

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

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Comments

The analysis was conducted in two phases. First, statistical analyses were 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. Second, standardized effect sizes and confidence intervals were calculated to provide a measure of treatment effect. Effect size (ES) is a name given to a family of indices that measure the magnitude of a treatment effect. Unlike significance tests, these indices are independent of sample size. ES measures are the common currency of all clinical studies that summarize the findings from a specific area of research.

Generally speaking the treatment appears to have a positive effect on all four outcomes. Statistical significance was uncovered for the measures (1) Stage-of-Sleep, (2) Epworth Sleepiness Scale, and (3) SF-36 Mental Health Subscale ($p < .05$). Borderline statistical significance was found for Sleep Efficiency ($p < .10$), and no difference was detected for SF-36 Physical Functioning subscale. Nevertheless, given the small sample size ($n=10$) and the fact that there is no control group, it is important to remain cautious of any interpretation.

Stage of Sleep

Statistical Analysis

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. The modified paired t-test ($p < .01$) and the Wilcoxon Sign-Rank ($p < .01$) tests were used and both demonstrated statistical significance. 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 significant improvement in “Quality” sleep. Using Cohen’s D the standardized effect size estimate is 0.86 which is a large effect. Table 1 provides descriptive statistics for group changes in sleep stage. Table 2 provides information about subject-specific changes in stage of sleep while Graph 1 plots the changes in sleep stage by each subject.

Table 1. Descriptive Statistics for Group Changes--Stages of Sleep

Time	Statistic	Stage 1	Stage 2	Stage 3	REM	Stage III and REM
Baseline	Mean	12.62%	55.83%	19.62%	8.68%	28.30%
	SD	7.39%	9.91%	8.68%	9.18%	17.86%
Termination	Mean	8.89%	46.04%	26.81%	18.24%	45.05%
	SD	7.24%	10.00%	13.06%	8.30%	21.36%
Difference	Mean	-3.73%	-9.79%	7.19%	9.56%	16.75%
	SD	-0.15%	0.09%	4.38%	-0.88%	3.50%

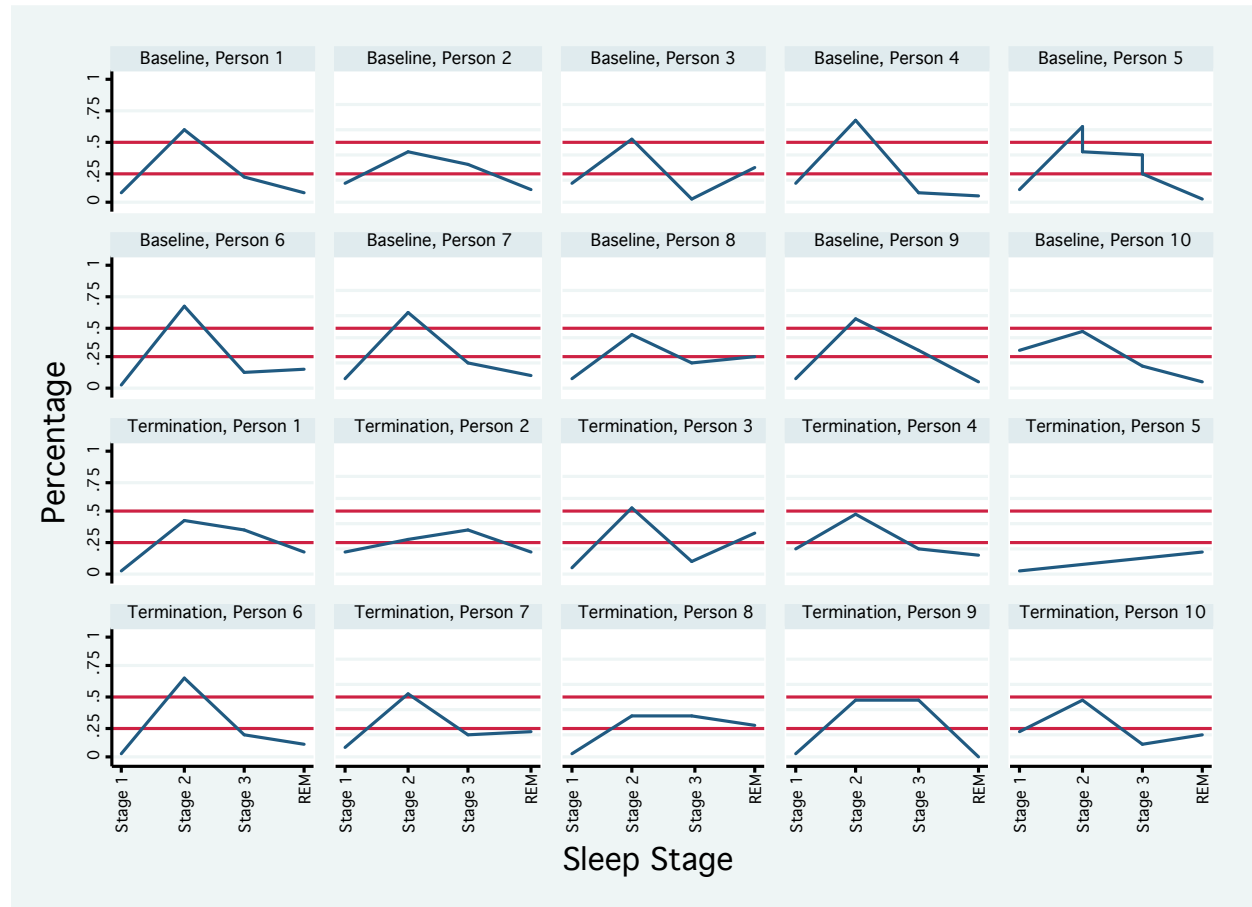
Table 2. Person Specific Changes in Sleep Stage

