



Effect of a 6-week Lifestyle Program on Mood State and Metabolic Parameters in Moderately Overweight Subjects

Background:

Today, more than 65 percent of adults in the United States are overweight or obese. Poor nutrition and physical inactivity account for some 300,000 premature deaths in the United States each year. Obesity puts people at increased risk for chronic diseases such as heart disease, type 2 diabetes, high blood pressure, stroke, and some forms of cancer. Obesity-related illness results in hundreds of thousands of preventable deaths each year in the United States and billions of dollars in health care costs.

Popular diet programs in the market:

Diet Program	Concept	Calories	Weight Loss (kg/week)	Attrition Rate
Atkins	High protein/fat, Low carb	~1,500-1,800	0.45	~50%
Protein Power	High protein/fat, Low carb	~1,500-1,800		
Zone (Sears)	Moderate 40/30/30	~1,500-1,800	0.48	~35%
Pritikin	Low fat, high carb	~1,500-1,800	0.14-0.45	~50%
South Beach	High protein/fat, Low carb	~1,500-1,800		
Weight Watcher	Low fat, balanced protein/carbs	~1,500-1,800	0.13-0.44	~35%
Other LCD		~1,500-1,800	0.07-0.48	~30-60%
CitrusSlim®	High fiber, balance protein/carb	~1,500-1,800	0.46	~ 10%

All these popular diet programs typically recommend between 1500 to 1800 calories daily. Virtually any of these low calorie diet programs works if followed properly with regular



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exercise. However, most of these low calorie restricted diet program is hard to follow, as shown in the attrition rate. This maybe due to low energy level, increased stress due to diet program, and a diet program that is tough to follow.

Previous studies have shown that CitruSlim[®] supplementation in a weight loss dietary regimen in conjunction with aerobic and resistance exercise helps maintain anabolic state and results in favorable changes in body composition, metabolic hormones, mood, and cardiovascular parameters. Participants taking CitruSlim[®] also have better overall mood profile and energy levels that may help keep them in the program to complete the previous 12 weeks trials.

Purpose: The purpose of this study is to examine the effects of CitruSlim[®] vs placebo when used in conjunction with a lifestyle program incorporating stress management, exercise, nutrition, and dietary supplement components on weight loss, metabolic parameters, and mood state.

Objective: To measure if CitruSlim[®] supplementation can help increase participants completion rate while achieve a meaningful weight loss goal.

Methods:

50 moderately overweight men and women were recruited to participate in a 6-week program of stress management, nutrition intervention, exercise, and CitruSlim[®] supplementation. 40 were given CitruSlim[®] supplement, and 10 were given placebo. All subjects followed a moderate calorie-restricted diet based on resting metabolic rate (RMR), plus a moderate exercise program (5 d/wk including aerobic & strength training), and stress management techniques (daily).

Participants met weekly for group educational seminars

- **Stress management** - yoga, guided imagery, deep breathing, etc.
- **Exercise** - customized by CPT - 5d/wk (3 aerobic/2 strength)
- **Nutrition** - based on RMR for no more than 500 kcal/d deficit
- **Supplementation** – 200mg CitruSlim[®] (Proprietary blend of Citrus flavanone-O-glycosides and Eurycoma longifolia extract) or placebo
- **Evaluation** - identification of stressful events and interventions

Before and after the 6-week lifestyle intervention, we measured:

- body weight (BW),
- RMR,
- body fat percentage (BF by BIA and skinfold),
- cortisol and testosterone (C and T by salivary enzyme immunoassay),
- total cholesterol (TC), LDL

- global mood state (MOOD by Profile of Mood States)

Paired Student's t-tests were used to assess differences between pre/post measures. Statistical significance was accepted at $P < 0.05$. Data are expressed as mean + SD.

