

# Chiropractic Care and Changes in Physical State and Self-Perceptions in Domains of Health among Public Safety Personnel: A Longitudinal Follow up Study

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## ABSTRACT

**Objective:** Conduct a follow-up study to a published pilot study.

**Introduction:** A pilot study was published in 2007 regarding chiropractic care and its impact on public safety personnel. The pilot study assessed changes in participants' self perceptions of five health related quality of life domains and combined wellness of the five domains (HRQL). As well, from baseline throughout the duration of care, chiropractic assessments of physical/neurological changes were recorded. Based on the results, a follow up study was undertaken.

**Methods:** The study was conducted with public safety personnel representing police, firefighters, 911 operators, and others associated with public safety. The study commenced in mid February, 2008 and was completed in February, 2009. Participants were assessed at baseline, after 8 visits, then 16 visits.

**Results:** Sixty-two participants were enrolled. Thirty-two completed  $5.3 \pm 0.84$  months of continuous care (52% retention

rate). Twenty-two of thirty-two participants (69%) reported statistically significant improvements in self perceptions in health related quality of life domains (HRQL). Ten of the participants (31%) reported negative or no change. All thirty-two of the participants showed significant improvements in physical/neurological chiropractic assessment findings.

**Conclusions:** Participants benefited promptly in regard to improvements in physical/neurological findings, but differed in regard to self perceptions of HRQL. Continued study of similar populations under diverse settings will be required. It is recommended that structural equation models be developed to further assess the relationships between variables that affect HRQL, self perceptions, and improvement in physical state through chiropractic care.

**Key Words:** Public safety, self perception, physical state, chiropractic, public safety personnel.

## Introduction

A pilot study was published in 2007 regarding chiropractic care and its impact on public safety personnel.<sup>1</sup> The pilot study assessed changes in participants' self perceptions of five health related quality of life domains and combined wellness of the five domains.

As well, from baseline throughout the duration of care, chiropractic assessments of physical/neurological changes were also recorded. The results of that study suggested that a larger follow up study should be undertaken. The follow up study has been completed and is herein reported. It has been pointed out that the role public safety personnel fulfill in regard to the day to day protection of global citizens is evident.<sup>1</sup> It is of interest, however, that governmental as well as private sector support for the safety and advanced training, especially for firefighters, remains lacking irrespective of the

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never ending demands placed upon first responders.<sup>1-2</sup> Moreover, during the current economic crisis, public safety personnel are now coming under risk of job loss, accompanied by recommendations that those employed take on the additional stress of assuming dual appointments in different public safety arenas. An excerpt from Woodland California is likely to be representative of many other locals.<sup>3</sup>

While information continues to be dispersed concerning the safety of these personnel,<sup>4,6</sup> implementation of services that have evidentially demonstrated positive outcomes for those involved with public safety, is in need of improvement.<sup>7</sup> Important needs for all public safety personnel include: (1) potential to substantially lower costs in regard to lessening sick time, (2) lessening the duration of injury, (3) decreasing recidivism, (4) improving a sense of well-being, (5) enhancing stress related coping ability, (6) and improving one's physical state.<sup>8-9</sup>

As reported previously,<sup>1</sup> injuries leading to a decline in physical state are common among public safety personnel. There is a strong impetus in the public safety arena to discourage lengthy recovery time, though frequency often cannot be avoided depending on level of risk. In this regard, recent research by Liao et al.<sup>10</sup> revealed that such factors as age, tenure, gender, marital status, type of injury, and wage variables served as predictors of the duration of injuries. That is, the lower ranks of any of these scales were matched by prolonged recovery periods. Moreover, several Minnesota Multiphasic Personality Inventory (MMPI) scales were positively related to injury frequency. These included: (1) conversion hysteria, (2) psychopathic deviate, (3) and social introversion, while (4) psychopathic deviate and schizophrenia were also related to injury duration. These findings suggest that physical and mental/emotional stability are likely to be key elements in sustaining the performance level and overall functional ability of our public safety personnel.<sup>8-9</sup>

In 1998, the Crew System Ergonomics Information Analysis Center (CSERIAC) prepared recommendations for the Physical Fitness-Wellness Workshop Force Enhancement and Fitness Division, Department of Aerospace and Physiology and Human Performance USAF School of Aerospace Medicine.<sup>11</sup> The content was directed toward firefighters, as they are recognized as serving in one of the most dangerous public service entities, but applicable to any public safety area. Notable among the recommendations were: (1) absence of a health education wellness program, (2) adding health and wellness would be a plus, (3) do any of the health/wellness programs work? (4) why is a health/wellness program needed? (5) how could a health - wellness program meet needs of firefighters? Military firefighters? What are their unique needs?

