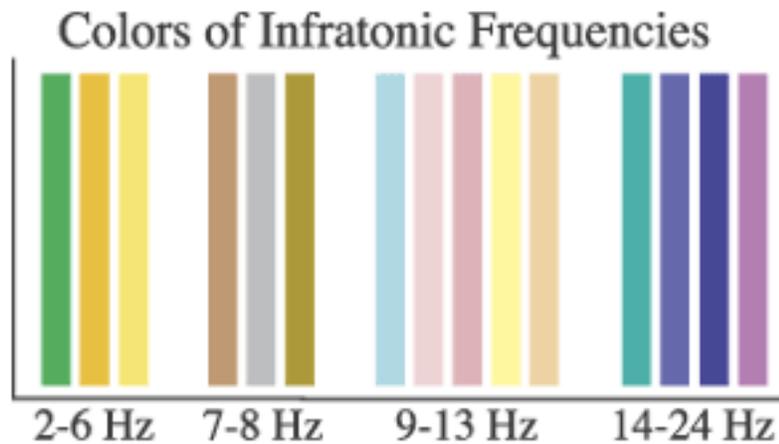
biomagnetic field produced by the human body (brain, heart, eye, muscles, organs, or hands of a therapist or Qigong practitioner) will also be associated with scalar waves and vector potentials.¹⁰¹

Richard H. Lee built a magnetic longitudinal wave sensor in 2004. In California, it registered the scalar waves from European and Asian power grids, and the waves of high magnetic activity of a recent solar magnetic storm. In a telephone interview, Lee depicted the scalar waves as having the attribute of a concentration of some singular dimensional magnetic substance as compared to the multidimensional characteristics of electromagnetic phenomena or light waves.

Glen Rein, a biophysicist at the Institute of HeartMath called this singular dimensional subtle energy non-Herzian, or scalar energy. He found that exposing cultured nerve cells (neurons) in a Petri dish to healing energy from a practitioner caused them to fire in their synapses.¹⁰² Lee admitted that they may be describing the same kind of subtle energy in different ways, and his observation was that they do not appear to be part of the electromagnetic spectrum as we understand it. Lee also discovered that the signals produced by the Infratonic 8 (see description under “Infratonic Therapeutic Devices”) were easily measurable by the magnetic sensor from several feet away, and they easily penetrated a steel box (as might be expected for scalar waves).¹⁰³

In 1995, Lee organized experiments with an 11-year-old boy who could see the aura surrounding people and also colors emanating from the transducer of the Infratonic device. He saw blue coming from frequencies below 8.5 Hz, white from 8.5-12.5 Hz, and gold from a signal 8-14 Hz.

In another experiment, set up an Infratonic device with a narrow frequency bandwidth and invited Cheryl Houghton, an aura video photography consultant with an ability to discern clear colors in the human aura, to act as the aura reader. Cheryl saw colors from the Infratonic distinctly from the aura colors of a test subject.¹⁰⁴ This occurred only when the Infratonic device was within 18 inches of the test subject. Otherwise, she saw only clear waviness from the device, indicating that Cheryl saw the color of the influenced aura, not the color of the Infratonic signal directly. Knowing when the frequency was changed but not to which frequency, she saw different color ranges with different frequencies. However, when the chaotic Alpha signal (random frequencies in the Alpha range) was applied, she observed a consistent effect different from the individual frequency signals: a large flow of energy as if the two fields were blending smoothly, a union between the Infratonic signal and the aura. Lee intends to repeat this aura reading study, feeding us with this possibility: that the Infratonic may be emitting scalar waves which he identifies as qi, that life force energy that can influence our auras, minds and bodies. This theory remains to be established scientifically.



This graph shows the colors projecting from the Infratonic at different frequencies observed by Cheryl Houghton.

(Reproduced with permission from Richard H. Lee, CHI Institute, San Clemente, CA)

Figure 1. Cheryl Houghton’s Infrasound Frequency Observations.

Throughout history others have used clairvoyants and aura readers to examine aspects of magnetic energy. In the nineteenth century, German industrialist Karl Von Richenbach conducted studies with magnets.¹⁰⁵ He used clairvoyantly sensitive observers who could see luminous fields of color around the north and south poles of strong magnets that were indistinguishable from the auric fields of human beings. He concluded that magnetic and auric fields were the same energy, which he called odyle or the odic force.

Infratonic Therapeutic Devices

History

Prof. Lu Yan Fang built a device at the National Electroacoustics Laboratory, Beijing, China that simulated the infrasonic output of the Qigong masters and tested it in hospitals throughout China. Known as the Infratonic Qigong Machine (QGM), it was shown to relieve pain and assist recovery in a wide variety of patients.¹⁰⁶ This device

was awarded three awards for outstanding contribution to science and medicine from Chinese national science organizations.¹⁰⁷ It was brought to the United States by Richard H. Lee and distributed by the CHI Institute, San Clemente, CA.

Description

The Infratonic 8 and Infrasound 8, classified by the FDA as Therapeutic Massagers, are improved and updated versions of the QGM, distributed by the CHI Institute, San Clemente, CA. The mechanisms are identical in both devices. The Infratonic 8 is black and has three signals labeled “Body, Mind, and Spirit.” The Infrasound 8 is white, and the three signals are labeled “1, 2, and 3.” Each delivers millions of randomly delivered ripples, or infrasound waves (called Chaotic Alpha), ranging from 8.5 to 13.8 Hz. According to Richard H. Lee, president of the CHI Institute, the ripples are similar in frequency to the communication signals that are carried by the nervous system and intracellular matrix. Lee explained in a personal interview that the alpha rhythm is in the middle of the range of signals that travels through the nervous system. It is also in the middle of the range he measured in his trembling analysis research, indicative of what is traveling mechanically or acoustically through the cellular matrix.



(Reproduced with permission from Richard H. Lee, CHI Institute, San Clemente, CA.)

Figure 2. Infrasonic 8 Therapeutic Massager.

A marketing brochure produced by the CHI Institute makes the following claim:

“These signals, which govern the activity of the individual cells, can be distorted by physical trauma or any kind of shock, even from strong emotions, causing abnormal cellular activities like inflammation, pain, and impeded healing. The ripples, introduced during Infrasonic Therapy, interact with the body’s communication signals, disrupting abnormal activity and replacing it with calm healing activity. The result is a decrease in inflammation and edema, the immediate relief of pain, and accelerated healing. The Infrasonic signal also travels easily through the nervous system, breaking up patterns of stress, worry, depression, and annoyance, leaving you feeling relaxed, calm, and optimistic.”¹⁰⁸

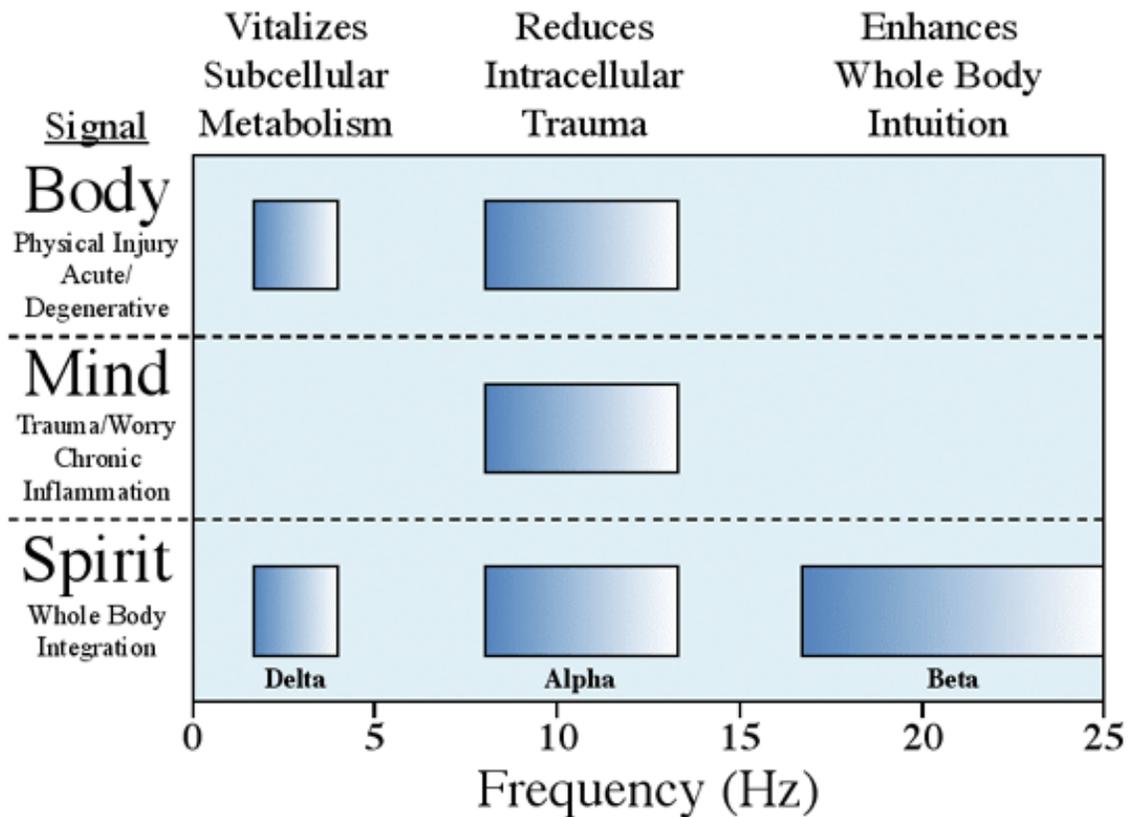
These claims are based on Lee's work and anecdotal observations of healers. However, it has not yet been scientifically established whether the infratonic signal travels easily through the nervous system. The proposed study will investigate an aspect of this claim.

The literature reveals the following information regarding the four basic brain waves, or states, that make up the EEG (electroencephalogram): Delta, Theta, Alpha and Beta: Each oscillates at different frequencies.¹⁰⁹ Delta state is the slowest, at about 0-4 cycles per second. It occurs during deep sleep, reflects the unconscious mind, and is involved with our ability to integrate and let go. Theta, at 4-7 cycles per second, occurs in the state of drowsiness, meditation, and spiritual awareness. It is connected with daydreaming, creativity, and fantasizing. The Alpha, brainwaves were first discovered around 1908 by Austrian Psychiatrist Hans Berger. These waves oscillate at approximately 8-13 cycles per second and enhance the overall sense of relaxation and detached calmness, alertness and mental coordination, and creative inspiration. An increase in Alpha waves helps reduce feelings of stress and anxiety. Beta waves oscillate at approximately 13-40 cycles per second and are characteristic of a strongly engaged mind.

The Infrasonic 8 has three infrasonic therapy signals that simulate Delta, Alpha and Beta brain wave frequencies. They are labeled 1, 2, and 3 (Body, Mind, and Spirit on the Infrasonic 8). A brochure titled "Infrasonic 8: Guidelines for Signal Selection" summarizes the three signals: Signal number 1 is the "repairing signal," said to accelerate repair of damaged cells once nerves and tissues have been calmed. It is a signal in the Delta range with a frequency band around 2 Hz, stimulating subcellular metabolic activity. Signal number 2 is the Alpha range, or "calming signal." It is the primary

signal used first in every treatment program as it is said to calm the nerves and cellular tissues, reducing inflammation and swelling, and reducing anxiety. It is the range emitted from healers with a signal of 8 to 14 Hz. Signal number 3, with a frequency band from 17 to 25 Hz (Beta) provides a bridge between analytical consciousness, between logic and intuitive knowing, and offers a sense of mental “insight” into life’s challenges.

3 Vitalizing Frequencies



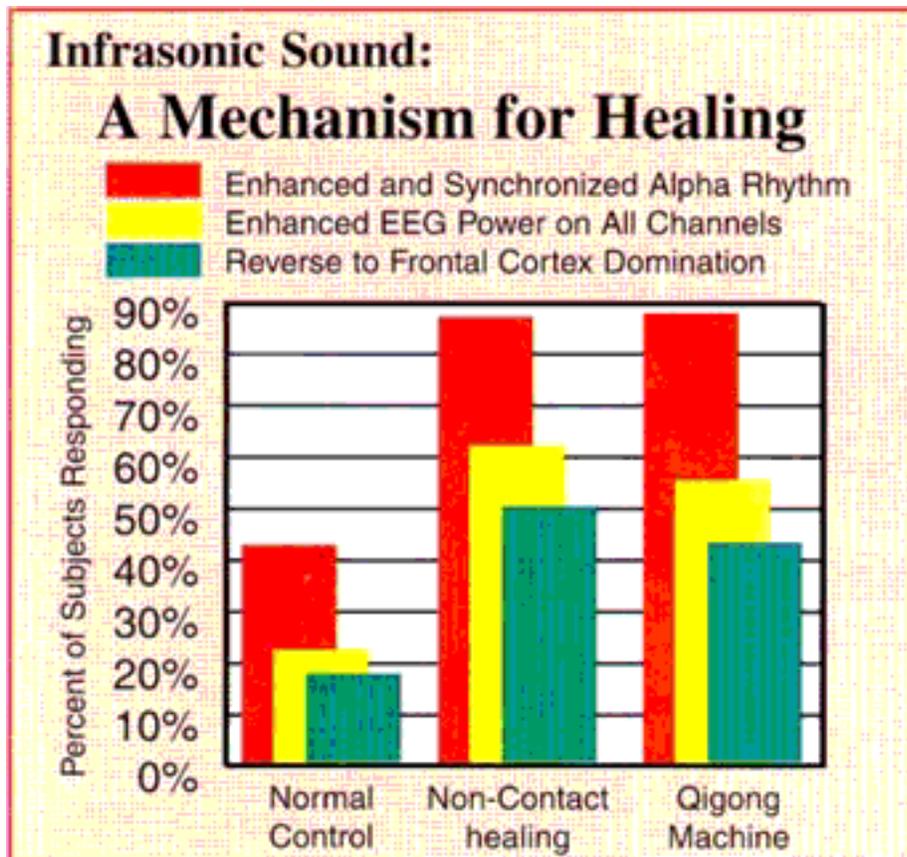
(Reproduced with permission from Richard H. Lee, CHI Institute, San Clemente, CA.)

