EXECUTIVE SUMMARY

Prospective, Randomized, Placebo-Controlled, Double-Blinded Clinical Trial to Test the Efficacy and Short-Term Safety of "Neuroquell"®, an Oil-Based All Natural Product Intended to Relieve Sore Muscles, Joint Discomfort, and Minor Aches and Pain

Product: "Neuroquell"®
Client: Claire Ellen Topicals, LLC.

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Clinical Site

Bangor, Maine:
Marshall-Blum: Clinical Outcomes Specialists (parent company)
Herbal Research Clinic
Independent Medical Research Center
James M. Blum, PhD, Study Coordinator, Epidemiologist and Biostatistician
Medical Director: Ronald I. Blum, MD
Medical Advisor: Felix Hernandez, MD

PROTOCOL

Design

• Prospective, randomized, double-blind, placebo-based, parallel-group, clinicaltrial
• This trial had IRB approval from Fox Commercial IRB, Candice Woods, Exec. Director, Springfield, IL
• Randomization determined who was on placebo and who started with the active product; randomization were unequal (4:1 product:placebo)
• The duration was episodic in nature (5 episodes maximum)
• Evaluation was within a thirty-minute period
• All subject contact was with a study coordinator or research nurse who was blinded to the randomization scheme
• Subjects were paid $25 for completion of their participation in this trial
• Subjects were recruited from the general population of Bangor, Maine; the major exclusion criteria were major medical problems or individuals taking chronic pain medication

Product Usage (Episodic)

• Apply product liberally to areas under evaluation
• A second application may be administered within 15 minutes if the first does not appear to be effective

Placebo Product

The placebo was similar in appearance (color, density) to the actual product except that it only contained inert substances and had a different odor. Both were dispensed in unlabeled clear bottles that appeared identical.

Inclusion Criteria

• Men and women with any of the following symptoms:

    o Sore muscles
    o Mild-to-severe aches and pains
    o Mild-to-moderate joint inflammation

•To any body areas, including head, neck, back, legs, arms, hands, ankles, feet, or torso who express an interest in taking the product for reasons of reducing their symptoms

- Age range: 18 – 70
- Subjects who pass a compliance-screening test
- Subjects able to tolerate the active product and placebo
- Subjects who sign a consent form

Exclusion Criteria

- Subjects not meeting the age requirements
- Subjects who are non-compliant with testing and taking treatment regimens
- Subjects unable to tolerate specific ingredients in either regimen
- Subjects with severe co-morbid disease (cardiac, pulmonary, cancer, etc.); at the discretion of the medical team
- Subjects with alcohol abuse as determined by provider interviews

Cautionary Criteria

- Subjects who take more than two aspirins a day
- Subjects who take the blood thinners Coumadin or Heparin

Confounding Factors

- Severity and complexity of symptoms
- Age
- Co-morbid conditions

Primary End-Points

- General effectiveness at relieving symptoms
- Abdominal
- Back
- Hands
- Head and neck
- Legs

Secondary End-Points

- Activities of daily living
- Mood swings
- Moderate level of activities: mowing the lawn, moving furniture, bowling, etc.
- Ability to work

Other End-Points

- Recommend product
- Quality-of-life

ANALYTICAL METHODS

Methods

• Answers from survey tools were coded from 1 to 5
• Answers from the follow-up questionnaires were subtracted from each subject's baseline data to create the outcome measures

Example

Please write in the appropriate space, on the scale below, your rating for the symptoms:

1	2	3	4	5
Not Present	Slight	Moderate	Severe	Very Severe

For example, a subject answering the question about leg aches at baseline and following the episode give the following responses,

Time	***Response***
Baseline	*4*
After 30 minutes	*2*

The subtraction of the responses yields a point improvement for this subject on this question:

4 – 2 = 2 point improvement

• The responses for the two groups (placebo and treatment) for each symptom were summed. This forms the basis of the results.
• Differences in the means between the treatment and placebo groups were analyzed using the t-test.

Types of Responses

• *Average*: the average of each episode reported (ranges from 1 to 5)
• *Highest*: the highest difference between baseline and post-episode response
• *Episodic*: each episode represents an independent record (based on the assumption that each episode is independent

Categorical Analysis

• One or more point differences have been classified as "any improvement", while two or more point differences as "moderate", three or more point differences as "significant", and lastly, four or more point differences as "significant".

- *No Improvement*
- *Any Improvement*: One point or greater
- *Moderate Improvement*: Specifically two or more point improvement
- *Significant Improvement*: Specifically three or more point improvement

• All categories were analyzed using the Chi-Square test.
• These category improvements were determined *a priori* by the medical advisory group

Statistical Significance

•These criteria were set prior to the analysis.

- *Highly Significant*: $p < 0.05$
- *Significant*: $p < 0.10$
- *Statistical Trend*: $p < 0.15$

RANDOMIZED, PLACEBO-CONTROLLED CLINICAL TRIAL RESULTS

Subject Numbers

Thirty-two (32) subjects completed the product phase compared to twelve (12) in the placebo arms. The end-point final numbers varied, since not all subjects experienced each different symptom at baseline. For example, a subject may have reported only on backache, but not leg, hands, or head.

Baseline Characteristics

There were few differences with respect to the many baseline characteristics, although none reached statistical levels. These indicators includes demographics, medical and behavioral risks (alcohol and caffeine intake, smoking), education, jobs, income, and family parameters.

The placebo group had a slightly higher weight and associated body mass index. They also reported a higher income when adjusted for the number of adults and children living at home. There were slightly fewer women in the product group, whose average age was a little over two years higher. The differences in age distributions between the two groups is apparent in the 25–29 age group, where the placebos out distanced the product numbers while the product group had higher numbers in the 50–59 categories. Otherwise the age distribution appeared equal.

None of the major risk factors, such as diabetes, hypertension, thyroid and others were different.

Parameter	**Placebo** (*mean unless specified)*	**Product** (*mean unless specified)*	**P Value**
Age	39.8 years	42.2 years	N.S.
Weight	194.5 pounds	176.8 pounds	0.29
Height	64.4 inches	64.4 inches	N.S.
Body Mass Index (BMI)	33.9	29.9	0.17
Real Income I*	1.47	1.13	0.17
Real Income II**	0.72	0.62	N.S.
Female	92%	81%	N.S.

