

# **Report for Pilot Human Clinical Study of the Efficacy of the LifeWave Body Sculpting System in Improving Body Composition**

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Submitted by **Energy Medicine Research Institute**, Lisa Tully, PhD, founder

*I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.*

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LISA TULLY, PRIMARY INVESTIGATOR

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## **Introduction**

The LifeWave Body Shaping System developed by LifeWave called WinFit was designed to rapidly change body composition through modifications of diet, exercise and supplementation. Its goal is to reduce body fat, increase muscle strength, provide greater energy and improve overall well-being. It's important to note that this program is not a diet. It does not include calorie counting or calorie restriction. Rather, it's a lifestyle change designed to produce both immediate and measurable, long-term results.

### **The program included the following six key components:**

1. Drinking 16 oz. of water upon awakening
2. Light Exercise Window twice a week (10 minutes, 4 days/week)
3. LifeWave WinFit patch (for daytime use)
4. Eating Window (timed eating and moderate food recommendations)
5. LifeWave Theta One and Theta Activate
6. LifeWave Y-Age Carnosine patch (for nighttime use)

## **Methods**

Thirty one (12 male, 19 female) subjects with no history of disease, pregnancy, drug or alcohol use, or on any medications were recruited for this study. All subjects were between the ages of 35-64 and in good general health.

Institutional Review Board approval was obtained for this study. A baseline measurement was conducted and the groups were divided into a weight loss group (people who are at least ten pounds overweight, 16) and an increased performance (people who only want to improve body toning, 15) group. At the baseline testing, 31 subjects were given instructions on how to perform the proto-

col and asked to fill out a daily log, so that compliance can be measured. All measurements were repeated at 30 and 60 days. Before each test, subjects were asked to rate their energy level on a scale of 1 to 10.

### **Assessments**

Outcome measures include: body fat (via a handheld tester), weight (lbs.), biceps, waist, hips, thighs and chest at the site visit by the trained staff. The completions of these checklists are required for compliance. An exit survey asked questions about energy levels after using the WinFit system and if the subjects noticed any changes in body composition.

### **Statistical Methods:**

All study outcome parameters were summarized in terms of means and standard deviations. Percentage changes from baseline to day 30 and changes from baseline to day 60 were calculated. Compliance parameters were summarized in terms of median and ranges. Percentage and absolute changes in outcome parameters within groups (within segment groups, within gender groups) were performed using a paired t-test. A two-sample t-test was used to compare percentage and absolute changes from baseline to day 30 and changes from baseline to day 60 between groups (i.e., between segment groups and between gender). Normal probability plots were evaluated to verify the normality assumption). Nonparametric Spearman's rank correlation analysis was conducted to correlate compliance with percentage and absolute changes in outcome parameters. All reported P-values are two-sided and  $P < 0.05$  was used to define statistical significance.

### **Study Protocol included the following components:**

- Drinking 16 oz. of water upon awakening
- LifeWave WinFit patch (for daytime use): this patch is for muscle strength and tone
- LifeWave Y-Age Carnosine patch (for nighttime use) this patch aids in recovery
- Theta One and Theta Activate
  - Women:** One stick of Theta One and one full dropper of Theta Activate (before bedtime) mixed in water
  - Men:** Two sticks of Theta One and two full droppers of Theta Activate (before bedtime) mixed in water
- Protein Shake: For those interested in building muscle or toning, participants had the option to drink a protein shake (40 grams of protein for men, 20 grams of protein for women) for the first meal of the day.
- Dietary guidelines – timed eating in an 8 hour window (known as intermittent fasting) and moderate food recommendations
- Exercise guidelines – outlined in DVD video tutorials

Subjects tracked their daily progress in a diary as shown here. It should be noted that the exercise was 4 days per week, but subjects were given the flexibility to choose the days.

