SOCIO-BEHAVIORAL PILOT STUDY TO DETERMINE THE EFFECT OF TESLAR WATCH IN HEALTHY VOLUNTEERS WITH NON-RESTORATIVE SLEEP

PROTOCOL DRAFT
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ABSTRACT

This socio-behavioral pilot study will evaluate the potential benefits of the Teslar watch on healthy volunteers with non-restorative sleep. A total of ten (10) healthy volunteers will participate by using the Teslar watch over the course of one week period.
Five (5) healthy volunteers will initially be enrolled and at completion an interim analysis will be done to determine if another 5 volunteers should be enrolled. Assessment will include clinical sleep quality questionnaires, Polysonographic testing, and diary. Additional measures at pre and post test will include medical history, sleep history, pregnancy screen, and basic clinical evaluation. The primary outcome is evaluating the potential benefits and socio-behavioral changes in restoring non-restorative sleep for healthy volunteers using the Teslar watch.

INVESTIGATORS

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SPONSORS

Teslar

STUDY SITE

Sleep Disorder Solutions, Inc
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INTRODUCTION

This document is a protocol for a human research study. This study is to be conducted according to federal standards of Good Clinical Practice (FDA Title 21 part 50), applicable government regulations and international research policies and procedures (Helsinki Declaration).

BURDEN OF DISEASE

In the modern industrialized society many people have severe sleeping problems or a lack of restorative sleep. Instead of feeling refreshed upon awakening they complain about tiredness, lack of concentration, irritability and negative influences of their working performances although they had enough sleeping time. [1]

Non-restorative sleep is associated with daytime impairment (irritability, physical and mental fatigue) and deterioration of performance. Historically, "nonrestorative sleep appeared as an insomnia symptom in the DSM-III-R of the American Psychiatric Association in 1987".[2] Since then, there has been various epidemiological studies and clinical studies.[2] However, NRS has been associated with obesity [2], cardiovascular disease [3-4], chronic fatigue syndrome [2,6,7], and fibromyalgia [2]. Also as previously mentioned, NSR is a symptom for insomnia, restless leg syndrome, and periodic limb movement disorder. [1]

"In western industrial nations, approximately 15 - 35% of the populations suffer from light to heavy sleep disorders, which are known to cause severe discomfort and even cardiovascular health risks. A significant number of those suffering from non- restorative sleep are not properly diagnosed; in the U.S. alone 10% of the roughly 10 - 20 million affected people do not receive medical attention."[5] Dr. Ohayon study of 25580 individuals in 7 European countries showed that the prevalence of NSR was 10.8%; thereby having increased societal costs with regards to decreased productivity and diminished quality of life. [2]

Presently, the conventional approach towards nonrestorative sleep is evaluating different causes such as circadian rhythm disturbances, psychiatric or organic causes, sleep hygiene, and or intake of sleep disturbing substances.[1] Addressing these underlying causes may be difficult as times as many people do not recognize the causes of nonrestorative sleep.

Awareness and education on managing nonrestorative sleep are the most common ways of addressing the issues associated with nonrestorative sleep as its effects can be detrimental to daytime performance.

Recently testimonials from wearers of the Teslar watch have reported that feeling better in the morning or having slept better. The Teslar Technology has been used for the last 20 years to assist the body in fortifying its own biofield, resulting in wearers being calmer and less tense.

It is the purpose of this preliminary socio-behavioral, pilot study to further explore the effects of wearing the Teslar watch, on healthy volunteers with nonrestorative sleep.

BACKGROUND: TESLAR TECHNOLOGY

Present in every watch are two chips that assist the body's meridians to return to a state of alpha (calmness felt while in meditation or prayer). The following paragraphs will historically discuss the development of the chip with Teslar Technology.

The works of Nikola Tesla, who, in addition to inventing Alternating Current (AC) electricity, performed extensive research into coils, resonance, standing-wave/scalar fields and free energy was studied.[13] The beneficial effects of extreme low frequencies found in electricity were studied to determine whether it was possible to prevent or reduce the harmful ELF from interacting with the physical body. The possibility of bathing the body in the frequency environment emits naturally by the earth, the Schumann Resonance (currently monitored by scientists at UC-Berkeley's Seismology Laboratory to average around 7.83 Hertz) was researched to assist in reducing the adverse effects of electromagnetic field (EMF).[14]

The research focus was to reestablish the natural frequency envelope around the body - by reducing the effects of increasingly chaotic invasion of man-made electromagnetic field (EMF). The results provided the human body an opportunity to reestablish its own natural electromagnetic environment. It was also hypothesized that bathing the body inside this earth signal would provide a steady, calming frequency in the Theta/Alpha brainwave region, normally associated with relaxation and creativity, meditation and prayer.