Person	Sleep Stage	Baseline	Termination	Difference
1	Stage 1	8.46%	2.43%	-6.03%
1	Stage 2	61.12%	43.14%	-17.98%
1	Stage 3	21.82%	36.17%	14.35%
1	REM	8.57%	18.25%	9.68%
1	Stage III & REM	30.39%	54.42%	24.03%
2	Stage 1	15.43%	4.59%	-10.84%
2	Stage 2	51.53%	52.78%	1.25%
2	Stage 3	3.63%	9.29%	5.66%
2	REM	29.39%	33.30%	3.91%
2	Stage III & REM	33.02%	42.59%	9.57%
3	Stage 1	16.78%	19.53%	2.75%
3	Stage 2	68.00%	46.96%	-21.04%
3	Stage 3	9.48%	19.41%	9.93%
3	REM	5.71%	14.08%	8.37%
3	Stage III & REM	15.19%	33.49%	18.30%
4	Stage 1	10.32%	2.42%	-7.90%
4	Stage 2	62.73%	41.61%	-21.12%
4	Stage 3	23.68%	38.41%	14.73%
4	REM	3.25%	17.54%	14.29%
4	Stage III & REM	26.93%	55.95%	29.02%
5	Stage 1	3.71%	4.45%	0.74%
5	Stage 2	67.09%	64.85%	-2.24%
5	Stage 3	13.95%	18.15%	4.20%
5	REM	15.23%	12.53%	-2.70%
5	Stage III & REM	29.18%	30.68%	1.50%

Table 2. Person Specific Changes in Sleep Stage (Continued)

Person	Sleep Stage	Baseline	Termination	Difference
6	Stage 1	7.31%	8.37%	1.06%
6	Stage 2	67.09%	52.50%	-14.59%
6	Stage 3	13.95%	18.12%	4.17%
6	REM	15.23%	21.00%	5.77%
6	Stage III & REM	29.18%	39.12%	9.94%
7	Stage 1	8.88%	4.85%	-4.03%
7	Stage 2	42.87%	34.80%	-8.07%
7	Stage 3	21.74%	34.09%	12.35%
7	REM	26.49%	26.24%	-0.25%
7	Stage III & REM	48.23%	60.33%	12.10%
8	Stage 1	8.64%	4.66%	-3.98%
8	Stage 2	56.51%	46.42%	-10.09%
8	Stage 3	30.33%	47.07%	16.74%
8	REM	4.50%	1.84%	-2.66%
8	Stage III & REM	34.83%	48.91%	14.08%
9	Stage 1	29.59%	20.53%	-9.06%
9	Stage 2	46.23%	48.58%	2.35%
9	Stage 3	19.08%	11.04%	-8.04%
9	REM	5.07%	19.83%	14.76%
9	Stage III & REM	24.15%	30.87%	6.72%
10	Stage 1	17.03%	17.08%	0.05%
10	Stage 2	40.83%	28.75%	-12.08%
10	Stage 3	31.72%	36.35%	4.63%
10	REM	10.40%	17.81%	7.41%
10	Stage III & REM	42.12%	54.16%	12.04%