Figure 3. Frequency settings of Infrasound 8.

Lee explains that his research has demonstrated that the heart trembles in the range of 25-40 Hz, which means the range 17-25 stands between SMR (sensory motor range) and the heart signal, providing a bridge between analytical consciousness and heart consciousness.¹¹⁰ Subjective reports of the pure 17-25 Hz signal support the

proposed “intuition” result of this signal. The delta range signals appear to induce a switch from sympathetic to parasympathetic nervous system activity, which engages a healing response. The delta signal Lee selected appears to be a signal in that range that activates healing. Again, there is only subjective support for this. The proposed study will use only the #2 signal, as it is suggested to be the calming frequency that may reduce anxiety.

Professor Liu Guolong, M.D., Ph.D., used EEG’s to show how both Qigong healers and an early version of the Qigong machine could alter blindfolded test subjects’ EEG’s from across a room, even when the subject was an anesthetized animal. Results from both showed enhanced and synchronized Alpha rhythm in 89% of the subjects. enhanced EEG on all channels in 60% of subjects from non-contact healing and 55% of subjects from Qigong Machine; and reverse to frontal cortex domination in 50% of non-contact healing subjects and 45% of subjects receiving QGM treatment.¹¹¹



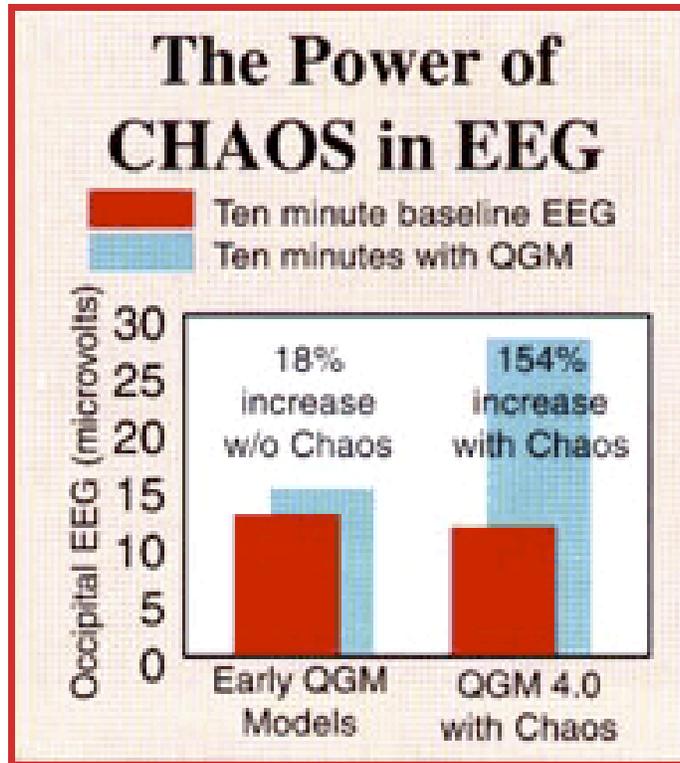
Prof. Liu Guolong, M.D., Ph.D., EEG. EEG has shown the Qigong masters and the Infrasonic cause a reversal from the occipital brainwave activity to frontal cortex domination as alpha induction brings an emotional state of calm clarity.¹¹² (Reproduced with permission from Richard H. Lee, CHI Institute, San Clemente, CA.)

Figure 4. Qigong and Infrasonic effects on EEG's.

Questions have been raised regarding how the device actually works mechanically. Acoustical/mechanical waves vibrate along with electromagnetic energy. The transducer produces magnetic fields, but magnetic fields by themselves do not provide the same effects as the transducer, according to Richard Lee. Mechanically the Infrasonic works much like a speaker with a heavy bass to create the massage effect. The device also contains some brass, therefore creating some electrical interaction, and a permanent magnet, introducing a magnetic field into the workings.

Richard Lee maintains that the concept of chaos and vibrational trembling is key in understanding how the Infratonic device affects the subject. Chaos theory, as expounded in *Order Out of Chaos*, by Ilya Prigogine and Isabelle Stengers,¹¹³ proposes that life requires chaos, that higher forms of organization emerge out of chaos, and that raising the energy of a system allows it to reconfigure into a higher order of organization. Based on anecdotal observations and reports from body-workers and healers, Lee explains that vibrational trembling is a way that memory is stored or processed in the physical body. According to Lee, chaotic ripple (infrasound) penetrates this field of vibrational activity, softening this memory and allowing the person to let go of fixated thoughts, addictive desires, and compulsive actions.

Dale M. Patterson, a board certified EEG technician trained in biofeedback recorded multichannel EEG brain maps using with an early model of the QGM and compared it to the later model that introduced chaotic sounds. He found that the first machine produced an 18% increase in Alpha and the second showed 8 times the Alpha activity of the first. No other observations were made of the brain maps.¹¹⁴



Dale Patterson EEG Brain Maps show an 18% increase in Alpha with Q4. (Reprinted with permission from Richard H. Lee, CHI Institute, San Clemente, CA.)

Figure 5. Effects of QGM on EEG's.

The CHI Institute presents the following comparison of the Infratonic treatment, using either the Infratonic 8 or Infrasonic 8 with Ultrasound, the TENS, and Pain Pills:¹¹⁵ Ultrasound is described as very high frequency (in the range of 100,000 Hz.) and is used for heating and agitation of subsurface tissue at specific points. An attendant is required to avoid tissue damage from localized heating. The TENS applies electrical stimulation (compared to magnetic/mechanical waves of the infratonic devices) through the skin to create direct nerve stimulation through predictable single frequency pulses (compared to unpredictable, continuous- like sinusoidal- waves of a delimited spectrum of frequencies), encouraging the brain to produce pain-killing chemicals and promote local activity. It is Lee's understanding that this desensitizes the brain to the pain signal.

The stimulation that confuses, desensitizes or artificially induces firing of neurons to interfere with pain conduction, makes it less sensitive to the body's healing needs.

However, the actual comparative research has not yet been performed.

Pain pills work by numbing the nerves and the brain, but they also impair awareness and impede healing.¹¹⁶ As tolerance to drugs increases, higher doses are required, creating side effects such as reduced physical and mental performance and addiction. The CHI Institute posits that Infratonic therapy infuses the body with random low frequency signals that break up patterns of encapsulated trauma and pain and open neural pathways. Lee explains in an interview that he has noted increase in pain sensations at first, from as much as a foot away, from the point of injury or surgery. Thus, the device does not sedate, but increase sensitivity. Anecdotal reports to Lee in cases of stroke attribute the use of the infratonic device to recovery of nerve function. Actual nerve conduction studies have not yet been performed.

Research on Related Therapies

Medical or External Qigong

Infratonic therapy has emerged from medical, or external qigong therapy. It replicates the low frequency sound waves emitted from the hands of qigong master healers. This section offers an overview of the research on qigong therapy. More than 500 research papers exploring the effects of External Qigong (EQ) have been published or presented in China.¹¹⁷ Of these studies, not all have adhered to the three major characteristics, or conditions, of EQ as established by the Chinese Society of Qigong Science. The three conditions are: 1. A well-trained practitioner in a qigong state, 2. Traveling a distance from the practitioner, 3. Directional, but not affecting nearby

targets.¹¹⁸ Most of the information on the scientific basis for EQ is in Chinese. Over 1500 abstracts in English have been collected in the Computerized Qigong Database, provided by the Qigong Institute in Menlo Park. They include studies on the qigong treatment of anxiety,¹¹⁹ rheumatoid arthritis,¹²⁰ coronary heart disease,¹²¹ neuroasthenia,¹²² and other diseases. However, they are not translated from Chinese and important details are missing in the translated abstracts.

Kenneth M. Sancier, Ph.D. and Bingkun Hu, Ph.D. of the Qigong Institute in Menlo Park, CA, discuss selected scientific reports pertaining to emitted Qi that were presented at two international conferences held in 1990. The reports document some of the significant changes produced when Qigong practitioners, or “Masters,” emit Qi to living systems: humans, animals, cell cultures and plants. Sancier and Hu maintain that these research studies have been done in accordance with acceptable scientific protocol.¹²³ Sancier also published an article with Linda Hole, M.D. titled “Qigong and Neurologic Illness”¹²⁴ It reviews over 100 studies, including 14 related to anxiety with positive results. A pilot study, conducted by Frances V. Gaik, Psy.D., conducted at the Adler School of Professional Psychology, researched the effect of Qigong on Depression with unclear results.¹²⁵ Other studies that demonstrated significant results using qigong on various illnesses can be found in the Qigong database available online at <http://www.qigonginstitute.com>.

Richard Lee cited studies on emitted Qi from the 1988 First World Conference for Academic Exchange of Medical Qigong in Beijing, China.¹²⁶ Topics include:

- Infrasonic Simulation of Emitted Qi From Qigong Masters
- Measurement and Analysis of Infrasonic Waves from Emitted Qi
- Nerve Impingement and Emitted Qi
- Effects of Emitted Qi on Healing of Experimental Fracture

- Physiological change in blood during Qigong Exercises
- Effects of Qigong on Neurotransmitters
- Physical Characteristics of Emitted Qi
- Superconducting magnetometer Measures Changes During Qigong
- Qigong and Cancer
- Effect of Emitted Qi on Carcinoma Cells

These studies, presented in abstract form, are in Chinese; therefore, evaluation is not made in this chapter.

Kevin Chen and Raphael Yeung reviewed more than fifty studies that had a focus on qigong therapy for treating cancer over the past twenty years that provided evidence that qigong therapy has an inhibitory effect on cancer growth, both in vitro and in vivo studies as well as in clinical observation.¹²⁷ Some of these studies required replication in order to verify their findings.

Nine studies involving External Qigong were found online at the PubMed website, using “external qigong” as a search phrase. They studies indicated that EQ may be an effective in promoting health and wellness in older adults,¹²⁸ biochemical functions of cells,¹²⁹ changes in EEG’s in rabbits and rats,¹³⁰ inhibiting tumor growth in mice,¹³¹ relieving symptoms of arteriosclerotic obstruction,¹³² and recovery from multiple symptoms,¹³³ and other positive health results.

Infrasound/Infrasonic Therapy

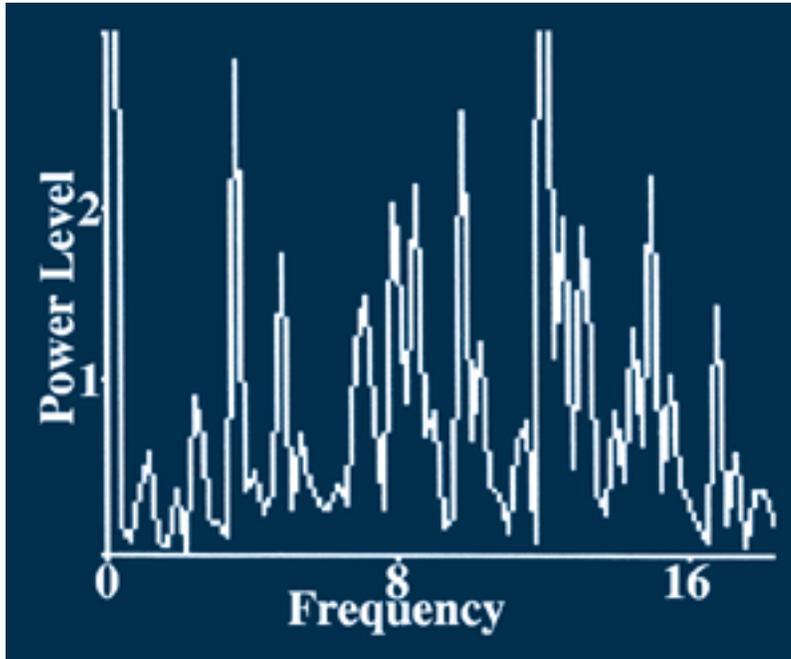
As in many other energetic interventions, both positive and negative effects can result from the use of infrasound. Detrimental effects of infrasound mentioned in some studies and experiments include uneasy, nervous feelings¹³⁴ and pathological discomfort.¹³⁵ Other studies refute detrimental effects on infrasound on the human

body.¹³⁶ Still others merely report changes in physical conditions such as blood pressure¹³⁷ brain biorhythms,¹³⁸ and properties of water and DNA solution.¹³⁹

Richard Lee and the CHI Institute of San Clemente are the only resources found for studies in English using the Infratonic Therapy devices. Most of the studies were performed in China, including one involving 50 cases of Child Bronchial Asthma performed by Dr. Su Cheng Wu using the Infratonic QGM. The results showed improvement in 94% of the children in the treatment group.¹⁴⁰ Another study using the Infratonic QGM showed statistically significant improvement ($p < .001$) in children with digestive problems ranging from loss of appetite and stomachache to diarrhea, constipation, and night sweating.¹⁴¹ Relevant to the proposed study is one related to stress in which Su Chen Wu treated each student in a high school class for 3 days before a college entrance exam with the Infratonic QGM. Failure in this exam is a common cause of suicide in China. Dr. Su theorized that the QGM would induce the calmness and clarity of Alpha brainwaves, and thus help the students to relax and overcome the mental overload that causes the brain to “lock up” during tests. Whereas the average pass rate for all of the senior classes was 50%, this class, rated “average” in skills and ability, had an 86% pass rate for 5-year colleges. The remaining 14% got high enough scores to be accepted into 3-year trade schools.¹⁴²