Using Nikola Tesla's standing-wave theories, an early prototype of the TESLAR technology was developed. Using a flat, special coil wound inside a battery-powered watch, the TESLAR chip was developed. Confirmed by earlier physics studies, TESLAR technology showed biological effects on the human body's own electromagnetic field. [8-12]

Functional Description

The TESLAR technology was designed to resonate with the earth's unique 7 to 9 Hz Alpha wave-like signal that interacts with and strengthens the body's own electromagnetic energy field. Similar to the Earth's natural 7.8 Hz signal and the Alpha wave signals emitted by the brain when the body is calm or meditating or when athletes are in states of high performance, this TESLAR signal was also designed to help reinforce the body's energy field against the possible negative effects of external, low-energy electromagnetic fields (EMF).[14]

In a TESLAR watch there are two specially designed TESLAR chips. This technology works with the watch's standard components:

1) The watch battery, which creates an electric field
2) The quartz-crystal timing coil, which creates a magnetic field

The TESLAR chips interact with these two fields to create a resonant circuit which produces a zero-point (scalar) waveform. Modulated on this scalar waveform, the TESLAR chip sends a 7 to 9 hertz frequency into and around the body via the left arm's triple warmer meridian (energy conduit). The TESLAR watch is an active device and it oscillates around the earth's natural Schumann Resonance frequency. The TESLAR technology's frequent oscillation allows the

signal to stay energetically interactive, which is important because the body can acclimate to a stimulus that stays constant for any given period of time.

The TESLAR technology works via the triple warmer meridian. The triple warmer meridian is one of the body's primary energy conduits. Dr. Charles Shang, M.D. in Internal Medicine, describes the body's meridian system as a measurable, distinct signal communication system with a high electric conductance of the meridian system.[15] Dr. Shang also states that stimulation of the meridian system may activate the self-organizing system of an organism and improve its structure and function at a more fundamental level. [16]

The triple warmer meridian starts at the 4th finger (from the thumb) and travels up the arm, through the shoulder, behind the ear and finally to the corner of the eye. It is the energy conduit has been known to activate the immune system. [17]

This meridian enables the TESLAR technology's signal to be carried throughout the body. This process bolsters the body's naturally occurring electromagnetic field – the biofield - working much like a protective shield. Dr. Valerie Hunt, UCLA Prof Emeritus, describes the Teslar technology as helping to create a biofield with more coherency, strength, and greater breadth of frequency.[18]

Figure 1 – Teslar watch and Teslar bracelet

Technical Specifications

The Teslar technology works with a commercially available wristwatch movement. The measurable energy emitted from the watch is primarily due to the watch movement and battery. The TESLAR technology does not emit electromagnetic energy above the ambient noise of the environment, as measured by Underwriter's Laboratory (Product Safety Testing) in 2002.

Mechanism of Action

Teslar watches contain a non-Hertzian signal-producing chip. The non-Hertzian, scalar chip functions as described in Block Diagram (see Figure 2).

In a paper on Scalar Energy, Glen Rein, Ph.D. states that, "biological systems are sensitive to non-hertzian energy..." "Although such energy has not been measured in the body and is not being considered by the bio-medical community (they barely recognize a functional role for conventional EM fields), it is likely to be involved in biological processes since quantum mechanical analysis of biological systems has recently indicated their inherent nonlinearality."[8]

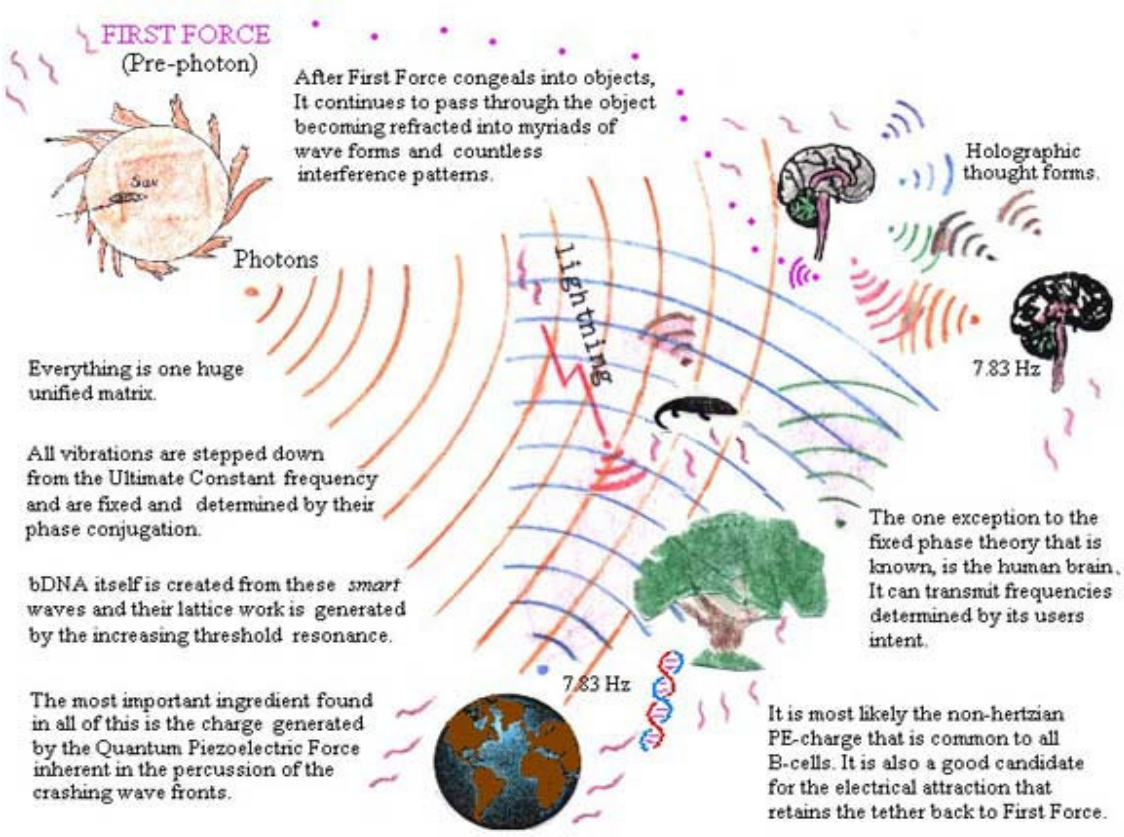


Figure 2 – Block Diagram

When understood, we will find that practitioners such as Reiki and CranioSacral types are not sending specific frequencies, such as for liver repair or stomach repair, but ONE basic non-hertzian PE-charge that "systemically" ignites each and every B-cell. Otherwise, it is like the analogy of towing a broken car and expecting the tow to fix it.[8]

