

CLINICAL PILOT STUDY TO DETERMINE THE EFFICACY OF TESLAR WATCHES TO ASSIST IN REDUCING STRESS IN BRITISH MEMBERS OF PARLIAMENT

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ABSTRACT

This pilot study was designed to evaluate the efficacy and potential benefit of the Teslar Watch to assist in reducing stress levels in British Members of Parliament working in high stress environments. A total of 25 healthy British Members of Parliament took part. Participants were assigned either a Live Teslar Watch or a placebo over the course of a four-week period. Stress was assessed subjectively by Clinical stress questionnaires and visual analogue scale, and stress resilience by heart rate variability (HRV). Additional measures at pre and post- test were used on SF8 Health questionnaires. The primary outcomes were efficacy as measured by a reduction of stress levels, improvement of sleep, and an increase of energy.

Despite the lack of statistical significance there were some interesting trends to note.

- (1) The placebo group showed on average an increase in stress whereas the live group a larger decrease in stress. If this difference in change of approximately 4 units is clinically important then we would need a larger study to detect this with statistical significance.
- (2) The direction of the change in health looks in favour of Teslar compared with placebo.
- (3) The Tension Index in the upright position reduced by 11 on average for the Live group whereas the placebo group showed an increase on average.
- (4) There was also a trend towards improvement in sleep in the Teslar group. This was supported by the observation of several positive comments from MPs in this regard that had been wearing the Live device but not from those that were wearing placebos. The significance of this result was compromised by 65% of MPs not reporting any sleep disturbance at the outset. It is likely that this trend may prove significant in a larger study.

The results of this pilot study are of sufficient interest and potential importance to now lead us to conduct a larger study.

SPONSORS

Success By Association, Inc (SBA)

STUDY SITE

Houses of Parliament, London, UK

PRIMARY OBJECTIVE

Determine the efficacy of the Teslar watch to improve stress, sleep, and energy of British Members of Parliament in a high stress environment, in comparison with sham watch.

INTRODUCTION

Stress is one of the leading causes for absenteeism in the workplace in the UK. According to the Health and Safety Commission (HSC) and Health and Safety Executive (HSE), who are responsible for the regulation of almost all the risks to health and safety arising from work activity in Britain, stress is a major cause of disease in the workplace. The following bullet points summarize the latest studies done in the UK to determine the severity of this preventable disease.

- The 2003/4 survey of Self-reported Work-related Illness (SWI03/04) prevalence estimate indicated that over half a million individuals in Britain believed in 2003/4 that they were

experiencing work-related stress at a level that was making them ill. The Stress and Health at Work Study (SHAW) indicated that nearly 1 in 5 of all working individuals thought their job was very or extremely stressful.

- Estimates from SWI03/04 indicate that self-reported work-related stress, depression or anxiety account for an estimated thirteen million reported lost working days per year in Britain.
- Survey data suggest that the incidence of work-related stress and related disorders in the British population was unchanged between 2001/2 and 2003/4 although there is evidence of a rise in incidence from 1995 to 2001/02. The latest years of THOR surveillance data indicated a fall in cases of work-related mental ill-health. Overall this suggests that the incidence of work stress is no longer rising in Britain. However, interpretation of these data are complex and imprecise, and more years of data are required to properly assess trends.
- Occupation and industry groups containing teachers and nurses, along with protective service occupations and some managerial groups have high prevalence rates of work-related stress in the SWI and SHAW surveys. The THOR datasets SOSMI and OPRA also report high incident rates of work-related mental illness for these occupational groups, along with other public sector workers such as police officers, social workers, prison officers, UK armed forces personnel, medical practitioners and those related administrative or managerial roles. Although based on smaller case numbers train drivers and telephonists also had relatively high rates of work-related mental ill-health in THOR data.²⁰

Presently, the conventional approach towards stress is minimal. Most workplace environments use the standard approach of education and awareness such as the HSE's case study of Somerset County Council. The organization, Somerset County Council, used the following components as their interventions to combat stress:

Listeners' Service, Training documents for Managers to identify and assist with coping with stress, Comprehensive 2 day training course, Comprehensive 21 page document, Counseling Services, Awareness Training Day Program, and Presentations and pamphlets. This program cost the County more than £100,000 to implement with regards to design, implementation, monitoring, and documenting results.³

Although awareness and education on managing stress are important for those working in high stress environments, at times the interventions can be time-consuming and costly.

Aside from work related pressures, stress also originates from different sources: lifestyle, family, work, etc. Not often considered as sources of stress are environmental pollutants related to our daily use of modern devices that can lead to increasing stress in the body. Less than 75 years ago, we did not have cell phones, computers or live near high-tension wires and our bodies were in balance with the earth's natural frequencies. Today, electronic pollution has increased multifold as we have increased our usage of television, radio, cellphones and other electronic gadgets. As a result of this drastic and relatively sudden increase, scientists worldwide have been routinely demonstrating, since the 1970's and still today, the resulting harmful biological effects on the human species. Today, a technology exists that can assist employees without time-consuming workshops or presentations to be more productive in the workplace. This technology

has been used in the Teslar watch for 20 years and helps address these harmful environmental pollutants by assisting the body to fortify its own biofield (electromagnetic field), resulting in wearers noticing they are generally calmer and less tense when using the technology.

BACKGROUND: TESLAR WATCH

For the past 25 years, scientists have been gathering data showing that exposure to electromagnetic frequencies (EMF) may have non-thermal biological effects on the human body. In 1979, Johns Hopkins University published a study in the American Journal of Epidemiology indicated that homes of children who developed cancer were often found near high-tension electric power lines (Wertheimer and Leeper).

Following this landmark study, many statistical and laboratory studies showed links between EMF and disease and actual biological effects of EMF. Some of these studies have been published in scientific journals such as the American Journal of Epidemiology, Nature, American Journal of Industrial Medicine, and Carcinogenesis, to name a few. In 1989, scientists reported to the US Congress on these studies and the biological effects of EMF from power transmission lines (Nair, Morgan, Florig). Only recently have local governments in countries like Spain and France begun enacting legislation outlawing cell-phone relay towers near schools and apartment buildings due to strong public demands. Some countries, like Switzerland and parts of Italy, have already adopted precautionary exposure limits to EMF.

Yet in most countries, scientific and political communities continue only to debate whether EMF even affects the human body (non-thermally), despite 25 years of research warning of EMF's danger. Like tobacco, for many years the official position was "There is no clear link to disease, but smoking MAY be harmful to health"; the de facto U.S. government response to EMF has become, "There is no clear link to disease, but you MAY want to limit your exposure."

In 1976, Dr. Andrija Puharich became interested in the biological effects of EMF when Aviation Week & Space Technology reported on strange radio signals coming from the USSR, to which the US Government was protesting. Concerned about the possible biological effects intended with that signal, Puharich began research into the biological effects of ELF. Around the same time, Ilonka Harezi was researching bio-electromagnetic phenomena and its influence on the body and mind with Dr. Patrick Flanagan, PhD. Her research brought her into the realm of energy, resonance, and the mobius coil.

In 1984, Dr. Andrija Puharich and Ilonka Harezi joined forces. Rather than focusing on the possible deleterious effects of EMF or ELF, Puharich and Harezi chose to look at whether there could be beneficial effects of ELF on the body and whether it was possible to prevent or reduce the harmful ELF from interacting with the physical body.

Together, Dr. Puharich and Ms. Harezi studied 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. They also researched the possibility of bathing the body in the frequency environment emitted naturally by the earth, the Schumann

Resonance (currently monitored by scientists at UC-Berkeley's Seismology Laboratory to average around 7.83 Hertz) to assist in reducing the adverse effects of EMF.

Over the past 50 years, society has seen an increase of technological advancements which have increased our exposure to hazardous EMF. Hence, Dr. Puharich and Ms. Harezi's focus was to reestablish the natural frequency envelope around the body - by blocking out or reducing the effects of this increasingly chaotic invasion of man-made EMF. The results provided the human body an opportunity to reestablish its own natural electromagnetic environment. They 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.

Combining their own experience and knowledge with Nikola Tesla's standing-wave theories, Dr. Puharich and Ms. Harezi developed an early prototype of the TESLAR technology in 1985. Using a special coil wound inside a battery-powered bracelet, preliminary results were promising. However, the design needed improvement so Ms. Harezi set out to develop a process whereby the coil would fit onto a smaller, more flat surface. She succeeded with the TESLAR chip.