#### *Longitudinal Study*

With the current concern regarding the health and stability of public safety workers under consideration, the present study acknowledged the necessity to provide longitudinal data from a larger population of public safety personnel. This study was conducted to provide more insight into answers to some of the concerns of groups such as CSERIAC and contribute to the physical and emotional health of our local public safety personnel.

## **Methods**

Based on findings derived from an initial pilot study,<sup>1</sup> a longitudinal investigation was commenced February 20<sup>th</sup> of 2008 which culminated February 5<sup>th</sup> 2009, to evaluate the impact of chiropractic care on participants' respective physical/neurological and self-perceived health status. The follow-up study involved the same design as the pilot study, involving public safety personnel representing county, city, and state police, firefighters, 911 operators, and administrators associated with public safety.

The research hypothesis remained the same as the pilot study. That is, chiropractic care will provide demonstrable positive benefits in regard to physical/neurological state as well as self perceptions of improved health related quality of life and wellness domains among public safety personnel.

Prior to collection of data, each participant was required to sign a human consent form approved by the College's Institutional Review Board (IRB). Each participant received standard chiropractic care provided by clinic interns, supervised by licensed practitioners, at the College clinic.<sup>12</sup> Participants first provided a case history, after which each received a chiropractic examination followed by an assigned plan of care.

#### *Health Related Quality of Life Questionnaire*

In addition to standard clinic protocols, each participant completed a Health Related Quality of Life questionnaire (HRQL).<sup>13</sup> The questionnaire was also completed by participants after eight, then 16 visits. Each questionnaire required self-ratings of domains of health including: (1) Physical State, (2) Mental/Emotional State, (3) Stress Evaluation, (4) Life Enjoyment (5) Overall Quality of Life, and (6) a "Combined Wellness" assessment that represented a sum of all other domains. The questionnaires were coded, scored, and analyzed by individuals blinded to the care received by the participants. Interns caring for the patients were also blinded to the results of the questionnaires or information related to other participants not under their care.

#### *Physical/Neurological Findings*

Physical/neurological assessments were conducted on the participants during the initial visit (baseline), followed by a reassessment at the eight visits, then 16 visits periods throughout the duration of the study. The eight and 16 visits re-assessment periods were dependent upon the accumulation of patient findings which in turn determined the time between subsequent visits. The physical/neurological assessments, listed by categories, included: (1) visual postural analyses (6 tests), (2) cervical range of motion (6 tests), (3) lumbar range of motion (6 tests), (4) spinal balance and leg length (5 tests), (5) orthopedics (19 tests), (6) motor strength (11 tests), (7) deep tendon reflexes (5 tests), (8) superficial reflexes (3 tests), and (9) sensory testing (14 tests). Positive tests (adverse findings) were assigned a numeric of +1 and no adverse finding a "0."

## Statistical Analyses

Both changes in physical/neurological findings and HRQL self-ratings were assessed by Cohen's method of determining effect size (ES, mean 1- mean 2/ sd of mean 1), or size of the clinical effect (Cohen's *d*). Cohen considered a value equal to 0.50 to 0.74 to be a moderate clinical effect, and a value of 0.80 or greater to represent a large clinical effect.<sup>14</sup> All data were evaluated by paired two-tailed Students' t-test for repeated samples and the Mann-Whitney test when comparing separate populations for differences. As well, assessments employing Spearman's correlation were used when evaluating relationships between different variables. An alpha of 0.05 was assigned to each test.

## Results

The population of 32 participants was 75% male and 25% female, ranging in age from 21 – 57 ( $36.5 \pm 10.0$ ) years of age. Approximately 34% were in various police forces, 53% volunteer firefighters, and 13% a mixture of firefighter/police, one mayor, firefighter/emergency medical technicians and 911 personnel (Table 1).

### Physical/Neurological Findings

Table 2 shows the sum of all physical/neurological assessment findings (9 categories, 75 possible points) for 32 participants averaging longevity of  $5.3 \pm 0.84$  months of continuous chiropractic care. As a group, when all 9 assessment tests were combined, the participants' physical/neurological findings decreased from a total of  $10.67 \pm 4.23$  at baseline to  $7.27 \pm 3.86$  at the completion of 8 visits, a statistically significant reduction ( $p = 0.000$ ) in findings, indicating significant improvement. As well, the improvement trend continued, as by the 16 visits reassessment period the sum total was  $4.60 \pm 2.13$ , a significant decrease from baseline ( $p = 0.000$ ) as well from the 8 visits reassessment ( $p = 0.008$ ).