The non-hertzian PE-charge relieves the body of stress. Peter Kelly of Dimensional Science states, "It is well known that physical stress hampers the body's immune system. Therefore, the release of stress, particularly chronic stress, can have beneficial effects by enabling the body to relax and recover the normal level of its own natural and vital immune and healing qualities."[8]

The Quantum Piezoelectric Force (QPF) states that "rhythmic percussion generates a non-hertzian PE-charge that systemically ignites every cell."[8]

In 2004, laboratory studies led by physicist, Dr. Volodymyr Krasnoholovets at the National Institute of Physics in Kiev, Ukraine, investigators discovered that effects of the Teslar technology can be measured using various water-based solutions (including blood plasma). Specifically, in a series of 5 studies, exposure to Teslar technology was shown to have some affect on (1) the polarization and alignment of water molecules and thus their electrical characteristics; (2) certain electromagnetic frequencies traveling through blood plasma solution; (3) internal vibrational dynamics of certain crystals; (4) rates of molecular vibration at particular frequencies under certain conditions; and (5) the crystal formation of an oxygen-saturated amino acid solution. The in-vivo implications of these results is the subject of further research.[1,2,4,5,6,7]

SAFETY

In September 2002, Underwriter's Laboratory (UL) International EMC Services in Northbrook, IL, measured two quartz movement watches provided by ELF Laboratories, original manufacturer and supplier of TESLAR technology since 1986. One watch included TESLAR technology while the other watch, identical in style and material, did not include TESLAR technology. The watches were tested in a fully anechoic chamber to allow for minute electromagnetic field measurements.[10]

UL EMC Services found no significant electromagnetic field (10 KHz to 30 MHz) for either watch above the noise floor of the measurement system. Using a magnetic field meter, they found a difference in magnetic field strength for the watch incorporating TESLAR technology, yet both watches were still below typical ambient magnetic field strengths, as defined by UL EMC Services.[10]

UL found no electromagnetic field strengths above typical environment levels in either the quartz watch incorporating TESLAR technology or the quartz watch without TESLAR technology. Based on that finding, there is no indication quartz watches incorporating TESLAR technology should present an increased safety risk to the wearer beyond that of standard quartz wrist watches.[10]

PRIMARY OBJECTIVE

Evaluate the potential benefits and socio-behavioral changes in healthy volunteers using the Teslar watch in restoring non-restorative sleep.

This socio-behavioral pilot study will evaluate the potential benefits of the Teslar Watch. A total of 10 healthy volunteers will participate by using the Teslar Watch over the course of one week period. Five (5) healthy volunteers will initially be enrolled and at completion an interim analysis will be done to determine if another 5 volunteers should be enrolled. Assessment will include clinical sleep quality questionnaires, Polysonographic testing, and diary. Additional measures at pre and post test will include medical history, sleep history, pregnancy screen, and basic clinical evaluation. The primary outcome is evaluating the potential benefits and socio-behavioral changes in restoring non-restorative sleep for healthy volunteers using the Teslar watch.

HYPOTHESIS
A watch with Teslar technology is more effective for helping restoring non-restorative sleep (a non-medical sleeping problem) in healthy volunteers within eight days.

RESEARCH PLAN

POPULATION RECRUITMENT AND SCREENING
The study population is to consist of 10 healthy volunteers with non-restorative sleep (a non-medical sleeping problem).

Screening Process: Prior to the screening process, all subjects will be informed and voluntarily sign the informed consent, if the volunteer agrees to participate in the study, he/she would begin the screening process. Prior to enrollment, each patient will go through a screening process of a telephone interview and a polysomnographic (PSG) screening night to determine if the subject is eligible. There is no compensation for screening failures. At enrollment, inclusion and exclusion criteria will be reviewed and subjects will be enrolled with a TESLAR watch at baseline for commencement of study participation.

INCLUSION CRITERIA
- Participants are 18 years or older
  Female subjects of childbearing potential must be nonpregnant and nonlactatin; they also must a a negative pregnancy test results prior to pre-screening PSG
- The participant should be healthy individual adults.
- The subject has a confirmed Non-Restorative Sleep from the Pre-Screening Polysomnography.
- Participant should be capable of understanding and willing to comply to study protocol and signed Informed Consent at screening prior to any study-related procedures being performed.
- The subject should have a body mass index (BMI) between 18 and 34, inclusive.