In 1986, Ms. Harezi and Dr. Puharich placed the TESLAR chip inside a standard wristwatch. Confirmed by early studies, TESLAR technology reinforced the human body's own electromagnetic field, 24-hours a day.

Functional Description

The TESLAR technology has been designed to emit a 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).

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 stimuli that stay 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 which "overlaps and interacts with other systems but is not simply part of the nervous system or circulatory system." 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 than symptomatic relief."

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 ben known to activate the immune system.

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.



Figure 1 – Teslar watch

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 nonlinearity.”⁸

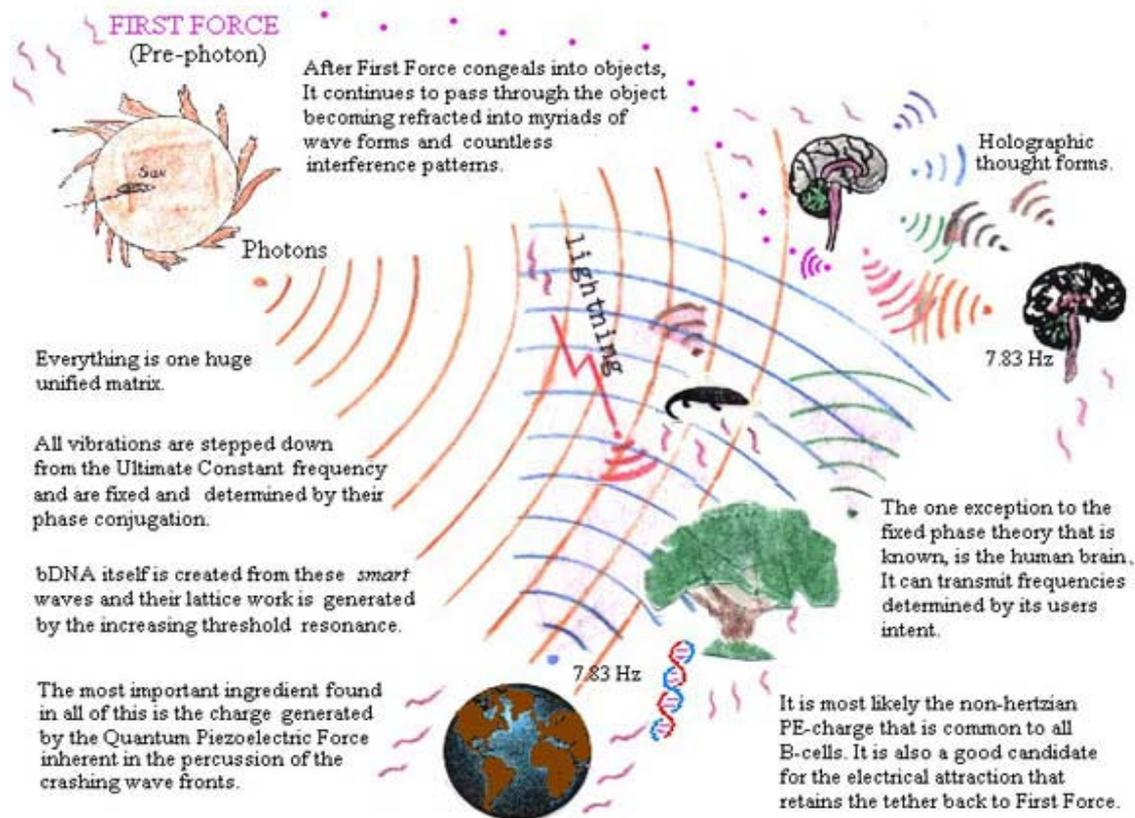


Figure 2 – Block Diagram

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.

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."

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

POTENTIAL BENEFITS:

The theory of Teslar shielding is that it transforms harmful ELF signals and provides an enhanced body electric pathway for the harmful frequencies to use in bypassing the body's nervous system. The Teslar uses subtle energy technology to screen the body from potentially harmful electronic pollution caused by the abundance of machines, electronic gadgetry, and power lines, 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.

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.

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

RESEARCH

Researchers began independent testing on the original TESLAR watch in 1988. In an independent pilot study done in 1989, Dr. Eldon Byrd, PhD, former U.S. Navy scientist for the investigation and research of the biological effects of ELF, observed a decrease in overall frequency amplitude and a shift toward lower frequencies in EEG recordings from individuals wearing the TESLAR watch. This pilot study demonstrated that the brain throws off 80% of the assaulting ELF with the help of the TESLAR.¹¹

Other studies have used Electro-dermal Screening (EDS). Electro-dermal screening was developed 35 years ago by Dr. Reinhold Voll, M.D., who combined the principles of acupuncture with modern technology. Each individual structure in the body has its own

electromagnetic field. According to EDS, the strength of this electromagnetic field can be measured at identified acupuncture points, each point having a direct relationship to a specific organ. Using sensitive instruments, one can measure the electromagnetic potential at each point and thus draw a conclusion as to the electrical balance of the inner organs.

Using EDS in 1991, Dr. Anthony Scott-Morley, PhD, M.D., tested a variety of devices claiming to protect the subject from various environmental stresses. While testing an early version of the analog TESLAR watch, Dr. Scott-Morley showed the presence of the watch enabled the body to screen out or block ambient signals within our environment and those produced by generators and computer terminals. Testing the TESLAR on many of his patients, he recorded dramatic improvements in the energy level readings of most organs.¹² Wolde Korol, Diplomat of Acupuncture, replicated Dr. Scott-Morley's findings in 1992.¹³

Dr. Glen Rein, PhD, while at Stanford Medical School, conducted in-vitro research using the TESLAR watch. Dr. Rein's results showed that the presence of the TESLAR watch provided an environment in which there was, on average, 137% enhancement of human lymphocyte proliferation (immune function).¹⁴ Another test demonstrated that nerve cells could inhibit their uptake of noradrenalin (a depression-fighting process) by as much as 19.5% in the presence of the TESLAR watch.¹⁵

In June, 2002, the results of a pilot Heart-Rate Variability (HRV) study conducted by Dr. Michael Borkin, N.D., appeared in *Alternative Medicine Magazine* demonstrating the TESLAR watch's positive influence in the presence of a cell phone.¹⁶ HRV is the measurement of the beat-to-beat changes in heart rate, giving a dynamic glimpse into the autonomic nervous system's (ANS) state. This system controls the beating of the heart, the movement of the gastrointestinal tract and the secretion of hormones by the endocrine glands, among other vital functions. Thus, an HRV test is a good measurement of a body's overall response to stimuli.¹⁷ Dr. Borkin stated that his HRV study showed that the use of the TESLAR watch "may in fact compensate for some of the negative impact of using a cell phone."

In 2003, British Medical Doctor, Nyjon Eccles, Member of the Royal College of Physicians, saw similar results on patients. Dr. Eccles' HRV testing confirmed that without the TESLAR watch, the autonomic nervous system becomes stressed when exposed to an energized mobile phone. While wearing the TESLAR watch in the presence of an energized cell phone, Dr. Eccles' results revealed a "stabilizing effect" on or even "beneficial stimulation" of parasympathetic regulatory system activity.¹⁸

Dr. Valerie Hunt, professor emeritus of UCLA and founder of the BioEnergy Fields Foundation, has performed extensive research on the human body's electromagnetic field.⁹ Dr. Hunt's experience with the TESLAR technology has led her to conclude that wearing the TESLAR watch "makes the [biofield] more dynamic and coherent, so that its transactions with the world are not just reactionary, but also selective."¹⁹

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}

METHODS

The study population consisted of 25 British Members of Parliament (MP) who had been identified as healthy MPs working in a high stress environment and meeting the inclusion and exclusion criteria detailed below.