* *Income (by categories) is adjusted for Number of Adults living at home*
** *Income (by categories) is adjusted for Number of Adults and children living at home*
N.S. = *Not Significant*

Age Categories:

Age Categories	Placebo (%)	Product (%)
19 or 19	8.30	9.40
20–24	0.00	6.30
25–29	25.00	3.10
30–34	8.30	9.40
40–44	8.30	12.50
45–49	25.00	15.60
50–54	0.00	18.80
55–59	0.00	3.10
60–64	16.70	12.50

Average Difference of Means:

Parameter	Placebo	Product	P Value
Abdominal	-0.33	1.88	0.002
Back	0.62	1.79	0.006
Hands	0.25	2.31	0.0001
Head and Neck	0.60	1.93	0.01
Legs	0.75	1.96	0.004
Activities of Daily Living	0.00	1.72	0.0001
Mood	0.71	1.88	0.008
Moderate Activities	0.53	1.33	0.02
Work	0.17	1.48	0.0004

Using Highest Difference of Means for Each Subject:

Parameter	Placebo	Product	P Value
Abdominal	-0.33	2.00	0.002
Back	0.86	1.88	0.03
Hands	0.60	2.45	0.0004
Head and Neck	0.80	2.07	0.16
Legs	1.00	2.07	0.04
Activities of Daily Living	0.00	1.79	0.0001
Mood	0.83	1.88	0.015
Moderate Activities	0.60	1.40	0.07
Work	0.25	1.67	0.005

Average Score Improvements (Cumulative Percents)

Parameter	Treatment	1+ (%)	2+ (%)	3+ (%)
Abdominal	Placebo (n=3)	0	0	0
	Placebo (n=9)	100	44	22
Back	Placebo (n=7)	57	0	0
	Placebo (n=17)	94	59	18
Hands	Placebo (n=5)	20	0	0
	Placebo (n=21)	100	76	33
Head and Neck	Placebo (n=5)	60	20	0
	Placebo (n=14)	100	71	7
Legs	Placebo (n=4)	50	0	0
	Placebo (n=14)	100	79	14
Activities of Daily Living	Placebo (n=7)	14	0	0
	Placebo (n=28)	89	64	11
Mood	Placebo (n=5)	50	17	0
	Placebo (n=19)	100	59	29
Moderate Activities	Placebo (n=6)	40	0	0
	Placebo (n=17)	89	37	0
Work	Placebo (n=4)	0	0	0
	Placebo (n=12)	100	42	0

Percent Improvements

Parameter	Placebo (%)	Product (%)	P Value
Abdominal	-20.00	86.30	0.0001
Back	22.60	73.80	0.0001
Hands	13.60	85.20	0.0001
Head and Neck	44.40	92.40	0.002
Legs	23.30	81.90	0.0002
Activities of Daily Living	25.00	68.10	0.03
Mood	20.00	90.60	0.0008
Moderate Activities	31.80	73.70	0.01
Work	22.20	93.80	0.0001

Adverse Events

There were no adverse events reported in this trial.

The only concerns came from individuals who did not like the odor or felt they couldn't apply the oil at work, especially if needs to be applied under clothing.

Conclusions

Clearly, "Neuroquell"® is extremely effective in relieving a number of common pain and ache symptoms that improved quality of life indicators. The group that met the 0.05 criteria included discomfort associated with hands, back, legs, head and neck areas including headaches.

There were no statistical or clinical differences among baseline characteristics.

Each of the major outcomes demonstrated a difference compared to placebo for the difference of means using both the average and the highest level of improvement, as well as the categorical analysis (1+, 2+, or 3+), as well as the percent improvement scores.

There were no reports of adverse events associated with the use of this product or the placebo. The strong odor of the product is a concern with some individuals in some situations. The mechanism of action remains to be elucidated.

Based on this trial, it appears that "Neuroquell"® is effective in relieving minor aches and pains and improves ones' ability to function normally. Based on this study, "Neuroquell"® appears to be safe to use as indicated.

Further testing is warranted to confirm these results.

Product: "Neuroquell"®
Client: Claire Ellen Topicals, LLC.

DEMOGRAPHICS AND BASELINE PROFILE

All data is a percentage (%) unless indicated	**Control**	**"Neuroquell"®**
Risk Factors		
Age: Mean	39.80	42.20
Weight: Mean	194.54	178.80
Gender: Female	91.70	81.30
Body Mass Index: Mean	33.90	29.90
Behavioral		
Caffeine (3 or > cups/day)	6.20	12.40
Caffeine (mean cups/day)	1.50	1.80
Alcohol (> 3 drinks/week)	13.00	0.00
Smoking		
Never	75.00	50.00
No; quit < 2 years	0.00	15.60
No; quit > 2 years	16.70	18.80
Yes; < 1 pack/day	8.30	9.40
Yes; > 1 pack/day	0.00	6.30
Demographics		
Job		
Clerical	8.30	3.10
Homemaker	16.70	12.50
Management	0.00	3.10
Professional	25.00	25.00
Retired/Self Employed	16.70	21.90
Teaching/Student	16.70	18.80
Other*	16.70	15.60

**Other includes craft/technical. military service and not working*

Product: "Neuroquell"®
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DEMOGRAPHICS AND BASELINE PROFILE

All data is a percentage (%) unless indicated	**Control**	**"Neuroquell"®**
Hours Worked Per Week		
36 or more	45.50	51.60
Less than 36	45.50	19.40
Income		
< $20k	9.10	32.30
$20k – < $40k	63.60	41.90
$40k – < $60k	27.30	16.10
$60k – < $80k	0.00	6.50
$80k – < $100k	0.00	0.00
$100k +	0.00	3.20
Adults in Household		
1	50.00	21.90
2	33.30	62.50
3	8.30	6.30
4 or more	8.30	9.40
Children in Household		
0	45.50	68.80
1	27.30	18.80
2	18.20	12.50
3	9.10	0.00
4 or more	0.00	0.00
Education		
Less than high school	8.30	9.40
High school	41.70	25.00
Vocational/A.S. degree	33.30	37.50

All data is a percentage (%) unless indicated	**Control**	**“Neuroquell”®**
B.S. degree	16.70	25.00
Graduate degree	0.00	3.10
Doctorate or professional	0.00	0.00
Exercise Times/Week		
1	16.70	13.30
2	33.30	36.70
3	33.30	30.00
4	0.00	16.70
5 or more	16.70	3.30
Health Self-Assessment		
Excellent	0.00	6.30
Very good	58.30	43.80
Good	25.00	37.50
Fair	16.70	9.40
Poor	0.00	3.10
Use Vitamins		
Yes	50.00	68.80
Sometimes	8.30	12.50
No	41.70	18.80
Use Herbal Supplements		
Yes	41.70	31.30
Sometimes	8.30	18.80
No	50.00	50.00
Use Non-Physical Healthcare		
Yes	0.00	17.30
Sometimes	33.30	3.50
No	66.70	79.30

All data is a percentage (%) unless indicated	**Control**	**“Neuroquell”®**
Real Income: Adults**		
< 0.5	0.00	6.50
0.5 — < 1.0	18.20	29.00
1.0 — < 1.5	27.30	32.30
1.5 — < 2.0	18.20	9.70
2.0 or >	36.40	22.60
Mean	1.47	1.13
Real Income*: Adults and Children**		
< 0.5	30.00	38.70
0.5 — < 1.0	40.00	38.70
1.0 — < 1.5	20.00	19.40
1.5 — < 2.0	10.00	3.20
2.0 or >	0.00	0.00
Mean	0.72	0.62

*** = income/# of adults in the household.*
**** = income/# of adults and children in the household*

Prospective, randomized, double-blind placebo-controlled clinical trial for:

