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RESEARCH ARTICLE

LifeWave X49™ Patch Supports Improved Results in Fitness, Strength and Stamina

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Abstract

Purpose: To determine if the LifeWave X49™ patch supports exercise fitness and strength development in men ages 40-81.

Materials and method: LifeWave X49™ non-transdermal patches, lavender top blood tubes, BD Vacutainers with Pre-attached holders, cryo tubes, centrifuge, urine test kits, saliva test kits, racking, freezer, gloves, band aids, alcohol wipes, masks, UVC sterilizing wands, sterile eye droppers, sterile cotton balls, tourniquets, dry ice, shipping containers and exercise bike. Resistance bands, dumb bells, and hand grips were supplied to each participant.

Measures were taken at baseline, day 2, 7, 14, 30 and 60 days of wearing the patch. A sample of 22 subjects made up of men aged 40-80 with 19 subjects completing the study, was selected to participate. Participants were recruited by flyer, email, radio advertisements and Clinical Connections recruiting platform. Participants used the X49™ patch at the GB34 point or the CV6 point.

Metabolic testing (amino acid panel) consisted of one 10 am urine taken at baseline/day one, day two, day 7, day 14, day 30 and 60, as well as one 10 am saliva swab taken at baseline/day one, day two, day 7, day 30 and 60. Samples were kept in the freezer at -20 °C and were shipped with ice by UPS to the Sabre Science lab in Carlsbad, CA. A lavender top tube was drawn from each participant at each data point to learn the levels of AHK utilization. Plasma was separated, placed in cryo tubes and flash frozen. Samples were kept in the freezer at -20 °C and at study end were shipped to Axis Pharm in San Diego for analysis of AHK.

Questionnaires included PASE, GPAQ, SEQ, AIOS-VAS, Stress scale, and REAP-S were filled out at each data point. Styku™ 3-dimentional body scans were taken at baseline, day 30 and day 60 to track weight and body shape changes. Baseline fitness evaluation was done at day one for use in creating customized training program. Fitness testing was done on day 30 and 60 to compare with baseline. Test measures included 3 min bike ride, push-ups, sit ups, squats, bicep curls, grip strength and resistance band weight and number of repetitions. Participants were asked to exercise for 20 min three times per week and wear the patches for 8-12 hours per day. A fresh patch was applied each day during the test period.

Results: Significant improvement from baseline were observed for AHK usage across all days at $p < 0.0001$ with Cohen's $d = 1.35$. Exercise performance, strength and stamina with a population age 40-81 showed significant increase ranging from 31%-70% which were observed for all exercise outcomes from day 1 to day 30 or day 60.

Conclusion: There was a significant change in both AHK-Cu usage from peak to least across all days at $p < 0.0001$ with Cohen's $d = 1.35$ and exercise performance, strength and stamina. Overall changes in the population age 40-81 showed 31% to 70% fitness improvement in sixty days. Study data warrants further research.

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Keywords

LifeWave, X49 ™, Men's Health, Exercise, AHK, Alanine, Lucine, Tripeptide

Introduction

Amino Acids are used to create proteins and peptides in the human body. Some amino acids can be produced out of smaller component pieces, but nine of them must be obtained through diet [1]. Two of these amino acids which cannot be created by the body are essential amino acids and are utilized in AHK. Because these amino acids can be used to create a broad variety of important components, they also have a broad variety of functions. L-Alanine-L-Histidyl-L-Lysine Copper (AHK) is a copper polypeptide with a variety of different functions.