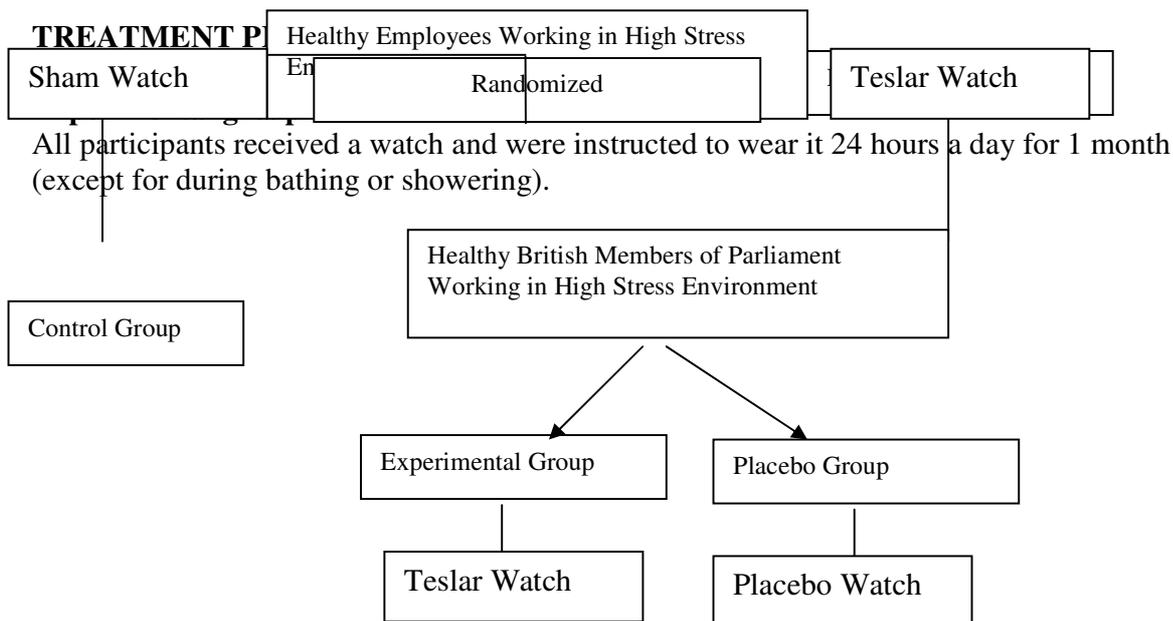
Before being selected, the British Members of Parliament were provided with an outline of the study and requested to voluntarily sign the informed consent.

INCLUSION CRITERIA

- Participants were 18 years or older
- Healthy individuals
- Working in high-stressed environment
- Difficulty sleeping or other symptoms related to high stress
- Be willing to sign an Informed Consent

EXCLUSION CRITERIA

- Low stress lifestyle and workplace, no stress
- Clinically diagnosed and taking medications for depression, sleep or anxiety (Paxel, Prozac, Zoloft, sleeping pills, (See Appendix I)
- Clinically diagnosed with cardiovascular problems
- Clinically diagnosed with diabetes
- Pregnant or attempting to be pregnant during the month while participating
- Simultaneous participation or participation in another study in the last 30 days
- Wearing an electrical device such as a pace maker
- Traveling/ unavailable from enrollment of study through the month
- Unwilling to sign informed consent



They were not informed whether they were receiving a Live or a placebo device. In this respect the Study was conducted single blind.

COMPLIANCE TO TREATMENT

Interruption or discontinuation of using teslar watch

An interruption or discontinuation of the use the Teslar watch occurred for the patients

1. whose sensitivity was so great that the participant was unable to wear the watch 24 hours/day
2. who did not comply to treatment or were difficult to locate
3. who did not wear the watch 24 hours a day

Participants who discontinued using the watch after initiation of the study were not replaced. If a participant discontinued wearing the watch or the participant discontinued his/her participation, their information was still collected and analyzed as secondary information, if this was at all possible.

Any additional changes in activity of of the participants, e.g. addition of a medication or anyother lifestyle changes were documented. Participants were visited twice for observation (baseline, Day 30 for termination) with a midpoint check in, to document any adverse effects and whether there had been compliance with the study protocol.

DATA COLLECTION

Baseline Data

Basic demographic data, medical history, and concomitant medications were collected following informed consent into the study. Questionnaires include the SF-8 (Quality of Life measurement) and the Perceived Stress Scale 10. In addition 2 further questions were incorporated on a visual analogue scale basis to assess quality of sleep and subjective stress levels.

Quality of Life

The SF-8TM Health Survey was selected for use as a general functional health status (FHS) questionnaire because it is reliable, valid, and takes only one or two minutes to administer. The SF-8TM uses a single question to capture each of the eight health domains originally validated in the widely-used functional health status measurement tool the SF-36[®]. The eight domains are physical functioning, social functioning, role limitations due to physical problems, role limitations due to emotional problems, emotional well-being, energy/fatigue, pain, general health perception and health change. An example of the SF-8 can be found in appendix II. The SF-8TM served as a secondary outcome measure and will be administered at baseline and at the one month termination.

Perceived Stress Measures

The instrument used most often is the Perceived Stress Scale (PSS; Cohen, Kamarck & Mermelstein, 1983; Cohen & Williamson, 1988). The PSS is a measure of the degree to which situations in one's life are appraised as stressful. Items were designed to tap how unpredictable, uncontrollable, and overloaded respondents find their lives. There are three versions of the scale, with 4-items, 10-items, or 14-items. The 10-item version was used since it is thought to have maximum reliability, although the 4-item version can be used for telephone interviews and situations where the number of items is critical. This scale assessed the amount of stress in one's life rather than in response to a specific stressor and has been used widely in studies of both mental and physical health.

Heart Rate Variability

Based on Heart Rate Variability (HRV) analysis, Nerve-Express is a fully automatic, non-invasive computer-based system designed for quantitative assessment of the Autonomic Nervous System (ANS). HRV analysis is based on measuring variability in heart rate; specifically, variability in intervals between R waves - "RR intervals". These RR intervals are then analyzed by spectral (as in Nerve-Express) or some other form of mathematical analysis (e.g., chaos, wavelet theories). Such mathematical analysis generates multiple parameters; typically 20-30. The problem of Sympathetic Nervous System (SNS)- Parasympathetic Nervous System (PSNS) quantification, which has remained for many years the principal dilemma of HRV analysis, is specifically in reducing all possible variations of these multiple parameters to a quantitative relationship between only two parameters: the SNS and the PSNS. Nerve-Express focuses on solving the problem of SNS-PSNS quantification. This is achieved by using algorithms and a new approach based on one of the leading theories of Artificial Intelligence - Marvin Minsky's Frame Theory. Nerve-Express objectively and reliably evaluates the state of ANS in "real-time" (up to 24 hours) as well as during Orthostatic test and Valsalva maneuver combined with Deep Breathing. Due to its highly sophisticated HRV analysis, Nerve-Express results uses precise recognition and classification of 74 ANS states with a corresponding qualitative description for each one.

CRITERIUM OF EVALUATION

1. Clinical History
2. Quality of Life: Quality of Life (SF 8)
3. Clinical Stress Evaluation: Stress Response Inventory and VAS
4. Heart Rate Variability

PATIENT PROGRESSION

The evaluations would occur:

1. At the moment of entering the study:
 - a. Clinical History
 - b. Quality of Life: Quality of Life (SF 8)
 - c. Clinical Stress Evaluation: Stress Response Inventory
 - d. Subjective Stress Test: Visual Analogue Scale
 - e. Heart Rate Variability
2. At the 15 day after using the watch
 - a. Check in
 - b. Telephone interview with Personal Assistant
3. At the 30 day after using the watch/ Termination Date:
 - a. Lifestyle change checklist
 - b. Quality of Life: Quality of Life (SF 8)
 - c. Clinical Stress Evaluation: Stress Response Inventory
 - d. Subjective Stress Test: Visual Analogue Scale
 - e. Heart Rate Variability

Safety: The evaluation of safety was based on the monitoring and the registration of all adverse events recorded on a monthly basis through termination date.

Any adverse events was communicated by the participant and recorded at the questioning period by the investigator, collected and registered in the Case Report Form –Adverse Events and followed in the appropriate manner by research staff. A non-serious adverse event was deemed to be a sign, symptom or undesirable illness that occurred after the initiation of the administration of the treatment, even though the event is not related to the treatment. A serious adverse event was defined as pregnancy during the study, overnight hospitalization, or death. In any case, all adverse events were recorded on the Case Report forms. (See Appendix III: *Exact Definitions and Procedures*).

Note: Any information collected on participants that discontinued due to adverse events or drop out was still used for secondary endpoint analysis as deemed by the biostatistician.