Neuroquell

Conducted By:
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January 2003

CONFIDENTIAL DATA

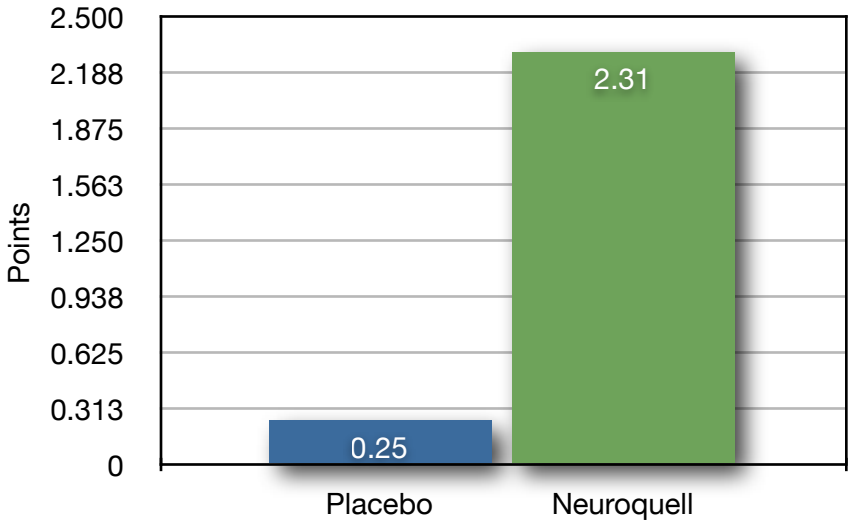
Key: Reduction of Pain and Aches*
Cumulative Scale

Response		Award
No improvement	=	Less than 1-point
Any	=	1 or more points
Moderate	=	2 or more points
Significant	=	3 or more points

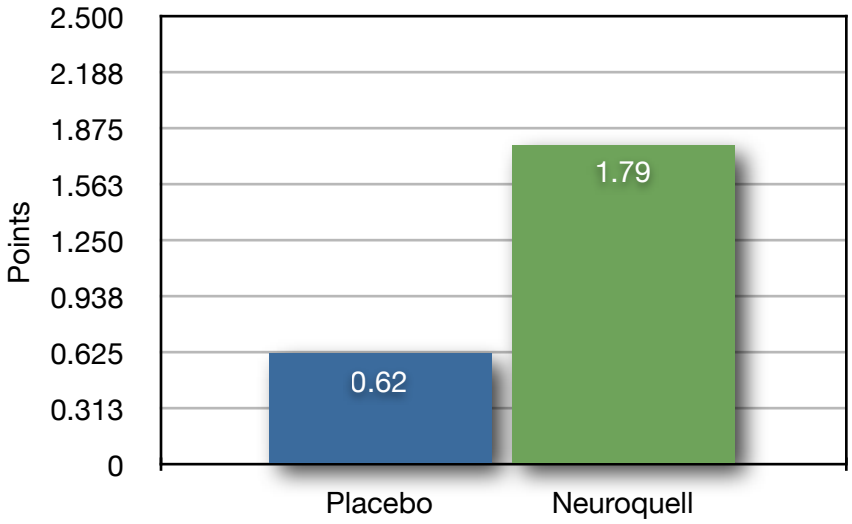
**5-point scale. 4-point improvement = maximum possible. Based upon initial response*

The trial chart summations that follow are an accurate representation of the larger collection of trial summations gleaned from the clinical trial results.

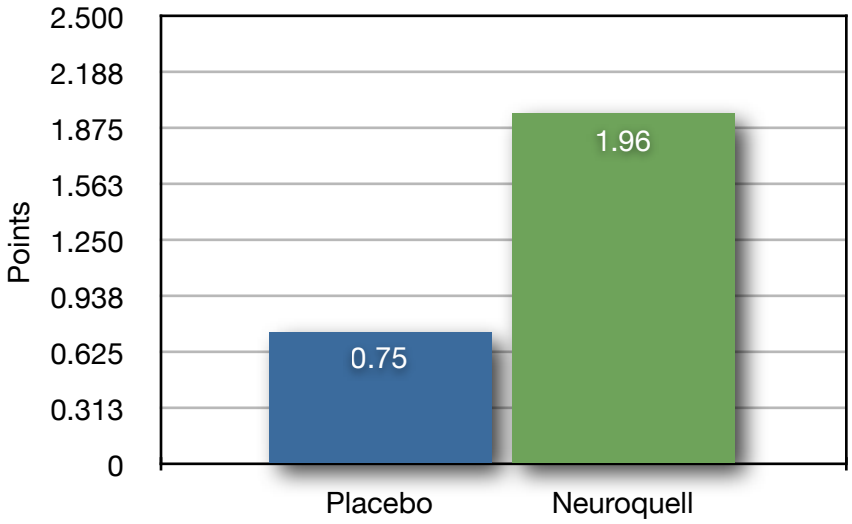
Neuroquell®
Difference of Average Mean: **Hands and Feet**
(P < 0.0001)



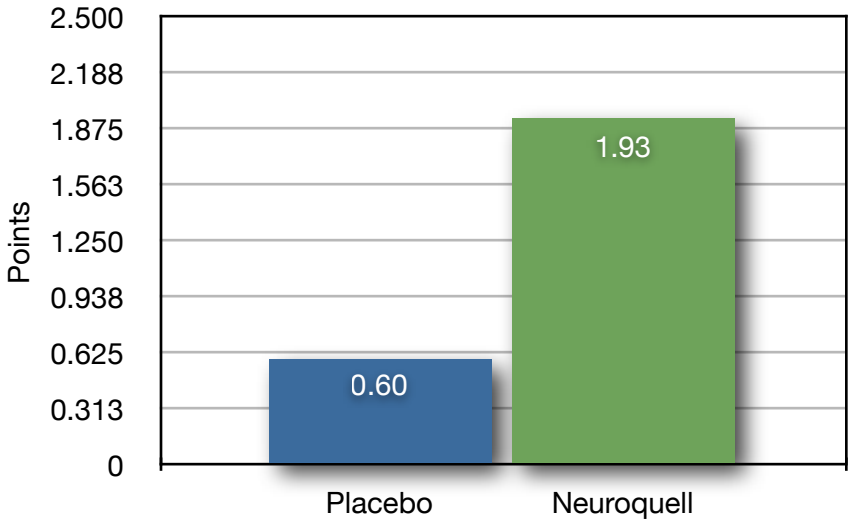
Neuroquell®
Difference of Average Mean: **Back Pain**
(P < 0.006)



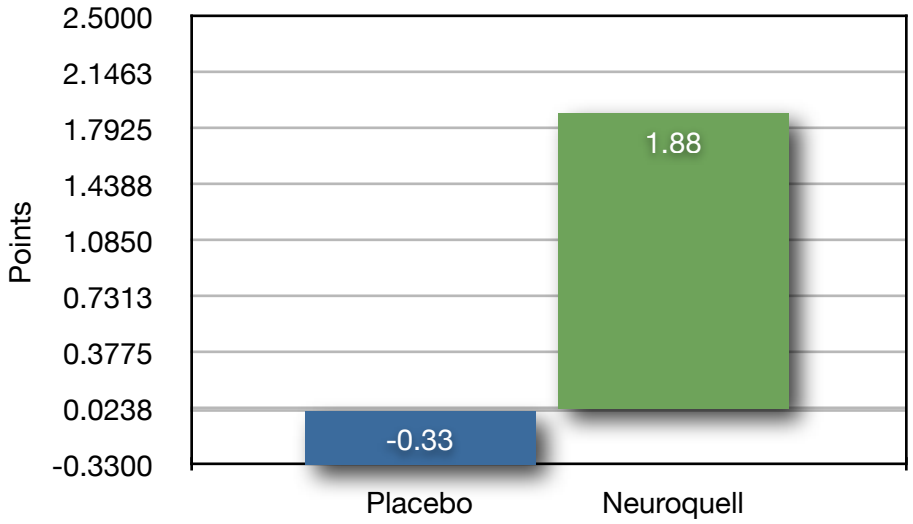
Neuroquell®
Difference of Average Mean: **Leg Pain**
(P < 0.004)