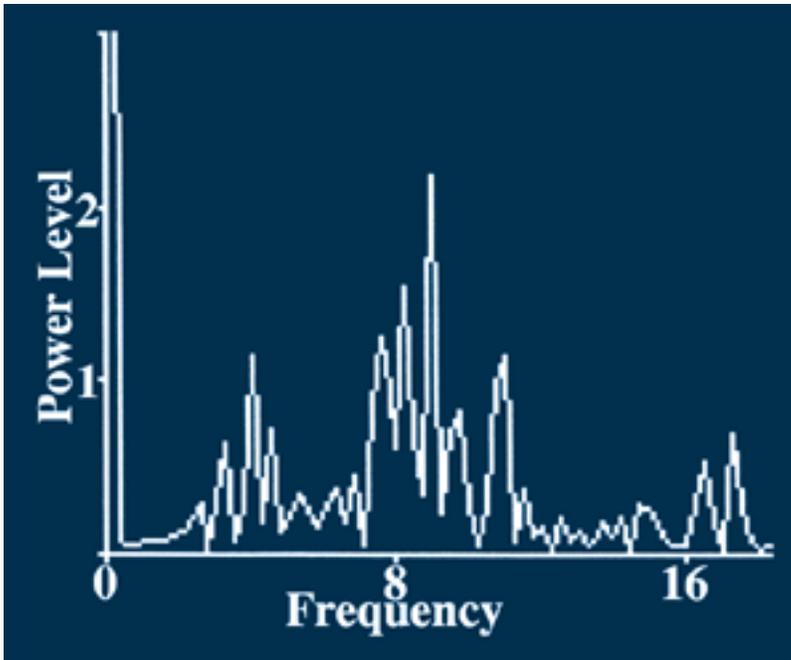
Richard Lee performed his own studies in the U.S., one related to stress management. It involved measuring involuntary muscle contractions that revealed noise in the nervous system measurable as involuntary muscle contractions.¹⁴³ Lee believed that noise in the nervous system was a sign that subconscious programming invaded our

bodies so that we were out of control of our thoughts and actions. After 3 minutes of Infratonic Therapy, a subject's trembling changed from very intense to very calm.¹⁴⁴



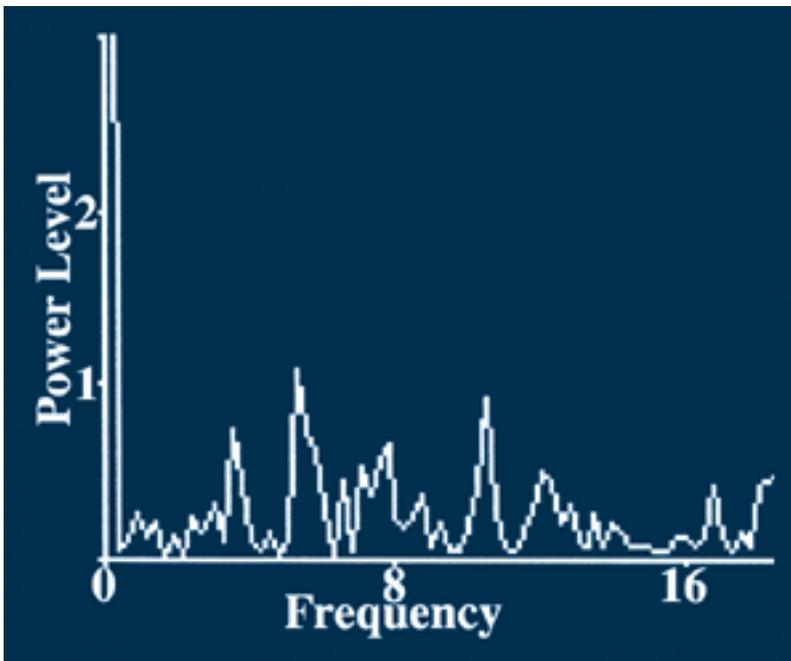
Test subject's trembling just before starting Infratonic Therapy, with noise across the spectrum. (Reprinted with permission from Richard H. Lee, CHI Institute, San Clemente, CA.)

Figure 6. Trembling frequencies before Infratonic Therapy.



After 3 minutes of Infratonic Therapy, the noise has decreased and is predominantly in the alpha range. (Reprinted with permission from Richard H. Lee, CHI Institute, San Clemente, CA.)

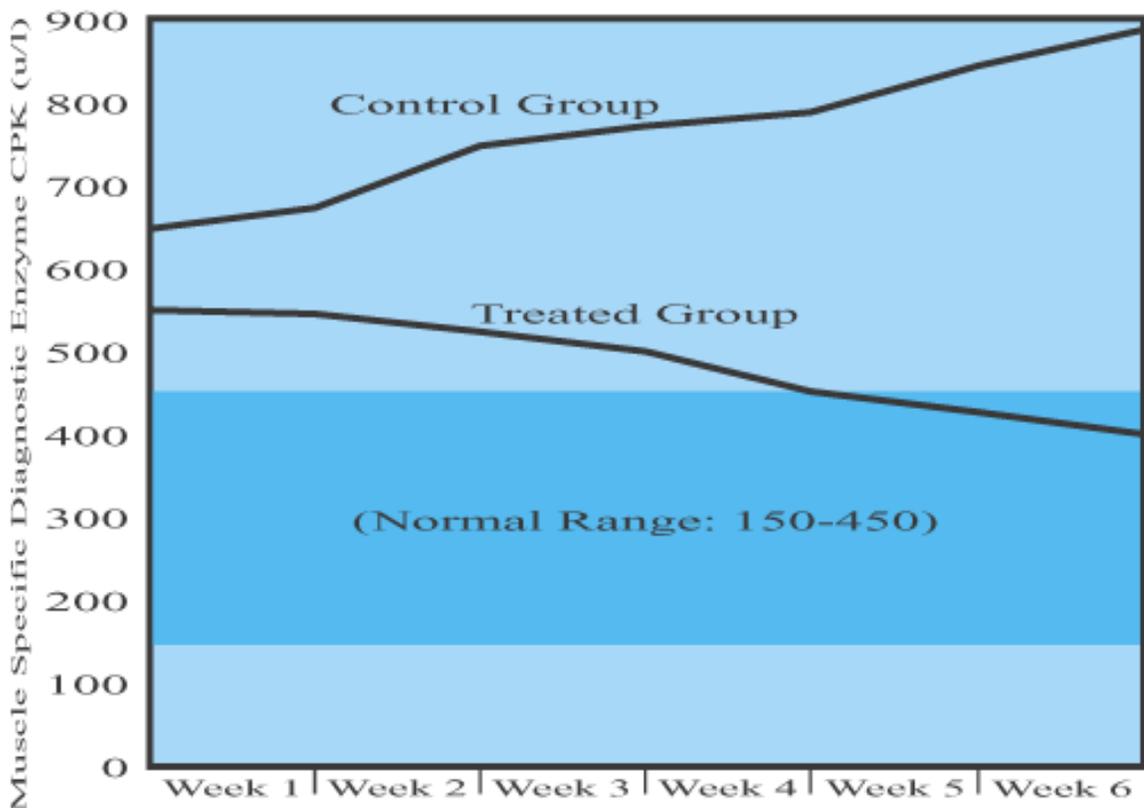
Figure 7. Trembling frequencies after 3 min of Infratonic Therapy.



Noise has decreased further, after 2 minutes of rest after Infratonic Therapy. (Reprinted with permission from Richard H. Lee, CHI Institute, San Clemente, CA.)

Figure 8. Trembling frequencies after 2 min. rest.

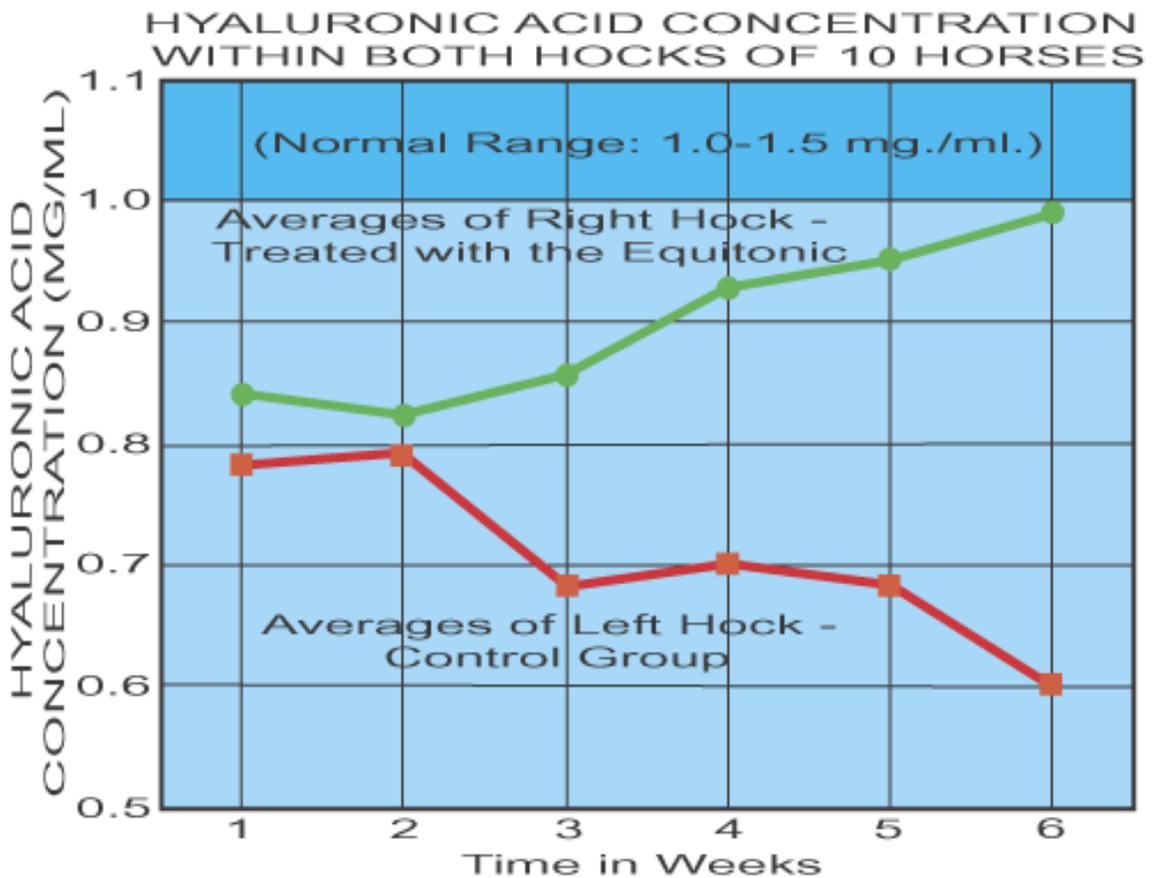
A controlled study by Ronald J. Rigel, D.V.M. involved the effectiveness of the Equisonic QGM on standard-bred horses.¹⁴⁵ Nine of 10 horses in the control group showed worsening race times and blood work, and 4 of the 10 became lame and dropped out part way through the study. Meanwhile 10 of the 10 treated horses showed better blood work: a decline in the diagnostic enzymes AST (aspartate amino transferase) and CPK (creatine phosphokinase). In addition the same horses showed improvements in the rate of recovery after races, and the shaving of 1.65 seconds off their race time over a period of 6 weeks.



With 10 horses as control, the group treated with Infratonic Therapy showed substantial reduction in CPK levels, indicating healing of damaged muscles. (Reprinted with permission from Richard H. Lee, CHI Institute, San Clemente, CA.)

Figure 9. Effects of Infratonic Therapy on CPK levels.

Rigel performed another controlled study, comparing the treated front right hock of 10 standard-bred horses with the untreated left hock. The right hock showed a substantial decrease in AST and CPK and increase in Hyaluronic Acid (HA), viscous oil that lubricates joints, heals wounds, and binds up to 1000 times its weight in water to keep skin smooth and soft.¹⁴⁶ Lee hypothesized that the decrease in AST and CPK came from increased coherence in cell walls. He based this conclusion on information concerning the concept of HA creating coherence in cell walls and other structures, discussed in *Measurements of Ki in Diagnosis and Treatment*, by Motoyama.



The average Hyaluronic Acid concentration (MG/ML) levels within the synovial fluid of both right and left hock of standardbred horses. (Reprinted with permission from Richard H. Lee, CHI Institute, San Clemente, CA.)

Figure 10. Effects of Infratonic Therapy on hyaluronic acid levels.

Since Infratonic Therapy increases HA production in horses, strengthening the cellular walls and reducing inflammation, it would be of value to conduct controlled studies to assess the effect on humans. HA levels are currently used as markers for the diagnosis, progression, or stasis of diseases such as osteoarthritis, suggesting that normalized HA levels can lessen or prevent symptoms of such diseases.¹⁴⁷

Scientific Basis for Infratonic Therapy

Autonomic Nervous System

The Infrasound 8 is theorized to work to promote healing and release trauma, anxiety, and depression. One might begin by looking at the autonomic nervous system (ANS). Michael Winkelman provides a clear description of the autonomic nervous system (ANS).¹⁴⁸ Complementary activities of the sympathetic and parasympathetic divisions of the ANS controls organic functions of the human body. The ANS consists of the hypothalamus, portions of the endocrine system, the reticular activating, the limbic system, and the frontal cortex. It controls bodily functions such as the digestive system, the heart, and mediates balance between stimulation and relaxation. The sympathetic system furnishes adaptive responses to the external environment, whereas the parasympathetic maintains a homeostatic balance. Winkelman informs us that the balance between these external/internal needs is created through conditioning, which sets the relationships that establish and maintain the rhythmic interactions between waking and sleeping modes of consciousness. The sympathetic division subserves the fight-or-flight response, providing a global activation of the body for short-term adaptation. This activation is associated with either positive or negative emotions, depending on the interpretation made of the physiological changes and immediate situation. The

parasympathetic system regulates the vegetative nervous system, from cellular activity to digestive functions and sleep. In addition, it synchronizes the cortical EEG patterns for relaxation, control of somatic functions vital for long-term wellbeing. Its primary function is repair and development of the organism.