STUDY PLAN

	Pre-X	Day 15	Day 30/ Termination Date
Clinical History/ Lifestyle change	X		X
Clinical Stress Evaluation: Stress Inventory Response	X		X
QoL SF8	X		X
Subjective Stress Test: Visual Analogue Scale	X		X
Heart Rate Variability	X		X
Check In		X	

DATA MANAGEMENT

The data collection forms were developed by SBA staff, in collaboration with Dr. Nyjon Eccles. The data were collected on these forms by Dr. Eccles’ and his research staff and stored in locked file cabinets according to Data Protection Act (DPA) standards.

Information about study subjects was kept confidential.

All subjects for this study were provided with a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. See Appendix I for a copy of the Subject Informed Consent Form.

STATISTICAL METHODS

All outcome measures are summarised using median (interquartile range) (IQR). The change (month1 – baseline) in each outcome measure was calculated for each subject. The changes were compared between groups (placebo / live) using the Mann-Whitney test. Note that a statistical test to evaluate whether the two groups were different at baseline was not undertaken because the change from baseline the primary analysis.

The sample size is 25 and reflects a pilot study only – to observe any possible benefits and the safety of the Teslar watch.

FUNDING SOURCE

This study was financed through a grant from the manufacturers of the Teslar technology, Success By Association.

CONFLICT OF INTEREST

There were no conflicts of interest and all data was analysed by a third party statistician who also had no vested interest in the outcome of the study.

SUBJECT STIPENDS OR PAYMENTS

All participants at the completion of the study were allowed to keep their Teslar watch/ bracelet in compensation for participating and those that had received a placebo were informed of this at the completion of the study and given a Live Teslar watch to keep. No monetary compensation was provided.

ETHICAL APPROVAL

The East London and the City Research Ethics Committee has been sent all the necessary documentation and their decision is still awaited.

RESULTS

The Live Teslar group was comprised of 16 participants, 14 males and 2 females, average age 48.6 ± 10.95 (Mean \pm SD). The placebo group comprised 9 participants, 8 males and 1 female, average age 46.6 ± 10.1 .

Twenty-five subjects entered the study of which 9 were allocated to placebo. Some participants did not have all outcome measures at all time points so a change could not be calculated. For all outcome measures except VAS changes could be calculated for 22 subjects (7 in placebo group). For VAS the calculations could be completed on 6 from the placebo group and 14 from the Live group. One subject, a male MP in the Live group discontinued the study stating that wearing the device at night disturbed his sleep. We do not have sufficient information to clarify whether this was due to its physical presence or whether this represented another effect of the watch. His results were therefore excluded from the primary outcome analysis.

The results are presented in tables 1a and 1b, with the heart rate variability data in Table 1b. Table 2 shows analysis of the key HRV parameters measured in the supine and upright position. The purpose of this analysis was to look for any potential changes in response of the autonomic nervous system to challenge that might be explained by the treatment. Baseline values are reported as well as the change from baseline at 1 month. Thus a negative value indicates a reduction in the measure of interest.

Table 1a. Statistical analysis of Questionnaire data

Outcome measure		Group		p-value for difference in change
		Placebo	Teslar	
Health	baseline change	5.0 (2.0,11) -2.0(-2.0,0.0)	5.0 (3.0,9.0) 0.0 (-2.0,1.0)	0.298
Pain	baseline change	1.0 (0.0,2.0) 0.0 (-1.0, 0.0)	1.0 (0.0, 1.0) 0.0 (0.0, 1.0)	0.162
Sleep	baseline change	1.0 (0.0,2.0) 0.0 (-1.0, 0.0)	1.0 (1.0,2.0) 0.0 (-1.0, 0.0)	0.783
Stress	baseline change	11 (8.0, 15) 1.0 (-5.0, 5.0)	13 (12, 18) -3.0 (-7.0,0.0)	0.210
VAS (subjective stress)	baseline change	4.0 (2.9, 5.3) 0.0 (-1.0, 2.3)	5.3 (3.6, 6.1) -1.0 (-2.0, 0.5)	0.274

Table 1b. Statistical analysis of HRV data (see also Table 2)

Outcome measure		Group		p-value for difference in change
		Placebo	Teslar	
SDNNS	baseline change	34 (24, 58) 7 (-14, 27)	44 (33, 59) -3(-17, 7)	0.267
SDNNU	baseline change	39 (13, 54) 9 (-6, 21)	48 (32, 52) -3 (-4, 5)	0.407
TI_S	baseline change	149 (78, 228) 29 (-127, 102)	115 (70, 222) 24 (-18, 72)	0.731
TI_U	baseline change	114 (86, 493) 4.0(-439, 45)	166 (89, 229) -11 (-35, 35)	0.581
HRV	baseline change	5.0 (4.0, 7.0) 0.0 (0.0, 1.0)	5.0 (4.0, 7.0) 0.0 (-2.0, 1.0)	0.490
TP_S	baseline change	338 (152,1153) 335(-586, 588)	836(426, 1829) -283(-846, 287)	0.237
TP_U	baseline change	733 (72,1108) 178 (-31, 362)	738 (327,1048) 141(-86, 627)	0.891
H/L_S	baseline change	0.39(0.18,1.1) 0.13(-0.29,0.24)	0.33(0.21,0.59) 0.07(-0.12,0.51)	0.581
H/L_U	baseline change	0.12(0.08,0.29) 0.06 (-0.02, 0.16)	0.25(0.18,0.39) -0.01(-0.19,0.18)	0.298

Table 2. Analysis of HRV differences in the upright compared with the supine position

Outcome measure		Group		p-value for difference in change
		Placebo	Teslar	
SDNN_USdiff	baseline change	1.0 (-11, 14) -4.0(-20, 16)	-1.0(-13,8.0) -1.0(-8.0,38)	0.581
TI_USdiff	baseline change	8.0(-131, 365) 49(-280,172)	18 (-13, 8.0) -9 (-57,39)	0.535
TP_USdiff	baseline change	-3.0(-157,830) -41(-577,555)	-154 (-1091,96) 235(-373,2191)	0.267
HL_USdiff	baseline change	-0.33(-0.78,0.11) 0.26(-0.23,0.74)	-0.10(-0.25,-0.04) -0.01(-0.20,0.28)	0.298

Example:

TI_USdiff

Baseline value is TI in upright – TI in supine: TI_U1-TI_S1

So, the change is (TI_U2-TI_S2) – (TI_U1-TI_S1)

If change is negative then the difference between Upright and Supine values is smaller at 1 month than at baseline.

Calculations for SF8 scores

A mean score was calculated for each subject, before and after (called scoreA and scoreB). The change in score was then calculated for each subject and compared with the changes between groups using a Mann Whitney test.

Results

The change in score was available for 6 subjects in the placebo group and 14 in the live group. For those 6 and 14 subjects the mean (sd) score **before** treatment (Score A) was 53.1 (2.4) and 52.4 (3.0) respectively. The mean (sd) score **after** treatment (score B) was 54.2(2.9) and 51.9(3.0) for the placebo and live groups respectively. The median (IQR) **change** in scores was 0.69(-0.06, 2.05) and 0.00(-1.00, 0.96) for the placebo and live groups respectively. The difference in change between the groups was not statistically significant (p=0.153).

DISCUSSION

Both groups were well matched for age although there was a male dominance in volunteers for the study.

One can see from the tables that no differences reached statistical significance, but this is not unexpected in a small study. Unfortunately, not all the data could be analysed by the statistician and this led to a reduction in data in an already small study. However, one must bear in mind the pilot nature of the study and as noted below there are sufficient interesting trends to warrant progress to a larger study.

Our statistician has computed that using the results in table 1a for the changes in stress, a difference of 3.5 units between the groups would be detected with at least 50 participants completing the study in each group. This was based on 5% significance level and 80% power. No statistically significant differences were observed in the Health SF8 scores.

Despite the lack of statistical significance there are some interesting trends to note.

- (5) Firstly, the placebo group showed on average an increase in stress whereas the live group a larger decrease in stress. If this difference in change of approximately 4 units is clinically important then we would need a larger study to detect this with statistical significance.
- (6) The direction of the change in health looks in favour of Teslar compared with placebo.
- (7) The Tension Index in the upright position reduced by 11 on average for the Live group whereas the placebo group showed an increase on average.
- (8) There was also a trend towards improvement in sleep in the Teslar group. This was supported by the observation of several positive comments from MPs in this regard that had been wearing the Live device but not from those that were wearing placebos. The significance of this result was compromised by 65% of MPs not reporting any sleep disturbance at the outset. It is likely that this trend may prove significant in a larger study.