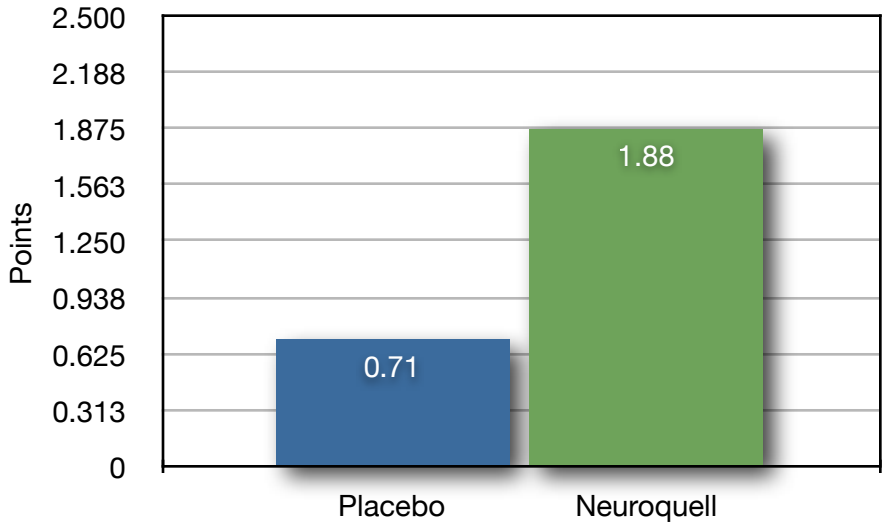
Neuroquell®
Difference of Average Mean: **Head Ache**
(P < 0.1)



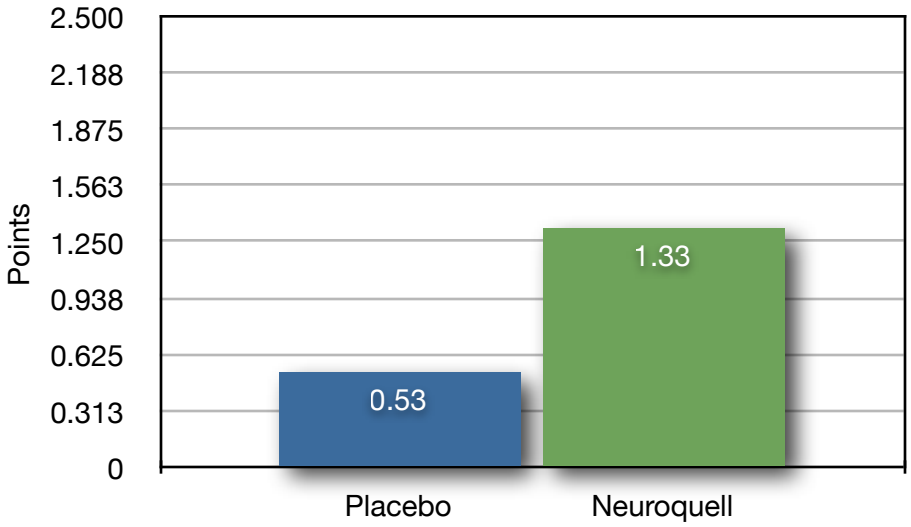
Neuroquell®
Difference of Average Mean: **Abdominal Pain/Ache**
(P < 0.002)



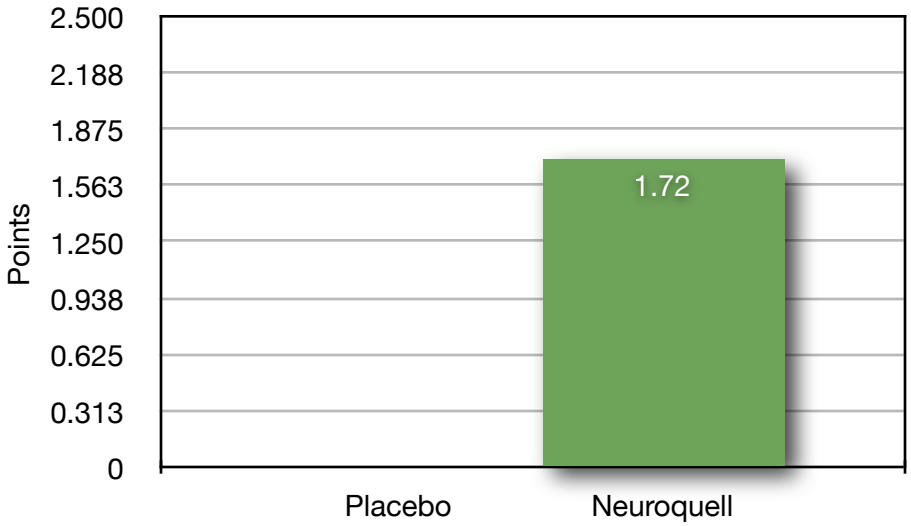
Neuroquell®
Difference of Average Mean: **Mood**
(P < 0.008)



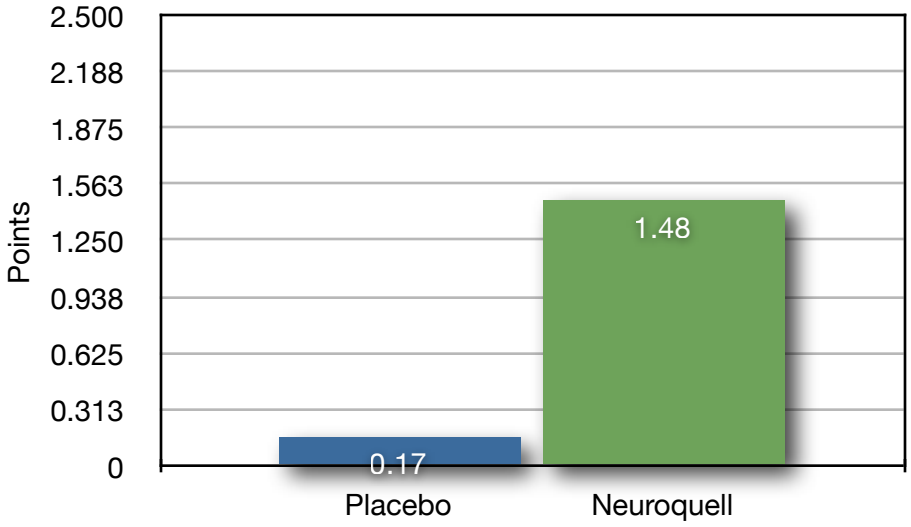
Neuroquell®
Difference of Average Mean: **Moderate Activities**
(P < 0.02)