<p><b>Wednesday:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Drink water (morning)</li> <li><input type="checkbox"/> Wear X32 patch (morning)</li> <li><input type="checkbox"/> Exercise (follow exercise video) (morning)</li> <li><input type="checkbox"/> Eat within 8 hour window</li> <li><input type="checkbox"/> Theta One/Activate 1-2 hours before bed (evening)</li> <li><input type="checkbox"/> Wear Carnosine patch (evening)</li> </ul>	<p><b>Sunday:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Drink water (morning)</li> <li><input type="checkbox"/> Wear X32 patch (morning)</li> <li><input type="checkbox"/> Exercise (follow exercise video) (morning)</li> <li><input type="checkbox"/> Eat within 8 hour window</li> <li><input type="checkbox"/> Theta One/Activate 1-2 hours before bed (evening)</li> <li><input type="checkbox"/> Wear Carnosine patch (evening)</li> </ul>
<p><b>Thursday:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Drink water (morning)</li> <li><input type="checkbox"/> Wear X32 patch (morning)</li> <li><input type="checkbox"/> Exercise (follow exercise video) (morning)</li> <li><input type="checkbox"/> Eat within 8 hour window</li> <li><input type="checkbox"/> Theta One/Activate 1-2 hours before bed (evening)</li> <li><input type="checkbox"/> Wear Carnosine patch (evening)</li> </ul>	<p><b>Monday:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Drink water (morning)</li> <li><input type="checkbox"/> Wear X32 patch (morning)</li> <li><input type="checkbox"/> Exercise (follow exercise video) (morning)</li> <li><input type="checkbox"/> Eat within 8 hour window</li> <li><input type="checkbox"/> Theta One/Activate 1-2 hours before bed (evening)</li> <li><input type="checkbox"/> Wear Carnosine patch (evening)</li> </ul>

<p><b>Friday:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Drink water (morning)</li> <li><input type="checkbox"/> Wear X32 patch (morning)</li> <li><input type="checkbox"/> Exercise (follow exercise video) (morning)</li> <li><input type="checkbox"/> Eat within 8 hour window</li> <li><input type="checkbox"/> Theta One/Activate 1-2 hours before bed (evening)</li> <li><input type="checkbox"/> Wear Carnosine patch (evening)</li> </ul>	<p><b>Tuesday:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Drink water (morning)</li> <li><input type="checkbox"/> Wear X32 patch (morning)</li> <li><input type="checkbox"/> Exercise (follow exercise video) (morning)</li> <li><input type="checkbox"/> Eat within 8 hour window</li> <li><input type="checkbox"/> Theta One/Activate 1-2 hours before bed (evening)</li> <li><input type="checkbox"/> Wear Carnosine patch (evening)</li> </ul>
<p><b>Saturday:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Drink water (morning)</li> <li><input type="checkbox"/> Wear X32 patch (morning)</li> <li><input type="checkbox"/> Exercise (follow exercise video) (morning)</li> <li><input type="checkbox"/> Eat within 8 hour window</li> <li><input type="checkbox"/> Theta One/Activate 1-2 hours before bed (evening)</li> <li><input type="checkbox"/> Wear Carnosine patch (evening)</li> </ul>	<p><b>Summary:</b></p> <p># of days doing recommended exercises ____</p> <p># of days eating only within 8 hour window ____</p> <p>Please use this additional space to record any brief notes about how you are feeling or your perspective on following the program:</p>
<p><b><u>For Interviewer Use Only</u></b></p> <p>Weight ____</p> <p>Measurements        _____/_____/_____/_____</p>	<hr/> <hr/> <hr/> <hr/>

This program focuses on a “minimally effective dose” mentality exercising 10 minutes a day, 4 times a week. The exercise includes a combination of one day resistance training with exercise bands followed by one day of mild cardio exercise. This schedule is repeated twice during a week. This progression of exercise accomplished a complete full-body workout in less than one full hour of exercise a week. Participants pick what days to do the exercise.

Warm-up and stretch for a few minutes then exercise:

- **Isometric/Resistance training with exercise bands:** twice weekly for 10 minutes
- **Cardio:** twice weekly for 10 minutes

A DVD was provided that will include four different 10 minute exercise routines. The exercise bands to be used in the isometric/resistance training were supplied in the product package at initial check-in. Subjects were instructed that they could continue with and other exercise regimen or activity they were already doing throughout this study if desired.

**LifeWave WinFit patch** – was developed to accelerate changes in body composition and is targeting muscle strength and tone. At the time this study was conducted, this product was not yet available for sale. In the United States, it will be classified as a General Wellness product and the mechanism of action is phototherapy. Where a patch covers the skin, infrared light emitted from the body is reflected back into the tissue. This stimulates the skin, which in turn, stimulates specific regions of the brain to create a particular health benefit. As new muscle is built this will help increase body metabolism. The WinFit Patch is strictly for daytime use and is worn throughout the day. The patch is applied in the morning and removed in the evening and then the Y-Age Carnosine is applied. The Carnosine patch is worn till the following morning and then removed. After washing up a new WinFit patch is applied.