Alanine has been shown to "reduce lactate concentrations during exercise and thus can improve exercise performance in endurance athletes" [2]. Alanine also has a stabilizing impact on glucose levels in the human body [3]. Histidine is used as a "component of solutions used for organ preservation and myocardial protection in cardiac surgery" [4]. It also seems to have an impact on "neurological disorders, atopic dermatitis, metabolic syndrome, diabetes, uraemic anaemia, ulcers, inflammatory bowel diseases, malignancies, and muscle performance during strenuous exercise" [4], though unfortunately more research is needed in those areas to clarify the impact. Lysine is "crucial for collagen fibre crosslinking" [5]. All of these areas are likely to have an impact on bone development. L-Alanine-L-Histidyl-L-Lysine Copper (AHK) has a documented impact on a variety of areas in the body, specifically skin, hair, and bone [6,7]. AHK "increases dermal cell proliferation and viability while increasing the deposition of collagen to renew the extracellular matrix" [6]. It also "promotes the growth of human hair follicles, as is caused by stimulation of the proliferation and the preclusion of the apoptosis of dermal papilla cells" [7]. AHK linked to Vitamin C has also been shown to have "an enhancing effect on osteoblast proliferation and differentiation through activation of Smad1/5/8 and MAPK ERK1/2 and p38 signaling and without significant cytotoxicity" [8]. These functions make a fair amount of sense given the individual actions and effects of the amino acid components.

Research has found that only 8.2% of Americans over 50 did sufficient cardio and strength-training exercise [9]. A higher percentage of individuals are doing some exercise, but either not enough, or not of sufficient types, such as a combination of strength training and cardio [9]. This is important because "Up to 5 million deaths a year could be averted if the global population was more active" [10].

Background

Phototherapy

Merriam-Webster Dictionary defines "Phototherapy" as "light therapy" "It is the use of light in specific wavelengths that vary based on the intended effect to stimulate a specific physiological change" [11]. Phototherapy has shown benefits for a variety of skin diseases [12], foot ulcer healing, specifically with diabetes [13], and even a first line therapy for mycosis fungoides [14] and has been used in various forms for over 100 years. Few negative side effects have been found so that phototherapy has been found to be a relatively safe process.

The LifeWave X49™ patch uses phototherapy to stimulate production of specific frequencies which support the positive balance of the body and changes in production of specific chemicals. Research has identified that peptides are used to support the natural repair process and demonstrated to improve tissue remodeling [15].

Non-transdermal Patch

All LifeWave X49™ patches are sealed, which means that none of the substances, which are contained in the acrylic sleeve of the patch, actually penetrate the skin. These patches are designed to reflect a variety of wavelengths of light in the infrared, near infrared, and visible light bands. This means that the patches act as a transducer and transmitter, like a router on a computer network, or one of the old crystal radio sets. This allows for patch promotion of the electrodermal skin response. Electrodermal activity (EDA) is a property of the human body, one that causes continuous variation in the electrical characteristics of the skin. These patches receive signals from the body, strengthens them, and sends them back. These signals promote specific frequencies to support specific body processes. The patches also the same adhesives as band-aids, which limits the level of irritation caused by the adhesive which might be developed through consistent daily use of the patch.

Purpose

To determine if the LifeWave X49™ patch supports exercise fitness and strength development in men ages 40-81.

Materials

LifeWave X49™ non-transdermal patches, lavender top blood tubes, BD Vacutainers with Pre-attached holders, cryo tubes, urine test kits, saliva test kits, racking, freezer, gloves, band aids, wipes, masks, UVC sterilizing wands, sterile eye droppers, sterile cotton balls, tourniquets, dry ice, shipping containers and exercise bike. Resistance bands of two types, dumb

bells, and hand grips were supplied to each participant. Participants who completed the study were allowed to keep the supplied equipment as a thank you for their participation.

Ethics Permission

Human Studies Research Ethics review was provided by NFFEH approval 04-6-21-4.

Method

Measures were taken at baseline, day 2, 7, 14, 30 and 60 days of wearing the patch. A random sample of 22 subjects was made up of men aged 40-81 with 19 subjects completing the study. Participants were recruited by flyer, email, radio advertisements and Clinical Connections recruiting platform.

Participants placed the X49 ™ patch at the GB34 point or the CV6 point. Acupuncture points were utilized for ease of correct patch placement. Participants were asked to exercise for 20 min three times per week and wear the patches for 8-12 hours per day. A fresh patch was applied each day during the sixty-day test period.

Participants received custom fitness plans provided by an exercise and fitness specialist which included training on the equipment provided to reduce the potential risk of injury, a nutritional counseling session, and a meditation session learning how to reduce the residual body aches which can be created by exercising. All specialists were available for questions on an ongoing basis throughout the study period.

