SUMMARY REPORT FOR SLEEP STUDY NOV-JAN 2008

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

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A total of 10 healthy volunteers were randomly enrolled to participate in study by using the Teslar Watch over the course of one week period at Sleep Solutions' Sleep Labs under principal investigator, Dr. Lettelier, a research pulmonary doctor in the Miami area. Inclusion eligibility criteria included any persons over 18 years of age with the complaint of non-restorative sleep. Principal exclusion criteria included any volunteer that after obtaining medical history, clinical evaluation and screening polysomnographic test was diagnosed with a medical condition related to sleep.

Five (5) healthy volunteers were initially enrolled and at completion an interim analysis was done and it was determined that another 5 volunteers should be enrolled; totaling 10 volunteers. Pre-and Post -Assessment included clinical sleep quality questionnaires, Polysomnography testing, and diary. Additional measures at pre and post test included medical history, sleep history, pregnancy screen, and basic clinical evaluation. The primary outcome evaluated the potential benefits and socio-behavioral changes in restoring non-restorative sleep for healthy volunteers using the Teslar watch.

PRIMARY OBJECTIVE

The primary objective of this socio-behavioral study was to evaluate the potential benefits and socio behavioral changes in healthy volunteers using the Teslar watch in restoring non-restorative sleep.

HYPOTHESIS

The hypothesis tested was: 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.

RESULTS

As previously stated, the interim analysis showed initial positive results; therefore, it was concluded that an additional five volunteers be enrolled. Upon study completion, all the data was collected and organized for biostatistician review. Dr. Hardigan, Executive Director of Assessment, Evaluation, and Faculty Development Center at NOVA Southeastern University reviewed the data and submitted the report to the sponsor, Teslar.

The statistical report included statistical analyses conducted to see if differences exist between the baseline and termination phases of the study's four outcomes: (1) Sleep Phase, (2) Sleep Efficiency, (3) Epworth Scale (sleepiness) and (4) SF-36 physical and mental functioning.

According to the statistical report, generally speaking the watch appeared to have a positive effect on all four outcomes. However, specific statistical significance was uncovered for the following measures (1) Stage-of-Sleep, (2) Epworth Sleepiness Scale, and (3) SF-36 Mental Health Subscale ($p < .05$).

(1) Stage-of-Sleep

Stage-of-Sleep specifically determines how long a volunteer remained in one of the four stages of sleep; Stage I, Stage II, Stage III and REM. Note: Stage III (Delta) and REM are the restorative stages of sleep which affect quality of sleep. The study investigated whether there was an increase in these two specific stages of sleep. A comparison was made for change in "Quality" sleep, defined as the percentage of sleep in Stage 3 and REM, between the baseline and termination measurements. A 13.5 percent (confidence interval of 7.6% <> 19.4%) improvement in "Quality" sleep was noted between the baseline and termination phases of the study. All subjects reported a statistically significant improvement in "Quality" sleep.

(2) Epworth Sleepiness Scale

Epworth Sleepiness Scale determines the daytime sleepiness. Nine of the ten patients reported an improvement in sleepiness.

(3) SF 36

The SF 36 is a clinically validated questionnaire investigating quality of life; specifically in two areas, physical functioning and mental functioning.

Two analyses were conducted to look for differences between the baseline and termination stages for SF-36 subscales physical functioning (PCS) and mental health (MCS). Five patients reported an improvement in physical functioning, two reported no change, and three subjects reported a decrease in performance. For the MCS subscale the modified paired t-test ($p < .06$) and the Wilcoxon Sign-Rank ($p < .03$) tests did demonstrate statistical significance. Overall mental health improved by an average of 4.43 percent (confidence interval of 1.46<>10.33). Nine subjects reported an improvement in mental health while one patient reported a decrease. Patient ten presented the largest improvement in mental health (24.6%).

CONCLUSION

TheTeslarwatch appears to be an effective tool for improving Stage III and REM sleep, daytime sleepiness and mental capacity. It is likely in part that a possible theoretical explanation may be that by improving Stage III and REM sleep, the volunteer is waking up more refreshed, hence indirectly improving daytime sleepiness and mental capacity functioning during the day. The Teslar watch appears to be safe as there were no adverse events documented. The testimonials of the volunteers suggested that they felt calmer by the end of the week. As a small outcome pilot study, a larger placebo-controlled study is recommended by the biostatistician and research staff. Based upon the suggested favorable data presented in this initial study further clinical investigations are warranted.