### Self-Assessments of Health Related Quality of Life

Volunteers were asked to self-evaluate areas of their health related quality of life. These included Physical State, Mental/Emotional State, Stress, Life Enjoyment, Quality of Life and "Combined Wellness" representing a culmination of all other domains. When all domains were assessed for the volunteers ( $N = 32$ ) the group self-reported no significant improvements in any of the domains represented.

It was evident, however, that the population of 32 participants was clearly divided into those that did report improvement ( $N = 22$ , Group A) and those that did not ( $N = 10$ , Group B). The separation into groups was done in order to evaluate the significance of the different responses in conjunction with improvement in physical/neurological findings, which occurred in both groups (population as a whole  $N = 32$ , Table 2).

Table 3 reveals that among the 22 participants that improved, statistically significant positive changes occurred in Physical State ( $p = 0.005$ ), Mental/Emotional State ( $p = 0.000$ ), Stress ( $p = 0.029$ ), Life Enjoyment ( $p = 0.007$ ) and "Combined

Wellness" ( $p = 0.000$ ), between baseline and the 16 visits reassessment period. With the exception of Overall Quality of Life, all other domains exhibited moderate to large clinical effects (Cohen's *d*, see Methods).

Table 4 revealed that 10 participants showed no change, or a decline in self perceptions. Within Group B, statistically significant negative change occurred in regard to Physical State ( $p = 0.025$ ) and "Combined Wellness" ( $p = 0.008$ ) over the same baseline to 16 visits reassessment period. These two domains were also accompanied by moderate to large clinical effects. The Stress domain, while not statistically significant, also expressed a large clinical effect.

### Comparison of Groups Physical/Neurological Assessments

Groups A and B were assessed for both inter and intra Group comparisons for baseline (pre) and 16 visits (post) duration. Table 5 reveals a statistically significant pre to post decrease within each group, with no significant differences between groups for either baseline or 16 visits duration.

### Health Related Quality of Life Domains (HRQL)

Based on the data revealing two different populations among the 32 participants, inter and intra group comparisons were conducted with regard to HRQL. Table 6 shows that pre to post perception scores increased significantly within Group A, and decreased significantly within Group B. Intra Group comparisons demonstrated that HRQL self perceptions were significantly higher ( $p = 0.039$ ) at baseline for Group B (no change or negative overall perceptions) compared to Group A (positive improvement in self perceptions). Alternatively, Group B showed significantly lower perceptions ( $0.022$ ) than Group A after 16 visits duration ( $5.3 \pm 0.84$  months of care).

## Discussion

The high stress and/or physical demands experienced by public safety personnel are well documented.<sup>1</sup> Moreover, since the stress and physical demands experienced by public safety personnel are not likely to decrease, the need to provide health benefits to these personnel is viewed as being continuous, not short term. The pilot study coupled with the present study have provided data which suggests that over relatively short periods of time chiropractic care provides significant benefits. These benefits include improvement in both physical/neurological findings and enhanced self perceptions of Physical Status, Stress Evaluation, Life Enjoyment, and "Combined Wellness." These elements are all important benefits for public safety personnel, as attested to through current and past literature.<sup>1, 15</sup>

However, through the course of expanding the population size receiving care, it became evident that not all recipients progress at the same pace, or in the same manner. It appears from physical/neurological assessments that virtually all participants benefited, while the level of self perceptions of improvement in HRQL domains was divided into positive versus no change or negative perceptions. This, of course, begs the question as to how these populations may have differed and the significance of the difference in self perceptions. Although the number of participants still remains

too low to arrive at concrete answers, the initial information provided in this study allows for preliminary observations.

