

Title: Statistical Analysis of SF-36 data and Sexual Questionnaire  
By: Robert F. Waters, Ph.D.  
Date: Friday, August 12, 2011

**Preface:**

All data to be analyzed was delivered to me in electronic form (Excel Spreadsheets) with all personal data removed. SPSS™ was used to statistically analyze the data after the raw data was transformed from the Excel Spreadsheet(s) to the SPSS data input format used in computation. All information presented is without knowledge of the factor nuances associated specifically with this clinical trial thus minimizing (or eliminating) any analytical bias.

**SF-36:**

SF-36 information is important in the understanding of subjective responses in a clinical trial. This scientifically accepted format may illuminate changes prior to laboratory or other clinical and analytical diagnostic systems.

A parametric paired t-tested was used and the following results are indicated:

**Correlations:**

Most of the correlations between the PRE and POST data were  $p < .001$ , an indicator of a probable valid delivery of the SF-36 system. Subsequent statistical analysis has a higher probability of being valid.

Table 1:

**Paired Samples Correlations**

		N	Correlation	Sig.
Pair 1	Physical Function Pre & Physical Function Post	33	.513	.002
Pair 2	Role-Physical Pre & Role-Physical Post	33	.568	.001
Pair 3	Body Pain Pre & Body Pain Post	33	.753	.000
Pair 4	General Health Pre & General Health Post	33	.897	.000
Pair 5	Vitality Pre & Vitality Post	33	.634	.000
Pair 6	Social Functioning Pre & Social Functioning Post	33	.737	.000
Pair 7	Role-Emotional Pre & Role-Emotional Post	33	.579	.000
Pair 8	Mental Health Pre & Mental Health Post	33	.719	.000
Pair 9	Overall Physical Health Pre & Overall Physical Health Post	33	.818	.000
Pair 10	Overall Mental Health Pre & Overall Mental Health Post	33	.781	.000
Pair 11	Total SF36 V2 Pre & Total SF36 V2 Post	33	.834	.000

**T-test results:**

The 2-tailed significance levels across all categories are the red highlighted values in the table below.(Table 2) (Note: The smaller the number, the greater the statistical significance. For example, a  $p < .05$  indicates a less than 1 in 20 chance of error (being wrong) while a  $p < .001$  suggests a less than 1 in 1000 chance of “being incorrect” based on the data analysis.) All of the factors were  $p < .001$  except for General Health  $p < .023$ , and Physical Function  $p < .133$ . In biological systems many scientists suggest  $p < .05$  or better as an acceptable statistical significance level. Physical Function ( $P < .133$ ) is not strictly statistically significant ( $p < .05$ ), however, many analysts indicate there is a “trend” and should not be rejected.

In summary, based on the analysis of these data in this clinical trial, the treatment effect was very significant (most were  $p < .001$ ).

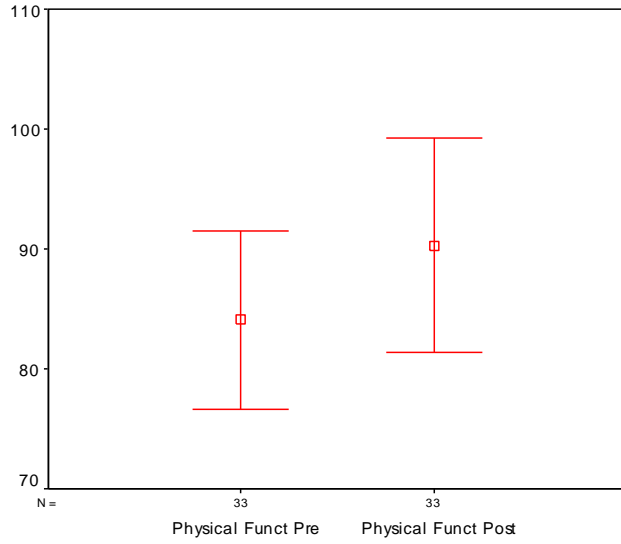
Table 2:

**Paired Samples Test**

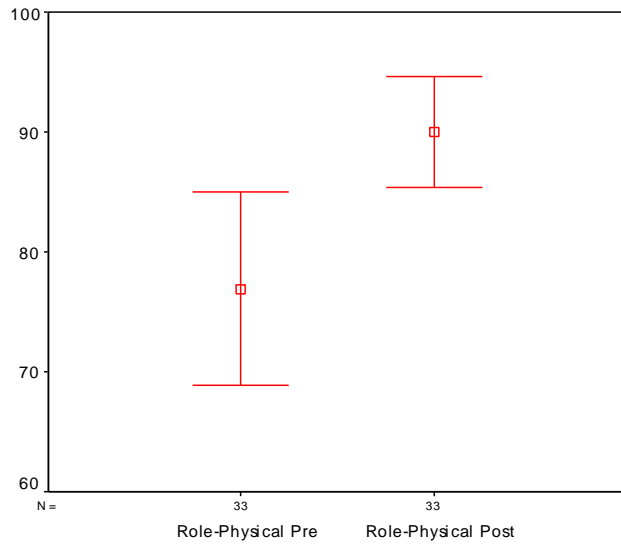
		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Physical Function Pre - Physical Function Post	-6.2121	23.11758	4.02425	-14.4093	1.9850	-1.544	32	.133
Pair 2	Role-Physical Pre - Role-Physical Post	-13.0606	18.70200	3.25560	-19.6920	-6.4292	-4.012	32	.000
Pair 3	Body Pain Pre - Body Pain Post	-12.1212	15.46318	2.69179	-17.6042	-6.6382	-4.503	32	.000
Pair 4	General Health Pre - General Health Post	-4.0606	9.80095	1.70613	-7.5359	-.5853	-2.380	32	.023
Pair 5	Vitality Pre - Vitality Post	-21.5909	16.62337	2.89376	-27.4853	-15.6965	-7.461	32	.000
Pair 6	Social Functioning Pre - Social Functioning Post	-13.2576	18.73421	3.26121	-19.9004	-6.6147	-4.065	32	.000
Pair 7	Role-Emotional Pre - Role-Emotional Post	-13.8970	21.00776	3.65698	-21.3460	-6.4479	-3.800	32	.001
Pair 8	Mental Health Pre - Mental Health Post	-9.3939	12.42211	2.16241	-13.7986	-4.9893	-4.344	32	.000
Pair 9	Overall Physical Health Pre - Overall Physical Health Post	-11.4061	9.72680	1.69322	-14.8550	-7.9571	-6.736	32	.000
Pair 10	Overall Mental Health Pre - Overall Mental Health Post	-12.4455	11.79738	2.05366	-16.6286	-8.2623	-6.060	32	.000
Pair 11	Total SF36 V2 Pre - Total SF36 V2 Post	-11.6970	9.59178	1.66971	-15.0981	-8.2959	-7.005	32	.000