Salient to this study is that the sympathetic and parasympathetic systems can be driven top down or bottom up, operating on the principle of homeomorphogenetic recruitment across different levels of the nervous system and body.¹⁴⁹ Winkelman posits that the manipulation of the ANS balance is a central mechanism of shamanistic healing, as are stress responses and psychosomatic reactions.

Dr. Jerry Alan Johnson states that ancient Eastern philosophers recognized the interdependence of mind and body, viewing function from a holographic perspective, each part reflecting the whole. “For the whole to function harmoniously, he asserts, “every part must remain in balance. Therefore the role of the Oriental physician is more similar to a gardener, following the patterns of change, diagnosing functional disharmony and restoring overall balance.”¹⁵⁰ The manipulation of the balance of bodily systems, including the ANS is central to Medical Qigong Therapy and other hands-on and hands-off complementary therapies such as Reiki, Therapeutic Touch, Touch for Health, and Healing Touch, to name a few. Infratonic Therapy is also based on this notion of balancing systems. The chaotic sound is intended to break up repeated patterns of stress and disease in order for all the bodily systems to reorganize themselves into health and balance.

Other Communication Systems and Healing Effects

Through her laboratory investigations, Candace Pert, Ph.D., found that the flow of neuropeptides and receptors arose from many sites in the different systems simultaneously- the immune, the nervous, the endocrine, and the gastrointestinal systems.¹⁵¹ These sites formed nodal points on the complex network of internal information exchange taking place on the molecular level. According to Pert, intelligence is diffused throughout the system, rather than a one-way operation from the centers in the brain. An intercommunication system of opioids and emotions allows for opioid release to stimulate emotional experience and emotional experiences to stimulate opioid release. The use of Infratonic Therapy on one part of the body may indeed send information and healing messages to the whole body.

Many scientists have attempted to explain the common energetic denominator to all healing. James Oschman offers an explanation based on research performed by Donald Ingber and colleagues who concluded that many unrelated diseases seem to have a common dependence on abnormal mechanical influences triggered by local inflammation. “My guess is that the best of our electromagnetic healing devices and the best of our hands-on and hands-off therapies work in part by bringing about changes in the degree of electric polarization in localized areas of inflammation.”¹⁵²

In *Energy Medicine in Therapeutics and Human Performance*, Oschman postulates that we are dealing with a vast network of processes in the body matrix: “proliferations, specializations, movements, differentiations, dedifferentiations, interactions, cross-linkages, feed-forwards and feedbacks of startling complexity and diversity-all directed at the goal of maintaining and restoring the orderly pattern of the whole.”¹⁵³ He informs us that structural and movement approaches of complementary

medicine stimulate the body's repair systems to repair themselves, restoring "systemic cooperation." Oschman believes that "hands-on" and "hands-off" therapies in complementary medicines focus on the physical and energetic matrix that supports essential communications and cell migrations instead of trying to deal with specific disorders. He concludes:

"If there is one lesson to be learned from the broad spectrum of experiences of complementary practitioners, it is the detailed understandings of physiological and molecular processes, although of interest, are not essential for working at the level of the whole...The whole is not the sum of the parts, and its behavior is not a synthesis of the behaviors of the parts. The whole is governed by certain natural processes, wisdoms, rules, or principles that are practical and discernable. Continuum is one of these principles...continuum refers to the state of continuous organic wholeness fundamental to the structure and behavior of the natural world."¹⁵⁴

Many attempts have been made to explain the healer's effect on another. Richard Gerber, M.D. examines several theories. One is the theory that the bioenergy coming from a healer's hands is directly transferred to the water molecules of the body and this "bioactivated" water brings about inner healing changes. Some Russian scientists who studied the healing effects of conventional magnetism concluded that magnetic energy from the hands of healers creates an energetic alteration in the water content of the body much like the healing power of a magnet.¹⁵⁵ Gerber suggests that healers may somehow connect their patients with the planetary geomagnetic field in a way that may promote a healing response.¹⁵⁶ He explains that it could be a resonance between the healer and patient. Researchers have observed how the physiological rhythms of both healer and patient go into synchrony during the act of healing. For example, in the late 1970's English biofeedback researcher, Maxwell Cade, used a brain-wave- biofeedback device called a Mind Mirror to discover a kind of entrainment in brain waves between a healer and the patient.¹⁵⁷ The Mind Mirror translates the lines of the EEG into a dynamic

visual graph that shows real-time frequency patterns of human brain-wave activity in both right and left hemispheres of the brain.

Dr. John Zimmerman used the ultrasensitive SQUID detectors (sensors of some of the weakest human biomagnetic fields, called evoked fields) to discover that healers emitted weak, low-frequency, pulsed magnetic fields from their hands. Gerber suggests that the SQUID detectors were being affected by a subtle magnetic life energy.¹⁵⁸

Clyde Ford, one of the researchers who conducted experiments involving Canadian healer Olga Worrell, speculated that biological microwaves or an organizing field might be transferred from the healer to the subject.¹⁵⁹

Qi

There are many bioenergy approaches to healing such as Therapeutic Touch, “chelation,” Reiki, Healing Touch, SHEN, Bioenergetics, among others. All of these techniques, including Medical Qigong healing claim to use a naturally occurring energetic aspect of life that follows specific laws. Various esoteric traditions have referred to it as qi, prana, orenda, mana, life force, or universal life energy. However, a caveat must be made that different healing techniques may employ a different aspect of the total life energy. Historically, awareness of this energy is anything but new. Pythagoras called it *pneuma*. Later it was called *od* by Von Reichenbach, *animal magnetism* by Mesmer, *vital force* by Hahnemann, the founder of homeopathy. Wilhelm Reich called it *orgone*. Russians have named it *bioplasma*. Post-Relativity physicists such as David Bohm now postulate its existence and call it the superquantum field. What that energetic aspect is and how it works on another remains open to discussion, study,

and speculation. The concepts are not identical, and much may be learned in the future by attending to just how they are different from each other.

The Chinese Society of Qigong Science defines external qi (EQ) as “the distant and directional effects produced by well-trained qigong practitioners under the qigong state.”¹⁶⁰ According to authors Zhongpeng Lin and Kevin Chen, the extant literature suggests that some form of bioinformation plays a critical role in its effect or characteristics, about which we know very little.¹⁶¹ They state that EQ may consist of matter, energy, and information. The authors add that it is easy to measure the objective existence of external qi, but it is much harder to measure the essence of qi or to explain the mechanism of qigong therapy.¹⁶² Some suggest that the power of intention is involved. Lin and Chen propose that once the existence of qi or the biofield effect is confirmed, the focus of qigong research should be on understanding the healing process of internal (self-practice) and external qi emission and the major benefits of qigong.

Kevin Chen also reviews the book *Scientific Qigong Exploration: The Wonders and Mysteries of Qi*, explaining that Traditional Chinese Medicine (TCM) posits the existence of a vital energy (qi) circulating throughout the entire human body. When strengthened or balanced, it can improve health and ward off or slow the progress of disease. Sickness and pain is a result of qi blockage and/or unbalanced qi. In EQ therapy the practitioner directs his qi energy to help others break qi blockages.¹⁶³

Oschman suggests that qi emission from the hands of healers may be a cooperative phenomenon produced by electronic or protonic conduction through the crystalline-like parts of the body fabric.¹⁶⁴ He proposes that the relaxation of tensions in the connective tissue, and reorganization of the fibers into a more structurally coherent

arrangement “or some other simple consequence of various practices,” may be central to bringing about this cooperation. Oschman also presents a hypothesis that is also a definition of this energy, called healing energy, whether produced by a medical device or projected from the healer’s hand:

“Healing energy, whether produced by a medical device or projected from the human body, is energy of a particular frequency or set of frequencies that stimulates the repair of one or more tissues.”¹⁶⁵

Richard H. Lee hypothesizes that “scalar waves” that surround us and are stronger at the surface of the human body could be the same longitudinal magnetic waves from the Infratonic device (see Infratonic Therapy).

Many aspects of qi have been reviewed here. There is no clear, agreed-upon definition of qi, yet the existence of some bioinformation, vital energy, or life force that is affected by various therapies seems to be central to the discussion of their efficacy.

Tensegrity

R. Buckminster Fuller introduced us to the architectural and energetic concept of tensegrity.¹⁶⁶ Based on artist Kenneth Snelson’s structural principle, this concept underlies geodesic domes, sailing vessels, cranes, and wire sculptures. Coined from the words tension and integrity, it uses a balance of tension-resisting elements (tendons) and compression-resisting elements. K.J. Pienta and D.S. Coffey define tensegrity:

“a structural system composed of the discontinuous compression elements connected by continuous tension cables, which interact in a dynamic fashion. A tensegrity tissue matrix system allows for specific transfer of information through the cell (and throughout the organism) by direct transmission of vibrational chemomechanical energy through harmonic wave motion.”¹⁶⁷

Cell biologist and medical doctor, Donald Ingber defines the concept as “a tensed network that stabilizes itself mechanically by incorporating other elements that resist

compression.”¹⁶⁸ He presents a model of the cytoskeletal structure and cell mechanics that is based on the concept that living cells use tensegrity architecture to control their shape and function.¹⁶⁹ This would indicate that cells are hard-wired to respond immediately to external mechanical stress. “This hard-wiring exists in the form of discrete cytoskeletal filament networks that mechanically couple specific cell surface receptors, such as integrins, to nuclear matrix scaffolds and to signal transducing molecules that physically associate with the cytoskeleton.”¹⁷⁰

Oshman demonstrates graphically the whole physical body as a living tensegrity system. .¹⁷¹ He further explicates that tensegrity accounts for the ability of the body to absorb impacts without being damaged because mechanical energy flows away from the site of impact through the tensegrous living matrix. Salient to the proposed study is Oshman’s explanation that the living tensegrity network of the body is simultaneously a mechanical and vibratory continuum. Restrictions in one part have structural and energetic consequences alike for the entire organism and that structural, vibratory, and energetic (informational) integrity go hand in hand. “One cannot influence the structural system without influencing the energetic/informational system, and vice versa.”¹⁷² This might explain how the vibrational information from Infratonic Therapy is transferred through the tissue tensegrity-matrix.

The research and concepts presented in this review of the literature suggest that the use of the Infrasonic 8 as Infratonic therapy for stress management has promise and plausibility. The idea of the living tensegrity-matrix of the physical organism and Pert’s research on non-local neuropeptides and receptors offers insight into how the vibrations might affect the ANS as well as other parts of the body, thus offering a reduction of

stress. Prigogine and Stanger's chaos theory suggests that the random sound of a chaos therapy device may break down psychological and physical patterns, old attitudes, beliefs and emotions. It may surpass our vibrational defenses and soften the thoughts and emotions in the target frequency range. As an increase of chaotic or undefined energy is introduced to the biological system via the Infrasonic transducer, it may create a transformation into a higher order of organization that handles all previous stressful requirements in a new way. This may explain why Richard Lee tells us that, after a treatment, people feel calm, clear thinking and liberated from the problems and worries of life.

Statement of Hypothesis

This study attempts to prove the following hypothesis: "Three 20-minute treatments, performed once weekly, using the Infrasound 8 Therapeutic Massager will significantly reduce levels of anxiety as measured on the State-Trait Anxiety Inventory." It attempts to disprove the null hypothesis: "Three 20-minute treatments, performed once weekly, using the Infrasound 8 Therapeutic Massager will not significantly reduce levels of anxiety as measured on the State-Trait Anxiety Inventory."

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CHAPTER 2: METHODOLGY

All matter originates and exists only by virtue of a force which brings the particles of an atom to vibration and holds this most minute solar system of the atom together...We must assume behind this force the existence of a conscious and intelligent mind. The mind is the matrix of all matter.

—Max Planck

Research Design

This study utilized a quasi-experimental double-blind pre-test/post-test control group design with repeated measure of the dependent variables. Subjects were arbitrarily assigned to receive treatment from either the active Infrasonic 8 Therapeutic Massager or the inactive (control) Infrasonic 8 Therapeutic Massager. The devices were identical in appearance, but the inactive device had the electronic mechanism for producing the low frequency sound waves removed by a technician. The principal investigator (PI) was unaware, until after the completion of data collection, which was the active and which was the control device.

Both groups in the study took each of the two pre-tests, post-tests, and follow-up post-tests. The pretest was taken immediately before to five days before the first treatment. The posttest was taken the day after the last treatment, and the follow-up post-test was taken four weeks following the last treatment. Intervention consisted of three twenty-minute self-administered treatments, once weekly. Interaction between the PI and the participants occurred during the recruitment, orientation, treatment, and assessments (pre, post, and follow-up). During the introductory and pre-test session, participants completed a demographic questionnaire and signed a consent form.

Because this study was designed to examine the effects of a device purporting to deliver randomly delivered ripples (infrasound waves) within a carefully prescribed frequency to penetrate the body, it should be noted that there was an absence of intention on the part of the PI with regard to the outcome favoring one result over another. Rather, the PI was interested in determining whether or not there would be any statistically significant differences between the treatment and control conditions.

Participants

Participants were recruited from six elementary schools in San Diego county (CA), a chiropractic center in Spring Valley, CA, a noetic sciences study group and bookstore in San Marcos, CA, and a dance community in San Diego, CA. Initially, the PI recruited 88 subjects from the staffs and parent volunteers of the six elementary schools. However, 51 of the subjects dropped out before treatment began or after one or two treatments. Therefore, the PI recruited from the other communities mentioned above to create a sample of convenience.