### *Characteristics of Groups A and B*

Both groups exhibited similar demographics and distribution of public safety involvement (Table 1). However, there was a distribution difference in regard to which branch of public safety was represented. Group A was 64% firefighters, 23% police, and 13% a mixture of dual appointments such as firefighter/police, firefighter/EMT. Group B, alternatively was 20% firefighter, 60% police, and 20% mixture of appointments. Studies have shown that self perceptions of health are influenced by age, and indeed the group that improved (Group A) was younger on the average than the group that did not (Group B). There is also support in the literature regarding self perceptions of health and occupation. Further it has been pointed out that firefighters are considered to be the most stressful public safety service (CERSIAC study). The shift in ratios between Group A and Group B with regard to the percentage of firefighters represented could, therefore, partially account for Group A being the most likely to perceive improvement in their health domains due to their more stressful occupation. Further study will be required to draw firmer relationships between improvement in health in and self perceptions in such a high stress job categories.

### *Assessment Differences between Groups A and B*

When assessing participants as a singular population, all 32 exhibited a significant decline in physical/neurological findings from baseline through 16 visits. Moreover, there were no significant differences in baseline findings (pre) or post findings between the two groups when compared to one another. These findings suggest that other parameters, discussed below, but not assessed in this study, may have played a significant role in differentiating the Groups A and B in terms of self perceptions of health related quality of life domains (HRQL).

The two groups did differ significantly in regard to self perceptions at both baseline and at 16 visits duration, but did not vary significantly in regard to physical/neurological findings (Tables 5, 6). Baseline HRQL scores were statistically higher among Group B participants (Table 6). This suggests that Group B may have presented for the study in a self perceived healthier state although their physical/neurological findings were not significantly different than Group A.

Group B also exhibited significantly lower HRQL scores than Group A at the 16 visits interval. This suggests that Group B not only presented with a higher self perception, but over the course of care did not undergo any positive change in self perceptions of HRQL domains. In fact, overall, Group B experienced a decline in HRQL, suggesting poorer self perceptions, even though their physical/neurological findings decreased, indicating improvement in physical state. Additionally, no significant correlations were shown between physical/neurological changes and HRQL scores for either group. This further suggests that other factors not assessed in this study could likely be important in determining self perceptions as opposed to changes in clinical findings.

### *Clinical Effects Associated with Groups A and B*

The moderate to large clinical effects associated with Group A's self-ratings in 4 of the 5 domains of HRQL as well as "Combined Wellness" (Table 3) also indicates that the response was of clinical importance as well as being statistically significant. In regard to Group B, moderate to large clinical effects were seen for 2 of the 5 HRQL domains as well as Combined Wellness. This suggests that while statistically significant decreases (Table 6) were observed, as with Group A, the clinical effects were also substantial in at least two of the 5 domains, and Combined Wellness. Nevertheless, the overall clinical effect appears to have been demonstrably greater in Group A than the less to no change Group B. It can be inferred from these observations that while a lesser percentage of participants reported no change to negative self perceptions, a substantially greater positive impact was seen for Group A which reported both physical/neurological improvements as well as significant increases in self perceptions of HRQL expressed as moderate to large overall clinical effects.

### *Summation*

In regard to the present study, several studies have presented findings that contribute to the benefits of positive health perceptions as a predictor of enhanced health and well being, pointing out that self perceptions of health are important in predicting morbidity and mortality.<sup>16-20</sup>

Consequently, while several reasons such as control over one's health, personal beliefs of what constitutes health, and cultural perspectives of how health is valued, may contribute to one's self perceptions, it is clear that physical improvement alone is not sufficient to predict mortality nor determine the state of individual health in some individuals. This information underpins the importance of investigating to what extent a linear relationship exists between one's physical/neurological state, and self perceptions in regard to HRQL domains.

The present study also elaborates the necessity in future studies to further assess the relationships between variables that are ordinarily associated with perceptions of health and wellness. These include, but are not limited to, age, gender, ethnicity, family support, physical state, self esteem, employment, financial stability, and cultural beliefs.

It is evident that more research is required to provide information regarding these relationships. The importance is linked to their value as predictors of morbidity and/or mortality which are only compounded in those individuals performing in the public safety arena. From the data presented in this study, it is suggested that structural equation modeling will be required to construct models relating as many of these variables as possible to the outcome of self perceptions of health.<sup>21-23</sup>

Larger populations with more diversity, studied over longer periods of time, will be essential in elucidating the significance of physical improvement and the myriad of other variables which contribute to self perceptions of health and well being among public safety personnel.