Graph 1. Subject-Specific Changes in Sleep Stage



Sleep Efficiency

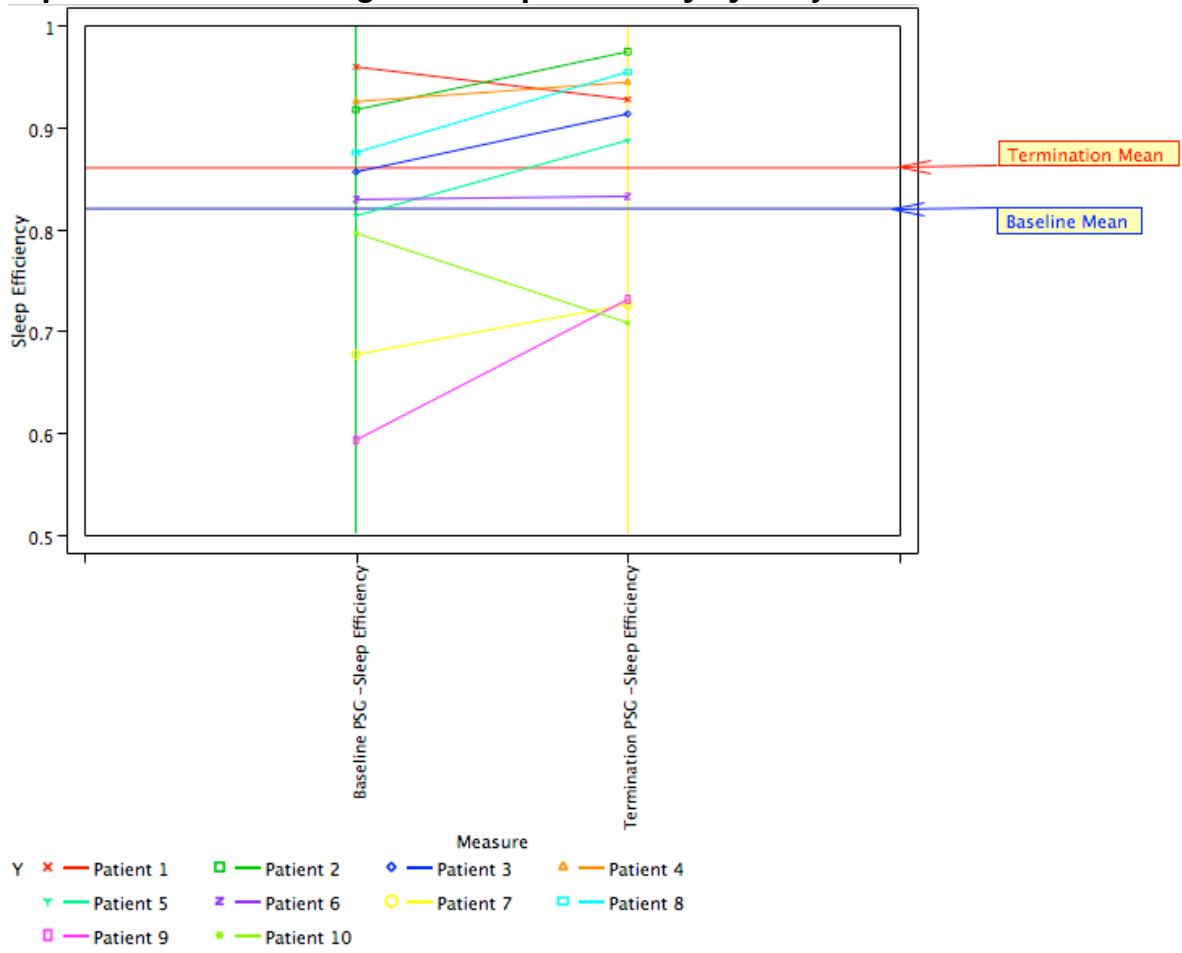
Statistical Analysis

Two analysis were conducted to look for differences between the baseline and termination measures for sleep efficiency. Overall sleep efficiency appears to improve by an average of 3.6 percent (confidence interval of -0.1%<>8.1%). A plot of the observed changes in sleep efficiency by subject shows us that eight of-the-ten persons improved. Nevertheless, both the modified paired t-test ($p < .10$) and the Wilcoxon Sign-Rank ($p < .12$) tests show no statistically significant improvement in sleep efficiency at the five percent level. If you increase the probability of a false positive (Type 1 error) to ten percent then there is evidence of statistical significance. A calculation of standardized effect (measure of treatment effect) using Cohen's D is 0.33, which is defined as a medium effect. Table 1 provides descriptive statistics for the change in sleep efficiency while Graph 1 shows this change with reference to each person and overall.

Table 1. Descriptive Statistics for Sleep Efficiency by Subject

Person	Baseline PSG Sleep Efficiency	Termination PSG Sleep Efficiency	Change
1	0.959	0.927	-0.032
2	0.917	0.974	0.057
3	0.856	0.913	0.057
4	0.925	0.944	0.019
5	0.813	0.887	0.074
6	0.829	0.832	0.003
7	0.677	0.726	0.049
8	0.875	0.954	0.079
9	0.593	0.731	0.138
10	0.796	0.708	-0.088
Mean	0.824	0.860	0.036
SD	0.114	0.103	-0.011