Exercise Regime

- Target = 5 days weekly
 - Counseling session with certified personal trainer
 - 2 days strength (1 exercise per major muscle group)
 - 30 min for Legs, Abs, Back, Chest, Shoulders, Bi/Triceps
 - 3 days aerobic (walk/jog interval training)
 - 28 min for Interval Training
 - 5 min warm-up / 5 min cool-down
 - 18 min intervals (1-2-3-2-1min alternating hard/easy RPE)
 - Achieved - approx 80% compliance (miss 1x/wk)

The Citruslim® Diet Program

400-600 kcal/meal



Fruits &
Veggies



Lean
Protein



Concentrated
Carbs



Added
Fat

Recommended Timing for Meal & Snacks

- 7AM = Breakfast (before leaving for work)
- 10AM = Snack (at work if needed)
- Noon = Lunch
- 4PM = Snack (before leaving work and exercise if possible. Exercise could be before lunch time or after work)
- 7PM = Dinner
- 10PM = Snack (if you have exercised, and only if needed)

- Each snack “lasts” for ~2 hours
- Each meal “lasts” for ~3 hours
- Snacks act as “bridges” to each meal

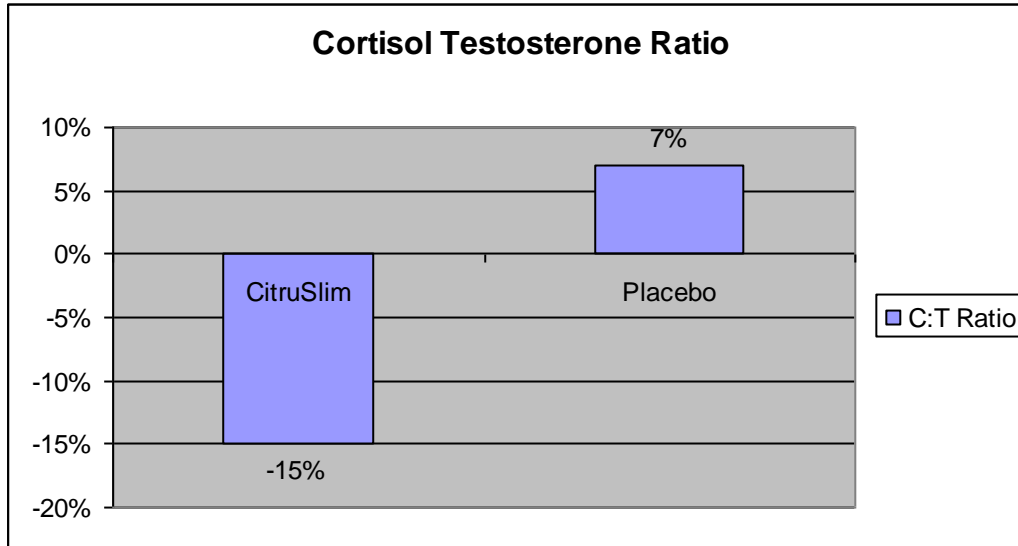
Results:

38 out of 40 subjects in the CitruSlim® group completed the program (95% completion rate), while eight out of ten subjects in the placebo group completed the program (80% completion rate), suggesting that the program was easy to follow and not overly restrictive.