#### **LifeWave Theta One and Theta Activate**

Background - Growth hormone (GH) is another important factor for rapidly building strength and reducing body fat. There are two biological windows for GH release: first thing in the morning (mild GH increase) or in the evening just before bed (large GH increase). Theta One contains growth factors and nutrients intended to support immune function. Research shows that by altering the dose and the time of day it’s taken, a larger increase in growth hormones may be achieved leading to faster increases in strength and decreases in body fat.

Theta One and Theta activate are dietary supplements, sold in the United States and European Union, as a food supplement. In the United States, the product is sold with the following ingredient label:



## Supplement Facts

Serving Size: 1 stick pack (17.4 g)

Servings Per Container: 30 stick packs

	Amount Per Serving	% DV
Calories	30	
Total Carbohydrate	8 g	3%*
Dietary Fiber	6 g	24%*
Protein	1 g	2%
Vitamin B6 (as pyridoxine hydrochloride)	1.4 mg	70%
Folate (folic acid)	200 mcg	50%
Vitamin B <sub>12</sub> (as methylcobalamin)	2.5 mcg	42%
Biotin (D-Biotin)	50 mcg	17%
Potassium (as potassium citrate)	500 mg	14%
Premium Matrix Blend	11.97 g	†
Corn Dextrin (Nutriose®) <sup>††</sup> , L-Arginine Hydrochloride, Colostrum (40% Immunoglobulin G), L-Arginine Aspartate, Lycium Berry Extract		

\* Percent Daily Values (DV) are based on 2,000 calorie diet.

† Daily value not established.

†† Non-Genetically Modified Organism

Other Ingredients: Citric acid, natural orange flavor, natural flavors, beta carotene (for color), stevia extract (leaf) (rebaudioside A 98%) and silica.

**Contains Milk.**

Figure 1: Nutrient label for dietary supplement (theta one)



<b>Supplement Facts</b>	
Serving Size: 23 Drops (1.155 ml)	Servings Per Container: 60
Amount Per Serving	% Daily Value
Proprietary Silica Gel 1.155 ml	**
**Daily Value not established	

**Other ingredients:** none

*Contains NO sugar, gluten and no artificial: sweeteners, flavors, colors or preservatives.*

Figure 2 : Nutrient Label for dietary supplement (theta activate)

### **LifeWave Y-Age Carnosine Patch**

The Y-Age Carnosine patch is available for retail purchase in the United States and a proven solution for improving athletic performance based on past LifeWave research on the use of Carnosine patch in strength and endurance testing. Regular use leads to increased strength, stamina and overall performance. It is targeted for recovery, helping the body to recover and repair more quickly after exercise. In the United States, it is classified as a General Wellness product and the mechanism of action is phototherapy. Where a patch covers the skin, infrared light emitted from the body is reflected back into the tissue. This stimulates the skin, which in turn, stimulates specific regions of the brain to create a particular health benefit.

### **Dietary Guidelines:**

This program was not a diet, but rather a series of guidelines that could potentially improve fat loss and muscle toning or muscle building. There was no calorie counting and no calorie restriction required.

### **Instructions to subjects**

#### **A. Restrict eating to an eight-hour period**

A cycle of eating during an 8-hour period and then not eating for 16 hours allows the body to tear down old tissue and build new tissue. Continuing to fuel the body with nutritious food in an 8-hour window allows a person to keep their body in a steady state of anabolic metabolism. After a few days of adjustment most people do not feel like they are hungry during the 8-hour window! One important tip was to focus on eating clean proteins such as grilled chicken and healthy fats such as avocados and coconuts.

#### **B. Make dinner the biggest meal of the day**

The body needs protein to build new muscle and make hormones, both of which occur in the evening.

#### **C. As much as possible, consume unprocessed foods**

It's best to reduce or eliminate sugar, processed foods, refined carbohydrates (e.g. bread, pasta, cereal, baked items) and grains. As an example, salmon with broccoli is a perfect dinner choice.

#### **D. Limit caffeine consumption**

Only consume caffeine before or during exercise, but not after exercise, because it interferes with muscle building. Although a person may have a caffeinated drink first thing in the morning before their prescribed exercises, but at no other time in the day. These dietary guidelines should be followed a minimum of four days per week, though daily compliance will yield the best results.