Recruitment

In February 2005, the principal investigator submitted a Request for Approval of Research Study to the Chula Vista Elementary School District, Chula Vista, CA (see Appendix A). The Superintendent and Cabinet approved the request on March 2, 2005 for the remainder of the school year. Approval was extended (verbally) to the fall/winter semester during the summer of 2005. Following the school district approval, the PI contacted the principals of six schools via a telephone call to schedule an introductory

meeting. During the meeting, the PI introduced herself, explained the purpose of the study, and requested time during a staff meeting to present information regarding the study, and recruit subjects. Principals made announcements regarding the presentation in electronic staff bulletins, on white boards in the staff lounges, and during daily announcements over the public address systems in the schools. Letters of introduction were placed in each staff member's school mailbox (see Appendix B). Within two weeks of the principal's meeting, the PI presented the pertinent information to school staff and parents, and recruited volunteers.

In May 2005, the PI was invited by the principal of two schools in another district to make a similar presentation and recruitment. Announcements, presentations, and recruitment of staff and parent volunteers were performed in a similar manner as in the larger school district.

In March 2006, additional subjects were recruited from a chiropractic center in Spring Valley, CA. In April 2006 subjects were recruited from a local noetic sciences study group along with patrons of a bookstore in San Marcos, CA via a point person who announced the upcoming study in that venue by email, word of mouth, and a posted announcement. Letters of introduction were placed on the front counter of the chiropractic office and the bookstore for clients and customers to read (see Appendix C). The PI presented the pertinent information regarding the study to the point person and other interested individuals on a one-to-one basis. In May 2006, volunteer subjects from a dance community in San Diego were recruited in small groups or individually in a similar manner as those in the study group and bookstore.

Inclusionary Criteria

Criteria for inclusion included: ages 22 to 75, self-identified as having “more than normal levels of stress” in their lives, attendance at an introductory session, completion of demographic questionnaire and assessments, signature on consent form, and participation in the three 20-minute treatments, once weekly, without discussing anything about their treatment experience with any other participants or the PI until the study was complete.

Exclusionary Criteria

Criteria for exclusion were: wearing an implanted electronic device, such as a pacemaker, and self-reporting a professional diagnosis of a severe mental disorder such as schizophrenia, manic depression, or some form of psychosis.

Description of Sample Population

Participants included 54 females and 16 males, totaling 70 subjects, with 32 randomly assigned to the Red group and 38 to the Blue group. The distribution for women was 26 Red and 28 Blue and for men was 6 Red and 10 Blue. Approximately 1/3 of the subjects were teachers (32.9%). The remainder of the subjects in both groups crossed a wide range of occupations such as: parent, clerical, ministerial, social work, technical, scientist, medical, musician, flight attendant, sales, and retired.

About half of all the participants earned an income below \$ 50,000.00 and half earned from \$ 50,000.00 to \$ 100,000.00+ with no significant differences in income category distribution between groups. There was no significant difference in marital status, with more than half of all participants married or living with a significant other. Seventeen percent of the subjects were divorced, four percent were widowed, and 14

percent were single. Approximately 66 percent of both groups had children, with the majority having two children.

The majority of participants in both groups were Caucasian, approximately ten percent were Hispanic, and a small percentage were Asian, African American, and from other ethnic groups. Most of the participants in both groups had not sought professional help for stress-related problems within the year before participating in the study.

Materials

Two measures were used in this study: the State-Trait Anxiety Inventory, Form Y, for Adults (Spielberger, Charles D., R.L. Gorsuch, R. Lushene, P.R. Vagg, and G.A. Jacobs, 1968, 1977) (see Appendix D), and the Outcome Rating Scale (Miller, Scott D. and Barry L. Duncan, 2000) (see Appendix E).

State-Trait Anxiety Inventory

The State-Trait Anxiety Inventory (STAI) was deemed appropriate for this study in part for its longstanding track record as a validated generic measure of anxiety in research and clinical practice.¹ According to Spielberger, the alpha coefficient measure of internal consistency for the Form Y S-Anxiety scales were above .90 for samples of working adults, students, and military recruits, with a median coefficient of .93. The alpha coefficients for the T-Anxiety scale had a median coefficient of .90. Construct, concurrent, divergent and convergent validity of the STAI scales was demonstrated by correlations to different anxiety measures as well as differentiation between stressful and non-stressful situations.² The STAI was also selected as a measure for its ease of acquisition, reproduction, and use. It is designed to be self-administering and requires

about ten minutes to complete both the 20-question S-Anxiety and T-Anxiety scales.³ It appears to be an appropriate measure to utilize with adults since it was normed for different adult age groups and occupations.⁴

State Anxiety refers to situational feelings such as apprehension, tension, nervousness and worry that are often transitory. The instructions on the State (Y-1) Anxiety Inventory emphasize that the examinee reports how they feel “right now...at this moment.” Trait Anxiety refers to anxiety-proneness, or, to differences between people in the tendency to perceive a stressful situation as dangerous or threatening and to respond in the intensity of their state anxiety reactions. The instructions on the Trait (Y-2) Anxiety Inventory ask examinees to indicate how they “generally” feel. The examinees’ copies of the State-Trait Anxiety Inventory were titled “Self-Evaluation Questionnaire,” with no mention of “anxiety” so as to maintain a neutral testing attitude.

Answers to the Inventory may be scored by hand with a scoring key. Each item on both scales is given a weighted score of 1 to 4, with a rating of 4 as the presence of a high level of anxiety present and a rating of 1 indicating the absence of anxiety. Ratings reflect anxiety-present items and anxiety-absence items alike. The scores for both scales can vary from a minimum of 20 to a maximum of 80.

Outcome Rating Scale

The Outcome Rating Scale (ORS) (Miller, Scott D. and Barry L. Duncan, 2000) (see Appendix E) was selected as a measurement of the treatment outcome, or clinical significance, due to its simplicity and correlation to the Outcome Questionnaire 45 (OQ-45) (Lambert, Hansen Umphress, Lunnen, Okiishi, Burlingame, Huefner, and Reisinger, 1996), a widely used and well-validated measure.⁵ Pearson product moment correlation

between the ORS and the OQ-45 yielded a concurrent validity coefficient of .58 in a study performed by Miller, et al., a figure considered adequate given the brevity of the ORS.⁶ The same study reported an internal consistency coefficient of .93 in a sample of general community mental health out patients (n=435). Both the ORS and OQ-45 were designed to assess change in three areas of client functioning widely considered indicators of progress in treatment: individual (or symptomatic) functioning, interpersonal relationships, and social role performance (work adjustment and quality of life). An independent study of the reliability of the ORS conducted by the Center for Clinical Informatics reported an alpha coefficient of .79 (n=15,778) and test-retest reliability at second administration of .53 (n=1,710).⁷

The ORS is a visual analog scale in which clients or examinees simply place a hash mark on the line nearest to the pole that best describes their experience over the previous week since their last treatment. Administration and scoring requires less than two or three minutes.

Other Materials

Other materials used in this study were an Information Questionnaire (see Appendix F) and an Informed Consent Statement (see Appendix G). Participants completed the Information Questionnaire to provide information on the demographics of the sample population, and signed the Informed Consent as required by the FDA and the IRB.

Additional materials used in the study were the two Infrasound 8 Therapeutic Massagers, donated by the CHI Institute, San Clemente, CA (www.chiexplorer.com) to the PI for the study. The Infrasound 8 is a device that emits randomly delivered

infrasound waves within a carefully prescribed frequency that is said to easily penetrate deeply into the body. These infrasound waves are also called “ripples” in order to distinguish them from sound waves that people think of as traveling through the air to our ears. These ripples travel from the Infrasound 8 transducer through the body rather than through the air to the ear. They are the same sound frequencies of measured Qi emitted from the hands of Qigong healing masters in China.⁸ The real and sham devices were identical in appearance, and both exhibited red consecutive flashing indicator lights when the power button was pressed. The devices differed only in regards to having or not having the internal mechanism for producing the ripples. A technician from the CHI Institute, San Clemente, CA, placed a red and blue dot on the respective devices so that neither the PI nor the participants were aware of which was the real and which was the sham device.

Procedure

The PI made presentations sequentially to the six Southern California school staffs and parent volunteers after receiving permission from the principals to conduct a phase of the study at the school site (see Appendix H). The same information was presented to small groups and individuals at the chiropractic office and the study group and bookstore. During each meeting, volunteers signed up to participate in the study and were given and explained the necessary forms and pretests (see Appendix I).

The PI informed participants of their right to drop out of the study at any time and emphasized the confidentiality of the information on the questionnaire and all of the tests taken. As data were entered into a database, the names of the participants were replaced by a code number. Both the STAI and ORS were referred to as “surveys,” rather than

tests to lower test-taking apprehension that might have occurred in the educational community. The treatment protocol was explained and demonstrated by the PI. The PI asked that participants agree NOT to talk in any way about their therapy sessions with each other until after completing the four-week follow-up post survey. They were requested not to talk with the PI about the treatment until the completion of the entire study. The PI explained that, after the real and sham Infrasound 8 devices were revealed at the end of the study, the real Infrasound 8 device would be available free of charge to those participants who were in the control group (who received treatments from the sham device). Most of the volunteer participants filled out the forms and completed the surveys in the same meeting. Others turned in the paperwork prior to the first treatment.

After turning in their paperwork (Information Questionnaire, Informed Consent, State-Trait Anxiety Inventory Form Y, and the Outcome Rating Scale), participants were randomly assigned to two groups by drawing a two-inch construction paper square from a top hat with equal numbers of red and blue squares. Participants drawing a red square received treatments from the device marked with a red dot, and participants drawing a blue square received treatments from the device marked with a blue dot.

The first week of treatment began the week after the staff meeting, followed by the next two weeks of treatment. Each week, participants received an email, letter or phone call reminding them to perform their treatment. After the third week of treatments, the PI removed the devices to set up in the next school participating in the study. Participants were given the STAI and ORS to complete one to two days following the last treatment and then again four weeks following the last treatment. A question was added

to the ORS post survey that asked subjects: How did you perceive the treatments (e.g., comfortable, uncomfortable, relaxing, calming, upsetting)?

A similar procedure was performed at the chiropractic office, at the bookstore and study group and at the church where the dancers hold their weekly dance. The biggest difference between these groups and the school groups was that the PI made many individual and small group presentations to these communities as people inquired or expressed interest in the study.

Setting

Each school principal and the PI walked through the respective schools to find a quiet and secured space in which to place the Infrasound 8 and the sham device. Some schools had spare rooms or small offices unused on certain days. Others had to clear space in a librarian's office or custodian's storeroom/office. In one school, a storage closet with electrical outlets was cleared to house one device. In all of the schools, each device was placed in a different room, and the teachers and parents were free to self-administer their treatment before or after school or during a break. The custodian in each school was informed so that the room or closet could be locked securely late in the day or evening. At the first two schools a sign-up sheet was used to reserve a time, but few participants kept to the time for which they signed up. For the remainder of the schools, participants did their treatment whenever convenient, and there seemed to be very little schedule conflicts.

In the chiropractic office, both devices were placed in a back room, and participants came in one at a time to do their treatment on the device indicated by the colored dot that corresponded to the colored square drawn from the hat. There were no

overlapping treatment times; therefore only one device was in use at a time. In the bookstore, the devices were set up in a quiet rear classroom in opposite corners. The participants from the bookstore and study group came in for their treatments during opening hours of the bookstore. The church in which the dancers held their weekly dances had a large sitting room/lounge near the entrance, apart from the community room where the dances were held. The PI received permission from the church officials to unlock the room weekly and set up the devices in opposite corners of the room. Dancers came in one at a time during the dance hours to receive treatment. The setting in all venues was quiet and reasonably free from distractions.

Treatment Protocol

The PI explained and demonstrated the treatment protocol before participants began self-administering the first treatment. Participants were urged before each treatment not to discuss the experience with each other or the PI. They signed in on a Sign-In/Out sheet by their respective device as a record of the completion of each treatment (See Appendix J). A sign posted in a plastic stand was placed near each device for the duration of the study in each venue, reminding subjects of the treatment protocol (see Appendix K).

Each participant reported for the self-administered treatment at a time convenient for his/her schedule. After signing in, the participant sat in a chair next to the Infrasound 8 or sham device (plugged into an electrical socket). The subject checked to make sure that the Infrasound 8 was set for 20 minutes on the #2 (Alpha, 8-12 Hz) signal and pushed the red on/off button to activate power. Red lights flashed on each device when the power was on. Each participant held the transducer comfortably over the middle of

the chest or the heart. After 20 minutes, the red lights stopped flashing to indicate that the power was off and the device was inactivated. At that time, each participant made three sweeps with the transducer from shoulders to the ground about three inches from the left, center, and right sides of body. Performed by many massage therapists and body-workers at the end of treatments, the purpose of the sweep was to clear any released or dislodged energy that may have resulted from the treatment. Participants could choose to stand or sit while performing the sweeps. When each treatment session was over, participants signed out on the Sign-In/Out sheet and checked the appropriate columns to verify that the transducer was held on the chest and that the three sweeps were made.

In order to determine which was the real Infrasonic 8, and which was the sham device, the PI turned the power on in each. The real device was fully functioning and emitting impulses, or vibrations, that could easily be felt. It was marked with the blue dot. The sham device did not vibrate or emit any impulses, although the red flashing lights indicated that the power was on. It was marked with the red dot. This determination was verified by the technician at the CHI Institute who had removed the electrical mechanism from the transducer of the sham device. From this point forward, these designations will be used to identify the two groups:

Blue Group= Treatment Group

Red Group= Control Group

Chapter 2 Endnotes:

¹ Spielberger, Charles D., R. L. Gorsuch, R. Lushene, P.R. Vagg, and G. A. Jacobs, *State-Trait Anxiety Inventory for Adults, Sampler Set: Manual, Test, Scoring Key* (Redwood City, CA: Mind Garden, 1968, 1977), 7.

² Ibid, 32-45.

³ Ibid, 9.

⁴ Ibid, 15-22.

⁵ Lambert, M.J., and Hill C.E., "Assessing psychotherapy outcomes and processes," in Bergin, A.E. and S.L. Garfield, eds., *Handbook of Psychotherapy and Behavior Change* (New York: John Wiley, 1994), 72-113.