# Error Bars for all Functions

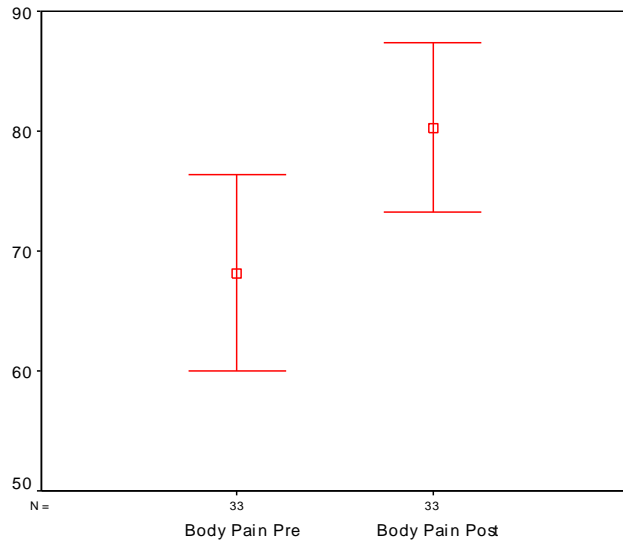
## Physical Function



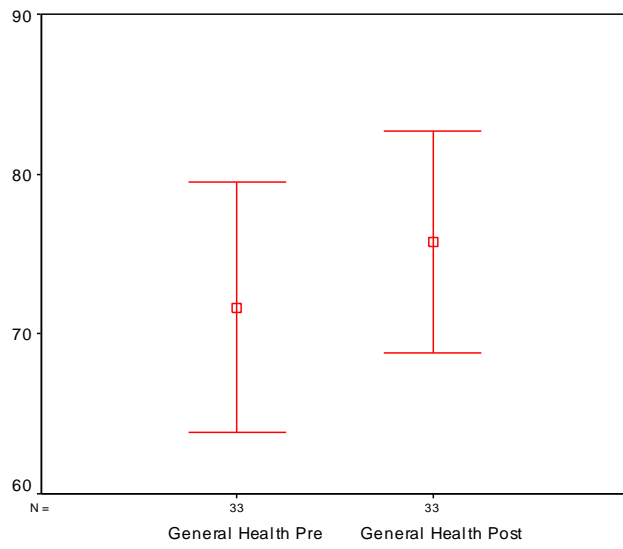
## Role-Physical



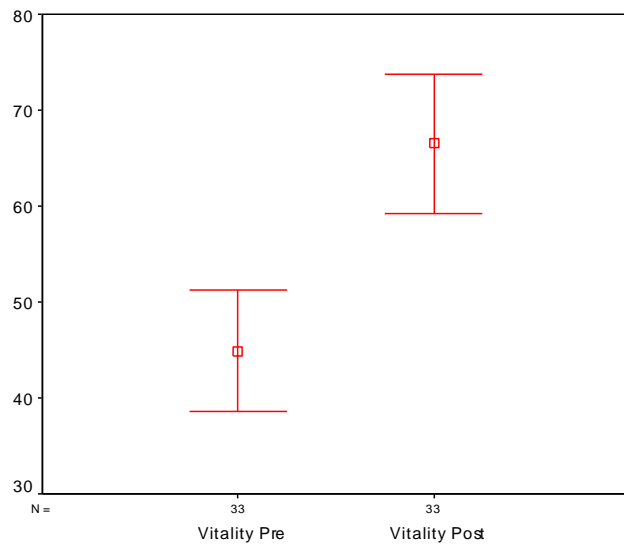
## Body Pain



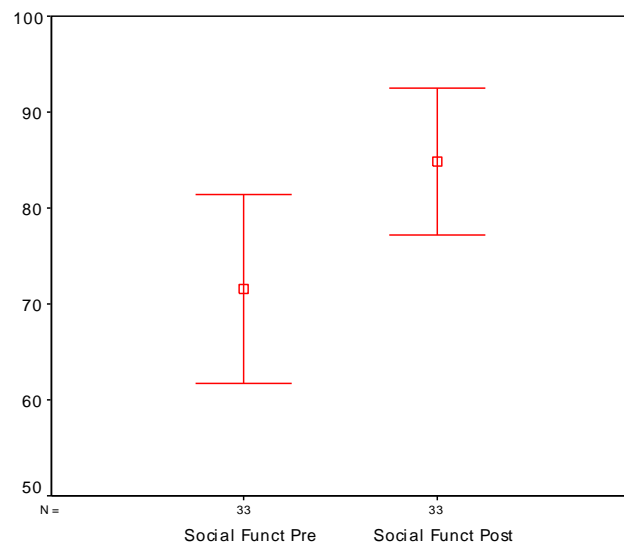
## General Health



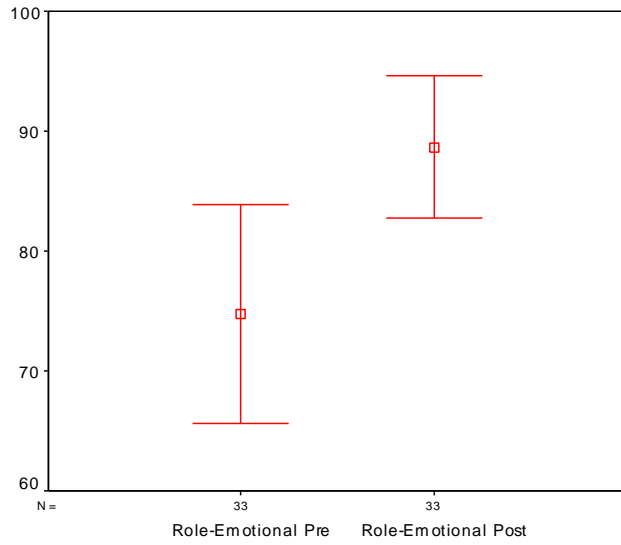
## Vitality



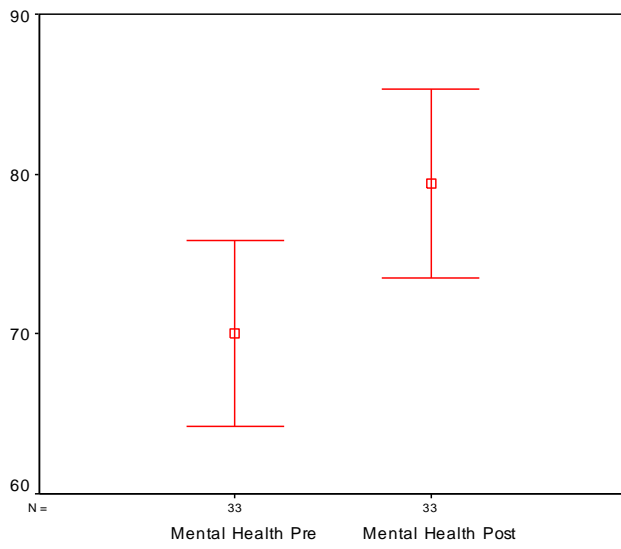
## Social Functioning



## Role-Emotional

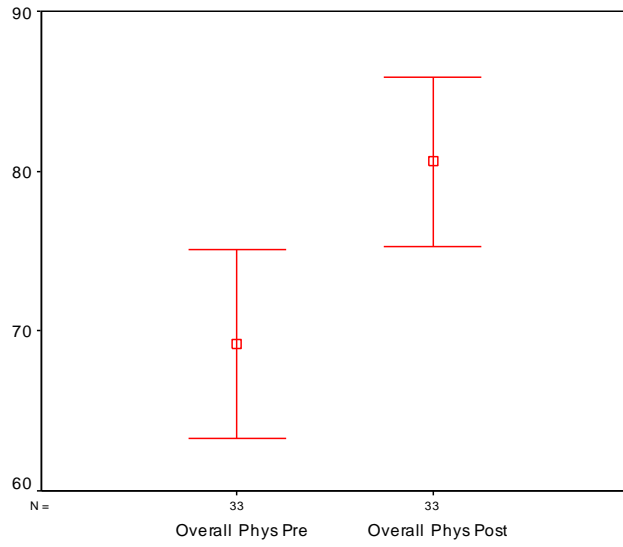


## Mental Health

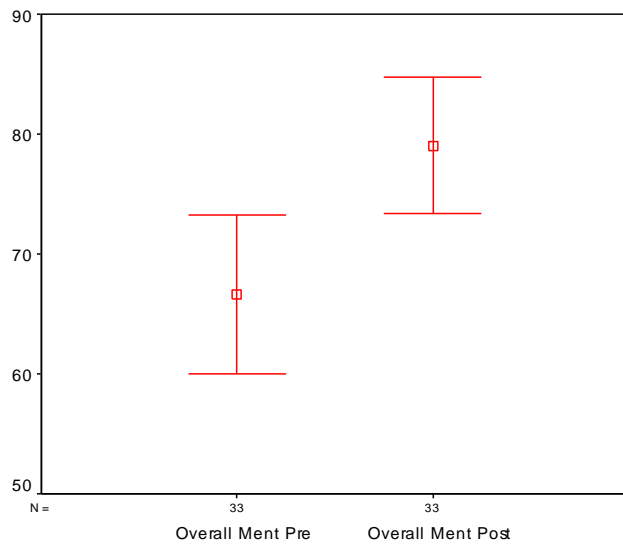




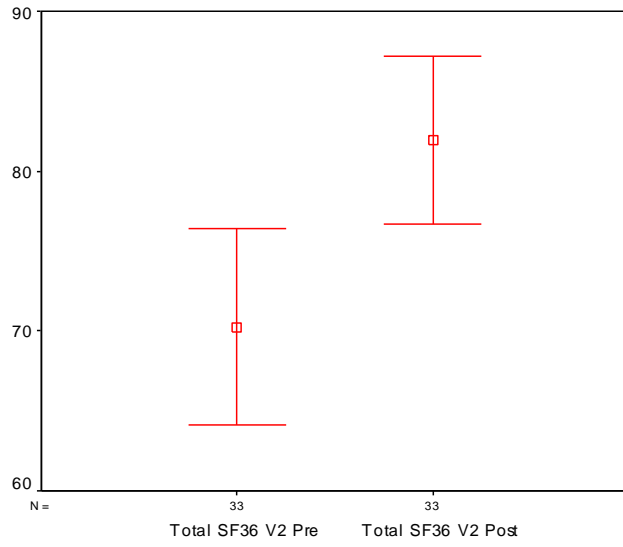
## Overall Physical Health



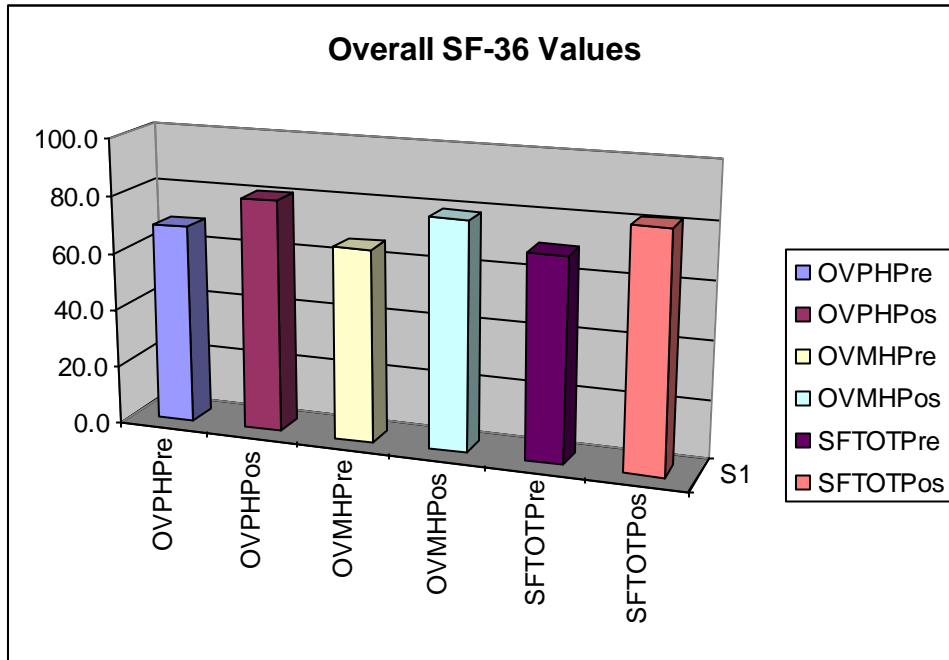
## Overall Mental Health



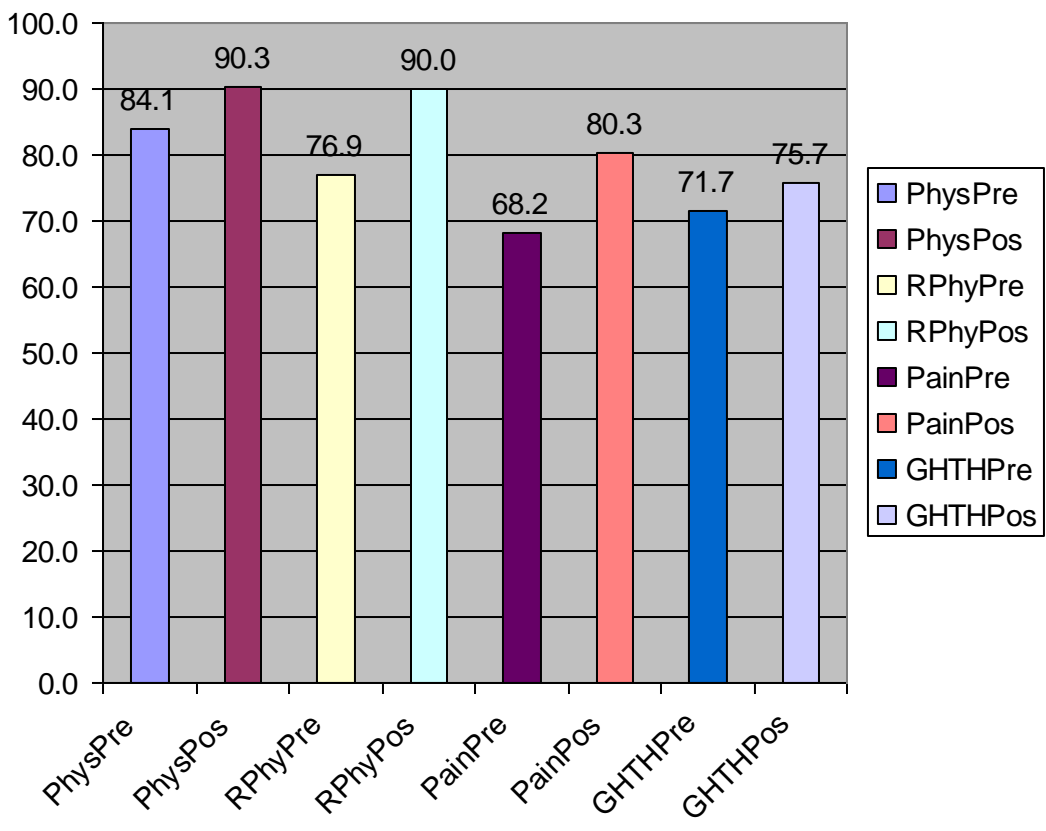
# Overall SF-36



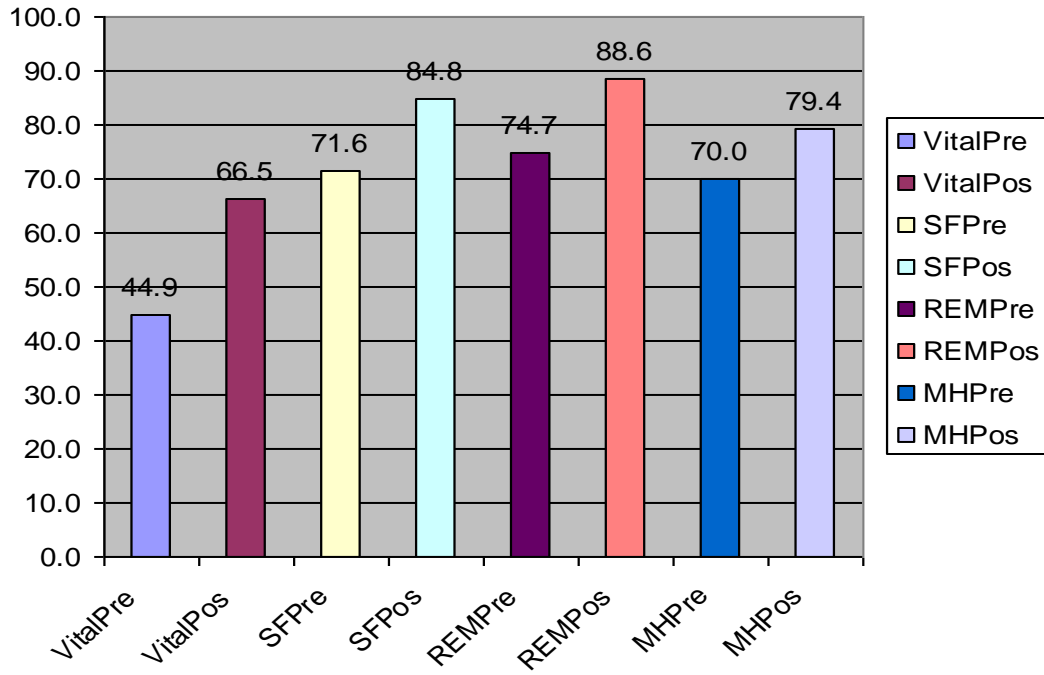