EXCLUSION CRITERIA
- The subject has no compliant of Non-Restorative sleep
- The subject has sleep schedule changes required by employment (e.g. shift worker) within one month prior to study pre-screening process.
- The subject has flown across greater than three time zones within 7 days prior to screening.
- Clinically diagnosed for depression, anxiety or any other psychiatric disorders
- Have other sleep disorders (DSM –IV) such as sleep related breathing disorders (AHI≥15), periodic leg movements with arousals (PLAMAI≥15), restless leg syndrome, narcolepsy, parasomnia, circadian sleep wake rhythm disorders, excessive morningness and eveningness (normal bedtime should be within the 21:00 hours -1:00 hour range)
- Clinically taking prescribed and OTC medications for depression, sleep or anxiety (Paxel, Prozac, Zoloft, sleeping pills, (See Appendix II) within the last two weeks
- The subject has a history of drug abuse within the pass 12 monts as defined in DSM-IV-TV
- Clinically diagnosed with cardiovascular problems, hepatic, renal, endocrine, gastrointestinal, pulmonary, hematologic, or metabolic disease within the last 30 days

- Other sleep-disturbing medical disorders (painful arthritis, thyroid condition, etc.)
- Subject is engaged in drug use.
- Pregnant or attempting to be pregnant during the month while participating
- Simultaneous participation or participation in another study in the last 30 days
- Electrical device, pace makers
- Traveling/ unavailable from enrollment of study through the month
- Unwilling to sign informed consent

SAMPLE SELECTION

Ten (10) participants will be randomly selected from Sleep Disorder Solutions, Inc's recruitment and advertisement efforts (local AARP chapters, Sleep Disorder Solutions, Inc's database, etc) to participate in the socio-behavioral study. Five (5) participants will initially be recruited, screened and enrolled. Upon termination of 5 participants, an interim analysis will be performed to determine whether the study should continue enrolling 5 more participants or terminate. Enrollment of all 10 participants is pending results of interim analysis. All participants will be part of the experimental group. This group will be observed to determine the sleep effects of the Teslar watch.

DESIGN

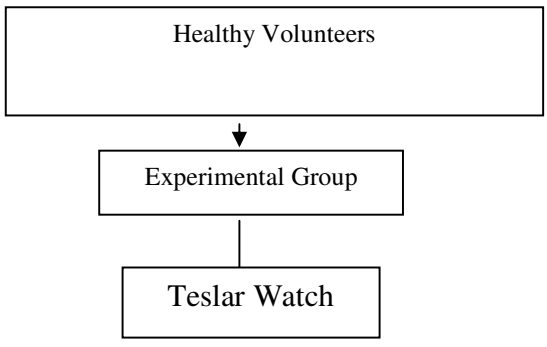
This is a prospective, socio-behavioral study. The study is proposed to evaluate the benefits and socio-behavioral changes of Teslar watch in healthy volunteers with non-restorative sleep..

TREATMENT PROTOCOL

EXPERIMENTAL GROUP

This group of 10 participants will receive Teslar watch to be worn 24 hours a day for 8 days.

The research staff will be trained to monitor wearer while participating in study.



POTENTIAL BENEFITS:
The theoretical applications of the Teslar watch as it relates to enhancing the triple warmer meridian function in the body is to return the body to a state of calmness using subtle energies. The Teslar watch uses subtle energy technology to reinforce the body's own defenses to screen the body from potentially harmful electronic pollution caused by the abundance of machines, electronic gadgetry, and power lines; all done in a way that allows the body to operate more harmoniously within the earth's natural resonance field.

POTENTIAL RISKS:
The Teslar watch is environmentally friendly, non-invasive without reported adverse effects, but with the possibility of discomfort depending on individual's sensitivity. The rubber material of the bracelet may cause irritation to the skin in individuals with allergies.

INTERRUPTION OR DISCONTINUATION OF USING TESLAR WATCH
An interruption or discontinuation of the using the Teslar watch would occur for the patients

1. whose sensitivity is so great that the participant is unable to wear the watch 24 hours/day
2. who do not comply to treatment or are difficult to locate
3. who do not wear the watch during the day

Participants who discontinue using the watch after initiation of the study will not be replaced. If a participant discontinues wearing the watch during the day or the participant decides to discontinue his/her participation, then the information collected will be analyzed as secondary information.

COMPLIANCE TO TREATMENT
All activities of the participants, i.e. all acceptable concomitant medications used, and the frequency of visits, will be documented. Participants will visit the Sleep Lab three times for observation (baseline, Day 30 for termination) with midpoint check in, to document any adverse effects that might occur.

DATA COLLECTION
Data Collection
Basic demographic data, medical history, and concomitant medications will be collected following informed consent into the study. A demographic questionnaire will include the following basic information. Pre-and Post Sleep Quality Questionnaire, Sleep Diary and Sleep Assessment Questionnaire were selected. The Epworth Sleepiness Scale score was used as a continuous variable.

Pre and Post Sleep Quality Questionnaire
The "Sleep Quality" questionnaire is designed to give an objective determination of the patient's sleep quality through sleep latency, duration, number of arousals, total sleep time and subjective measures, including the perceived restfulness of the sleep.[19] Sleep quality will be collected prior to each night's sleep at the Sleep Lab and again in the morning.

Sleep Diaries (i.e. Post Sleep Questionnaire)
The sleep diaries will be used to record the amount of sleep and awakenings, the medications taken and when, the amount of caffeine, alcohol, and drugs and when and the subject's activities before going to bed.[19] The subjects will be asked to keep the diary and complete on a daily bases for the duration of the one week study.