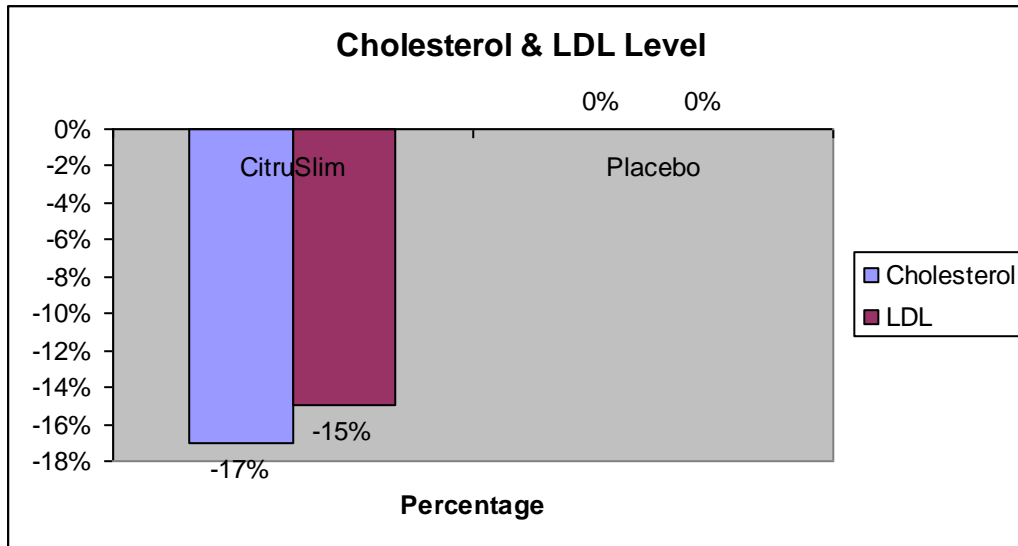


Results showed that the overall lifestyle program led to significant changes in Body Weight & Body Fat in the CitruSlim® Group. At the end of the 6 weeks trial, participants in the CitruSlim® Group showed significant body weight loss of an average of 2.7kg. 2.4kg is in body fat loss, suggesting 87% of the total weight loss is body fat loss. On the other hand, participants in the placebo group do not show significant body weight loss (0.78kg) or body fat loss (0.55kg).

One way of categorizing metabolic processes, whether at the cellular, organ or organism level is as anabolic or catabolic. Catabolism is the part of metabolism that breaks down molecules into smaller units to generate energy and simultaneously takes measures to conserve energy. Stress, such as during weight loss program, can put the body into the catabolic state, in which the body can experience muscle loss, reduced metabolic rate with a corresponding reduced calorie expenditure and lower perceived energy levels, and weight gain in the form of fat. One aspect of the catabolic state is that it can be characterized as having high cortisol (a catabolic stress hormone) levels and low testosterone (an anabolic hormone) levels. Conversely, in the anabolic state the body experiences muscle maintenance or growth, normal metabolic rates, and weight loss in the form of fat. The anabolic state can be characterized by relatively low cortisol levels and high testosterone levels.



The Cortisol Testosterone ratio decrease significantly by 15% at the end of the 6 weeks trial for the CitruSlim[®] group. On the other hand, Cortisol Testosterone ratio increased 7% for the placebo group. Cortisol is at normal range level for the CitruSlim[®] group indicating the modulation of cortisol according to the body's need. The increased testosterone level in the CitruSlim[®] group may contribute to increased vigor and reduced fatigue level. These results suggest that supplementation with CitruSlim[®] may help to maintain normal levels of cortisol (low) and testosterone (high) and thus promote an overall "anabolic" hormonal state (versus a "catabolic" state characterized by elevated cortisol and suppressed testosterone) during the CitruSlim[®] weight loss program. In addition, the higher testosterone level also contributes to higher energy level and reduced fatigue, making the CitruSlim[®] program easier to follow.



At the end of the 6 weeks trial, the CitruSlim[®] group showed significant reduction of total cholesterol by 17% and LDL by 15%. On the other hand, there are no changes in total cholesterol and LDL level in the placebo group at the end of 6 weeks.

Discussion & Conclusion:

Successful weight loss depends on long term adherence from participants. Most weight loss programs in the market has a high attrition rate as it is very difficult for participants to follow certain diet regimens over 8 weeks. Some diet programs can lead to rebound weight gain. Diets that are excessively low in calories can be dangerous and do not result in healthy weight loss. A more desirable method of weight reduction is one that is moderate in calories and that encourages routine exercise.

The low attrition rate of CitruSlim[®] suggests an easy weight loss and lifestyle program to follow, not overly restrictive, superior long-term adherence compared to other diet and weight loss program, which eventually leads to healthy body fat and weight loss. The CitruSlim[®] weight loss dietary regimen in conjunction with aerobic and resistance exercise and a daily CitruSlim[®] supplement helps to maintain anabolic state that prevents diets from binge eating and feeling fatigue, or depressed. Participants on CitruSlim[®] supplement are experiencing higher energy level, reduced fatigue, and overall better mood compared to the placebo group. The increase in energy and improved mood may contribute to the low attrition rate for the CitruSlim[®] group. The CitruSlim[®] group also lost significantly more body fat and weight loss compared to the placebo group, suggesting that CitruSlim[®] supplement in conjunction with diet and regular exercise help promote a long term successful healthy weight loss and fat loss, and results in favorable changes in body composition, metabolic hormones, mood, and cardiovascular parameters.



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Effect of a 12-week Lifestyle Program on Weight, Metabolism, and Blood Lipids in Overweight Subjects

Background: Previous studies have shown that weight loss induced only by dietary restriction results in undesirable losses in fat-free mass, elevations in cortisol, and reduction in testosterone levels. Combining dietary restriction with aerobic or strength training exercise, is known to enhance fat loss and attenuate the loss of muscle mass to varying degrees.