The Tension Index increases when there is less variability in the ANS and reduces when there is more flexibility in the ANS. The trend in differences in the Tension Index are interesting and consistent with those described previously (Eccles, 2003; Wasl, 2003) that demonstrate a greater ANS total power especially in the face of challenge after wearing the Teslar watch. This may suggest an ability of the watch to stimulate the parasympathetic component of the ANS.

The results of this pilot study are of sufficient interest and potential importance to now lead us to conduct a larger study.

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Special thanks to Milly Wiggin of Wiggin PR who coordinated the recruitment and measurements of MPs and to her husband Bill Wiggin MP for his assistance in this respect. Also thanks to the statistician Susan Charman who made time in her busy PhD preparation schedule to analyse the data statistically.

Thanks must also go to the staff at SBA in the USA and also to Dermott Dennehy in the UK for their support of this project.

APPENDICES

APPENDIX 1- QUESTIONNAIRES

DEMOGRAPHICS

Sex Male <input type="checkbox"/> Female <input type="checkbox"/>	Date of Birth <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Day Month Year	Age <input type="text"/> <input type="text"/>
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MEDICAL HISTORY

Concurrent disease(s)

Note: If treatment is currently taken for any of the above conditions, this must be recorded on the Concomitant Medications Form.

HEALTH SURVEY

1. Overall, how would you rate your health during the **past 4 weeks**?

Excellent	Very good	Good	Fair	Poor	Very poor
<input type="checkbox"/>					

2. During the **past 4 weeks**, how much did physical health problems limit your usual physical activities (such as walking or climbing stairs)?

Not at all	Very little	Somewhat	Quite a lot	Could not do physical activities
<input type="checkbox"/>				

3. During the **past 4 weeks**, how much difficulty did you have doing your daily work, both at home and away from home, because of your physical health?

None at all	A little bit	Some	Quite a lot	Could not do daily work
<input type="checkbox"/>				

4. How much **bodily** pain have you had during the **past 4 weeks**?

None	Very mild	Mild	Moderate	Severe	Very Severe
<input type="checkbox"/>					

5. During the **past 4 weeks**, how much energy did you have?

Very much	Quite a lot	Some	A little	None
<input type="checkbox"/>				

6. During the **past 4 weeks**, how much did your physical health or emotional problems limit your usual social activities with family or friends?

Not at all	Very little	Somewhat	Quite a lot	Could not do social activities
<input type="checkbox"/>				

7. During the **past 4 weeks**, how much have you been bothered by **emotional problems** (such as feeling anxious, depressed or irritable)?

Not at all	Slightly	Moderately	Quite a lot	Extremely
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8. During the **past 4 weeks**, how much did personal or emotional problems keep you from doing your usual work, school or other daily activities?

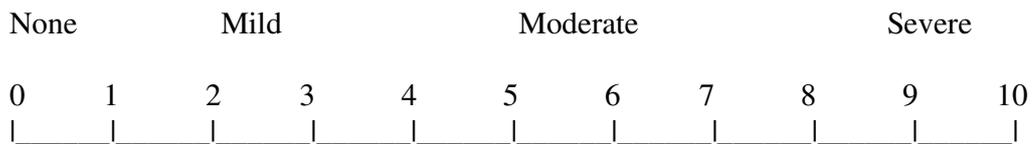
Not at all **Very little** **Somewhat** **Quite a lot** **Could not do daily activities**

9. During the **past 4 weeks**, you have slept well?

Very much **Quite a lot** **Somewhat** **Very little** **Not at all**

VISUAL ANALOGUE SCALE

How severe would you rate your stress level in the last 4 weeks? Place an "X" on the line below to indicate the average level that you feel is most appropriate.



PERCEIVED STRESS SCALE 10

1. In the last month, how often have you been upset because of something that happened unexpectedly?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

2. In the last month, how often have you felt that you were unable to control the important things in your life?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

3. In the last month, how often have you felt nervous and "stressed"?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

4. In the last month, how often have you felt confident about your ability to handle your personal problems?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

5. In the last month, how often have you felt that things were going your way?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

6. In the last month, how often have you found that you could not cope with all the things that you had to do?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

7. In the last month, how often have you been able to control irritations in your life?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

8. In the last month, how often have you felt that you were on top of things?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

9. In the last month, how often have you been angered because of things that were outside of your control?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?

___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

15- DAY CHECK

15 Day Interview with Personal Assistant

1.) Name of P.A. with whom you spoke with?

First name

Last name

2.) Is the participant wearing the watch 24 hours/ day or during daytime hours?

Yes No

3.) Any symptoms or complains regarding the watch?

Yes No

If yes, please explain: _____

Teslar Watch Study

Participant Identification

-
Investigator # Study #
Participant's Initials
 F M L

Visit 1 (PreRx)

/ /
Day Month Year

INFORMED CONSENT/ INCLUSION CRITERIA

Informed Consent

Date Signed: / /
 Day Month Year

Inclusion Criteria

Note: All of these questions should be marked "YES" so that the participant is eligible to participate.

- Yes No 1. The participant understood and signed the informed consent prior to participating in any activity related to the study.
- Yes No 2. The participant is 18 years or older.
- Yes No 3. The participant is a healthy individual.
- Yes No 4. The participant works in a high- stress environment.
- Yes No 5. The participant has difficulty sleeping or other symptoms related to high stress.
- Yes No 6. The participant is not participating in any other study at the time of enrollment into the Teslar watch company.

Teslar Watch Study

Participant Identification

Visit 1 (PreRx)

-
Investigator # Study #
Participant's Initials
 F M L

/ /
Day Month Year

EXCLUSION CRITERIA

Exclusion Criteria

Note: All of these questions should be marked "NO" so that the participant is eligible to participate.

- Yes No 1. The participant leads a low stress lifestyle and no/ low stress in the workplace.
- Yes No 2. The participant is taking **any of the regular medications listed in Appendix 1** for hypertension, angina, allergies, insomnia, depression, urinary problems, prostate problems, bowel disorders, neuromuscular disease, Parkinsons.
- Yes No 3. The participant has been clinically diagnosed with diabetes.
- Yes No 4. The participant is pregnant or attempting to be pregnant during the month while participating
- Yes No 5. The participant is simultaneous participation or participation in another study in the last 30 days.
- Yes No 6. The participant has an electrical device, pace makers implanted.
- Yes No 7. The participant will be traveling/ unavailable to keep his/ her visits from the time of enrollment through the final appointment at the end of the month.
- Yes No 8. The participant is unwilling to sign informed consent

Conclusion

All selection criteria fulfilled
If No, withdraw patient

Yes No

APPENDIX 2

LIST OF PROHIBITED MEDICATIONS

Please see alternative list below. These are medications that could potentially affect HRV.

PROZAC
PAXIL
ZOLOFT

Hypertension

ACEBUTOLOL (SECTRAL, SECADREX)
ATENOLOL (TENORMIN, CO-TENIDONE, KALTEN, TENBET, TENORETIC, BETA-ADALAT, TENIF)
BETAXOLOL (KERLONE)
BISOPROLOL (CARDICOR, EMCOR, MONOCOR, MONOZIDE)
CARVEDIOL (EUCARDIC)
CELIPROLOL (CELECTOL)
CLONIDINE (CATAPRESS, DIXARIT)
DOXAZOSIN (CARDURA)
ESMOLOL (BREVIBLOC)
INDORAMIN (BARATOL)
LABETOLOL (TRANDATE)
METHYLDOPA (ALDOMET)
METOPROLOL (BETALOC, LOPRESOR)
NADOLOL (CORGARD, CORGARETIC)
NEBIVOLOL (NEBILET)
OXPRENOLOL (TRASICOR, TRASIDREX)
PHENOXYBENZAMINE (DIBENYLIN)
PHENTOLAMINE (ROGITINE)
PINDOLOL (VISKEN, VISCALDIX)
PRAZOSIN (HYPOVASE)
PROPRANALOL (INDERAL)
SOTALOLOL (BETA-CARDONE, SOTACOR)
TIMOLOL (BETIM, MODUCREN, PRESTIM)

Angina

DILTIAZEM (TILDEM, ADIZEM, ANGITIL, CALCICARD, DILCARDIA, DILZEM, SLOZEM, VIAZEM, ZEMTARD)
VERAPAMIL (CORDILOX, SECURON, UNIVER, VARAPRESS, VERTAB)