SF 36 Quality of Life Questionnaire
RAND developed the 36-Item Short Form Health Survey (SF-36). SF-36 is a set of generic, coherent, and easily administered quality-of-life measures. These measures use patient self-reporting and are now widely utilized by research organizations for assessment of quality of life outcomes in adults.[20]

Epworth Sleepiness Scale
The Epworth Sleepiness Scale was developed by Dr. Murray Johns of Melbourne, Australia to measure daytime sleepiness.[21] The Epworth Sleep Scale will be administered at Day 0, Day 4, and Day 8.

Polysomnography
Polysomnography is a sleep study. It measures your sleep cycles and stages by recording brain waves (EEG), electrical activity of muscles, eye movement, breathing rate, blood pressure, blood oxygen saturation, and heart rhythm.[22] If subject passes the screening polysomnography, then two more polysomnography will be done at Day 0 and Day 7 with termination at Day 8.

Urine Drug Test and Pregnancy Test
Both a urine drug test and pregnancy test will be administered to female subjects enrolled in the study at Screening to ensure that drug and/or pregnancy is not an exclusion.

CRITERIUM OF EVALUATION

1. Clinical and Sleep History
2. SF 36
3. Sleep Diary
4. Sleep Quality Questionnaire
5. Epworth Scale
6. Polysomnography

PATIENT PROGRESSION

The evaluations would occur:

1. Screening (Day -1):
    a. Pre-Screening Questionnaire
    b. Inclusion/ Exclusion Review
    c. Informed Consent
    d. Clinical and Sleep History with Vitals
    e. Pregnancy Test
    f. Urine Drug Test

g. Epworth Scale
h. SF 36
i. Con Meds
j. Non-serious AE
k. Pre-Sleep Questionnaire (also review all the caffeine, alcohol requirements)
l. Polysomnography

2. At the moment of entering the study (Day 0):

Morning

a. Post-Sleep Questionnaire
b. Vitals
c. Inclusion/Exclusion Review
d. Call subject to notify if qualified for study participation

Evening

e. Medical History and Sleep History
f. Sleep Diary Review
g. Vitals
h. Pre-Sleep Questionnaire
i. Polysomnography
j. Con Meds
k. Non-serious AE
l. Schedule for study participation
m. Sleep Diary given and explanation of Sleep Diary to be completed during the study
n. Watch given to subject

3. The morning on the day after the 1st PSG (Day 1):
   a. Post-Sleep Questionnaire
   b. Vitals
   c. Confirmation that patient left with copy of IC, schedule and reminders

4. Mid-study participation check-in (Day 3 or 4):
   a. Check in
   b. Inclusion/Exclusion Review
   c. Sleep Diary review (Check to make sure watch is being worn)
   d. Con Meds
   e. Non-serious AE

5. In preparation for Termination Date (Day 7)
   a. Inclusion/ Exclusion Criteria
   b. Check to make sure wearing the watch 24/7

c. Pre-Sleep Questionnaire (also review all the caffeine, alcohol requirements)
d. PSG paperwork
e. Sleep Diary Review
f. Con Meds
g. Non-serious AE

6. Termination Date (Day 8)
    a. SF 36
    b. Post-Sleep Quality Questionnaire
    c. Epworth Scale
    d. Sleep Diary review
    e. Con Meds
    f. Non-serious AE
    g. Subject Compensation

Safety: The evaluation of safety would be based on the monitoring and the registration of all adverse events recorded on a daily basis through termination date: clinical history (the vital signs, the physical conditions and the weight) and other biometric measurements.

The information of all adverse events would be communicated in real time by the participant, to be recorded at the questioning period by the investigator, or detected during the physical exam which would be collected and registered in the Case Report Form –Adverse Events and followed in the appropriate manner by research staff. A non-serious adverse event is a sign, symptom or undesirable illness that occurs after the initiation of the administration of the modality of the study, even though the event is not related to the modality. A serious adverse event is defined as pregnancy during the study, overnight hospitalization, or death. In either case, all adverse events will be recorded on the Case Report forms. In the case of a serious adverse event, the research staff must communicate the serious adverse effect to the Principal Investigator so that he/she may determine the relevancy of the modality to the adverse event and report to the IRB. The lab values or abnormal test results constitute an adverse event only if it induces clinical symptoms; if the patient needs treatment or if it is considered to be of clinical significance, it would be registered. (See Appendix II: *Exact Definitions and Procedures*)

Each adverse event should be described on the Case Report Form –Adverse Events including the following:

1. Duration (Initial date and Termination date)
2. Severity (Mild, Moderate, Severe)
3. Related to Treatment (Related, Not related)
4. Actions taken and if Adverse Event resolved

Note: Information collected on participants that discontinue due to adverse events or drop out may still be used for secondary endpoint analysis as deemed by the biostatician.

STUDY PLAN

	Day -0	Day 0	Day 0-7	Day 8/ Termination Date
Inclusion/ Exclusion Review	X	X	X	X
Informed Consent	X			
Clinical and Sleep History with Vitals	X			X
Pregnancy Test	X			
Urine Drug Test	X			
Sleep Diary	X	X	X	X
SF 36©	X			X
Sleep Quality Questionnaire	X	X	X	X
Epworth Scale	X	X	X	X
Polysomnography	X	X	X	
Dispense Teslar Watch		X		
Concomitant Meds and Adverse Events	X	X	X	X

DATA MANAGEMENT

The data collection forms will be developed by research staff, in collaboration with the Sleep Lab and its staff. The data will be collected on the source documents by site coordinator and Sleep lab staff and stored in locked file cabinets according to the HIPAA.