### **Results**

Table 1 shows a summary of compliance at days 30 and 60. As seen at the 30 day time point, overall compliance was 100% for drinking water, wearing the WinFit patch and 8 hour restriction of eating. Compliance was 92.9% for wearing the Carnosine patch, 87.5% for doing exercise and 17.9% for drinking the protein shake. At 60 days, compliance was 100% for only drinking water and was over 90% for wearing the Carnosine and WinFit patches and exercise. Compliance was 71.4% for 8 hour restriction of eating and was 19.6% for the protein shake.

**Table 1. Summary of compliance at day 30 and 60.**

	Day 30			Day 60		
	Median	Minimum	Maximum	Median	Minimum	Maximum
Carnosine	92.9%	0.0%	100.0%	94.6%	50.0%	100.0%
Exercise	87.5%	0.0%	100.0%	93.8%	34.4%	100.0%
Protein	17.9%	0.0%	100.0%	19.6%	0.0%	96.4%
Water	100.0%	0.0%	100.0%	100.0%	50.0%	100.0%
X32	100.0%	0.0%	100.0%	98.2%	50.0%	100.0%
8 Hour	100.0%	0.0%	100.0%	71.4%	23.2%	98.2%

Table 2 shows the comparison of compliance between perform and weight groups. As shown, the only significant difference was in the exercise section (p=0.0234). There was a significant difference in compliance of the performance and weight groups at both time points, (difference in compliance at day 30 (100 vs. 75%). The difference between groups for exercise was the only section that was significantly different between groups. The other low compliance section was the protein shake section of both groups, which was 33.9% and 16.1% respectively and there is no other significant difference between groups.

**Table 2. Comparison of compliance between performance and weight groups at day 60.**

	Perform (N=16)			Weight (N=15)			p-value <sup>1</sup>
	Median	Minimum	Maximum	Median	Minimum	Maximum	
Carnosine	94.6%	50.0%	100.0%	94.6%	78.6%	96.4%	0.8891

Exercise	100.0%	100%	100.0%	75%	25.0%	100.0%	<0.0002
Protein	33.9%	0.0%	96.4%	16.1%	0.0%	66.6%	0.5599
Water	100.0%	100.0%	100.0%	98.2%	83.9%	100.0%	0.3394
WinFit	100.0%	100.0%	100.0%	96.4%	78.6%	100.0%	0.1204
8 Hour	71.4%	23.2%	96.4%	71.4%	46.4%	98.2%	0.9211

**Definition of statistical term in tables:**

- Mean=average values for all subjects
- SD-Standard Deviation, how much the data varies from the mean (average of all the data)
- Min-minimum or lowest value
- Max-maximum or highest value
- P-value the probability that the data is different than the comparison (baseline or placebo) value. A p-value of less than 0.05 indicates that the data is significantly different from the comparison measure. The lower the p-value, the more different the test value is from the comparison test value.

Table 3 shows the results for absolute change from baseline for all outcome measures at each time point for all of the subjects using the LifeWave Body Shaping System (WinFit) grouped together. There were decreases in all body measures at days 30 and 60. At both time points, there were significant decreases in the chest, hips, thigh, waist for all subjects ( $p < 0.0001$ ). At day 60, there were further decreases beyond day 30 and the weight decrease of (-2.79 lbs.) was highly significantly different ( $p < 0.0003$ ).

**Table 3. Absolute changes from baseline for all subjects grouped together for each body outcome measure at each time point.**

	Change from baseline to day 30	Change from baseline to day 60

Outcome Parameter	Mean	SD	p-value	Mean	SD	p-value
Bicep	-0.06	0.32	0.2743	-0.09	0.36	0.1833
Body Fat	-0.08	2.42	0.8484	-0.57	3.07	0.3057
Bust/Chest	-0.27	0.65	<0.0296	-0.56	0.77	<0.0004
Hips	-0.51	0.53	<0.0001	-0.73	0.60	<0.0001
Thigh	-0.34	0.42	<0.0001	-0.46	0.59	<0.0001
Waist	-0.97	1.24	<0.0001	-1.48	1.19	<0.0001
Weight	-0.90	2.84	0.0864	-2.79	3.74	<0.0003

Table 4 shows a comparison of absolute change from baseline to day 30 for all body measures between males and females. As shown, there were significant decreases in biceps, chest, hips, thigh and waist from baseline to day 30 for both females and males. Both sexes demonstrated a decrease in body measures except body fat, where females had an increase (0.56) at day 30, with a large standard deviation (2.15). When males and females are analyzed together, there is a decrease in body fat at day 60 (Table 3). There was a trend for significance between groups for weight loss at day 30, females lost a mean of .16 lbs. and males lost 2.08 lbs.