Metabolic testing

Metabolic testing (amino acid panel) consisted of one 10 am urine taken at baseline/day one, day two, day 7, day 14, 30 and 60 to determine if there were significant changes in levels of testosterone, as well as one 10 am saliva swab taken at baseline/day one, day two, day 7, 30 and 60. Samples were kept in the freezer at -20 °C and were shipped with ice by UPS to the Sabre Science lab in Carlsbad, CA.

Tri-peptide testing

A lavender top tube was drawn from each participant at each data point to learn the levels of AHK utilization. Plasma was separated by centrifuge, placed in cryo tubes and flash frozen. Samples were kept in the freezer at -20 °C and at study end were shipped frozen to Axis Pharm in San Diego for analysis of AHK. The blood samples were processed according to the following procedure: One lavender top tube was drawn per participant and then placed in the Kendro Sorvall Biofuge centrifuge 7500-5184+ HERAEUS 7591 with a 4000 RPM rotor. Samples were spun for 10 minutes at 1300 RCF at room temperature to separate the plasma. The plasma was separated, placed in cryo tubes and then flash frozen using a medical -22 °C degree freezer. Once frozen, the cryo tubes were then placed in 2 inch thick polystyrene containers, which were wrapped in thermal box liners and placed in double walled boxes. These boxes were shipped overnight to Axis Pharm in San Diego, CA for analysis. To 1 ml of each plasma sample, 1 M HCl was added to adjust pH to 4.5. The mixture was boiled for 20 min with stirring. 1 ml if acetone was added and suspension was vortexed, centrifuged. The supernatant was separated and filtered through an Amicon Ultrafilter. The clear solution was dried via speed-vac and reconstituted with de-ionized water to 50 µl and analyzed with AB Sciex API4000 Qtrap. The data was analyzed with Analyst software 1.6.2.

Questionnaires

Questionnaires were filled out at each data point. Questionnaires included: Physical Activity Scale for the Elderly (PASE), used as part of initial assessment only), Global Physical Activity Questionnaire (GPAQ), Single Ease Question (SEQ), Arizona Integrative Outcome Scale - Visual Analogue Scale (AIOS-VAS), Stress Questionnaire, and Rapid Eating Assessment for Participants (REAP-S).

PASE: PASE is a brief survey used to assess the activity levels of elderly individuals. Developed in the 1980-90's by Washburn, et al. [16,17]. For the purposes of this study, it was used as an initial assessment tool by the exercise physiologist.

GPAQ: "GPAQ covers components of physical activity, such as intensity, duration, and frequency, and three domains in which physical activity is performed (occupational physical activity, transport-related physical activity, and physical activity during discretionary or leisure time)". Developed in 2002 by the World Health Organization and presented in 2004 [18,19], this questionnaire was used to assess changes in physical activity in the daily life of participants over the course of the study period.

SEQ: "The Single Ease Question, (SEQ) a single-question post-task questionnaire measures users' perception of usability based on the last attempted task" [20]. It is a 7 point scale. This questionnaire was used to assess the ease of use of the patches on participants. This information on ease of use is valuable in determining if the patch usage will be supportive of individuals participating in exercise in the future.

AIOS-VAS: The Arizona Integrative Outcome Scale [21] - Visual analogue scale is a 100 mm line used to assess any changes in general sense of well-being. Participants mark an x on the line to share their current state of well-being.

Stress Questionnaire: The Stress Questionnaire was developed by ISMA Charity organization in the UK "promoting stress prevention and wellbeing" [22]. This instrument is a self-report questionnaire used to determine both what kinds and if there is ongoing stress in an individual's life. Answers to all questions are yes/

no with each yes answer counting as one point. This questionnaire was used to determine if there were changes in perceived levels of stress on participants as exercise has been long recognized as a stress relieving method.

REAP-S: The Rapid Eating Assessment for participants was developed by Brown University US department of Community Health in 2004 [23] to help care providers rapidly assess individuals diet and physical activity. In this study it was used for initial assessment of participants eating habits and for any ongoing changes in eating habits as participants changed levels of overall fitness.