# Preliminary Charts



### SF-36 Outcomes Series 1



### SF-36 Outcomes Series 2



# Sexual Response Questionnaire:

Due to the complexity in the interaction of the various factors associated with this questionnaire a Univariate Analysis of Co-Variance (ANCOVA) was used to determine which factor(s) may have the highest association with other factors, and determine if these factor inter-relationships are significant.

## Overall Data:

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Sex Cog. Pre	14.0606	33	8.44075	1.46935
	Sex Cog. Post	18.1515	33	9.43107	1.64174
Pair 2	Sex Ar. Pre	10.6364	33	4.60854	.80224
	Sex Ar. Post	13.5152	33	6.11924	1.06522
Pair 3	Sex Beh. Pre	11.3939	33	5.41952	.94342
	Sex Beh. Post	12.0606	33	6.06187	1.05524
Pair 4	Orgasm Pre	10.1515	33	4.96941	.86506
	Orgasm Post	13.9697	33	6.38595	1.11165
Pair 5	Sex Drv. Pre	12.6061	33	6.19949	1.07919
	Sex Drv. Post	13.1818	33	3.85239	.67062
Pair 6	Total Pre	57.9394	33	20.83108	3.62622
	Total Post	70.8788	33	25.81516	4.49384

## Pairwise Comparisons:

Based on the information in the table below, there is an indication that sexcog (factor) is significantly inter-related with sexar, sexdrv, orgasm, and sexbeh. All factors exhibited a positive treatment effect in this study (see subsequent charts) with most being highly statistically significant using the t-test. Using a robust ANCOVA, may allow the researchers to see more complex interaction of data than could be extracted using other statistical analytical approaches.

### Pairwise Comparisons

Dependent Variable: Post

(I) Factor	(J) Factor	Mean Difference (I-J)	Std. Error	Sig. <sup>a</sup>	95% Confidence Interval for Difference <sup>a</sup>	
					Lower Bound	Upper Bound