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period.

The site coordinator and Sleep Lab research staff will be responsible for collecting and entering the data; there will be a control of the validation programs to verify that no errors occurred. A data file and a hard copy of the data once participant has completed study will be sent to Teslar in the appropriate coded format where it will be input into a database, created especially to compile and analyze the information. Again, there will be a control of the validation programs to verify that no errors occurred. This process would signal appropriate measures to be taken to correct errors and to verify the correct information. Database and data analysis programs include Microsoft Access and SPSS or SAS for data analysis.

STATISTICAL METHODS

This socio-behavioral research study will explore the potential benefits of Teslar watch in healthy adults with non-restorative sleep.

- All statistical analysis would be done using the significant level of 0.05.
- To analyze the baseline information, descriptive statistics will be used and to observe the difference this will be done.
- To analyze the results, SPSS will be used.

The sample size is 10 and reflects a pilot study only – to observe any possible benefits of the Teslar watch.

ETHICS AND GOOD CLINICAL PRACTICE

The study will be conducted according to the protocol and the principles of Good Clinical Practices, for that reason it should be done according to:

1. Helsinki Declaration
2. Informed Consent
3. Review of present protocol by Institutional Review Board/ Independent Ethics Committee (QMR International).

This protocol and any amendments will be submitted to a properly constituted independent Ethics Committee (EC) or Institutional Review Board (IRB). The decision of the IRB concerning the conduct of the study will be made in writing to the investigator and a copy of this decision will be provided to the sponsor before commencement of this study. The IRB should provide a list of IRB members. All regulatory documents should be kept in regulatory binder.

All subjects for this study will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. See Attachment 1 for a copy of the Subject Informed Consent Form. If warranted, the consent form will be submitted with the protocol for review and approval by the IRB for the study. The formal consent of a subject must be obtained before that subject is submitted to any study procedure. This consent form must be signed by the subject or legally acceptable surrogate, and the investigator-designated research professional obtaining the consent.

FUNDING SOURCE

This study is financed through a grant from the manufacturers of the Teslar watch, Teslar Corporation. All funding will be arranged for the Sleep Disorder Solutions, Inc

to conduct the study appropriately according to national and international standards and Good Clinical Practices (GCP).

CONFLICT OF INTEREST

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by a properly constituted Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study.

SUBJECT STIPENDS OR PAYMENTS

All participants that completed PSG screening night and are later defined as screening failures ineligible to participate by the principal investigator will receive $50.00 in compensation. If subject withdraws from the study, the subject will be allowed to keep the watch; however, monetary compensation will be forfeited. Subjects who complete the study will be allowed to keep their watch and will receive $300.00 in compensation for participating upon study completion (Day 8).

PUBLICATION PLAN

Neither the complete nor any part of the results of the study carried out under this protocol, nor any of the information provided by the sponsor for the purposes of performing the study, will be published or passed on to any third party without the consent of the study sponsor, Teslar. Any investigator involved with this study is obligated to provide Teslar with complete test results and all data derived from the study.

Fabriccio Lettelier, MD will be the principle author of the final report, with a draft due to Teslar within 30 days of study termination (last subject data collected). This schedule allows 15 days for the biostatician's analysis and 15 days for Principal Investigator's final report. Unless stated otherwise by the sponsor, the intended use of the study's results is for internal company use only and not for research publication purposes.

TIMELINE

ACTIVITY ON MONTHLY BASIS	1	2	3	4	5
DESIGN PROJECT	X				
PROJECT APPROVAL		X			
COORDINATION TO EXECUTE PROJECT		X			
SELECTION AND STRATIFICATION OF PATIENTS		X			
EVALUATION OF INITIATION		X			
FINAL EVALUATION			X	X	
INPUT DATA INTO DATABASE			X	X	
ANALYSIS AND EVALUATION OF DATA			X	X	
ANALYSIS OF STATISTICS			X	X	
FINAL REPORT			X	X	

The timeline represent beginning in August, 2007 with the projected completion of project in November, 2007 pending positive results from the interim analysis. If another 5 subjects are needed, then completion of the study will be January, 2008.

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INFORMED CONSENT FORM
See Attached 1

CASE REPORT FORMS
See Attached 2

APPENDIX I

Definitions:

Non-Restorative Sleep: is associated with daytime impairment (irritability, physical and mental fatigue) and deterioration of performance. NSR is a symptom for insomnia, restless leg syndrome, and periodic limb movement disorder.

Sleep Latency: is defined as the time it takes for one to fall asleep after the lights are turned off

Periodic Limb Movement: is a disorder of the nervous system that affects sensation and movement in the legs and causes the limbs to feel uncomfortable. Relief can be temporarily gained by moving the legs which cause sufferers to seem fidgety and restless.

Restless Leg Movement: is an uncomfortable creeping, crawling, tingling, pulling, twitching, tearing, aching, throbbing, prickling or grabbing sensation in the calves that occurs while sitting or while lying down. Whatever the nature of the sensation, the result is an uncontrollable urge to relieve it by moving the legs.

