Report for Pilot Human Clinical Study of the Efficacy of the LifeWave Carnosine Patch in Improving Flexibility, Strength, and Endurance in Healthy Humans

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Abstract: A pilot human clinical study examined the efficacy of the LifeWave Carnosine Patch to increase flexibility, strength, and endurance in 10 healthy subjects. Results demonstrate that the LifeWave Carnosine Patch significantly increases performance in a flexibility test and 12 different tests of strength and endurance.

In this clinical study, tests were conducted that measure flexibility, strength and endurance in 10 healthy humans. Tests conducted included: stretch and reach, hand strength, maximum sit ups in 30 seconds, maximum push-ups in 30 seconds, maximum bicep curl weight, maximum bicep curl repetitions and outcome measures with an ergometer bicycle (peak and average power and watts per kilogram, average and peak speed and speed per kilogram, distance and calories. These results demonstrate that the LifeWave Carnosine Patch improves performance in several different tests of flexibility, strength and endurance in healthy humans.

Introduction

The LifeWave Carnosine Patch is a non-transdermal patch system that utilizes innovative technology to gently stimulate acupuncture points –improving the flow of energy in the body to produce drug-free energy enhancement. The hypothesis of this study is that wearing LifeWave Carnosine patches would show objective improvements in tests of strength, flexibility and endurance

Methods

Ten healthy individuals (five male and five female) ranging from 18-65 years of age with no history of disease, pregnancy, drug or alcohol use, or on any medications were subjects in this pilot study. All subjects were in good general health and did not have a high level of fitness. Institutional Review Board (Foundation for Energy Healing) approval was obtained for this study. The subjects were accepted after they had read and signed the informed consent.

Inclusion Criteria:

1. Subjects who have signed a written informed consent consistent with required guidelines and meet prior to participation in the trial.
2. Subjects 18-65 years of age, either sex.
3. Subjects who are able to follow the protocol as designed by the Energy Medicine Research Institute
4. In generally good health.

Exclusion Criteria:

1. History of serious diseases or illness diagnosed at this time, including cancer, or undergoing chemotherapy.
2. Subjects currently taking Tylenol, haloperidol or any prescribed or non-prescribed medication that may, in the opinion of the researchers, alter testing results.
3. History of alcohol addiction or currently consuming more than four drinks per day.
4. Females who are pregnant, lactating, or nursing or who may become pregnant during the course of the study.
5. Subjects with any condition not previously named that, in the opinion of the investigators or intake staff, would jeopardize the safety of the patient or affect the validity of the data collected in this study.

Patch instructions and study procedures:

- Acupoints tested:
    A. Conception Vessel 6 (CV6).
    B. Conception vessel 17 (CV17)

A baseline measurement was conducted utilizing a flexibility test and 12 different strength and endurance tests, described below. At each testing, the participants were given an energy survey about whether they noticed energy changes.

A baseline measurement was conducted utilizing one flexibility test and 12 different strength and endurance tests, described below. After the baseline testing, subjects were shown how to apply the patch to CV6 (three fingers below the navel). The subjects were asked to return one week later to repeat the testing after applying the patch one hour prior to testing. At this visit and after testing, subjects were instructed how to apply patches at acupuncture point CV17. Subjects were then asked to wear the patch every day for one week, rotating the patch between the points. One week later they were retested.
The subjects were instructed to remain well hydrated when reporting for testing and refrain from strenuous exercise for 2 days prior to testing. The tests are described below.

Flexibility Test

Subjects sat on the floor against a wall with feet against the stretch and reach measuring device (http://www.fitnessgiant.com/noname16.html) and reach as far forward as they can. The distance reached was measured three times and the highest value recorded

Strength Tests

A) Digital Hydraulic Hand Grip Dynamometer

Subjects squeezed the hand grip dynamometer (http://www.topendsports.com/testing/store-strength.htm) as hard as they can in each hand. tested, with the arm at right angles and the elbow by the side of the body. The handle of the dynamometer was adjusted if required - the base should rest on first metacarpal (heel of palm), while the handle should rest on middle of four fingers. The subject squeezed the dynamometer with maximum isometric effort, which is maintained for about 5 seconds. No other body movement is allowed. The subject should be strongly encouraged to give a maximum effort. Two measurements with each hand were recorded and the highest score was recorded.

B) One Repetition Maximum Test to Measure Maximum Strength of the Bicep.
Bicep Curl maximum weight was determined by having the subject perform a bicep curl with a five pound free weight using the dominant arm. The weight was increased by five pounds until the subject could no longer lift the weight with proper form. If the subject was unable to lift the weight, 2.5 pound weights were used as increments to determine the maximum weight that can be lifted and this weight was recorded.