Styku scanning

Styku™ 3-dimentional body scans were taken at baseline, day 30 and day 60 to track weight, body mass index, associated measures and body shape changes. This device and imaging were found to be of particular importance to participants to be able to see the level of head thrust, slumped shoulders, compressed torso and hip placement over the course of the study period. Postural improvement created excitement and immediate visual impact on participants.

Exercise fitness evaluation and program

Baseline fitness evaluation was done at day one for use in creating customized training program. Fitness testing was done on day 30 and 60 to compare with baseline. Test measures included 3 min bike ride, push-ups, sit ups, squats, bicep curls, grip strength and resistance band weight and number of repetitions. All subjects were trained on the exercise equipment which was supplied to them.

Statistical analysis

Changes in between AHK peak and lowest levels and changes between AHK peak and baseline levels were evaluating using a paired t-test. Differences were quantified by calculating Cohen's effect sizes d. Using standard interpretation guidelines, a Cohen's d greater than 0.8 is considered a large standardized difference while a d between 0.5-0.8 is considered a moderate standardized difference. Exercise outcomes were analyzed as both percentage and absolute changes from baseline. Questionnaire outcomes were analyzed as absolute changes from baseline. A paired t-test was used to evaluate changes from baseline to post-treatment assessment. Normal probability plots were examined to verify the normality assumption. If the normality assumption could not be verified, then the nonparametric Wilcoxon signed rank test was used to evaluate changes from baseline. All reported p-values are two-sided and $P < 0.05$ was used to define statistical significance. Statistical analyses were conducted using R software version 4.2.1 (The R Foundation for Statistical Computing).

Results

Significant improvement from baseline were observed for AHK usage across all days at $p < 0.0001$ with Cohen's $d = 1.35$ and in exercise performance, strength and stamina. The population age 40-81 showed significant increase ranging from 31-70% which were observed for all exercise outcomes from day 1 to day 30 or day 60. Test measures included 3 min bike ride, push-ups, sit ups, squats, bicep curls, grip strength and resistance band weight and number of repetitions.

A reduction in peak available AHK shows increased utilization. The distribution of the AHK peak available levels and AHK utilization levels across all assessment times points are shown in Figure 1. The median AHK peak level was 2.45 ug/mL (range 1.31-5.71 ug/mL)

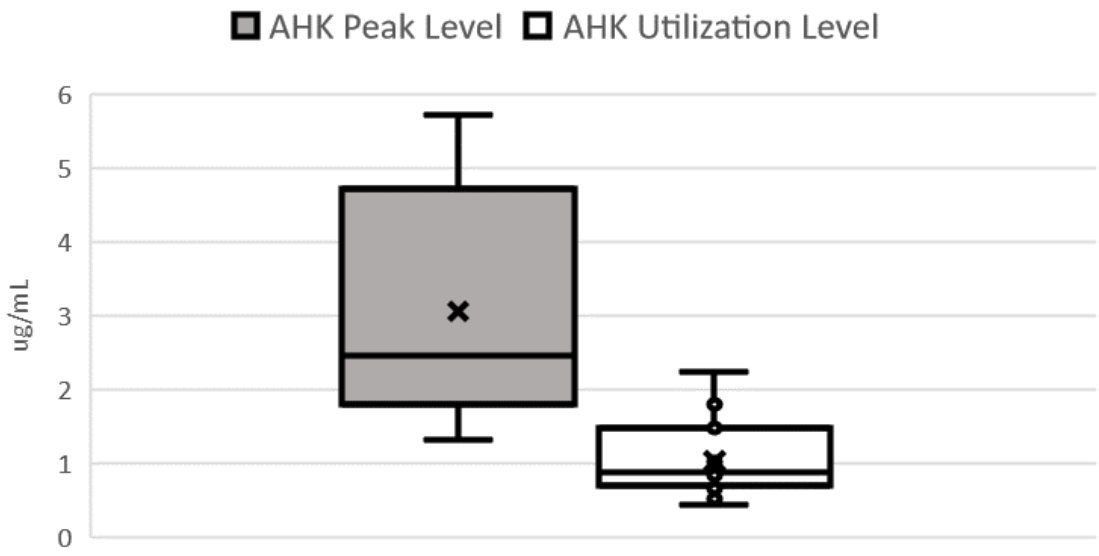

Figure 1: Box and Whisker plots for AHK peak available and utilization levels across all assessment time points showing increased utilization.