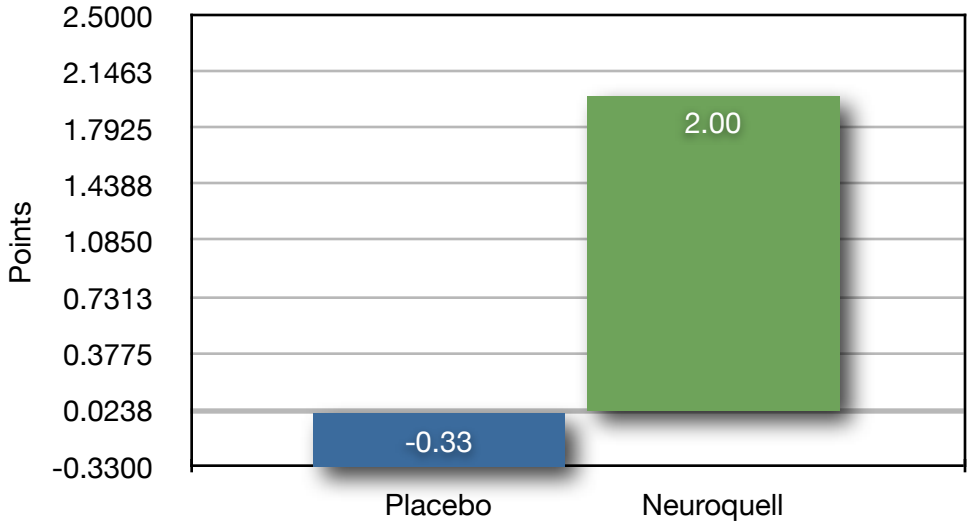
Neuroquell®
Difference of Average Mean: **Activities of Daily Living**
(P < 0.0001)



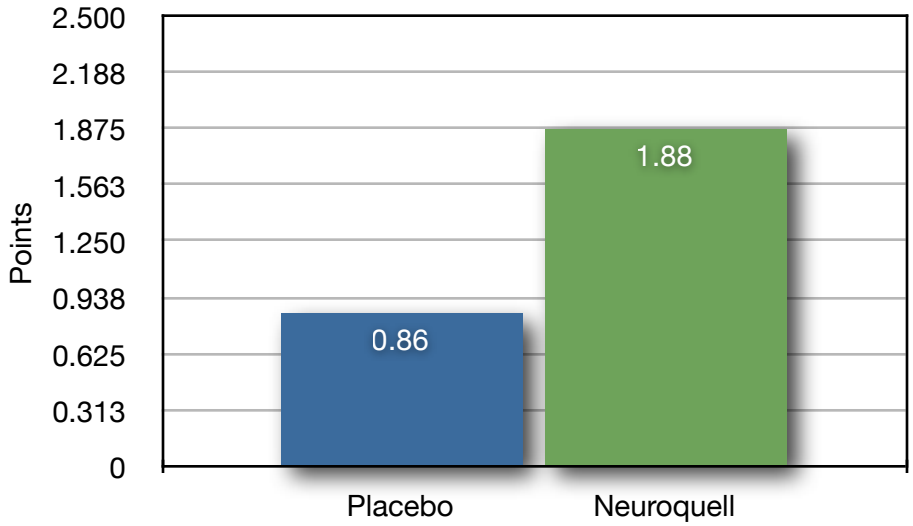
Neuroquell®
Difference of Average Mean: **Work**
(P < 0.0004)



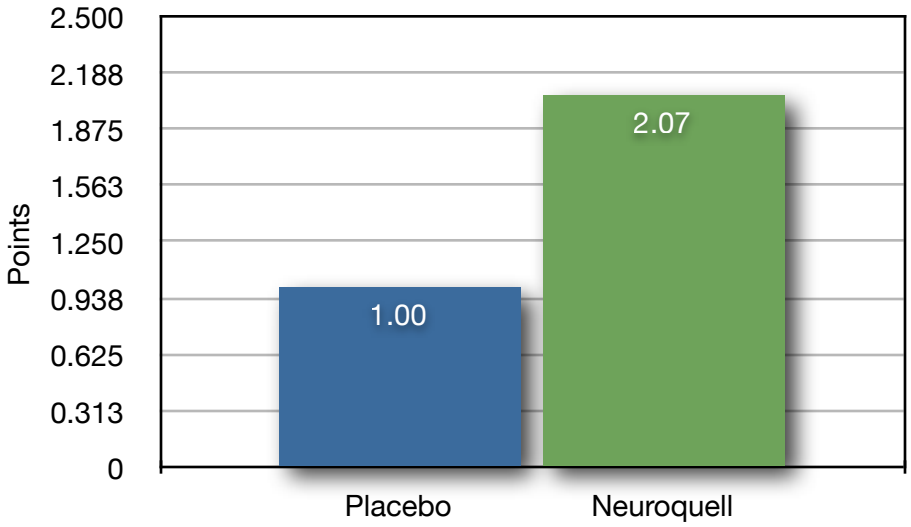
Neuroquell®
Difference of Mean Highest Score: **Hands & Feet**
(P < 0.002)



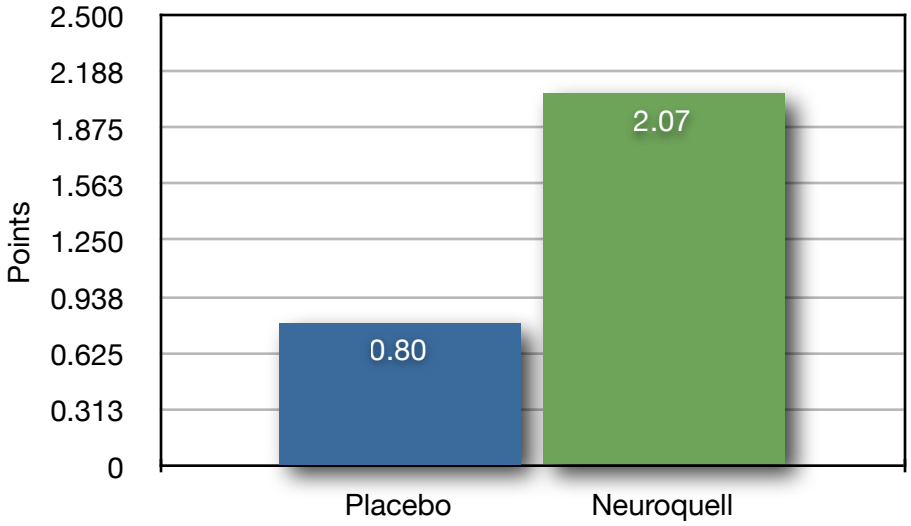
Neuroquell®
Difference of Mean Highest Score: **Back Pain**
(P < 0.03)