Graph 1. Observed changes in Sleep Efficiency by Subject



Epworth Sleepiness Scale

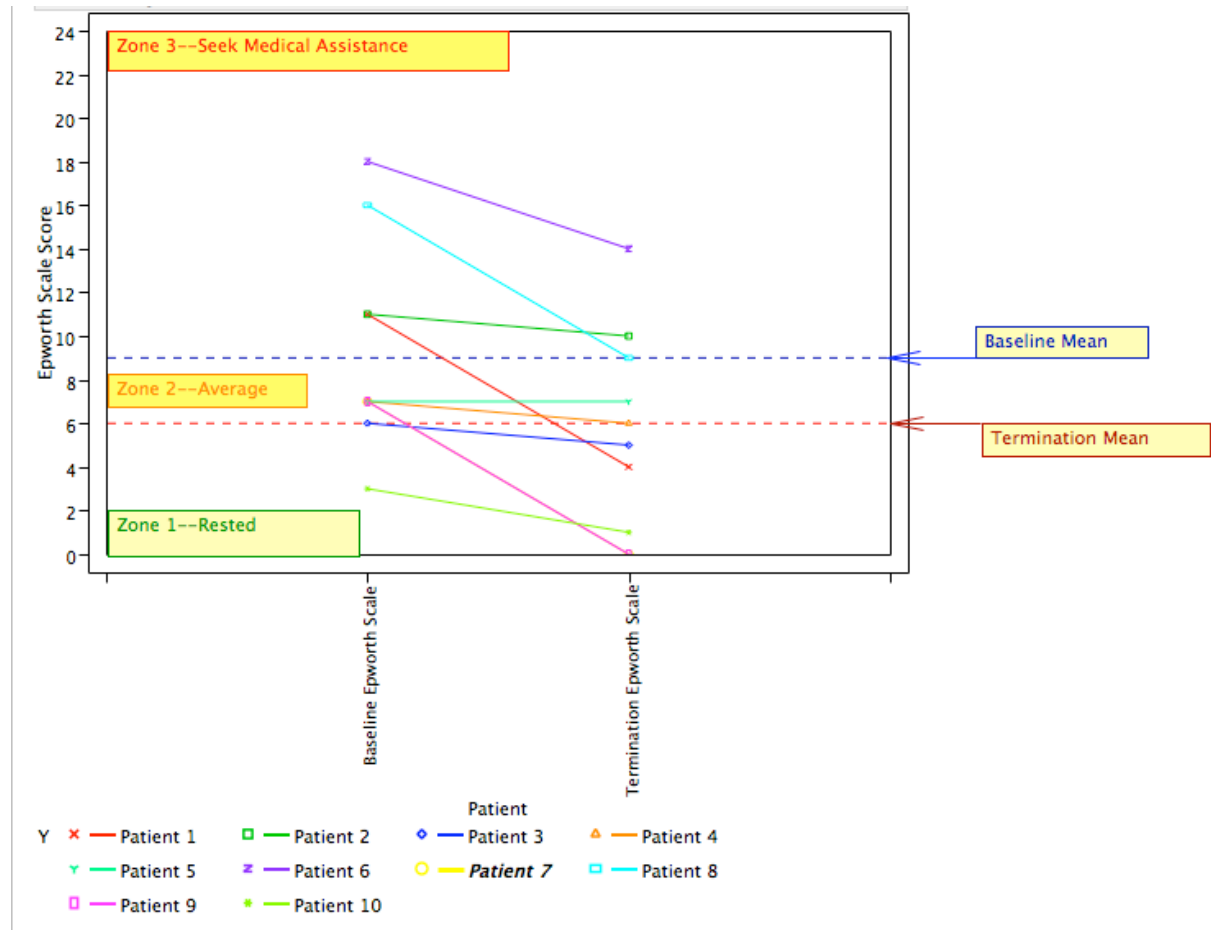
Statistical Analysis

Epworth Sleepiness Scale scores range between zero and 24. Scale Scores from one to six indicate that patients are getting enough sleep (**Zone 1**). Scale scores between seven and eight are average (**Zone 2**). Any score from nine and up indicates a potential sleep disorder (**Zone 3**). To analyze this data the modified paired t-test ($p < .01$) and the Wilcoxon Sign-Rank ($p < .01$) tests were used, and both results demonstrated statistical significance. Nine of the ten patients reported an improvement in sleepiness. Overall the intervention reduced sleepiness by an average of 3.70 points (confidence interval of 1.50<>5.90), thus taking the subjects from the “Seek Medical Assistance” zone to the “Rested” zone. Using Cohen’s D the standardized effect size (ES) estimate is 0.97 which is a very large effect. An ES of 0.97 indicates that the mean at the termination point is at the 82nd percentile of the baseline point. Table 1 provides descriptive statistics for the change in sleepiness scores while Graph 1 shows this change with reference to the major cut-points.

Table 1. Descriptive Statistics for Epworth Sleepiness Scale by Subject

Patient	Baseline Score	Termination Score	Difference	Descriptive