Sleep Apnea: is a cessation of breathing that occurs during sleep. Usually due to obstruction of the airway, it can also be due to inability of the brain to initiate respiration.

Insomnia: is the difficulty initiating sleep, difficulty maintaining sleep, early morning awakening, and non restorative sleep.

Narcolepsy: is a sleep disorder marked by sudden, uncontrollable urges to sleep, causing an individual to fall asleep at inappropriate times. Medications and behavioral approaches such as scheduled naps can help control narcolepsy.

Parasomnia: is a type of disorder characterized by abnormal behavioral or physiological events occurring in association with sleep, specific sleep stages, or sleep-wake transitions. Parasomnias listed in the DSM-IV include Nightmare Disorder, Sleep Terror Disorder, Sleepwalking Disorder, and Parasomnia Not Otherwise Specified. (DSM-IV; American Psychiatric Association, 1994, p.579).

Circardian Sleep-Wake Rhythm Disorders: is a persistent or recurring pattern of sleep disruption resulting either from an altered sleep-wake schedule or an inequality between a person's natural sleep-wake cycle and the sleep-related demands placed on him or her. The term circadian rhythm refers to a person's internal sleep and wake-related rhythms that occur throughout a 24-hour period.

APPENDIX II
List of drugs to be used as exclusion criteria:

Insomnia

ALPRAZOLAM (XANAX)
AMYTAL
BENZODIAZEPINES
BROMAZEPAM (LEXOTAN)
BYTYRATES DERIVATIVES
CHLORAL HYDRATE (WELLDORM)
CHLORDIAZEPOXIDE
CHLORMETHIAZOLE (HEMINEVRIN)
CLORAZEPATE (TRANXENE)
DIAZEPAM
DIPHENHYDRAMINE, DIMENHYDRINATE
FLUNITRAZEPAM (ROHYPNOL)
FLURAZEPAM (DALMANE)
GABAPENTIN
LOPRAZOLAM (DORMONOCT)
LORAZEPAM (ATIVAN)
LORMETAZEPAM
MIRTAPAZINE
NEFAZADONE
NITRAZEPAM (MOGADON)
OLANZEPINE
OXAZEPAM
QUETIAPINE
SECONAL
SONERYL
TEMAZEPAM
TOPIRATMATE
TRAZODONE
TRICLOFOS
TUINAL
ZALEPLON
ZELEPLON (SONATA)
ZOLPIDEM (STILNOCT)
ZOPICLONE (ZIMOVANE)

Depression

AMITRIPTYLINE (LENTIZOL, TRIPTAFEN)
AMOXAPINE (ASENDIS)
CLOMIPRAMINE (ANAFRANIL)
DOTHIEPIN (PROTHIADEN)
DOXEPIN (SINEQUAN)
IMIPRAMINE (TOFRANIL)
LOFEPRAMINE (GAMANIL)
MAPROTILINE (LUDIOMIL)
MIANSERIN
NORTRIPTYLINE (ALLEGRON, MOTIPRESS, MOTIVAL)
TRAZADONE (MOLIPAXIN)
TRIMIPRAMINE (SURMONTIL)

APPENDIX III

In the media, Teslar watches are being worn by likes of **Oprah, Madonna, Rupert Murdoch, and Pat Riley** to name a few.

Testimonials:

Mark Lancaster, the Tory Member of Parliament for Milton Keynes North-East said that the watch "seemed to make [him] sleep more deeply." October, 2006

Justine Greenan, the Tory Member of Parliament for Putney said that "she slept deeper" while wearing the watch. October, 2006

Kenta Bell, Triple Jumper, No. 2 in the world stated:
"This is single-handedly the most phenomenal piece of sports enhancement / sports recovery equipment available on the market today. When wearing the watch I experienced drastic changes in both my performance level and energy levels. I must say that at first I was a skeptic to the entire theory of if and how this all worked. However, after wearing the watch for an extended period of time over several days over a 24-hour period if time I began to notice that I was no longer capable of achieving a full nights sleep anymore. At first I put no thought into until one night I removed the watch before bed and slept the whole night through. At this point I realized that the watch had me so energized and wired up that I was recovering and feeling completely refreshed midway through, and I was no longer able to fall back asleep.

From **Laurie Trapp, DC, Chiropractor, 1992 & 1996 Olympic Trials Competitor**:
"I heard about the Teslar watch from Olympic coach Randy Huntington and other elite athletes… I noticed an immediate effect on my sleep: I slept deeper and through the night more often…"

From **Steve O'Brien, CBS-FM Radio On-Air Host**:
"Last summer I began wearing my Teslar watch, and since the first week, the reaction I have enjoyed most is a much more peaceful night's sleep. In addition, wearing the watch all day seems to improve my overall peace of mind and mood."

From the **White and Ivory Jewelry store website**:
As a result of the "TESLAR Effect", past wearers have experienced: Deeper, more restful sleep; More calm and less tension; Improved concentration; Increased levels of energy; An over-all improvement in well-being.

From **Spa week website**:
Various research studies by independent scientists since 1986 have shown a wide variety of interesting effects from TESLAR Technology, including improved sleep habits for professional athletes and less stress for British Parliament Members.

From the **Oprah website**:
(http://www.oprah.com/presents/holiday2003/gifts/pres_hol2003_gifts_cloth_02.jhtml):
Madonna gave Oprah this hip, colorful watch with six different bands. And it's not only fashionable, it's good for you too! A special chip in the watch emits a signal that they claim helps you sleep better, feel less stress and increase your energy!