⁶ Miller, Scott D., B.L. Duncan, J. Brown, J. Sparks, and D. Claud, "The outcome rating scale: A preliminary study of the reliability, validity, and feasibility of a brief visual analog measure," *Journal of Brief Therapy* 2, no. 2 (2003): 91-100.

⁷ Miller, Scott D., B.L. Duncan, J. Brown, and M.B. Chalk. "Using outcome to inform and improve treatment outcomes." *Journal of Brief Therapy* (2004).

⁸ Lee, Richard H., *Scientific Investigations into Chinese Qigong* (San Clemente, CA: CHI Institute, 1992, 2000), 15.

CHAPTER 3: RESULTS

**When we look at one thing in the world, we find that it is hitched to everything else.
—John Muir**

Independent Variable

The independent variable for this study was treatment type. Thirty-eight (54%) of the 70 participants received three 20-minute treatments, once weekly, with the real device and thirty-two (46%) received treatments from the inactive (sham) device.

Dependent Variables

The dependent variables in this study were the State and Trait Anxiety scores from the STAI and the Outcome Rating Scale score.

Population Demographics

A detailed description of the population is found in Chapter 2, Methodology. However, to summarize and expand on the demographics given there, the following information is presented. The 70 participants in the study were randomly assigned into treatment or control groups, with 38 (54%) in treatment and 32 (46%) in control groups. The target sample was 80 participants recruited from the schools only. However, of the 88 participants who signed up in the schools, 51 dropped out before the treatments began or after the first or second treatment, leaving 38. In order to obtain additional participants, the principal investigator recruited individuals from outside the schools.

There were 54 women (77%) and 16 men (23%). This gender imbalance may be due to the fact that 38 of the participants were recruited from schools where there are typically more female employees and parent volunteers than men. However, the gender distribution between groups is not significant with women accounting for 74% of the total in the treatment group and 81% of the total in the control group and men accounting for 26% of the treatment group and 19% of the control group. Differences in occupation, income, ethnicity, marital status, and having or not having children were not statistically significant between the groups. The distribution of those having and not having received psychological counseling in the past year was also equally distributed, with 74% of the treatment group and 81% of the control group not having had counseling in the past year. The only statistically significant variable difference between the groups was age ($t(68)=2.69, p=.01$). The mean age of the treatment group was 52.92 (± 9.62) years and the mean age of the control group was 46.53 (± 10.52) years.

Results

Efficacy of the intervention was assessed by a 2x3 repeated measures analysis of variance (ANOVA), performed using the Statistical Package for Social Sciences (SPSS) comparing the two condition groups across times between pre-test, post-test- and follow-up post-test on the STAI Y-1 and Y-2 and the ORS.

State-Trait Anxiety Inventory

Table 3 presents the State-Anxiety scores across time for treatment and control groups in terms of the means, standard deviations, and number in each group. The test of the group main effect for State-Anxiety was non significant ($F(1, 68) = 0.22, p=.64$),

indicating no difference between groups when information is combined from all three time periods. The group by time interaction was also not significant ($F(2, 136) = 0.24$, $p=.78$) indicating that there are no differences between treatment groups at each time point and no differences across time within each group.

Table 1. Summary of State-Anxiety Scores for Control and Treatment Groups.

State 1	Mean	Std. Dev.	n
Control group	37.16	9.65	32
Treatment group	35.42	11.74	38
Entire sample	36.21	10.79	70
State 2			
Control group	34.50	8.13	32
Treatment group	34.29	11.71	38
Entire sample	34.39	10.16	70
State 3			
Control group	34.34	10.05	32
Treatment group	33.26	10.41	38
Entire sample	33.76	10.19	70

Table 4 presents the means, standard deviation and number of participants for the Trait-Anxiety scores for treatment and control groups over time. The test of the group main effect for Trait-Anxiety was non-significant ($F(1,68) = 0.14$, $p=.71$). The interaction of group by time is also not significant ($F(2, 136) = 0.10$, $p=.90$).

Table 2. Summary of Trait-Anxiety Scores for Control and Treatment Groups.

Trait 1	Mean	Std. Dev.	n
Control group	36.38	8.21	32
Treatment group	37.58	11.41	38
Entire sample	37.03	10.02	70
Trait 2			
Control group	35.06	8.66	32
Treatment group	35.76	10.56	38
Entire sample	35.44	9.68	70
Trait 3			
Control group	34.28	8.60	32
Treatment group	34.79	10.42	38
Entire sample	34.56	9.57	70

Outcome Rating Scale

The Outcome Rating Scale was used to test Clinical Significance, which refers to whether or not the intervention made a positive or meaningful change in a person's life.

In this study it would mean that the treatments are worth the effort in terms of the positive changes in their lives and importance given to the effect of the intervention.

Table 5 presents the means, standard deviations and number of participants for the ORS pre-, post- and follow-up post-tests. The test of group was not significant ($F(1, 68) = 0.88, p = .35$). The group by time interaction was also not significant ($F(2, 136) = 0.06, p = .94$).

Table 3. Means, Standard Deviation and Number for ORS.

ORS 1	Mean	Std. Dev.	n
Control group	29.77	7.95	32
Treatment group	28.13	8.73	38
Entire sample	28.88	8.36	70
ORS 2			
Control group	31.27	7.08	32
Treatment group	30.03	7.66	38
Entire sample	30.59	7.37	70
ORS 3			
Control group	31.97	6.35	32
Treatment group	30.29	6.87	38
Entire sample	31.06	6.64	70

Summary of Results

The results of the repeated ANOVA on scores from the State-Trait Anxiety Inventory and the Outcome Rating Scale indicate that there is no significant change between the control and treatment groups across time or change within groups across time. Based on these results, the hypothesis that “three 20-minute treatments, performed once weekly using the Infrasound 8 Therapeutic Massager will significantly reduce the levels of stress as measured on the STAI” was rejected. The null hypothesis was not disproved, and, therefore is accepted at this time.

CHAPTER 4: DISCUSSION

**“There’s no use trying,” Alice said. “One can’t believe impossible things.”
“I dare say you haven’t had much practice,” said the Queen.
“When I was your age, I always did it for half-an hour a day.
“Why sometimes I’ve believed as many as six impossible things before breakfast.”
—Lewis Carroll**

Summary

The purpose of this study was to investigate the effects of three 20-minute treatments, using the Infrasonic 8 Therapeutic Massager, on levels of stress in adults. In this study, a quasi-experimental double-blind pre-test/post-test control group design was utilized with repeated measure of the dependent variables. The independent variable included three 20-minute self-administered treatments on the active or inactive (sham) Infrasonic 8 Therapeutic Massager (set on the #2 signal). The dependent variables were the results of State and Trait Anxiety scores on the STAI and the scores on the ORS. Seventy participants aged 25-75, were recruited from schools, a study group, the office of a chiropractor, and a dance community.

Conclusions

Using a repeated measures ANOVA with SPSS, results on the State-Trait Anxiety Inventory (STAI) and the Outcome Rating Scale (ORS) indicate no significant change between the control and treatment groups across time. These results reject the hypothesis that three 20-minute treatments, administered once a week, will significantly reduce levels of stress as measured by the STAI and the ORS.

Upon unraveling the data from this study and looking at it from different perspectives, an observation can be made that is not related to the purpose of this study but might have some value in understanding the outcome. A trend of positive change in the combined treatment and control groups can be seen on the State- and Trait-Anxiety and ORS from pretest to follow-up post-test with 93% confidence ($p < .1$) and 99% confidence ($p < .01$) respectively. What might have created an effect between pre-test and follow-up post-test in the combined groups? This change could have been due to a belief on the part of the participants that their respective device was the active Infrasound 8; thereby equating the placebo effect and treatment effect in the results. Or, perhaps it could indicate that taking 20 minutes to relax in a quiet setting can lower levels of stress. Finally, the fact that they were all volunteers and wanted to help out with the study by showing improvement may have created a bias. These hypotheses can be tested in a future design in which a wait-list group is added that does not have access to the real or the sham Infrasound 8. This phenomenon, however, does not change the conclusion that the treatment group did not show significantly lower levels of stress than the control group, but it does reveal that some degree of change took place.

Discussion

Pilot Study

The pre-study pilot study had ten participants, and the results of paired t-tests showed statistical significance on the State pre-to-post-test ($p = .025$) and on the Trait pre-to-post-test ($p = .025$) with a 97.5% confidence that the intervention was effective. These results show significant changes. The number of the participants was small, the three

treatments were administered within a 5-day period, and all participants who volunteered for the study finished all treatments and took pre-test and post-test alike. These results formed a basis on which the present study was designed.

Present Study

Strengths

Several components of the present study have strengths that contribute to its value as a good piece of research. They include a principal investigator (PI) that has the respect and love of the local community, persistence, and organizational skills. The local school district allowed for a study to be performed that had no direct relation to education in the public schools. However, the PI had been a teacher-trainer and language arts specialist in the district for many years and had the faith and trust of the school district Cabinet to conduct research that might benefit the community. In school staff meetings, the PI was able to make clear, motivating presentations to the school staff and volunteers. The chiropractic office, dance community, and local study group also honored the education, integrity, and spirit of the PI; thus opening themselves up to be participants in this study.

Another strength of the study was the research design: a quasi-experimental double-blind control group study. Neither the PI nor the participants knew which was the active Infrasound 8 and which was the inactive (sham) device. An emphasis was put on not making any assumptions about which was the real and which was the sham device. The PI reminded the participants weekly not to talk about their treatment experience with each other or with the PI herself. On one occasion, a participant tried to make a comment about the experience to the PI, and the PI abruptly stopped her and reminded her of the importance of this being a double-blind study. It is not known if the participants actually

kept their promise of not talking to each other about the study, but it is assumed (and hoped) that they did.

Having an identical-looking placebo device was also a valuable asset to the research design. One could not tell visually which one was the real device and which one was the sham device. Having two randomly selected groups added strength to the study. No one had the opportunity to consciously choose the group they would belong to for the duration of the study. This added to the attitude of openness and inquiry about the treatment.

The treatment protocol utilized in this study can be considered a strength. It is clear, easy to follow, and appropriate for the use of the Infrasound 8 as it has been used in the pilot study and by health practitioners alike. Participants check that the buttons on the front of the Infrasound 8 are set on the #2 setting for 20-minutes. This is a treatment setting and duration that has been used historically. After pushing the power button, participants hold the transducer over the middle of the chest or heart area until the power shut off. It is one of the areas of the body on which people naturally place the transducer when “playing” with the device. At the completion of the treatment, participants make three sweeps with the transducer from shoulders to ground about three inches from the left, center, and right sides of the body. These are movements used by many massage therapists and body-workers to move away any old or dislodged energy. Therefore, it seems in keeping with the practice for participants to perform these movements.

Although the settings were different for different groups of participants (school offices, lounges, storage closets, empty classrooms, etc), it appeared that most treatment locations were quiet and free from distractions. This was important so that external noise

and movement would not divert the participants' attention from self-administering the treatment in comfort.

There were advantages to the choice of measures for this study that can be considered an asset to the research design, as well as possible disadvantages that will be addressed in the next section. The STAI is an easy-to-administer, easy-to-score, reliable and valid index of either individual differences in proneness to anxiety or transitory experience of anxiety.¹ There has probably been more published research on the STAI, and more ongoing research on the STAI, than any other commercially available anxiety inventory.² The ORS is also easy- to-administer and easy-to-score.³ A visual analog measure of clinical significance, the ORS assesses change in three areas of client functioning generally considered valid indicators of treatment progress: individual or symptomatic functioning, interpersonal relationships, and social role performance such as work adjustment and quality of life.⁴ It is a brief alternative to the Outcome Questionnaire-45 (OQ-45), a widely used and well-validated measure.⁵ Participants completed these measures for the pre-test, post-test, and follow-up post-test without complaint or need for clarification.

Suggestions for Improvement

There are several factors that need to be addressed relative to this study that may be considered in subsequent replication studies, and therefore, may increase the overall strength of such studies. These factors are: population sample, time interval between treatment, number of treatments, exclusionary criteria, and possibly the dependent measures. Each of these considerations will be discussed below.

In the present study, there were 70 participants who were randomly placed into control (32) and treatment (38) groups. Differences related to the distribution of male/female, income levels, marital status, and other demographics between groups were not statistically significant. However, the original target population consisted of teachers, teacher-aides, and other adults from a public school setting. Eighty-eight volunteers from six schools initially signed up to be participants in the study. Of those 88 volunteers, 51 dropped out of the study at various junctures before the end of the study. That represents a 58% attrition rate and a possible confound to the study. Were the dropouts people who were experiencing the applied problem and the remaining participants experiencing less stress? Perhaps the clear, motivating presentations by the PI to the school staff and volunteers created a bias by giving rise to momentary enthusiasm that diminished when the commitment to taking time for treatments became a reality.

The reasons most often communicated by the dropouts were, in fact, stress-related: "I'm too stressed to continue in your study;" "I have too much on my plate to take on another project;" "I didn't have time to do my treatment;" "I had so much to do this week that I forgot to do the treatment." Often no communication occurred until the PI emailed, called, or visited the volunteer to inquire why a treatment had not been done (as indicated on the Sign-In/Out sheet) in a particular week. The unique feature of those remaining in the study (e.g., lower stress, loyalty, conscientiousness, persistence, compliance, etc.) may have influenced the results. In addition to these 37 remaining participants from the schools, a sample of convenience had to be recruited from a variety of other locations. That may also have created a bias since they were used because of their availability. The question remains, "Would the scores of those who were

unavailable have been equal to those who remained in the study or who were available as participants?”