1	11	4	-7	Zone 3 to Zone 1
2	11	10	-1	Zone 3 to Zone 3
3	6	5	-1	Zone 1 to Zone 1
4	7	6	-1	Zone 2 to Zone 1
5	7	7	No Change	Zone 2 to Zone 2
6	18	14	-4	Zone 3 to Zone 3
7	7	0	-7	Zone 2 to Zone 1
8	16	9	-7	Zone 3 to Zone 3
9	7	0	-7	Zone 2 to Zone 1
10	3	1	-2	Zone 1 to Zone 1
Mean	9.3	5.6	-3.7	Zone 3 to Zone 1
SD	4.7	4.6	-0.1	

Graph 1. Changes in Epworth Sleepiness Scale by Subject



SF-36

Statistical Analysis

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). For the PCS subscale the modified paired t-test ($p < .48$) and the Wilcoxon Sign-Rank ($p < .33$) tests showed no statistical significance. Five patients reported an improvement in physical functioning, two reported no change, and three subjects reported a decrease in performance. The aggregate effect of treatment on physical function was 1.35 percent (confidence interval of $-2.19 <> 4.89$). However, the majority of this change is accounted for by one subject (patient #6). 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%). A calculation of standardized effect (measure of treatment effect) using Cohen's D is 0.35 (small) for the PCS scale and 0.69 (large) for the MCS subscale. Tables 1 and 2 provide descriptive statistics for the change in physical functioning by subject. Graphs 1 and 2 show this change with reference to each patient.