orgasm	sexarp	-.638 <sup>b,c</sup>	1.915	.740	-4.441	3.166
	sexbeh	1.799 <sup>b,c</sup>	1.908	.348	-1.991	5.589
	sexcog	-4.458 <sup>*,t</sup>	1.841	.017	-8.115	-.801
	sexdrv	1.449 <sup>b,c</sup>	1.914	.451	-2.353	5.250
	total	-57.982 <sup>*,t</sup>	1.771	.000	-61.499	-54.465
sexarp	orgasm	.638 <sup>b,c</sup>	1.915	.740	-3.166	4.441
	sexbeh	2.437 <sup>b,c</sup>	1.986	.223	-1.507	6.380
	sexcog	-3.820 <sup>*,t</sup>	1.921	.050	-7.636	-.005
	sexdrv	2.086 <sup>b,c</sup>	1.991	.298	-1.869	6.041
	total	-57.344 <sup>*,t</sup>	1.854	.000	-61.027	-53.662
sexbeh	orgasm	-1.799 <sup>b,c</sup>	1.908	.348	-5.589	1.991
	sexarp	-2.437 <sup>b,c</sup>	1.986	.223	-6.380	1.507
	sexcog	-6.257 <sup>*,t</sup>	1.915	.002	-10.059	-2.455
	sexdrv	-.351 <sup>b,c</sup>	1.985	.860	-4.293	3.591
	total	-59.781 <sup>*,t</sup>	1.847	.000	-63.450	-56.113