while the median AHK utilization level was 0.87 (range 0.43-2.24 ug/mL). Cohen's effect size d for the difference between the peak available to the increased utilization of AHK levels was d = 1.35 ($p < 0.0001$). Analogously, a significant difference between the peak AHK levels across all assessment time points and the baseline AHK levels was observed with a Cohen's effect size d of 0.98 ($p = 0.0005$). Furthermore, when evaluating changes from the lowest AHK level across all assessment time points to the baseline values, a moderate standardized difference was observed with a Cohen's d of 0.67 ($p = 0.0087$).

Changes in exercise and questionnaire outcomes from baseline to the day 2, 7, 14, 30 and 60 assessments are shown in Table 1, Table 2 and Table 3.

Significant increase ranging from 31%-70% were observed for all exercise outcomes from day 1 to day 30 or day 60 on these standardized measures.

Speed and distance changes from baseline to both day 30 and day 60 were statistically significant demonstrating an improvement in stamina.

Reduction in stress level from baseline to day 60 of $p = 0.03$ was seen confirming data from many other studies that physical exercise supports reduction in stress levels.

Table 1: Exercise outcomes.

				% Change from Day 1			Absolute Change from Day 1		
Outcome	**Day**	**Mean**	**SD**	**Mean**	**SD**	**p-value[1]**	**Mean**	**SD**	**p-value[2]**
Sit-ups	1	20.6	8.1						
	30	26.0	9.0	30.5%	29.0%	0.0003	5.7	5.6	0.0005
	60	30.3	11.2	56.8%	40.0%	0.0001	10.4	6.9	0.0001
Squats	1	20.2	6.5						
	30	26.1	7.8	30.7%	32.8%	0.0010	5.8	5.3	0.0002
	60	29.8	7.8	57.9%	38.0%	0.0001	10.1	4.6	0.0001
Bicep-curl	1	23.2	7.1						
	30	29.8	8.3	40.7%	57.8%	0.0083	7.2	8.5	0.0022
	60	35.6	9.7	69.9%	69.7%	0.0005	13.0	10.5	0.0001
Resistance	1	24.0	8.3						
	30	32.4	11.7	39.4%	35.0%	0.0002	8.5	7.4	0.0001
	60	39.3	13.2	67.3%	45.1%	0.0001	14.8	10.4	0.0001
Grip	1	110.5	49.5						
	30	144.6	54.3	42.8%	47.3%	0.0013	35.9	31.7	0.0002
	60	164.2	47.2	68.3%	71.0%	0.0005	53.8	41.1	0.0001

[1]: p-value for evaluating % change from Day 1; [2]: p-value for evaluating absolute change from Day 1

Table 2: Bike outcomes for 3 min ride.

			% Change from Day 1		Absolute Change from Day 1	
Outcome	**Day**	**Median***	**Median***	**p-value[1]**	**Median***	**p-value[2]**
Calories	1	13.0				
	30	16.0	23.0%	0.0212	3.0	0.0212
	60	18.3	41.7%	0.1712	5.0	0.1712
Speed-top	1	15.3				
	30	16.2	5.2%	0.0300	1.0	0.0300
	60	18.7	20.0%	0.0100	2.8	0.0100
Pulse	1	104.9				
	30	103.5	1.7%	0.1574	-10.0	0.1574
	60	106.0	-2.0%	0.5530	-35.0	0.5530
Distance	1	0.7				
	30	0.8	10.1%	0.005	-0.1	0.0050
	60	0.9	30.5%	0.001	-0.1	0.0001

[1]: p-value for evaluating % change from Day 1 (non-parametric Wilcoxon signed rank test); [2]: p-value for evaluating absolute change from Day 1 (non-parametric Wilcoxon signed rank test); *Outcome measures were non-normally distributed so that medians were reported

Table 3: Analysis of absolute changes from baseline to post-treatment assessments for questionnaire outcomes.