C) Maximum Sit Ups and Push Ups in 30 Seconds
Subjects did as many sit ups as they could in 30 seconds with their feet held down and knees bent. The number was recorded. This was repeated after a 5 minute rest with push ups, either leaning against the wall, on knees or on toes. The same posture was used for all tests and the maximum number performed in 30 seconds was recorded.

D) Five Minute Road Course Ergomometer Measurements: Peak Speed . Watts and Peak Speed and Watts per Kilogram
Subjects were asked to pedal on a stationary bike with an ergomometer at their peak performance for five minutes. Peak speed and watts and peak speed and watts per kilogram were recorded.

Endurance
A) Bicep Curl Repetition to Failure
This test we done last to allow recovery time. The dominant arm was used to curl 70% of the maximum weight to failure and this number was recorded.

B) Maximum Sit Ups and Push Ups in 30 Seconds
Subjects did as many sit ups as they could in 30 seconds with their feet held down and knees bent. The number was recorded. This was repeated after a 5 minute rest with push ups, either leaning against the wall, on knees or on toes. The same posture was used for all tests and the maximum number performed in 30 seconds was recorded.

C) Five Minute Road Course Ergomometer Measurements: Average Speed and Watts. Average Speed and Watts per Kilogram, Calories and Distance
Subjects were asked to pedal on a stationary bike at their peak performance for five minutes. Distance, speed, distance, calories and peak watts per kilogram were recorded.

Statistical Methods:
Descriptive statistics were generated to summarize all outcome measures. Specifically, absolute changes for all outcome measures from baseline to 1 hour, baseline to 1 week and 1 hour to 1 week were summarized in terms of means, standard deviations, medians, and ranges. Changes from baseline to 1 hour, baseline to 1 week and 1 hour to 1 week were evaluated using a paired t-test. The normality assumption for all outcome measures were verified using normal probability plots and by conducting the Shaprio-Wilk test. Linear regression analysis was conducted to compute adjusted (for treatment compliance) p values. All p-values are two-sided, with $p<0.05$ indicating statistical significant differences.

Results

As shown in Table 1, wearing the LifeWave Carnosine Patch for one hour produced positive absolute changes from baseline values for all outcome measures except for peak power and peak watts/kg. The increases from baseline were significant for right hand strength (p=.0022), bicep curl maximum weight (p=.0172), bicep curl repetition to failure (p=.0392), maximum sit ups in 30 seconds (p=.0109), and maximum push ups in 30 seconds (p=.048).

Table 1. Absolute Changes from Baseline for Outcome Measures After Wearing LifeWave Carnosine Patch for One Hour

Measure	Mean	SD	Median	Min.	Max.	p value
Stretch and Reach (inches)	.64	0.71	0.54	-14.00	10.00	0.639
L Hand Strength	1.10	7.16	1.50	- 5.00	12.00	0.152
R Hand Strength	2.70	5.46	2.50	2.00	16.00	0.0022**
Bicep Curl Maximum Weight (lbs)	1.15	1.25	0.75	0.00	2.50	0.0172*
Bicep Curl Repetition to Failure	3.80	4.98	2.00	-1.00	13.00	0.0392*
Maximum Sit Ups in 30 Seconds	2.10	2.08	2.00	0.00	6.00	0.0109*
Maximum Push Ups in 30 Seconds	2.20	1.87	2.00	-1.00	5.00	0.048*
Average Speed (MPH)	0.38	0.99	0.49	-1.33	1.50	0.256
Peak Speed (MPH)	0.30	1.14	0.52	-1.72	1.72	0.432
Average Power (watts)	3.68	13.98	5.93	-23.39	21.95	0.427
Peak Power (watts)	-0.70	42.70	0.50	-76.00	84.00	0.96
Average Watts/kg	0.08	0.18	0.10	-0.30	0.30	0.197

Measure	Mean	SD	Median	Min.	Max.	p value
Peak-Peak Watts/kg	-0.02	0.63	0.05	-1.20	1.20	0.922
Distance	0.04	0.08	0.06	0.06	-0.10	0.16
Calories	2.21	3.46	3.45	-5.60	5.70	0.074

* p<0.05
** p<0.001

Table 2 shows the same outcome measures after wearing the Carnosine patch for one week. As shown, there were statistically significant improvements from baseline for every outcome measure except left hand strength and maximum sit ups in 30 seconds.