Allergies

AZATADINE (OPTIMINE)
CHLORPHENIRAMINE (PIRITON)
CLEMASTINE (TAVEGIL)
CYPROHEPTADINE (PERIACTIN)

DIMOTANE
HYDROXYZINE (ATARAX, UCERAX)
PROMETHAZINE (PHENERGAN)
VALLERGAN

Insomnia

ALPRAZOLAM (XANAX)
AMYTAL
BROMAZEPAM (LEXOTAN)
CHLORAL HYDRATE (WELLDORM)
CHLORDIAZEPOXIDE
CHLORMETHIAZOLE (HEMINEVRIN)
CLORAZEPATE (TRANXENE)
DIAZEPAM
FLUNITRAZEPAM (ROHYPNOL)
FLURAZEPAM (DALMANE)
LOPRAZOLAM (DORMONOCT)
LORAZEPAM (ATIVAN)
LORMETAZEPAM
NITRAZEPAM (MOGADON)
OXAZEPAM
SECONAL
SONERYL
TEMAZEPAM
TRICLOFOS
TUINAL
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)

Urinary problems

BETHANECHOL (MYOTININE)
CARBACHOL
DISTIGMINE (UBRETID)
FLAVOXATE (URISPAS)
OXYBUTININ (CYSTRIN, DITROPAN)
PROPANTHELINE
PROPIVERINE (DETRUNORM)
TOLTERODINE (DETRUSITOL)

Prostate problems

ALFUZOSIN (XATRAL)
DOXAZOSIN (CARDURA)
INDORAMIN (DORALESE)
PRAZOSIN (HYPOVASE)
TAMSULOSIN (FLOMAX)
TERAZOSIN (HYTRIN)

Bowel disorders

DICYCLOVERINE (MERBENTYL, KOLANTICON)
HYOSCINE (BUSCOPAN)
PROPANTHELINE (PRO-BANTHINE)

Neuromuscular disorders

DISTIGMINE (UBRETID)
EDROPHONIUM
NEOSTIGMINE
PYRIDOSTIGMINE (MESTINON)

Parkinson's disease or Dementia

BENZATROPINE (COGENTIN)
BIPERIDEN (AKINETON)
DONEPEZIL (ARICEPT)
ORPHENADRINE (BIORPHEN, DISIPAL)
PROCYCLIDINE (ARPICOLIN, KEMADRIN)
RAVISTIGMINE (EXELON)
TRIHEXYPHENIDYL (BENZHEXOL, BROFLEX)

INFORMED CONSENT

Title of Research: **Clinical Pilot Study to Determine the Efficacy of Teslar watches to assist in Reducing Stress in British Members of Parliament working in high stress environments**

Principal Investigator: Nyjon Eccles, BSc MBBS MRCP PhD Harley Street, London, UK
Telephone: 020 72244622 Email: info@chironclinic.com

Staff Members: Mischa Sunstad

International medical ethics mandate that the human subject participants of a research protocol are informed of the purpose and benefits of the project; the research methods to be used; the potential risks or hazards of participation and the right to ask for further information at any time during the research procedure. You have the right to know whether medical treatment or compensation is available for physical injuries incurred as a result of participation in the project. Your choice to participate is a voluntary one, and you are free to withdraw from the research project at any time. Your signature at the end of this consent form will indicate that the principal investigator, or his/her agent, has answered all your questions and that you voluntarily consent to participate in this investigation.

FUNDING SOURCE

This study is financed through a grant from the manufacturers of the Teslar technology, Success By Association. All funding will be arranged between SBA and Dr. Nyjon Eccles to conduct the study appropriately according to national and international standards and Good Clinical Practices (GCP).

SITE OF THE RESEARCH STUDY

Houses of Parliament

PURPOSE OF THE RESEARCH STUDY

This pilot study will evaluate the efficacy and potential benefit of the Teslar Watch to assist in reducing stress levels for British Members of Parliament working in high stress environments. A total of 25 healthy British Members of Parliament will participate by using the Teslar Watch over the course of a four week period. Assessment will include clinical stress questionnaires, visual analogue, and heart rate variability. Additional measures at pre and post test will include quality of life and basic clinical evaluation. The primary outcome is efficacy resulting in a reduction of stress levels, improvement of sleep, and an increase of energy.

ELIGIBILITY

You are being asked to participate in this study because you are a healthy, adult employee with symptoms of stress, working in a high stress environment.

PROCEDURES

If you decide to take part in this research study, you will undergo the following procedures.

The clinical history of the participant will be taken by the doctor. The participant would then complete the following visual and written questionnaires: Quality of Life (SF 36) questionnaire, Visual Analogue Scale and Stress Response Inventory. Heart Rate Variability would also be taken by the nurse or the staff technician.

The clinical history and questionnaires should take about 30 minutes to complete. The heart rate variability test will last 15 minutes and be conducted in a private room by a trained staff member. Nerve-Express is a fully automatic, non-invasive computer-based system designed for quantitative assessment of the Autonomic Nervous System (ANS) based on Heart Rate Variability (HRV) analysis. HRV analysis is based on measuring variability in heart rate; specifically, variability in intervals between R waves - "RR intervals". The participant will be asked to attach a convenient polar belt firmly fixed around the patient's chest, while a receiver transmits the signal to the PC

for the screen report. Upon completing all tests, the participant would receive the watch to be worn for the next 30 with optional removal at night. At the 15 day, one of our staff members will call your P.A. to check in with your progress. After 30 days, the participant will be asked to return for another visit to terminate their participation in the study by completing the same tests that were done at baseline. Total visit time: 45 minutes

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. The participant may also feel some discomfort when fixing polar belt to chest for the heart rate variability test.

BENEFITS

The theory of Teslar shielding is that it transforms harmful ELF signals and provides an enhanced body electric pathway for the harmful frequencies to use in bypassing the body's nervous system. The Teslar uses subtle energy technology to screen the body from potentially harmful electronic pollution caused by the abundance of machines, electronic gadgetry, and power lines, in a way that allows the body to operate more harmoniously within the earth's natural resonance field.

NEW FINDINGS

You will be notified of any significant new developments that may cause you to change your mind about participating in the research study.

COSTS ASSOCIATED WITH THE RESEARCH STUDY

There are no costs to you associated with this study.

REIMBURSEMENT FOR MEDICAL TREATMENT

Dr. Nyjon Eccles, its sponsors, or its employees do not compensate for or provide free medical care for human subjects/ participants in the event that any injury results from participation in the Teslar watch research study.

COMPENSATION FOR SUBJECT PARTICIPATION

All participants at the completion of the study will be allowed to keep their Teslar watch/ bracelet in compensation for participating. No monetary compensation will be provided.

CONFIDENTIALITY

Information related to you will be treated in strict confidence to the extent provided by law. Your identity will be coded and will not be associated with any published results. Your code number and identity will be kept in a secured file of the Principal Investigator. In order to monitor this research study, representatives from the MHRA (Medicines and Health Care Products Regulatory Agency) may inspect the research records which may reveal your identity. Your records containing your name will not be removed from the Principal Investigator's office nor will any copies of these records with your name be made. Any records or data sent to sponsors will have your identity protected by subject code and will not contain your name.

FREEDOM TO WITHDRAW

Your participation in this study is voluntary and you may stop your participation at any time without prejudice.

**Voluntary Consent
(Signature page)**

All of the above has been explained to me and all of my current questions have been answered. I am encouraged to ask questions about any aspects of this research study, and that future questions will be answered by the researchers listed on the front page of this form.

Any questions I have about my rights as a research participant will be answered by the staff at the Office of Dr. Nyjon Eccles. Once the study is completed, you may receive the results of the study. If you would like these results, or if you have any questions in the meantime, please contact:

Dr. Nyjon Eccles
121 Harley Street
London, UK
020 72244622

By signing this form I do not waive any of my legal rights.

By signing this form, I agree to participate in this research study. A signed copy of this consent form will be given to me.

_____	_____	_____
Participant's Name	Participant's Signature	Date
_____	_____	_____
Witness' Name	Witness' Signature	Date

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered.