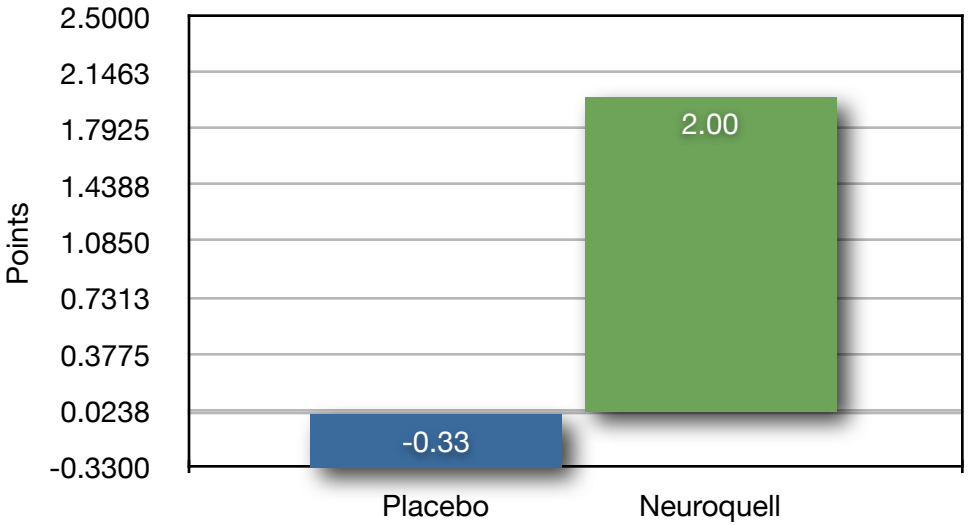
Neuroquell®
Difference of Mean Highest Score: **Leg Pain**
(P < 0.04)



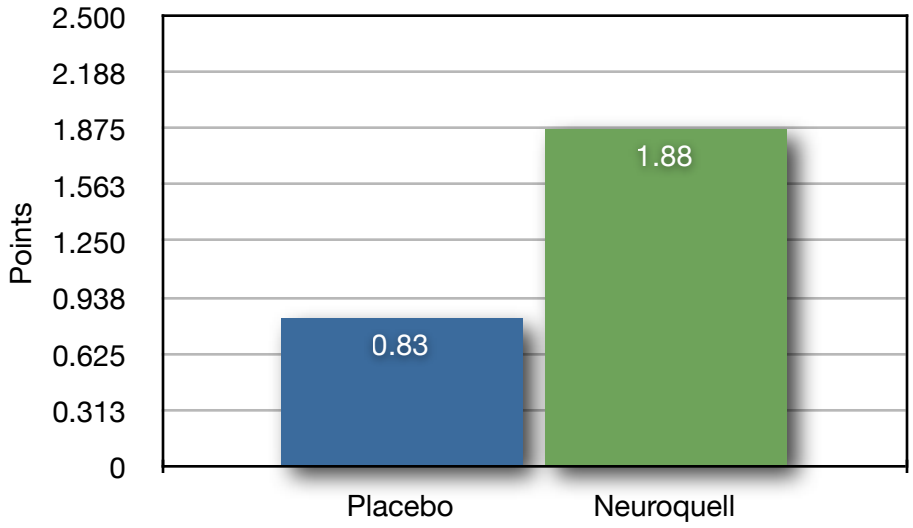
Neuroquell®
Difference of Mean Highest Score: **Headache**
(P < 0.16)



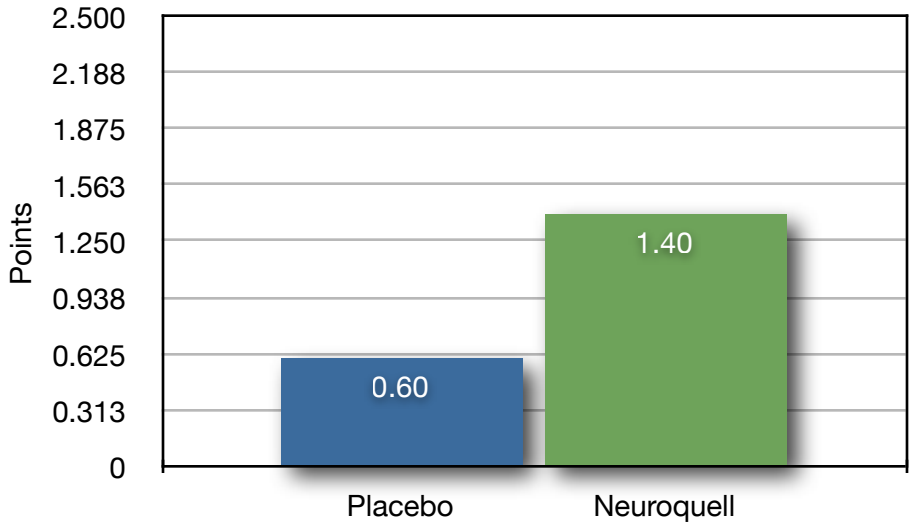
Neuroquell®
Difference of Mean Highest Score: **Abdominal Pain/Ache**
(P < 0.002)



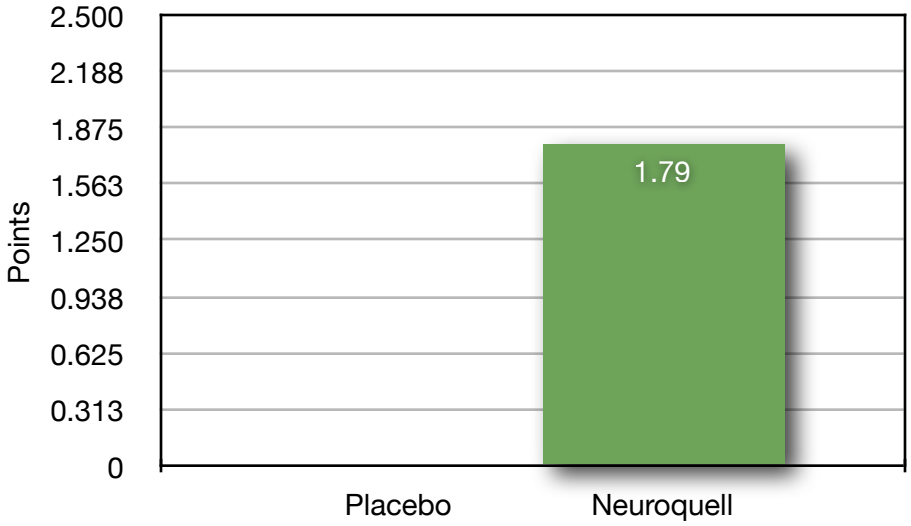
Neuroquell®
Difference of Mean Highest Score: **Mood**
(P < 0.02)