**Table 4. Absolute change from baseline between females vs. males for all body outcome measures at day 30 time point.**

Study Parameter	Female (N=19)			Male (N=12)			p-value <sup>2</sup>
	Mean	SD	p-value <sup>1</sup>	Mean	SD	p-value <sup>1</sup>	
Bicep	-0.16	0.28	<0.0239	0.08	0.34	0.4175	<0.0403
Body Fat	0.56	2.15	0.2735	-1.10	2.56	0.1653	0.0621

Bust/Chest	-0.34	0.76	0.0655	-0.15	0.42	0.2534	0.4210
Hips	-0.45	0.48	<0.0007	-0.60	0.63	<0.0065	0.4353
Thigh	-0.29	0.36	<0.0023	-0.42	0.50	<0.0154	0.4163
Waist	-1.08	1.47	<0.0050	-0.79	0.76	<0.0041	0.5376
Weight	-0.16	2.12	0.7492	-2.08	3.48	0.0624	0.0645

Table 5 shows a comparison of absolute change from baseline to day 60 for all body measures between males and females. As shown, significant decreases in biceps, chest, hips, thigh and waist occurred from baseline to day 60 for both females and males. There is a significant difference between females and males when comparing changes in bicep from baseline to day 60 ( $p=0.033$ ), men had a greater decrease in bicep measure. In females, the body fat measure dropped from 0.56 to 0.29. Females lost a mean of 1.04 lbs. and males lost 5.55 lbs., which was a highly significant difference ( $p=0.0004$ ).

**Table 5. Comparison of absolute change from baseline to day 60 between males vs. females.**

Study Parameter	Female (N=19)			Male (N=12)			p-value <sup>2</sup>
	Mean	SD	p-value <sup>1</sup>	Mean	SD	p-value <sup>1</sup>	
Bicep	-0.20	0.32	<0.0145	0.08	0.37	0.4569	<0.0333
Body Fat	0.29	2.36	0.5936	-1.95	3.63	0.0894	<0.0452
Bust/Chest	-0.57	0.82	<0.0076	-0.54	0.71	<0.0235	0.9339
Hips	-0.67	0.60	<0.0001	-0.81	0.61	<0.0008	0.5316
Thigh	-0.48	0.50	<0.0006	-0.44	0.72	0.0603	0.8609

Waist	-1.58	1.36	<0.0001	-1.33	0.87	<0.0002	0.5833
Weight	-1.04	2.78	0.1202	-5.55	3.45	<0.0002	<0.0004

<sup>1</sup>: p-value for evaluating absolute changes from baseline to day 30 within females and within males

<sup>2</sup>: p-value for comparing absolute changes from baseline to day 30 between females vs. males

### Summary of Decreases in Body Measures

An average total of 3.5 inches was lost in all regions for all subjects using the WinFit system during the 60-day study, with the following breakdown of inches lost for each region: 0.2 inches in the bicep, 0.57 inches in the chest/bust, 0.67 inches in the hips, 0.48 inches in the thigh and 1.58 inches in the waist. The total average weight loss for all subjects was 2.79 lbs. Body mass index was calculated for all subjects and the results follow: there was a total decrease in BMI of 5.7 in 18 of 31 subjects (58% of subjects, with the decreases ranging from 0.1-1.4) no change in 3 subjects and increase of 3.2 BMI units in 10 subjects (with the increase ranging from 0.1-.8). This was correlated with an average weight loss of 2.79 lbs. for all subjects during the 60-day study. These changes were correlated with results from an exit survey (not shown).

Results of the exit survey demonstrate that 94% of the subjects reported greatly increased energy levels, 97% felt their body was more firm and toned and their clothes fit better and WinFit met or exceeded their fitness goals and 100% felt they had more muscle strength and stamina since using WinFit. Furthermore, 87% felt that WinFit was crucial in achieving their fitness goals and 97% felt that it was easy to incorporate WinFit into their lifestyle. These results are impressive and indicate that the subjects felt that WinFit increased their body composition and is easy to incorporate into a fitness regime.