sexcog	orgasm	4.458 <sup>*,t</sup>	1.841	.017	.801	8.115
	sexarp	3.820 <sup>*,t</sup>	1.921	.050	.005	7.636
	sexbeh	6.257 <sup>*,t</sup>	1.915	.002	2.455	10.059
	sexdrv	5.906 <sup>*,t</sup>	1.921	.003	2.092	9.721
	total	-53.524 <sup>*,t</sup>	1.778	.000	-57.055	-49.993
sexdrv	orgasm	-1.449 <sup>b,c</sup>	1.914	.451	-5.250	2.353
	sexarp	-2.086 <sup>b,c</sup>	1.991	.298	-6.041	1.869
	sexbeh	.351 <sup>b,c</sup>	1.985	.860	-3.591	4.293
	sexcog	-5.906 <sup>*,t</sup>	1.921	.003	-9.721	-2.092
	total	-59.431 <sup>*,t</sup>	1.853	.000	-63.112	-55.750
total	orgasm	57.982 <sup>*,t</sup>	1.771	.000	54.465	61.499
	sexarp	57.344 <sup>*,t</sup>	1.854	.000	53.662	61.027
	sexbeh	59.781 <sup>*,t</sup>	1.847	.000	56.113	63.450
	sexcog	53.524 <sup>*,t</sup>	1.778	.000	49.993	57.055
	sexdrv	59.431 <sup>*,t</sup>	1.853	.000	55.750	63.112