## Conclusions

1. These data suggest that short to long term chiropractic care has demonstrable physical/neurological benefits and enhanced self perceptions of HRQ for the majority of volunteers serving in acknowledged areas of stressful public safety arenas. These data are supportive of preliminary published pilot study data.
2. These findings also underpin the need to continue to study larger populations. A more diverse range of public safety personnel prone to extremes of stress related job vulnerabilities in different parts of the world should constitute the pool of participants. These studies should be conducted for longer periods of time to more thoroughly assess the benefits that have been reported.
3. In health related studies, self-ratings are an important complement to numerical evaluations of the statistical differences observed between pre and post evaluations. However, these studies should require sophisticated structural equations models to glean the most thorough understanding of the relationship between a wide range of variables.
4. Cohen's *d* as a measurement of clinical effect should be included in all studies that assess self perceptions and objective measurements as the statistic is a measure of the magnitude of changes occurring rather than a direct test of numeric differences.
5. Greater emphasis should be placed on assessing population differences in regard to acquired benefits. As mentioned, structural equation modeling should be employed to more thoroughly assess the impact of multiple variables in the final outcome assessments.

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**Table 1. Characteristics of Public Safety Personnel as a Singular Group, and as separate Populations either improving (Group A) or not improving (Group B).\***

Categories	Singular Group (N = 32)	Group A** (N =22)	Group B*** (N = 10)
Males	75%	77%	70%
Females	25%	23%	30%
Firefighters	53%	64%	20%
Police	34%	23%	60%
Dual Service	13%	13%	20%

\* As described in Results

\*\* Percentage of occupation types among twenty two participants as described in Results.

\*\*\* Percentage of occupation types among ten participants as described in Results.

**Table 2. Changes in Physical/Neurological Assessment Scores from Baseline through two Reassessments in a Group of thirty two Participants.<sup>1</sup>**

Assessment <sup>2</sup> (N = 32)	Baseline	Reassessment 1 (8visits)	Reassessment 2 (16 visits)
VPA			
Possible Score (6)	3.30 ± 1.36	2.25 ± 1.14	1.69 ± 0.96
CRM			
Possible Score (6)	1.50 ± 1.44	0.59 ± 1.02	0.58 ± 0.71
LRM			
Possible Score (6)	1.02 ± 1.31	0.38 ± 0.93	0.21 ± 0.45
SB/LL			
Possible Score (5)	3.59 ± 1.31	2.32 ± 1.41	1.39 ± 0.80
Ortho			
Possible Score (19)	0.74 ± 1.42	0.59 ± 1.18	0.22 ± 0.84
MS			
Possible Score (11)	0.00 ± 0.00	0.02 ± 0.15	0.00 ± 0.00
DTR			
Possible Score (5)	0.24 ± 0.82	0.21 ± 0.80	0.40 ± 0.63
SR			
Possible Score (3)	0.06 ± 0.25	0.09 ± 0.3	0.00 ± 0.00
ST			
Possible Score (14)	0.22 ± 0.76	0.82 ± 1.12	0.11 ± 0.05
Total (75)	10.67 ± 4.23	7.27 ± 3.86 (p = 0.000) <sup>4</sup>	4.60 ± 2.13 (p = 0.000) <sup>5</sup> (p = 0.008) <sup>6</sup>

1. Nine categories, with individual possible positive points scores ranging from 3 to 19, were assigned a value of “1” for each positive, or “0” for each negative finding. The N for the group was 32.
2. VPA (visual postural analysis), CRM (cervical range of motion), LRM (lumbar range of motion), SB and LL (spinal balance, leg length), Ortho (orthopedics), MS (muscle strength), DTR (deep tendon reflexes), SR (superficial reflexes), ST (sensory testing).
3. P < 0.05, t-test, two tailed repeated measures.
4. Eight visits assessments significantly lower than baseline.
5. Sixteen visits assessments significantly lower than baseline.
6. Sixteen visits assessments significantly lower than eight weeks assessments.

**Table 3. Positive Changes in Health Related Quality of Life Domains and overall Wellness among twenty-two Public Safety Personnel from Baseline to the second Reassessment \***

Domain **, 1	Baseline	Reassessment 2 (16visits)	Effect Size Cohen's <i>d</i>
N = 22			
Physical State (10 items)	0.70 ± 0.11	0.76 ± 0.11 <b>(p = 0.005)</b>	0.6
Mental/Emotional State (10 items)	0.71 ± 0.11	0.79 ± 0.13 <b>(p = 0.000)</b>	0.7
Stress Evaluation (10 items)	0.74 ± 0.09	0.79 ± 0.13 <b>(p = 0.029)</b>	0.6
Life Enjoyment (11 items)	0.55 ± 0.08	0.61 ± 0.09 <b>(p = 0.007)</b>	0.8
Overall Quality of Life (14 items)	0.69 ± 0.08	0.70 ± 0.09 <b>(p = 0.213)</b>	0.1
Combined Wellness (Summation of all Domains)	0.68 ± 0.06	0.74 ± 0.07 <b>(p = 0.000)</b>	1.00

\* Twenty-two participants as described in Results.