Outcome	Day	Mean	SD	p-value[1]
SEQ	30	0.8	1.5	0.3910
	60	0.0	0.6	0.9999
REAPS	2	1.5	4.1	0.3320
	7	2.3	4.0	0.0334
	14	2.6	4.0	0.0105
	30	2.5	5.4	0.0777
	60	2.8	3.5	0.0050
AIOS-VAS	30	-0.3	11.0	0.9584
	60	8.3	17.6	0.1156
Stress	30	-18.5	22.4	0.0152
	60	-16.2	27.8	0.0340
GPAQ: Activity: Work (Days)	7	1.6	2.3	0.0610
	14	1.0	2.1	0.1950
	30	0.6	1.4	0.1503
	60	0.7	1.3	0.0515
GPAQ: Activity: Work (Minutes)	7	54.0	100.8	0.1244
	14	36.7	89.7	0.2551
	30	21.4	50.5	0.1365
	60	22.0	43.1	0.0682
GPAQ: Travel (Days)	7	0.7	4.1	0.6311
	14	-0.4	3.2	0.6884
	30	0.1	3.1	0.8983
	60	0.4	3.4	0.6514
GPAQ: Travel (Minutes)	7	45.5	130.5	0.2989
	14	10.6	40	0.4542
	30	-1.8	28	0.8150
	60	-3.9	48	0.7557
GPAQ: Recreation (Days)	7	0.7	4.1	0.6311
	14	-0.4	3.2	0.6888
	30	0.1	3.1	0.8983
	60	0.4	3.4	0.6514
GPAQ: Recreation (Minutes)	7	45.4	130.5	0.2989
	14	10.6	40	0.4518
	30	-1.8	28	0.8150
	60	-3.9	48	0.7556

[1]: p-value for evaluating change from baseline to post-treatment assessments

Discussion

Use of the LifeWave X49™ patch showed statistically significant large standardized differences which were observed when comparing peak AHK levels to maximum usage of AHK across all assessment time points and when comparing peak AHK levels to baseline levels. These changes show a level of increased usage of the AHK peptide returning to levels expected in individuals in their twenties and thirties. Usage of the AHK peptide improves muscle development, supports skin, hair, tendon and improves retention in bone tissue and may support improved longevity and quality of life when combined with regular exercise. Exercise has been demonstrated to support increased longevity [9].

This study demonstrated improvements in strength as measured by standard fitness measures within 60 days (aprox. 8 weeks) at a rate of 31%-70% in participants using the LifeWave X49™ patch. Clear improvement in stamina was measured by speed (day 30 of $p = 0.03$ day 60 of $p = 0.01$) and distance (day 30 of $p = 0.005$ day 60 of $p = 0.0001$) from baseline to both 30 and 60 day measures on 3 min exercise bike testing. Other research on exercise improvements in similar age ranges were checked to determine the expected degree of improvement from exercise alone. The highest percentage improvement found was 17% improvement in "maximum voluntary isometric strength" after 12 weeks [24]. An additional benefit of the exercise routine was a statistically significant reduction in stress levels of all individuals at a rate of $p = 0.03$ by day 60.

Conclusion

This study explores changes produced by LifeWave X49™ patch in promoting the usage of the AHK-Cu peptide. There was a significant change in both AHK-Cu usage from peak production to maximum usage across all days at $p < 0.0001$ with Cohen's $d = 1.35$ and in exercise performance, strength and stamina Overall changes in the population age 40-81 showed 31% to 70% fitness improvement in sixty days. Clear improvement in stamina was measured by speed (day 30 of $p = 0.03$ day 60 of $p = 0.01$) and distance (day 30 of $p = 0.005$ day 60 of $p = 0.0001$) from baseline to both 30 and 60 day measures on 3 min exercise bike testing. A limitation of the study is the small sample size. The promising results of this study, however, warrants further research on the effects of the LifeWave X49™ patch supporting fitness, strength and stamina.

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Authors Contribution

All authors' contributed to this study and this paper.

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