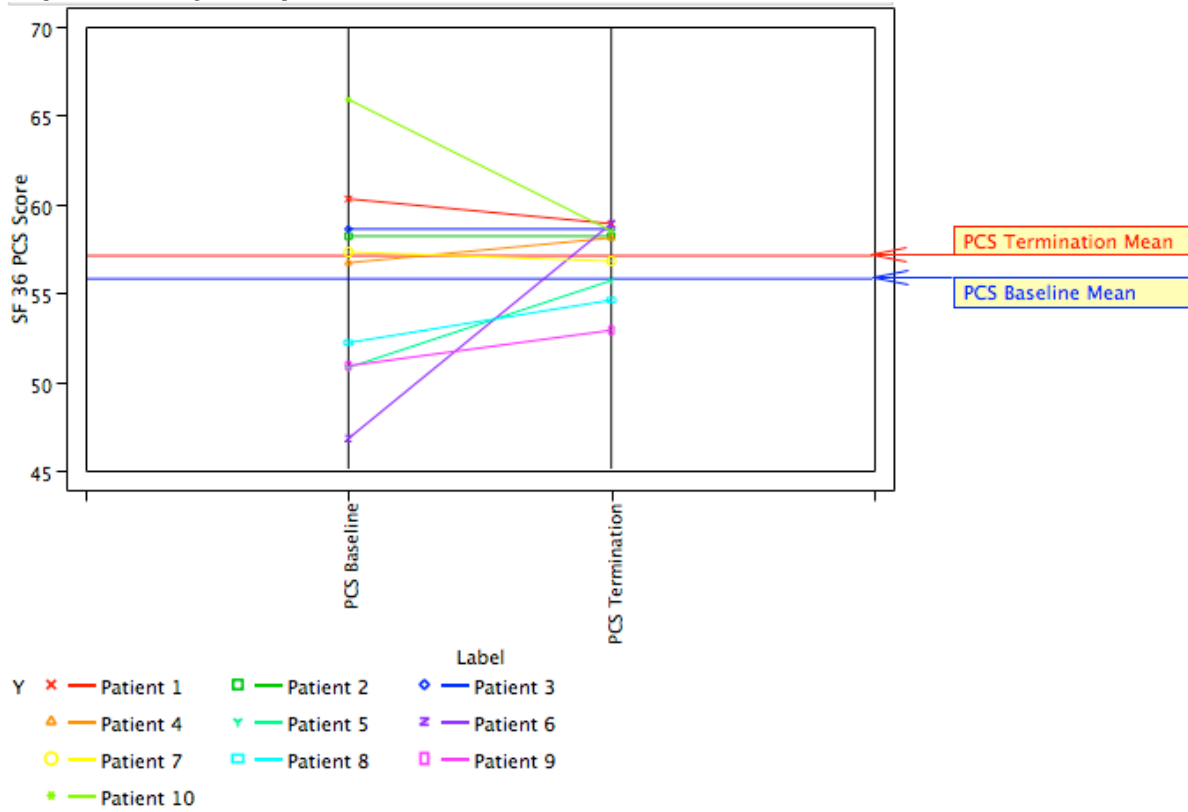
Table 1. Descriptive Statistics for Physical Subscale of SF-36 (PCS)

Patient	Baseline PCS	Termination PCS	Change
1	60.3	58.9	-1.4
2	58.2	58.2	0.0
3	58.6	58.6	0.0
4	56.7	58.1	1.4
5	50.8	55.7	4.9
6	46.8	58.9	12.1
7	57.3	56.8	-0.5
8	52.2	54.6	2.4
9	50.9	52.9	2.0
10	65.9	58.5	-7.4
Mean	55.8	57.1	1.4
SD	5.6	2.1	5.0

Table 2. Descriptive Statistics for Mental Subscale of SF-36 (MCS)

Patient	Baseline MCS	Termination MCS	Change
1	51.2	55.5	4.3
2	54.2	59.4	5.2
3	55.6	56.1	0.5
4	53.4	57.2	3.8
5	56.9	61.4	4.5
6	40.8	46	5.2
7	60.5	51.6	-8.9
8	55.4	59.1	3.7
9	55.7	57.1	1.4
10	32.6	57.2	24.6
Mean	51.6	56.1	4.4
SD	8.4	4.4	8.2

Graph 1. Subject Specific and Overall Scores for PCS



Graph 2. Subject Specific and Overall Scores for MCS