\*\* Methodology after Blanks et al.

1. All domains, plus combined wellness were assessed collectively. t-test  $p < 0.05$ , repeated measures and Cohen's *d* (See Methods) for clinical effect (mean 1 – mean 2/ sd of mean 1; .2 = small effect, .5 = moderate effect, .8 or greater = a large effect). In this instance, all effect sizes were averaged for a total combined effect size.

**Table 4. Negative or no Change in Health Related Quality of Life Domains and overall Wellness among ten Public Safety Personnel from Baseline to the second Reassessment \***

Domain **, 1	Baseline	Reassessment 2 (16visits)	Effect Size Cohen's <i>d</i>
N = 10			
Physical State (10 items)	0.73 ± 0.10	0.68 ± 0.10 <b>(p = 0.025)</b>	0.5
Mental/Emotional State (10 items)	0.77 ± 0.13	0.75 ± 0.10 <b>(p = 0.131)</b>	0.2
Stress Evaluation (10 items)	0.84 ± 0.11	0.70 ± 0.21 <b>(p = 0.050)</b>	1.3
Life Enjoyment (11 items)	0.67 ± 0.10	0.66 ± 0.14 <b>(p = 0.291)</b>	0.1
Overall Quality of Life (14 items)	0.76 ± 0.12	0.75 ± 0.08 <b>(p = 0.481)</b>	0.1
Combined Wellness	0.75 ± 0.09	0.67 ± 0.09 <b>(p = 0.008)</b>	0.9

\* Ten participants as described in Results.

\*\* Methodology after Blanks et al.

1. All domains, plus combined wellness were assessed collectively. t-test  $p < 0.05$ , repeated measures and Cohen's *d* (See Methods) for clinical Effect (mean 1 – mean 2/ sd of mean 1; .2 = small effect, .5 = moderate effect, .8 or greater = a large effect). In this instance, all effect sizes were averaged for a total combined effect size.

**Table 5. Inter and Intra Groups A and B Comparisons of Physical/Neurological Assessments.\***

Groups	Baseline (Pre)	2 <sup>nd</sup> Reassessment (16 visits, Post)
A**		
Improved Responders Mean scores	11.0 ± 3.6	7.7 ± 4.2
N = 22	<b>p = 0.000 (intra Group A, Pre to Post)</b>	
B***		
Negative or no Change responders Mean scores	10.8 ± 4.6	6.6 ± 4.4
N = 10	<b>p = 0.033 (intra Group B, Pre to Post)</b>	
p value (inter Groups) ****	0.90 (Baseline to Baseline)	0.30 (16 visits to 16 visits)

\* As described in Methods

\*\* Twenty two participants compared as described in Results: Intra Group comparisons were two-tailed paired t-test < 0.05.

\*\*\* Ten participants compared as described in Results: Intra Group comparisons were by two-tailed paired t-test < 0.05.

\*\*\*\* Group A and B participants were compared using Mann-Whitney test for significance at P < 0.05 as described in Results.

**Table 6. Inter and Intra Groups A and B Comparisons of Health Related Quality of Life Domains (HRQL). \***

Groups	Baseline (Pre)	2 <sup>nd</sup> Reassessment (16 visits, Post)
A** Improved Responders Scores	0.67 ± 0.06	0.73 ± 0.07
N = 22	p = <b>0.000 (intra Group A, Pre to Post)</b>	
B*** Negative or no Changes responders Scores	0.74 ± 0.09	0.67 ± 0.08
N = 10	p = <b>0.015 (intra Group B, Pre to Post)</b>	
p value (inter Groups) ****	<b>0.039</b> (Baseline to Baseline)	<b>0.022</b> (16 visits to 16 visits)

\* Methodology after Blanks et al. as described in Methods.

\*\* Twenty two participants compared as described in Results: Intra Group comparisons were two-tailed paired t-test < 0.05.

\*\*\* Ten participants compared as described in Results: Intra Group comparisons were by two-tailed paired t-test < 0.05.

\*\*\*\* Group A and B participants were compared using Mann-Whitney test for significance at P < 0.05 as described in Results.