Based on estimated marginal means

\*. The mean difference is significant at the .05 level.

a. Adjustment for multiple comparisons: Least Significant Difference (equivalent to no adjustments).

b. An estimate of the modified population marginal mean (I).

c. An estimate of the modified population marginal mean (J).

### Univariate Tests

Dependent Variable: Post

	Sum of Squares	df	Mean Square	F	Sig.
Contrast	79562.543	5	15912.509	365.371	.000
Error	4006.750	92	43.552		

The F tests the effect of Factor. This test is based on the linearly independent pairwise comparisons among the estimated marginal means.

### T-Test

#### Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Sex Cog. Pre	14.0606	33	8.44075	1.46935
	Sex Cog. Post	18.1515	33	9.43107	1.64174
Pair 2	Sex Ar. Pre	10.6364	33	4.60854	.80224
	Sex Ar. Post	13.5152	33	6.11924	1.06522
Pair 3	Sex Beh. Pre	11.3939	33	5.41952	.94342
	Sex Beh. Post	12.0606	33	6.06187	1.05524
Pair 4	Orgasm Pre	10.1515	33	4.96941	.86506
	Orgasm Post	13.9697	33	6.38595	1.11165
Pair 5	Sex Drv. Pre	12.6061	33	6.19949	1.07919
	Sex Drv. Post	13.1818	33	3.85239	.67062
Pair 6	Total Pre	57.9394	33	20.83108	3.62622
	Total Post	70.8788	33	25.81516	4.49384

#### Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	Sex Cog. Pre & Sex Cog. Post	33	.676	.000
Pair 2	Sex Ar. Pre & Sex Ar. Post	33	.675	.000
Pair 3	Sex Beh. Pre & Sex Beh. Post	33	.633	.000
Pair 4	Orgasm Pre & Orgasm Post	33	.765	.000
Pair 5	Sex Drv. Pre & Sex Drv. Post	33	.321	.068
Pair 6	Total Pre & Total Post	33	.727	.000



**Paired Samples Test**

		Paired Differences				t	df	Sig. (2-tailed)	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower				Upper
Pair 1	Sex Cog. Pre - Sex Cog. Post	-4.0909	7.24726	1.26159	-6.6607	-1.5211	-3.243	32	.003
Pair 2	Sex Ar. Pre - Sex Ar. Post	-2.8788	4.53981	.79028	-4.4885	-1.2690	-3.643	32	.001
Pair 3	Sex Beh. Pre - Sex Beh. Post	-.6667	4.95395	.86237	-2.4233	1.0899	-.773	32	.445
Pair 4	Orgasm Pre - Orgasm Post	-3.8182	4.11138	.71570	-5.2760	-2.3604	-5.335	32	.000
Pair 5	Sex Drv. Pre - Sex Drv. Post	-.5758	6.15950	1.07223	-2.7598	1.6083	-.537	32	.595
Pair 6	Total Pre - Total Post	-12.9394	17.84821	3.10698	-19.2681	-6.6107	-4.165	32	.000