In this study, the time interval and number of treatments might have been a factor influencing the outcome. The one-week time interval between the treatments might have been too long for the treatment to lower levels of stress. The protocol in the pilot study included the three 20-minute treatments administered across a 5-day period. When Dr. Su Chen Wu treated high school students in Beijing, China with the QGM to lower levels of stress before the college entrance exams, he administered treatments for three days in a row, resulting in 100% of the class passing the exam for some kind of college.⁶ On the other hand, perhaps the number of treatments was not sufficient to show significant change on levels of stress given the time interval of a week in between each. Between-treatment intervals or number of treatments may have been a major factor in the results being not statistically significant.

Another factor that may have influenced the present results is the outcome of the pre-test scores on the ORS. On the ORS, the most helpful index on the scale is the clinical cut off, or the 25th percentile. Scores below the clinical cutoff at intake (before treatment) indicate that the respondents would like some aspect of their lives to change or be different and are associated with earlier and larger changes in scores over the course of treatment.⁷ It is also important to note that, according to the authors of the scale, both the amount and rate of change slows as ORS scores at intake approach the clinical cutoff of 25.⁸ For those scoring above 25, the probability of improvement is statistically small, and they are on average at greater risk for deterioration in treatment.⁹ Of the 70 participants in the study, only 18 scored below the clinical cutoff on the pre-test ORS.

The pre-test mean score was 29.8 for the control group and 28.1 for the treatment group, both above the clinical cut off point of 25. The results showed no clinically significant change over time ($p=.939$) with the participants. This might suggest that the participants in this study were too healthy to show any change. This is a factor that might be taken into account as part of the exclusionary criteria.

Although choosing the dependent measures of this study (STAI and ORS) offers some advantages mentioned in the section above, it may create some limitations to the actual outcomes. The question arises, “Is the STAI sufficiently sensitive to pick up any changes?” Perhaps another more sensitive dependent measure would result in a different outcome. Other choices such as the Profile of Mood States (POMS), Beck Anxiety Inventory (BAI), Anxiety Control Questionnaire (ACQ), and Hamilton Anxiety Rating Scale ought to be examined thoroughly as possible measures of stress in a replication study. Another question presents itself regarding the ORS, “Could the ORS be far too gross a measure to be of much use when participants might be working with some level of expectancy and hope that they have received the real treatment device?” The ORS is an altered and greatly abbreviated visual analog scale patterned after the widely used Q-45. The Q-45 might be subject to more dependent measure validity of clinical significance in this research design. Again, this possibility could be considered when replicating this study.

Suggestions for Further Research

Although the present study shows no significant results between treatment and control groups over time, much has been learned about possible confounds and biases that could affect outcomes. Replication studies on levels of stress utilizing the Infrasound

8 are needed. Further research using a treatment protocol that allows less time between treatments, or having more treatments, might bring about more significant results in lowering levels of stress. Recruiting all participants from a medical clinic or other healing facility might attract volunteers who are actively seeking help to lower their levels of stress. Focusing on a group of participants who have a specific malady in common might make it easier to get compliance in staying with the treatment protocol. Screening the participants using the clinical cut off of 25 on the ORS (or another measure of clinical significance) as exclusionary criteria could also increase the probability of improvement. Choosing other measures that are more sensitive to changes might show more accurate results. Perhaps adding a wait-list group to the treatment and control groups would determine if any change was a result of the real treatment or a placebo effect.

This has been the first formal research in the United States using the Infrasound 8 on humans. It is hopefully just the beginning. Another study using the improvements suggested above would add much to the knowledge base on Infratonic Therapy. Based on anecdotal evidence of the healing effects of Infratonic Therapy in the U.S. and on the studies that have been performed in China, further research is needed for other disorders and diseases. The following are suggestions for further research:

- A replication of the study in China by Dr. Su with cases of childhood asthma could examine the effects of Infratonic Therapy on the symptoms over time, curative effect on asthma attacks, and reproduction rate of T lymphocyte subpopulation in the blood.

- Another study could examine the effects of Infratonic therapy treatments on humans using the #1 signal for reducing inflammation, as was conducted with horses by Ronald J. Riegel, DVM.¹⁰ Measured levels of hyaluronic acid and the use of thermogram imaging might serve as measures.
- A possible study of the use of Infratonic Therapy on children with digestive disorders like the one performed at the Pediatrics Department of a Beijing, China, hospital would be of value.¹¹ Symptoms such as stomachache, loss of appetite, bloating stomach, diarrhea, and constipation could be observed to determine effectiveness of treatments.
- Further research is needed that explores the same symptoms and diseases as the 1000 patients at the Beijing Military Qigong Research Institute in a study by Sun Hua Ling, M.D. Some of these conditions include: reducing pain distention and edema in sprains, bone fractures, and arthritis; pain relief in sciatic neuralgia, cancer, lumbago, and muscle stiffness; and relief in symptoms of heart disease such as arrhythmia, palpitations, blood circulation, and shortness of breath.
- Another study might offer insight on the effectiveness of Infratonic Therapy on the immune system during bacterial infections, testing body temperature and blood serum antibody levels.
- Measuring C-reactive protein is an emerging method of detecting hidden inflammation and its associated cardiovascular disease risk.¹² With heart attacks and cardiovascular disease a major health concern, an appropriate and

timely study might measure the effects of Infratonic Therapy on levels of high sensitivity C-reactive protein in the blood.

The possibilities are endless and the need is great to study safe, non-invasive therapies such as Infratonic Therapy as an alternative to prescription medications. The obstacles to conducting good, clean research at times appear insurmountable, but the focus is one step at a time, or in this case, one study at a time.

Energy Medicine, Spiritual Healing, and Infratonic Therapy

With the turn of the millennium and the dawn of the Age of Aquarius, many are beginning to focus on their spiritual and energetic dimensions. Scientists and practitioners are looking to healing practices and techniques that include our entire living matrix and latticework of energies, exploring the interconnectedness of the invisible energies that shape the way we think, feel, and live. These energies that connect our body, mind, spirit, and soul are vibrational.¹³ The field of Energy Medicine, or Vibrational Medicine, recognizes that vibrations underlie every aspect of nature: sound, heat, radiowaves, microwaves, ultrasonic waves, X rays, light, etc. It also includes subtle energies that are intelligent forces in the environment and in the body.¹⁴ It seeks to understand this energetic matrix and interact with it to facilitate healing on all levels. It is an evolving viewpoint that recognizes “all the many forms and frequencies of vibrating energy that contribute to the ‘multidimensional’ human energy system.”¹⁵ The field of Energy Medicine taps into safe, non-polluting, non-toxic therapies that utilize the very energies of nature to heal and return the body to its vibrant, natural state.

In the field of Energy Medicine, Infratonic Therapy has its roots in the ancient practice of Qigong. One of the many forms of energy that has been measured from the

hands or bodies of Qigong practitioners is infrasound. As a vibratory therapy, the Infrasound 8 Therapeutic Massager reproduces the subsonic output of emitted Qi. Researchers in China assert that as far as acoustics is concerned, the most suitable resonant frequency of human tissues is within the range of infrasonic waves and that the human body easily receives infrasonic waves.¹⁶ This study was an attempt to show the effectiveness of Infrasonic Therapy on levels of stress in adults. Although there were no significant results, the study contributes to the knowledge base of research in the field. Simply by having been a research study based on one of the vibratory energies that are transmitted through the living matrix continuum, it recognizes and acknowledges possible healing effects of an energy practice that has scarcely been explored in the Western Hemisphere. It is relevant to the field of Energy Medicine and Spiritual Healing in that it represents a form of vibratory energy, not seen or heard, but which can be absorbed by the living matrix, measured, and tested for efficacy in healing.

Chapter 4 Endnotes:

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² William F. Chaplin, "State-Trait Anxiety Inventory," in *Test Critiques, Vol I*, ed. Daniel J. Keyser and Richard C. Sweetland (Kansas City, Mo: Test Corporation of America, 1984), 626.

³ Scott D. Miller and Barry L. Duncan, *The Outcome Rating and Session Scales, Administration and Scoring Manual* (Chicago: Institute for Study of Therapeutic Change, 2000), 6.

⁴ A. E. Kazdin, "Methodology, design, and evaluation in psychotherapy research," in *Handbook of Psychotherapy and Behavior Change*, ed. A.E. Bergin and S.L. Garfield, 19-71; M.J. Lambert, et al., "The reliability and validity of the Outcome Questionnaire," in *Clinical Psychology and Psychotherapy*, 3: 249-258; M.J. Lambert and C.E. Hill, "Assessing psychotherapy outcomes and processes," in *Handbook of Psychotherapy and Behavior Change*, ed. A.E. Bergin and S.L. Garfield (New York: John Wiley, 2003), 72-113.

⁵ M.J. Lambert, et al., "The reliability and validity of the Outcome Questionnaire," in *Clinical Psychology and Psychotherapy*, 3, 249-258.

⁶ Richard H. Lee, ed., *Scientific Investigations into Chinese Qigong* (San Clemente, CA: CHI Institute, 1992, 2001), 68.

⁸ Scott D. Miller, *The Outcome Rating and Session Scales*, 20.

⁹ *Ibid.*, 12.

¹⁰ Richard H. Lee, ed., *Scientific Investigations into Chinese Qigong*, 36-7.

¹¹ *Ibid.*, 40.

¹² S.S. Bassuk, N. Rifai, and P.M. Ridker, "High-sensitivity C-reactive protein: clinical importance," *Current Problems in Cardiology* 29, no. 8 (August 2004): 439-93.

¹³ James L. Oshman, *Energy Medicine: The Scientific Basis*, foreword by Candace Pert (New York: Elsevier, 200, 2004), 121.

¹⁴ William Collinge, *Subtle Energy* (New York: Warner Books, 1998), 1.

¹⁵ Richard Gerber, *Vibrational Medicine for the 21st Century: The Complete Guide to Energy Healing and Spiritual Transformation* (New York: Eagle Brook/Harper-Collins, 2000), 5.

¹⁶ Richard H. Lee, ed., *Scientific Investigations into Chinese Qigong*, 24.

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APPENDIX A
Request for Approval of Research Study

Chula Vista Elementary School District

Date February 16, 2005

Name Terri Akin
from Finney Elem.

School or Department Retired

Address 3030 Calle Alejandro
Retired

Position Language Arts Specialist,

Jamul, CA 91935

619/669-0147

619/669-0147

Business Phone

Home Phone

1. Reason for undertaking the study:

The study fulfills partial requirements for completion of doctorate (Th.D.) at Holos University Graduate Seminary, Fair Grove, Missouri. It's goal is to contribute to the field of Complementary and Alternative Medicine as a safe, non-invasive therapy for stress regulation in adults using the Infrasound 8 Therapeutic Massager (CHI Institute, San Clemente, CA, www.chiexplorer.com).

2. Brief statement of the problem the study addresses:

The study addresses the problem of increased stress in the lives of working adults, stress that reflects the times when our physiological/psychological balance can be pushed beyond its limits to respond and adapt. This can result in the possibility of both physical and emotional illness. In the educational community, stress often reaches higher than "normal" levels. If unnoticed or unchecked, stress can lead progressively to a decrease in performance, health injury, and absenteeism.

3. Questions to be answered by the study:

What are the effects of the Infrasound 8 Therapeutic Massager on stress levels in adults? Will 3 twenty-minute self-administered treatments with the Infrasound 8 significantly reduce stress levels in adults? Will levels of anxiety and depression as measured on the State-Trait Anxiety Inventory and Zung Self-Rating Depression Scale be

reduced significantly with 3 twenty-minute self-administered treatments with the Infrasond 8 Therapeutic Massager?

4. How would the results of this study contribute to the educational efforts of the school district?

The positive results of this study would show a significant decrease in stress in teachers and other district employees who self-administer 3 twenty-minute treatments using the Infrasond 8 Therapeutic Massager over a three-week period. This would lower stress levels without prescription drugs or medication in a safe, non-invasive way, thus freeing teachers to focus on the educational needs of students and other employees to focus on their respective workload. It could reduce absenteeism of teachers and other employees and enhance positive attitudes because of lower levels of stress. This benefits the students by having teachers and other district employees physically, emotionally, and psychologically present in their work situations.

5. **METHODOLOGY:** How do you propose to investigate this problem?

A) Population to be studied (grade level, numbers, selection process, etc.): Population will be district employees (teachers, aides, custodians, principals, etc.), between the ages of 22 and 65, who agree to participate in the three-week study. The study requires 70 to 80 participants. The principal and many teachers at Finney School have expressed interest as well as other individuals.

B) Data collecting procedures and/or instruments to be used (attach copies for examination):

Two instruments will be used in this double-blind pre-test, posttest study: the State-Trait Anxiety Inventory (STAI) and the Zung Self-Rating Depression Scale (SDS), both reliable measures that are well-established and used in the field of psychology and recommended by the U.S. Preventive Services Task Force (*Guide to Clinical Preventive Services*, Second Edition). Participants will take the pretest before self-administering the Infrasond 8 or “mock device” treatments; the posttest one day following the last treatment; and the follow-up posttest 4 weeks following the last treatment.

C) Time required of:	<u>2-1/2 hours</u>	<u>N/A</u>
<u>2-1/2 hours</u>	Teachers	Pupils
Others		

D) Calendar:	<u>April 2005</u>
<u>June 2005</u>	Expected starting date
Expected completion date	

Continues

6. What assistance will you need from the school or district? (Staff time, records, etc.)

I will need 15-30 minutes of staff meeting time to orient staff (1 to 3 schools) about the study and to administer permission forms, general information forms, and pretest. Staff that participates in the study will receive 3 *free* treatments with Infrasonound 8 Therapeutic Massager (worth \$50.00 each session). This can be done on lunch or recess breaks, or before or after school. Participants who receive treatments from “mock device” will be offered the 3 *free* Infrasonound 8 treatments upon completion of the study. The study will last 3 weeks for each participant. Post-test will be taken the day following the last treatment, and follow-up posttest will be taken approximately 4 weeks after the last treatment.