Table 2. Absolute Changes from Baseline for Outcome Measures After Wearing the LifeWave Carnosine Patch for One Week

Measure	Mean	SD	Median	Min.	Max.	p value
Stretch and Reach (inches)	1.26	0.66	1.21	0.09	2.09	0.0002**
L Hand Strength	5.60	7.16	1.50	-14.00	10.00	0.0614
R Hand Strength	7.70	5.96	7.50	1.00	19.00	0.0027*

Bicep Curl Maximum Weight (lbs)	3.10	2.17	3.75	0.00	5.00	0.0015*
Bicep Curl Repetition to Failure	7.10	7.19	5.00	0.00	20.00	0.0122*
Maximum Sit Ups in 30 Seconds	1.60	6.62	.00	-4.00	20.00	0.464
Maximum Push Ups in 30 Seconds	4.50	3.92	4.00	-1.00	14.00	0.0055*
Average Speed (MPH)	1.67	0.81	1.85	0.06	2.99	0.0001**
Peak Speed (MPH)	1.76	1.62	1.70	-1.06	5.00	0.0073*
Average Power (watts)	17.65	9.25	14.83	6.64	29.98	0.0002*
Peak Power (watts)	37.78	34.33	34.35	-8.00	95.00	0.0069*
Average Watts/kg	0.33	0.18	0.35	0.10	0.70	0.0002*
Peak Watts/kg	0.46	0.49	0.35	-0.20	1.40	0.016*
Distance	0.14	0.07	0.15	0.02	0.30	0.0002**
Calories	7.64	4.08	8.10	2.00	14.70	0.0002*

* p<0.05
** p<0.001

Table 3 shows that there was a significant difference between wearing the LifeWave Carnosine patch for every outcome measure except maximum number of sit ups and push ups in 30 seconds.

Table 3. Difference Between Active and Placebo Carnosine Patch

Measure	p value
Stretch and Reach (inches)	0.0469*
L Hand Strength	0.0303*
R Hand Strength	0.0027*
Bicep Curl Maximum Weight (lbs)	0.0171*
Bicep Curl Repetition to Failure	0.064
Maximum Sit Ups in 30 Seconds	0.052
Maximum Push Ups in 30 Seconds	0.14
Average Speed (MPH)	0.0053*
Peak Speed (MPH)	0.0147*
Average Power (watts)	0.0138*
Peak Power (watts)	0.0105*
Average Watts/kg	0.0186*
Peak Watts/kg	0.0139*
Distance	0.0137*
Calories	0.014**

* p<0.05
** p<0.001

Discussion

Results of this pilot study demonstrate that wearing the LifeWave Carnosine patch for one hour produces a significant increase in performance in five of the tests of flexibility, strength

and endurance that were conducted. Wearing the LifeWave Carnosine patch for one week produced a significant improvement in all but two of the tests. Furthermore, there were significant differences in all but three of the tests between the two time points, indicating that wearing the patch for longer times produces larger changes. All subjects tolerated the patches well and no adverse effects occurred.

The tests utilized in this pilot study are objective measures of flexibility, strength and endurance that are used in standard athletic testing. They are academically credible and superior to applied kinesiology tests that are commonly used to demonstrate the efficacy of products that increase athletic performance.

Conclusions

This pilot clinical trial shows that the LifeWave Carnosine patch produces a significant increase in over a dozen tests of flexibility, strength and endurance in healthy humans when worn for one week. Therefore, the hypothesis was accepted as true.

Research Team

Research was conducted by Lisa Tully, PhD, owner of Energy Medicine Research Institute and Ryan Shilling, owner of Watts Up. Both companies are based in Boulder, Colorado.

Dr. Lisa Tully received her PhD in Pharmacology and Toxicology from the Indiana University School of Medicine. Dr. Tully has several publications in peer-reviewed medical journals and has presented her research at international scientific conferences. Following her postdoctoral fellowship, Dr. Tully shifted from academic medical research to pursuits in integrative medicine and has attended many international medical conferences over the past decade, evaluating low cost and effective health care.
Dr. Tully is currently on the Scientific Advisory Board of several companies and non-profit organizations and is founder of the Energy Medicine Research Institute, whose mission is to assess the efficacy of vibrational medicine technologies and therapies.

Ryan Shilling, owner of Watts Up, a company that specializes in athletic training, has professionally tested athletes for a decade. He has performed testing for Athletic Republic, a company that trains athletes. He has conducted field tests on athletes specific to running and cycling. He specializes in testing athletes for strength, flexibility and endurance for training purposes.