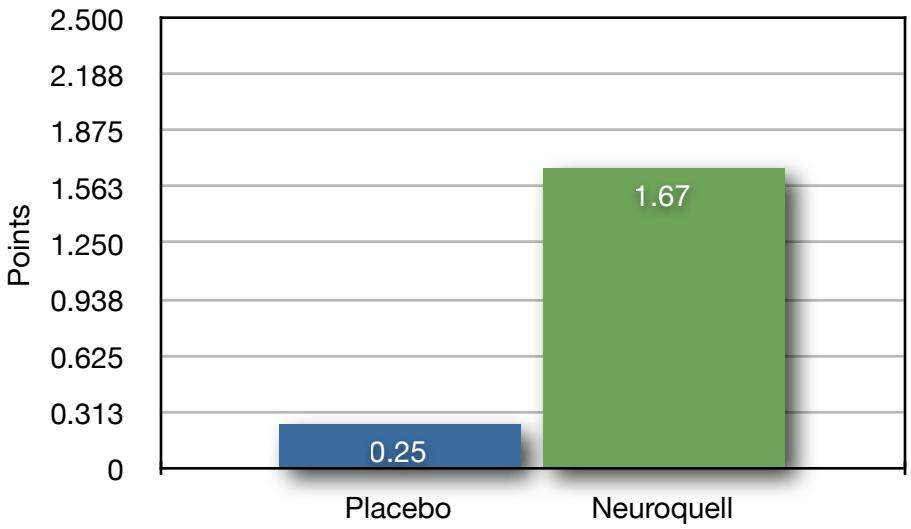
Neuroquell®
Difference of Mean Highest Score: **Moderate Activities**
(P < 0.07)



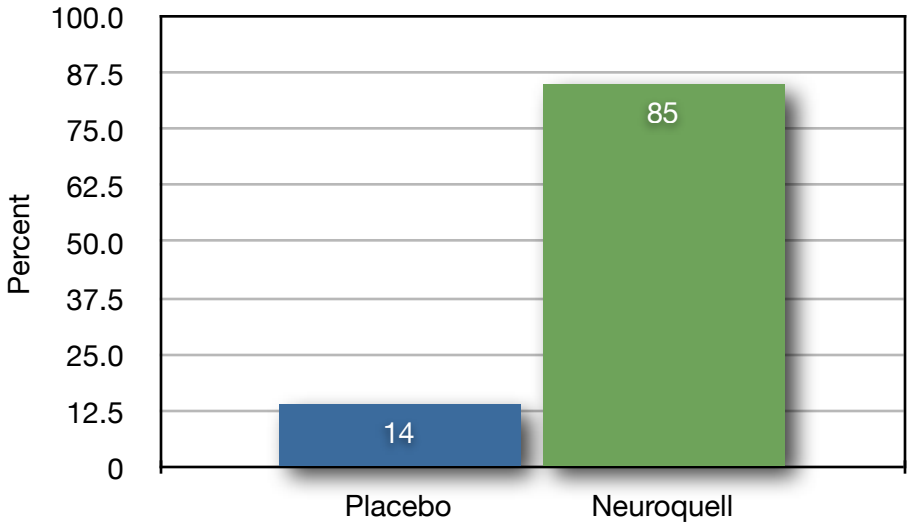
Neuroquell®
Difference of Mean Highest Score: **Activities of Daily Living**
(P < 0.0001)



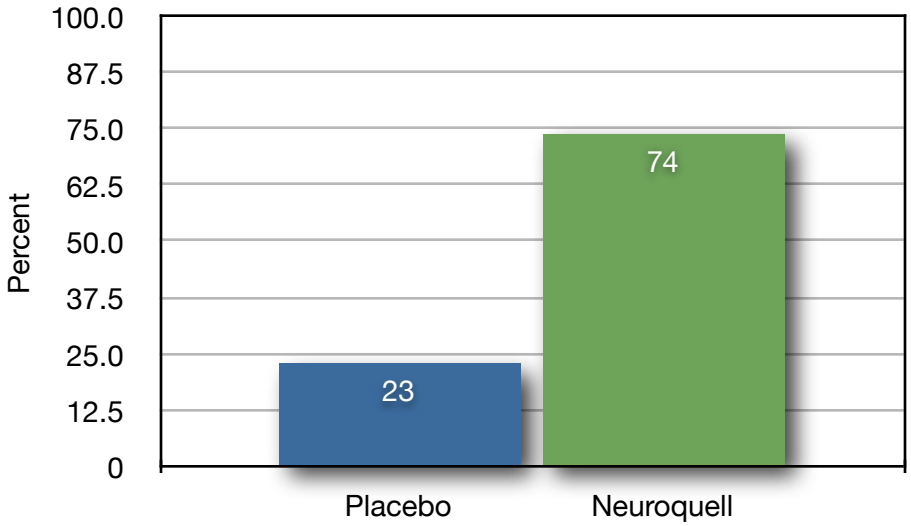
Neuroquell®
Difference of Mean Highest Score: **Work**
(P < 0.005)



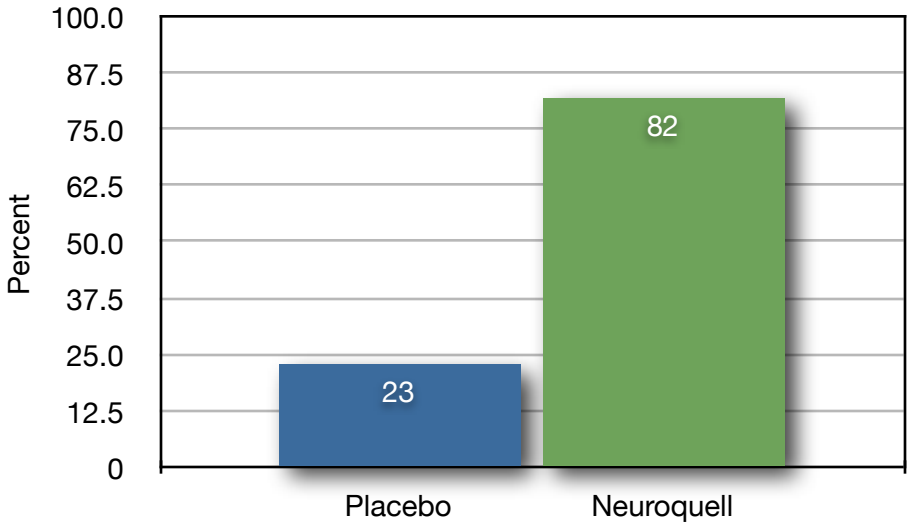
Neuroquell®
Percent Improvement: **Hands & Feet**
(P < 0.0001)



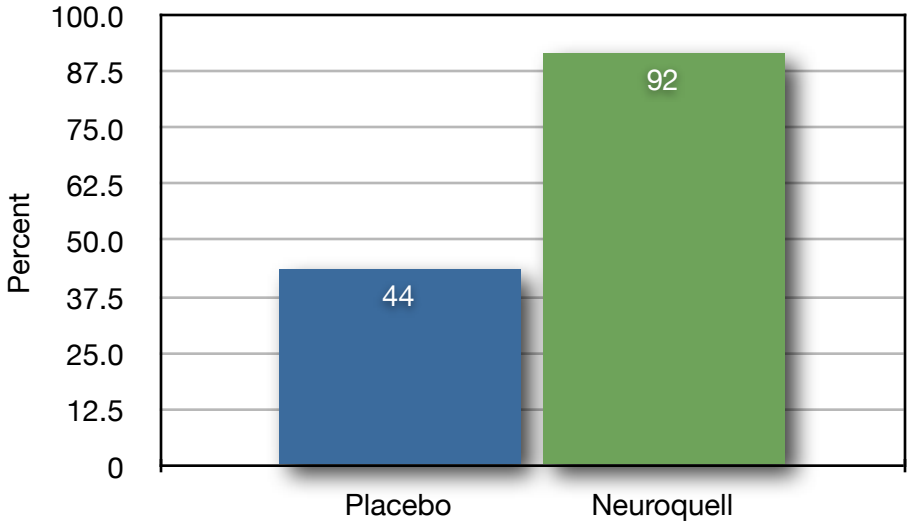
Neuroquell®
Percent Improvement: **Back Pain**
(P < 0.0001)