7. If this research is for a college course or degree, please indicate:

Course or Degree Doctorate (Th.D.) in Energy Medicine

College or University Holos University Graduate Seminary, Fair Grove, MO

Department N/A

Name of Instructor or Sponsor David Eichler, Ph.D., Committee Chair; C. Norman Shealy M.D., Ph.D., president, Holos University Graduate Seminary, and member of Committee

If this research is for a thesis or a dissertation, has the proposal been approved by your committee or chairperson? yes

8. **RIGHTS OF HUMAN SUBJECT AND CERTIFICATE OF CONFIDENTIALITY**

I understand that when students are used as subjects, parental notification and/or approval may be required.

I understand that all data for individuals and for schools are confidential. Individuals and schools are to remain anonymous to the reader of any report written as a consequence of this study.

Signature(s)

Date

Please return completed application to:

Dennis M. Doyle, Assistant Superintendent
Operations Services and Support
Chula Vista Elementary School District
84 East J Street
Chula Vista, CA 91910

FOR DISTRICT USE ONLY
ACTION OF CHULA VISTA ELEMENTARY SCHOOL DISTRICT

Approved

Not Approved

Any information sent to staff, parents or community must be approved by the principal prior to distribution. Participation and distribution of materials is optional. All materials must include a disclaimer: **“This is not a Chula Vista Elementary School District activity.”** Each parent, student, or staff member involved in the study must be informed it is voluntary. Participation cannot be during instructional time. Interviews are to be conducted outside the school premises. Fliers and surveys distributed to community must be in English and Spanish.

Dennis M. Doyle, Assistant Superintendent
Operations Services and Support

Date

Note: Upon completion of your study, a copy of a summary must be filed with this office.

Board of Education

CHERYL S. COX, ED.D. • LARRY CUNNINGHAM • PATRICK JUDD • PAMELA B. SMITH • BERTHA J. LÓPEZ
Lowell J. Biilings, Ed.D., Superintendent



The Chula Vista Elementary School District is committed to providing equal educational, contracting, and employment opportunity to all in strict compliance with all applicable State and Federal laws and regulations. The District official who monitors compliance is the Assistant Superintendent for Human Resources, Services and Support, 84 East J Street, Chula Vista, CA 91910, phone (619) 425-9600. Any individual who believes he/she has been a victim of unlawful discrimination in employment, contracting, or in an educational program may file a formal complaint with the District's Human Resources Office.

APPENDIX B
Letter to Schools

Terri Akin

3030 Calle Alejandro
Jamul, CA 91935-3109
Home & Work: 619/669-0147
Cel: 619/248-6255
Email: terri@terriakin.com

April 22, 2005

Dear Casillas Teachers and Staff,

I am a retired teacher of the Chula Vista Elementary School district, and am now a full-time doctoral student at Holos University Graduate Seminary, Fair Grove, Missouri. This semester, I am conducting my formal research, and its focus is stress management. For my study, I would like to discover if levels of stress experienced in adults can be lowered in a safe, effective way without the use of prescription drugs or other medications. Knowing how stressful working in a public school can be at times, I am offering you the opportunity to participate as subjects in my three-week study.

My goal is to discover whether three 20-minute treatments using a therapeutic hand-held device called the Infrasond 8 will significantly reduce levels of stress in adults. The treatment consists of sitting in a chair and holding the transducer of the device over your heart for 20 minutes, once weekly, for three weeks. Your participation in this double-blind control group study would consist of filling out a demographic questionnaire, signing a consent form, taking the pre-treatment inventories (approximately ten minutes total), self-administering three free Infrasond 8 treatments (valued at \$ 50.00 per session), and taking the post-treatment inventories following the

last treatment and again four weeks later. After the completion of the study, those participants who are in the control group will be offered the opportunity to receive the real Infrasound 8 treatments.

I am looking forward to meeting with you and explaining this in detail. Your participation in this study will be a major contribution to the field of Complementary and Alternative Health Care.

Sincerely,

Terri Akin

APPENDIX C
General Letter of Introduction

Terri Akin

3030 Calle Alejandro
Jamul, CA 91935-3109
Phone & FAX: 619/669-0147
Email: terri@terriakin.com

December 2005

To Whom It May Concern,

I am a thirty-five-year resident of San Diego, a retired teacher from the Chula Vista Elementary School District, and a doctoral candidate in Energy Medicine at Holos University Graduate Seminary, Fair Grove, Missouri. I hold an M.A. in Human Behavior and an M.S. in Education. I also am an author and co-author of over nine educational books on human development, anger management, character education, and affective education, now published by Pro-Ed in Austin, Texas. I am a contributor to the most recent *Chicken Soup for the Soul Books: Stories for a Better World*. At present, I am conducting research towards my doctorate on stress management. I would like to include any adult who feels a great deal of stress in their lives.

My research involves an electronic device known as the ***Infrasound 8*** Therapeutic Massager, distributed by the CHI Institute, San Clemente, CA (www.chi.us). This research is a double-blind placebo control group study to determine if three twenty-minute self-administered treatments using the ***Infrasound 8*** significantly reduce stress levels in adults. A pilot study conducted last December and January, using the State-Trait Anxiety Inventory, indicates that it may.

I am offering you, as a participant, three free infrasound treatments here in the doctor's office. Control group participants will be offered the "real" treatments at the end of the study. The protocol is easily manageable, as you self-administer each weekly twenty-minute treatment using the ***Infrasound 8*** right here in the office. Your commitment to filling out the information questionnaire, informed consent, and two pre-, post-, and follow-up post surveys will contribute an important piece of research to the field of complementary and alternative medicine. In turn, the treatments are an alternative to drugs in managing anxiety and stress.

You may contact me at the above email or phone numbers to answer any questions.

Sincerely,

Terri Akin

APPENDIX D
Sample Items from STAI

Self-Evaluation Questionnaire

(Printed with permission from Mind Garden, Inc.)

Sample Questions:

Directions: Read each statement and circle the appropriate number to the right of the statement to indicate how you feel:

- 1= NOT AT ALL
- 2= SOMEWHAT
- 3= MODERATELY SO
- 4= VERY MUCH SO

STAI Form Y-1
(How you feel *right now*)

I feel nervous	1	2	3	4
I feel at ease	1	2	3	4
I feel indecisive	1	2	3	4

STAI Form Y-2
(How you generally feel)

I feel satisfied with myself	1	2	3	4
I feel inadequate	1	2	3	4

For further information and ordering information of STAI, contact www.mindgarden.com or 650/261-3500.

APPENDIX E
Outcome Rating Scale

Outcome Rating Scale (ORS)

Name _____ Age (Yrs): _____
ID# _____ Sex: M / F
Session # _____ Date: _____

Looking back over the last week, including today, help us understand how you have been feeling by rating how well you have been doing in the following areas of your life, where marks to the left represent low levels and marks to the right indicate high levels.

Individually:
(Personal well-being)

I-----Examination-Copy-----I

Interpersonally:
(Family, close relationships)

I-----Examination-Copy-----I

Socially:
(Work, School, Friendships)

I-----Examination-Copy-----I

Overall:
(General sense of well-being)

I-----Examination-Copy-----I

Institute for the Study of Therapeutic Change

This form may be downloaded for free from: www.talkingcure.com

© 2000, Scott D. Miller and Barry L. Duncan

APPENDIX F
Questionnaire for Participants in Study

Information Questionnaire

Name: _____

Gender: _____

Age: _____

Occupation: _____

Annual Income: _____ \$0 to \$25,000. _____ \$26,000-\$ 50,000, _____ \$50,000 to \$100,000,
_____ above \$100,000.

Marital Status: _____ Married, _____ Divorced, _____ Widowed, _____ Single,
_____ Living with partner/significant other

Ethnicity: _____ Caucasian, _____ Asian, _____ African American, _____ Native American,
_____ Other (Please specify) _____

Children? _____ Yes, _____ No. If yes, how many _____ and ages? _____

Have you received professional help for any emotional or stress-related problems within the past year?
_____ Yes, _____ No. If yes, please specify.

Have you received a diagnosis by a licensed health care worker as having schizophrenia, manic depression,
or psychosis within the past 5 years? _____ Yes, _____ No

For office use only, Code number: _____

APPENDIX G

Informed Consent for Participants

Informed Consent Statement

(1 of 2)

Holos University Graduate Seminary supports the practice of protection for human subjects participating in research. The following information is provided for you to decide whether you wish to participate in the present study. You should be aware that even if you agree to participate, you are free to withdraw at any time without penalty.

We are interested in studying the effects of Infrasonic Therapy sessions on levels of stress in adults. It consists of three weekly sessions, self-administered, holding the transducer (hand-held portion of the device) of the Infrasound 8 Therapeutic Massager (or a placebo device) for twenty minutes against the chest or heart area while sitting in a chair in a quiet place.

There are many approaches utilized for the management of stress. If you feel that your present stress level is having a significant impact on your health, participation in this research study is not appropriate. If you need assistance accessing stress management resources in your community, we would be happy to assist you.

You will be asked to fill out a self-reporting inventory prior to the intervention sessions, one day after the sessions, and four weeks following the last session. You will be participating in three 20-minute sessions, one per week for three weeks. If at any time you feel too uncomfortable about the therapeutic sessions, you may choose to withdraw from the study, without penalty of any kind.

There are no known or anticipated risks to using this device on or near one's person, as long as one does not have an electronic device implanted in their body (such as a pacemaker). Benefits, while indirect to you, will provide our field with clinical information on the efficacy of using this device for the treatment of stress.

If you are a participant in the placebo group, it will be revealed to you after the study is complete, and you will be offered, free-of-charge, three twenty-minute sessions using the real Infrasound 8 Therapeutic Massager.

Your participation is solicited although strictly voluntary. We assure you that your name will not be associated in any way with the research findings. The inventories are not an evaluation of you, and the information will be identified only by a code number. All data will be kept in the bottom drawer of a locked file cabinet in the home office of the principal investigator. The FDA has the right to review the research files at any time.

Please sign your consent with full knowledge of the nature and purpose of the procedures, the benefits you may expect, and the discomforts and/or risks that may be encountered. I appreciate your assistance.

If you would like additional information concerning this study before or after it is complete, please feel free to contact me by phone, mail or email. If you have concerns or questions about your rights as a research participant you may contact the Holos University Graduate Seminary Dean of Academic Affairs at (888) 272-6109, 5607 S. 222nd Road, Fair Grove, Missouri, 65648.

(2 of 2)

Sincerely,

Terri Akin
Principal Investigator
3030 Calle Alejandro
Jamul, CA 91935
(619) 669-0147
email: terri@terriakin.com

David Eichler, M.A., Ph.D.
Research Committee Chairperson
Chrysalis Farm, 24900 Chieftan Road
Lawrence, KS 66044
(785) 841-3550
email: david4847@sbcglobal.net

Subject's Signature

With my signature I acknowledge that I have received a copy of the consent form to keep.

APPENDIX H

Outline of Presentation

Introductory Session

- Introduction of principal investigator as doctoral candidate of Holos University Graduate Seminary.
- Description of the research study and purpose: to determine if three 20-minute treatments, administered once per week, using the *Infrasound 8* will lower levels of stress as measured by the STAI and ORS.
- Description of the Infrasound 8, giving brief history and theory, and showing the device, unplugged.
- Description/demonstration of treatment protocol:
 - Sit comfortably in chair.
 - Make sure device is set on #2 setting. Push in “20- minute” button.
Turn on device by pressing red on/off button.
 - Hold transducer against chest or heart area until it turns itself off.
 - With device off, perform three sweeps with the transducer from chin to floor, a few inches from the body.
 - Replace transducer on device.
- Invitation to participate, using criteria for inclusion and exclusion, and offering three free Infratonic Therapy treatments, either during the study or after the study is complete. Consent form and confidentiality explained.

- All qualified volunteers fill out general information (demographic) questionnaire and sign general consent form to participate in study. All participants take State Trait Anxiety Inventory and Outcome Rating Scale pretests.
- Participants draw colored squares from top hat to determine which group they will be in. Participants sign sheets indicating Red or Blue group participation.
- Transparency of Check-In/Out sheet for use before and after treatments shown on overhead projector and explained.
- Participants begin weekly self-administered treatments in following week.

APPENDIX I Explanation of Procedures

Terri Akin

3030 Calle Alejandro
Jamul, CA 91935-3109
Home & Work: 619/669-0147
Cel: 619/248-6255
Email: terri@terriakin.com

Dear Research Participants,

Please fill out and return the following forms to reception desk:

- ***Information Questionnaire***- this is kept confidential and your name will be replaced with a code number.
- ***Informed Consent***- for the FDA; keep one and return one.
- ***Self-Evaluation Questionnaire***, both sides- one for right now condition; one for conditions over time. Fill out quickly without analyzing.
- ***Outcome Rating Scale***- put a vertical line where you perceive yourself now on the scale before treatments.

You will again fill out the ***Self-Evaluation Questionnaire*** and ***Outcome Rating Scale*** after your third treatment and then four weeks later. That will conclude the study for you.

When you do a treatment, **please** sign in on the form indicating which treatment you have done (Session 1, 2, or 3). All three sheets will be on the clipboard near the Infrasound 8. If you don't sign, your data will not be valid for the study.

Please do not discuss the treatment in any way with other study participants or with me. Wait until the conclusion of the study when you have filled out the follow-up post surveys.

Many thanks,

Terri Akin

APPENDIX K
Treatment Protocol Poster

Reminder to All Research Study Participants

- Sign name and times on sign-in/out sheet.
- Make sure that Infrasound 8 is set for 20 minutes on #2 signal (See dots on machine).
- If red on/off button is in, push on it; let it pop out; then push it in again to start power. Red lights will flash when power is on.
- Hold or place transducer (part with handle) comfortably over middle of chest or heart.
- Red lights will stop flashing after 20 minutes. If buzzer sounds, depress red on/off button.
- When finished, make 3 sweeps with the transducer from shoulders to ground about 3" from left, center and right sides of body. Do so standing or sitting. Replace transducer on unit.

Thanks,

Terri Akin