_____	_____	_____
Principal Investigator's Name or Designee	Principal Investigator's Signature	Date

NON-SERIOUS ADVERSE EVENTS

"X" if there were no adverse events to report during the study

Non Serious Adverse Events (i.e. cold, flu, indigestion, etc)	Initial Start Date Day Month Year	Maximum Intensity 1: Mild 2: Moderate 3: Serious 4: Not applicable	Resolution Date Day Month Year	Resolution 1: Resolved 2: Resolved but continued 3: Fatal 4: Not resolved
	__ / __ / ____		__ / __ / ____	
	__ / __ / ____		__ / __ / ____	
	__ / __ / ____		__ / __ / ____	
	__ / __ / ____		__ / __ / ____	
	__ / __ / ____		__ / __ / ____	
	__ / __ / ____		__ / __ / ____	
	__ / __ / ____		__ / __ / ____	
	__ / __ / ____		__ / __ / ____	

"X" if more pages are needed to report non-serious adverse events.

TTeslar Watch Study	Participant Identification <div style="text-align: center;"> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> </div> Investigator # Study # Participant's Initials <input type="text"/> <input type="text"/> <input type="text"/> <div style="text-align: center;"> F M L </div>	30 Day/ Final Visit <div style="text-align: center;"> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> </div> Day Month Year
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Teslar Watch Study	Participant Identification	30 Day/ Final Visit
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	F M L	Day Month Year

SERIOUS ADVERSE EVENTS (continued, pg 2)

Concomitant Medications:

Describe medical conditions, allergies, surgeries that would explain the event:	Start Date	Condition present when event occurred:	Resolution Date
	Day Month Year	1: Yes 2: No	Day Month Year
	__ / __ / ____		__ / __ / ____
	__ / __ / ____		__ / __ / ____
	__ / __ / ____		__ / __ / ____

Other risk factors:
Describe any other family, social conditions that may be related to the serious adverse event (i.e. smoking, obesity, alcohol, drug abuse, etc).

Period the Teslar Watch was worn:

Start Date: / / / / /

Stop Date: / / / / /

Concomitant Medications:

Medication <i>(Name, Dose, Frequency, Route)</i>	Start Date	Stop Date (√ if continued)↓	√ -If started before the study	√ continued after the study	-If the	Indicate Why	Reason
	Day Month Year	Day Month Year					
1.							
2.							
3.							

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 an 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 be 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

EC/IRB Notification by Investigator

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

UK Equivalent to FDA Notification by Sponsor

The study sponsor shall notify the FDA by telephone or by facsimile transmission of any unexpected fatal or life-threatening experience associated with the use of the drug as soon as possible but no later than 7 calendar days from the sponsor's original receipt of the information.

If a previous adverse event that was not initially deemed reportable is later found to fit the criteria for reporting, the study sponsor will submit the adverse event in a written report to the FDA as soon as possible, but no later than 15 calendar days from the time the determination is made.

APPENDIX 3

Results: After surveying the following measurement instruments, it was decided to use the Stress Response Inventory (SRI) as it is more measurable.

Questionnaires for Measuring Stress Identified:

- Stress Response Inventory (SRI)
- Perceived Stress Questionnaire (PSQ)
- Global Assessment of Recent Stress (GARS)
- Symptom Checklist 90 Revised (SCL-90-R)
- Maslach Burnout Inventory
- Rosenzweig Picture Frustration Study (P-F study)
- Psychological Stress Response Scale (PSRS)
- Occupational Stress Inventory (OSI-R)
- Work Ability Index (WAI)

RESEARCH:

Research states that the SRI seems to be more accurate when compared to others.

Psychosom Med. 2001 Jul-Aug;63(4):668-78.

[Related Articles, Links](#)

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psychosomaticmedicine.org

Development of the stress response inventory and its application in clinical practice.

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OBJECTIVE: The purpose of this study was to develop the Stress Response Inventory (SRI), which includes emotional, somatic, cognitive, and behavioral stress responses, and then to use the scale in clinical practice. **METHODS:** First, a preliminary survey was conducted using 109 healthy adults to obtain 75 response items. Second, the preliminary questionnaire was completed by 215 healthy subjects. Third, stress responses were compared among 242 patients (71 with anxiety disorder, 73 with depressive disorder, 47 with somatoform disorder, and 51 with psychosomatic disorder) and the 215 healthy subjects. **RESULTS:** Factor analysis yielded seven subscales: tension, aggression, somatization, anger, depression, fatigue, and frustration. Reliability was computed by

administering the SRI to 62 healthy subjects during a two-week interval. Test-retest reliability for the seven subscale scores and the total score was high, ranging between 0.69 and 0.96. Internal consistency was computed, and Cronbach's alpha for the seven subscales ranged between 0.76-0.91 and 0.97 for the total score. Convergent validity was computed by correlating the seven subscales and the total score of the SRI with the total score of the Global Assessment of Recent Stress (GARS) scale, the Perceived Stress Questionnaire (PSQ), and the subscale scores of the Symptom Checklist-90-Revised (SCL-90-R). The correlations were all at significant levels. The sensitivity of the SRI was 0.57, specificity 0.74, and the predictive value positive (PVP) was 0.71. The patient group also scored significantly higher on the six subscale scores and the total score than the control group, with the exception being the aggression subscale. The depressive disorder group was highest in total scores on the SRI among the four patient groups, and showed significantly higher total scores than the anxiety disorder and psychosomatic disorder groups. In total scores on the SRI, female subjects scored significantly higher than males. **CONCLUSIONS:** These results indicate that the SRI is highly reliable and valid, and that it can be utilized as an effective measure of stress for research in stress-related fields. The depressive disorder group showed more prominent stress responses than the anxiety and psychosomatic disorder groups.

PMID: 11485121 [PubMed - indexed for MEDLINE]

Research on the Perceived Stress Questionnaire:

J Psychosom Res. 1993 Jan;37(1):19-32.

[Related Articles, Links](#)

Development of the Perceived Stress Questionnaire: a new tool for psychosomatic research.

Levenstein S, Prantera C, Varvo V, Scribano ML, Berto E, Luzzi C, Andreoli A.

Gastroenterology Department, Nuovo Regina Margherita Hospital, Rome, Italy.

A 30-question Perceived Stress Questionnaire (PSQ) was validated, in Italian and English, among 230 subjects. Test-retest reliability was 0.82 for the General (past year or two) PSQ, while monthly Recent (past month) PSQs varied by a mean factor of 1.9 over 6 months; coefficient alpha > 0.9. General and/or Recent PSQ scores were associated with trait anxiety ($r = 0.75$), Cohen's Perceived Stress Scale ($r = 0.73$), depression ($r = 0.56$), self-rated stress ($r = 0.56$), and stressful life events ($p < 0.05$). The General PSQ was higher in in-patients than in out-patients ($p < 0.05$); both forms were correlated with a somatic complaints scale in a non-patient population ($r > 0.5$), and were higher, among 27 asymptomatic ulcerative colitis patients, in the seven who had rectal inflammation than in those with normal proctoscopy ($p = 0.03$). Factor analysis yielded seven factors, of which those reflecting interpersonal conflict and tension were significantly associated with health outcomes. The Perceived Stress Questionnaire may be a valuable addition to the armamentarium of psychosomatic researchers.

PMID: 8421257 [PubMed - indexed for MEDLINE]

Research on the Maclach Burnout Inventory:

J Adv Nurs. 2004 Dec;48(6):622-31.

[Related Articles, Links](#)



Stressors, burnout and social support: nurses in acute mental health settings.

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AIMS: This paper reports a study which aims (1) to investigate and compare levels of stressors and burnout of qualified and unqualified nursing staff in acute mental health settings; (2) to examine the relationships between stressors and burnout and (3) to assess the impact of social support on burnout and stressor-burnout relationships.

BACKGROUND: Several studies have noted that the work of mental health nurses can be highly stressful, but relatively few have focused specifically on staff working in acute inpatient settings. Although many of the pressures faced by this group are similar to those in other nursing specialties, a number of demands relate specifically to mental health settings, including the often intense nature of nurse-patient interaction and dealing with difficult and challenging patient behaviours on a regular basis. **METHODS:** A convenience sample of 93 nursing staff from 11 acute adult mental health wards completed the Mental Health Professionals Stress Scale, Maslach Burnout Inventory and House and Wells Social Support Scale. **RESULTS:** Lack of adequate staffing was the main stressor reported by qualified staff, while dealing with physically threatening, difficult or demanding patients was the most stressful aspect for unqualified staff.