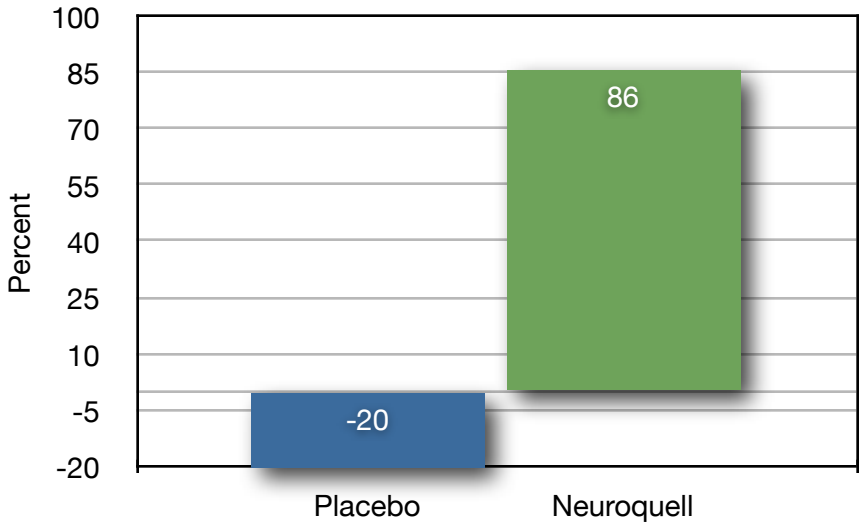
Neuroquell®
Percent Improvement: **Leg Pain**
(P < 0.0002)



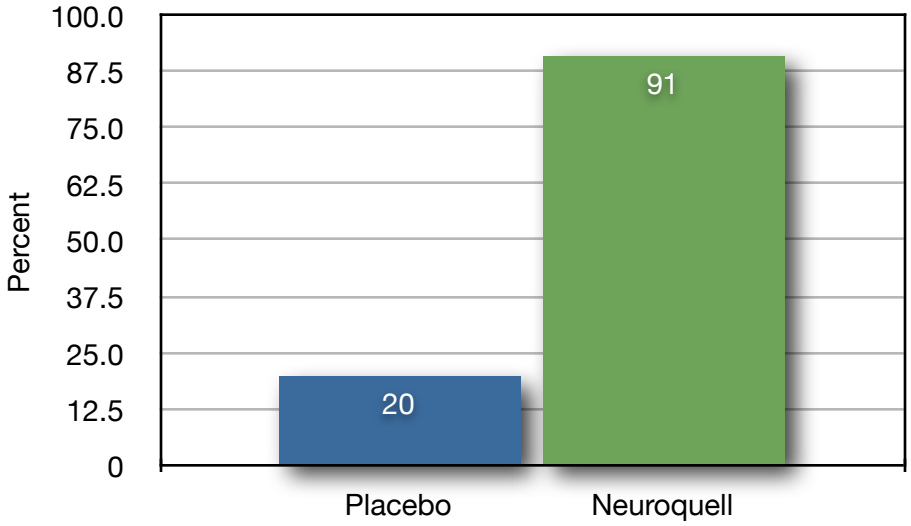
Neuroquell®
Percent Improvement: **Headache**
(P < 0.002)



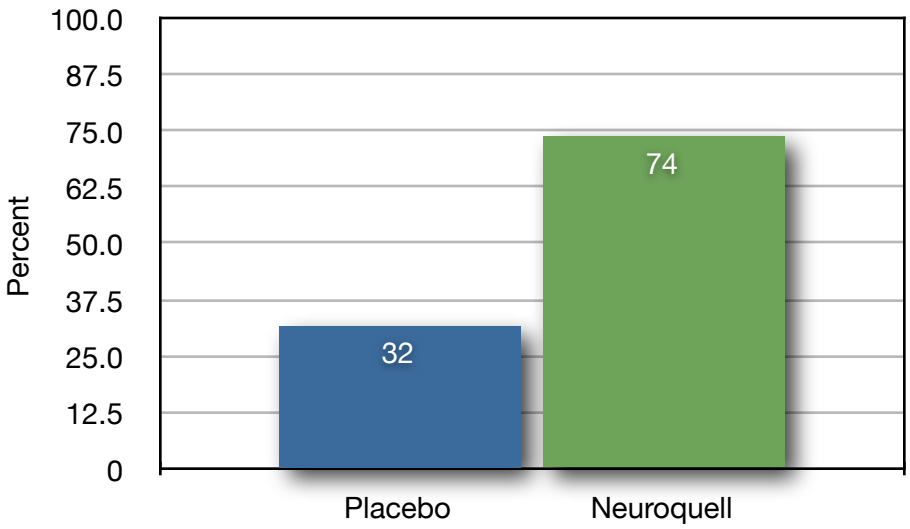
Neuroquell®
Percent Improvement: **Abdominal Pain/Ache**
(P < 0.002)



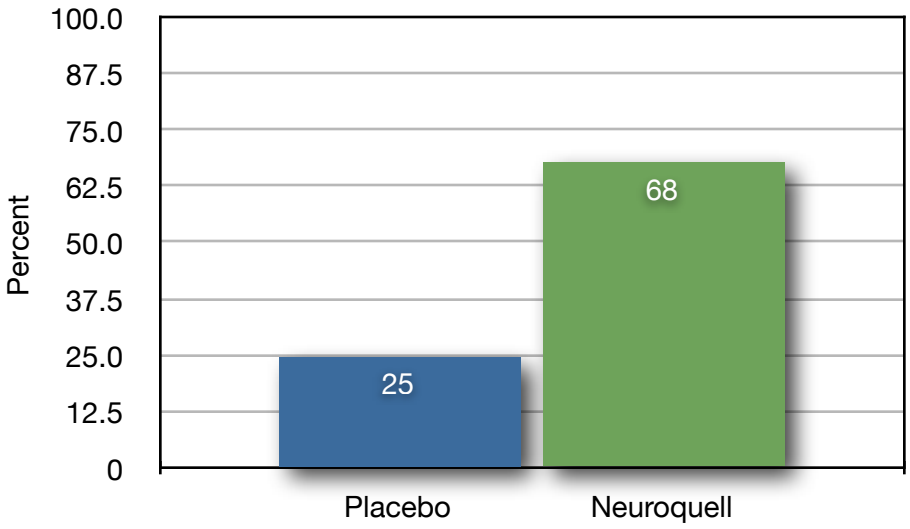
Neuroquell®
Percent Improvement: **Mood**
(P < 0.002)



Neuroquell®
Percent Improvement: **Moderate Activities**
(P < 0.01)



Neuroquell®
Percent Improvement: **Activities of Daily Living**
(P < 0.03)



Neuroquell®
Percent Improvement: **Work**
(P < 0.0001)