APPENDIX VI

Definitions

Adverse Event

An ***adverse event*** (AE) is any symptom, sign, illness or experience that develops or worsens in severity during the course of the study. Intercurrent illnesses or injuries should be regarded as adverse events. Abnormal results of diagnostic procedures are considered to be adverse events if the abnormality:

- results in study withdrawal
- is associated with a serious adverse event
- is associated with clinical signs or symptoms
- leads to additional treatment or to further diagnostic tests
- is considered by the investigator to be of clinical significance

Serious Adverse Event

Adverse events are classified as serious or non-serious. A ***serious adverse event*** is any AE that is:

- fatal
- life-threatening
- requires or prolongs hospital stay
- results in persistent or significant disability or incapacity
- a congenital anomaly or birth defect
- an important medical event

Important medical events are those that may not be immediately life threatening, but are clearly of major clinical significance. They may jeopardize the subject, and may require intervention to prevent one of the other serious outcomes noted above. For example, drug overdose or abuse, a seizure that did not result in in-patient hospitalization, or intensive treatment of bronchospasm in an emergency department would typically be considered serious.

All adverse events that do not meet any of the criteria for serious should be regarded as ***non-serious adverse events***.

Adverse Event Reporting Period

The study period during which adverse events must be reported is normally defined as the period from the initiation of any study procedures to the end of the study treatment follow-up. For this study, the study treatment follow-up is defined as 30 days following the last administration of study treatment.

Preexisting Condition

A preexisting condition is one that is present at the start of the study. A preexisting condition should be recorded as an adverse event if the frequency, intensity, or the character of the condition worsens during the study period.

General Physical Examination Findings

At screening, any clinically significant abnormality should be recorded as a preexisting condition. At the end of the study, any new clinically significant findings/abnormalities

that meet the definition of an adverse event must also be recorded and documented as an adverse event.

Post-study Adverse Event

All unresolved adverse events should be followed by the investigator until the events are resolved, the subject is lost to follow-up, or the adverse event is otherwise explained. At the last scheduled visit, the investigator should instruct each subject to report any subsequent event(s) that the subject, or the subject's personal physician, believes might reasonably be related to participation in this study. The investigator should notify the study sponsor of any death or adverse event occurring at any time after a subject has discontinued or terminated study participation that may reasonably be related to this study. The sponsor should also be notified if the investigator should become aware of the development of cancer or of a congenital anomaly in a subsequently conceived offspring of a subject that has participated in this study.

Hospitalization, Prolonged Hospitalization or Surgery

Any adverse event that results in hospitalization or prolonged hospitalization should be documented and reported as a serious adverse event unless specifically instructed otherwise in this protocol. Any condition responsible for surgery should be documented as an adverse event if the condition meets the criteria for and adverse event.

Neither the condition, hospitalization, prolonged hospitalization, nor surgery are reported as an adverse event in the following circumstances:

- Hospitalization or prolonged hospitalization for diagnostic or elective surgical procedures for a preexisting condition. Surgery should ***not*** be reported as an outcome of an adverse event if the purpose of the surgery was elective or diagnostic and the outcome was uneventful.
- Hospitalization or prolonged hospitalization required to allow efficacy measurement for the study.
- Hospitalization or prolonged hospitalization for therapy of the target disease of the study, unless it is a worsening or increase in frequency of hospital admissions as judged by the clinical investigator.

Recording of Adverse Events

At each contact with the subject, the investigator must seek information on adverse events by specific questioning and, as appropriate, by examination. Information on all adverse events should be recorded immediately in the source document, and also in the appropriate adverse event module of the case report form (CRF). All clearly related signs, symptoms, and abnormal diagnostic procedures results should recorded in the source document, though should be grouped under one diagnosis.

All adverse events occurring during the study period must be recorded. The clinical course of each event should be followed until resolution, stabilization, or until it has been determined that the study treatment or participation is not the cause. Serious adverse events that are still ongoing at the end of the study period must be followed up to determine the final outcome. Any serious adverse event that occurs after the study period and is considered to be possibly related to the study treatment or study participation should be recorded and reported immediately.

Reporting of Serious Adverse Events

Study Sponsor Notification by Investigator

A serious adverse event must be reported to the study sponsor by telephone within 24 hours of the event. A Serious Adverse Event (SAE) form must be completed by the investigator and faxed to the study sponsor within 24 hours. The investigator will keep a copy of this SAE form on file at the study site. Report serious adverse events by phone and facsimile to:

[Name of Sponsor contact phone fax]

At the time of the initial report, the following information should be provided:

- Study identifier
- Study Center
- Subject number
- A description of the event
- Date of onset
- Current status
- Whether study treatment was discontinued
- The reason why the event is classified as serious
- Investigator assessment of the association between the event and study treatment

Within the following 48 hours, the investigator must provide further information on the serious adverse event in the form of a written narrative. This should include a copy of the completed Serious Adverse Event form, and any other diagnostic information that will assist the understanding of the event. Significant new information on ongoing serious adverse events should be provided promptly to the study sponsor

IRB Notification by Investigator

Reports of all serious adverse events (including follow-up information) must be submitted to the IRB within 10 working days. Copies of each report and documentation of IRB notification and receipt will be kept in the Clinical Investigator's binder.