Qualified nurses reported significantly higher workload stress than unqualified staff. Approximately half of all nursing staff showed signs of high burnout in terms of emotional exhaustion. A variety of stressors were positively correlated with emotional exhaustion and depersonalization. Higher levels of support from co-workers were related to lower levels of emotional exhaustion. Higher stressor scores were associated with higher levels of depersonalization for staff reporting high levels of social support, but not for those reporting low levels of support (a reverse buffering effect). **CONCLUSIONS:** Qualified and unqualified nursing staff differed in terms of the prominence given to individual stressors in their work environment. The findings were consistent with the notion of burnout developing in response to job-related stressors. While staff support groups may be useful in alleviating feelings of burnout, the reverse buffering effect suggests that they should be structured in a way that minimizes negative communication

and encourages staff to discuss their concerns in a constructive way.

PMID: 15548253 [PubMed - indexed for MEDLINE]

Acad Psychiatry. 2004 Fall;28(3):240-2.

[Related Articles, Links](#)

Full text article at
ap.psychiatryonline.org

Burnout comparison among residents in different medical specialties.

Martini S, Arfken CL, Churchill A, Balon R.

Department of Psychiatry and Behavioral Neurosciences, UPC-Jefferson, 2751 E. Jefferson, Suite 400, Detroit, MI 48207, USA. shahm_martini@yahoo.com

OBJECTIVE: To investigate resident burnout in relation to work and home-related factors. **METHOD:** Maslach Burnout Inventory was mailed to residents in eight different medical specialties, with a response rate of 35%. **RESULTS:** Overall, 50% of residents met burnout criteria, ranging from 75% (obstetrics/gynecology) to 27% (family medicine). The first year of residency, being single, personal stress, and dissatisfaction with faculty were independently associated with burnout. **CONCLUSIONS:** Efforts to reduce resident burnout nationally would benefit from expanding beyond the work-hours regulation.

PMID: 15507560 [PubMed - indexed for MEDLINE]

Research on the Rosenzweig Picture Frustration Study (P-F study), the Psychological Stress Response Scale (PSRS):

Int J Behav Med. 2004;11(3):176-80.

[Related Articles, Links](#)

Preliminary study: psychological effects of muscle relaxation on juvenile delinquents.

Nakaya N, Kumano H, Minoda K, Koguchi T, Tanouchi K, Kanazawa M, Fukudo S.

Department of Behavioral Medicine, Tohoku University Graduate School of Medicine, Sendai, Japan. nakaya-thk@umin.ac.jp

The purpose of this study is to test our hypothesis that muscle relaxation is effective on the psychological well-being of juvenile delinquents. Subjects were 16 juvenile delinquents who had entered a reform school. Subjects were divided into two groups. The

muscle relaxation group received muscle relaxation therapy once a week for a total of 4 times. The control group spent an ordinary daily life in the reformatory. Psychological questionnaires used were the Rosenzweig Picture Frustration Study (P-F study), the Psychological Stress Response Scale (PSRS), and the Eysenck Personality Questionnaire (EPQ). There was a significant Group Time interaction of the Group Conformity Rating (GCR) of the P-F study ($F [1,14] = 10.1, P = 0.007$). There were no significant interactions in the other psychological subscales. Thus, muscle relaxation therapy may improve frustration tolerance among juvenile delinquents.

Publication Types:

- Clinical Trial
- Randomized Controlled Trial

PMID: 15496345 [PubMed - indexed for MEDLINE]

Research on the Occupational Stress Inventory (OSI-R) and Work Ability Index (WAI):

Zhonghua Lao Dong Wei Sheng Zhi Ye Bing Za Zhi. 2004 Apr;22(2):119-21.

[Related Articles, Links](#)

[Appraisal of occupational stress and its influential factors in nurses]

[Article in Chinese]

Yang XW, Wang ZM, Wang MZ, Lan YJ.

Department of Occupational Health, School of Huaxi Public Health, Sichuan University, Chengdu 610041, China.

OBJECTIVE: To assess the occupational stress and its influential factors in nurses.

METHODS: A test of occupational stress, its influential factors, work ability were carried out for 248 nurses and 319 controls with revised occupational stress inventory (OSI-R) and work ability index (WAI). **RESULTS:** The scores of personal cope resource (131.266 +/- 17.176) and work ability index (32.581 +/- 3.158) in nurse group were significantly higher than those in control group (126.931 +/- 19.108, 31.840 +/- 4.069) ($P < 0.05$). The main occupational stressors scores (role insufficiency, role clash, and responsibility) in nurses were higher than those in controls ($P < 0.05$). The stress response of interpersonal relationship in nurses was also higher. The items of personal cope resource, such as recreation, self-care and social support of nurses were superior to those of controls ($P < 0.05$). Stress response was positively correlated with occupational role ($r = 0.512, P < 0.01$), and negatively correlated with the personal cope resource ($r = -0.475, P < 0.01$). The primary influential factors of personal stress were recreation, social support, rational conduct, role insufficiency, role clash, responsibility, and poor work environment.

CONCLUSION: To strengthen social support, to improve work condition for nurses, so

as to reduce the occupational stress and to enhance the work ability of nurses are important task in occupational health field.

PMID: 15130442 [PubMed - indexed for MEDLINE]

J Adv Nurs. 2004 Jun;46(5):480-7.

[Related Articles, Links](#)



Occupational stress and constructive thinking: health and job satisfaction.

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BACKGROUND: Occupational stress is associated with specific situations, characteristics of the work environment, and individual perceptions and reactions in the context of the workplace, but many nursing studies of occupational stress have tended to analyse aspects related to the job itself. In Brazil nursing is acknowledged as a stressful occupation whose stresses are generally associated with the job itself, while the effects of personal characteristics on an individual's response to occupational stress are dismissed. **AIMS:** The aim of this paper is to describe: (1) occupational stress, job satisfaction and state of health in Brazilian nurses, and (2) the relationship of these variables to a constructive thinking coping style. **METHODS:** A correlational study was performed during 1999 with 461 nurses recruited from the public health and education system in the Federal District of Brazil. Instruments used were the Nursing Stress Inventory, Constructive Thinking Inventory, subscales of the Occupational Stress Indicator, and a researcher-designed questionnaire. **RESULTS:** Normal distributions were found for occupational stress, state of health (physical and psychological), and job satisfaction. Results suggest that nurses have fewer psychological health problems and similar job satisfaction compared with other Brazilian government white-collar workers. Occupational stress was directly associated with state of health, and inversely associated with global constructive thinking and job satisfaction. **CONCLUSIONS:** Brazilian nurses in this study seem to have adapted satisfactorily to their profession, but the finding that constructive thinking was significantly related to psychological ill-health, occupational stress and physical ill-health highlights a need to value individual coping styles in the work environment.

PMID: 15139936 [PubMed - indexed for MEDLINE]

APPENDIX 4

Anecdotal Feedback

Wiggin PR has had replies from 11 out of 16 MP's that were given activated watches. 8 were given placebo's and have therefore not been contacted.

To date, we have had mid-term replies back from 10.

- 90% worn watch 24:7
- 70% said they felt an overall improvement in well being since wearing the watch
- 70% noticed an improvement in their sleep patterns

Quotes from MP's wearing activated watches:

Bill Wiggin MP

"My wife says I am calmer and I have slept well... "

"I never had a problem sleeping but I have felt calmer when I would normally lose my temper so the effect is very positive"

Robert Spink MP

"I feel calmer...I really have been telling everyone how well I feel with it!"

Hugo Swire MP

" I really do feel pretty unstressed I must say."

Mark Lancaster MP

"Yes, I feel there is an overall improvement since wearing the watch and I have noticed I am sleeping more deeply. I have also stopped drinking coffee for some reason."

Anthony Steen MP

"I am possibly sleeping longer but it may be the time of year... I have also significantly reduced my alcohol intake and stopped drinking coffee"

Huw Irranca-Davies MP

"Hard to tell, although I would say that I am sleeping well – too well sometimes!"

John Greenway MP

"I have been wearing the watch for the past four weeks and can say without fear of contradiction that wearing the watch at night has improved my sleep – for example, if I wake up in the night I now go back to sleep much more quickly than I used to."

Greg Barker MP

"I am sleeping a bit better..."

Nigel Evans MP – WHO DOES NOT WANT HIS NAME MENTIONED IN RELATION TO STUDY

"I have noticed an improvement in my sleep patterns. I have also virtually given up coffee"

Martyn Jones MP

"I have noticed no difference I am afraid"