EXIT SURVEY QUESTIONS	YES/NO %	TOTAL % POSITIVE (of those who answered)
1. I have more energy since using WinFit	29/2	94
2. My body has become more firm and toned since using WinFit	30/1	97
3. I have increased muscle strength and stamina since using WinFit	31/0	100
4. The WinFit program was crucial in achieving my fitness goals	27/4	87
5. My clothes fit better since using WinFit	30/1	97

6. I am pleased with my results with WinFit	31/0	100
7. I felt healthier now since using WinFit	30/1	97
8. I am more fit now since using WinFit	30/1	97
9. I am more confident now since using WinFit	29/2	94
10. Incorporating "Water" every morning was easy to do	30/1	97
11. The X-32 [WinFit] patch was easy to use	31/0	100
12. Incorporating 10 minutes of exercise was easy to do	24/4	87
13. Incorporating the 8-hour window was easy to do	17/14	55
14. Theta One/Theta Activate was easy to use	29/2	94
15. The Carnosine patch was easy to use	31/0	100
16. The WinFit program was easy to use	31/0	100
17. I would recommend WinFit to friends and family	30/1	97
18. WinFit is not a diet; it's a lifestyle	30/1	97
19. I achieved better and more long-lasting results with WinFit than I have with "diets" I have tried in the past.	24/2	92
20. Before you started WinFit, what were your expectations?	N/A	N/A
21. Did WinFit meet or exceed your expectations?	29/1	97
22. Did you achieve your goals?	26/5	84
23. Did you follow the WinFit program guidelines as directed?	27/3	90
24. Would you consider using WinFit long-term?	27/3	90
25. If you said no/disagree with any of the above statements or questions, please explain:	N/A	N/A
26. Based on your experience, please rate your overall experience with WinFit:	30/0	100
27. Based on your experience, please rate the results you achieved with WinFit:	31/0	100
28. Please indicate your age in the range options below:	30s – four 40s-ten 50s-twelve 60s-five	N/A

29. Please indicate your sex in the options below:	17 female 10 male	N/A
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### Discussion

In this study, overall subject compliance was as much as 100% in every section except drinking the protein shake. The protein shake was not a requirement, but was recommended for use if a subject wanted to put on more muscle. The high overall compliance indicates the ease of integrating WinFit into the subject's lifestyle. Interestingly, the weight group had 87.5% compliance in exercise (compared to 100% compliance in the perform group), which was a group more interested in muscle gain group.

The responses from the exit survey were correlated with decreases in all body measures at both time points. There were significant decreases in bust/chest hips, thigh and waist from baseline to day 30 and 60 and for weight at day 60. There were significant decreases in all of the body regions measured and the total loss was 3.5 inches, which was associated with an overall weight loss of 2.79 lbs. There was an overall decrease in the BMI outcome measure in over 58% of the subjects. In the 10 subjects that demonstrated an increase in BMI, this could be associated with an increase in muscles mass, as indicated by the decrease in body fat.

For females, the absolute change from baseline for body fat measure was positive at day 30 and there was a large variability. This large variability and the observation that body fat in females dropped likely explains the lack of significance for this measure when the groups are combined. At day 60, there was a nearly 2-fold decrease in body fat for females from day 30, which suggests an overall decrease in body fat. However, there was a 0.57 decrease in body fat at day 60 for all subjects. Furthermore, when comparing males and females, the only significant difference between them was that males lost 5.55 vs. 1.04 lbs. for women at the 60 day time point. Since the males have more muscle mass than females and took twice as much Theta One as the females, these factors could explain the greater weight loss in males.

In a separate pilot study conducted by the Energy Medicine Research Institute, the WinFit patch, when used alone, produced significant decreases in the same body measures at day 60 and significant increases in all 14 outcome measures for strength, balance, flexibility and endurance and overall energy level. Furthermore, the WinFit Patch produced nearly a 4-fold increase in energy in the active over the control group. Of the 15 subjects in the active group, 13 reported that they felt much stronger when using the patch and 2 of the subjects reported maybe they felt stronger. No one said they did not feel a difference with the patch. This is quite remarkable. This demonstrates that only one component of WinFit produces impressive results.

### Conclusions

Results of this study demonstrate that 94% of the subjects reported greatly increased energy levels, 97% felt that their body was more firm and toned and 100% felt they had more muscle strength and stamina since using WinFit. This was correlated with significant decreases in body measures of a total of 3.5 inches (biceps, chest, hips, thigh and waist) for males and females at days 30 and 60. In addition, nearly 60% of the subjects decreased their weight by 2.79 lbs. and BMI by 3.5 units during the 60-day study. Males lost more weight than females, which could be explained by their consuming twice as much Theta One during the study. The overall compliance was over 80% and 97% of the subjects reported that was easy to incorporate WinFit into their lifestyle. All of the results combined indicate that WinFit is an easy and effective way to improve body composition.