Purpose: This study examined the effects of a combined diet/exercise/supplement regimen on weight loss and metabolic parameters.

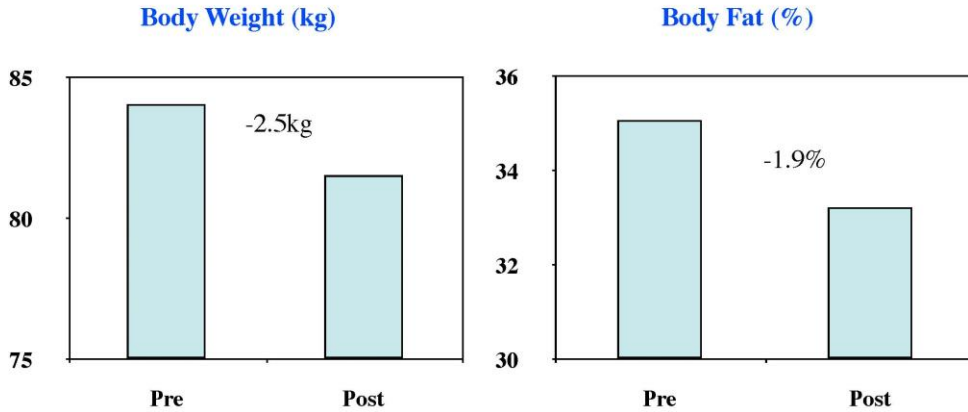
Methods: 32 moderately overweight men and women were recruited to participate in a 12-week program of stress management, nutrition intervention, exercise, and CitruSlim[®] supplementation. Subjects followed a moderate calorie-restricted diet based on resting metabolic rate (RMR), plus a moderate exercise program (5 d/wk including aerobic & strength training), stress management techniques (daily) and 200mg of CitruSlim[®] supplement (daily) intended to reduce stress and increase energy levels.

Participants met weekly for group educational seminars

- Stress management - yoga, guided imagery, deep breathing, etc.
- Exercise - customized by CPT - 5d/wk (3 aerobic/2 strength)
- Nutrition - based on RMR for no more than 500 kcal/d deficit
- Supplementation – 200mg CitruSlim[®] (Proprietary blend of Citrus flavanone-O-glycosides and Eurycoma longifolia extract)
- Evaluation - identification of stressful events and interventions

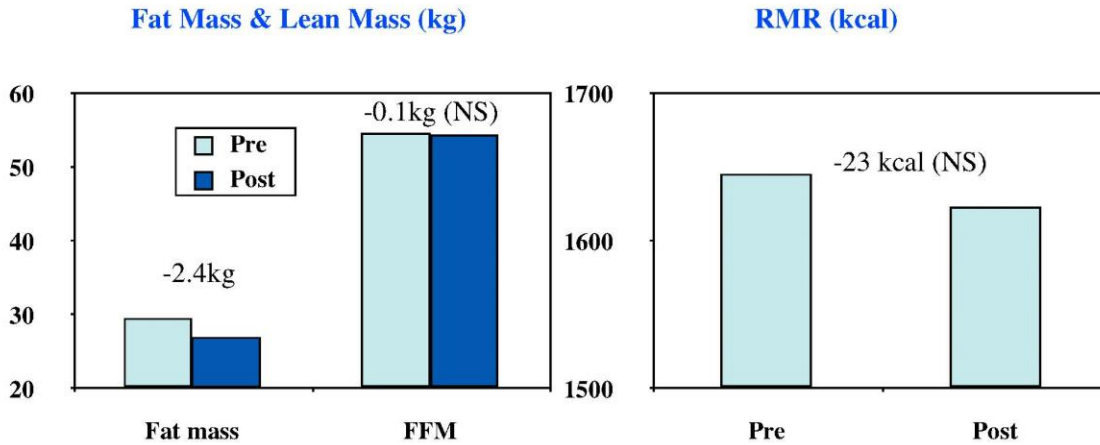
We measured body weight (BW), RMR, body fat (BF by BIA and skinfold), cortisol and testosterone (C and T by salivary enzyme immunoassay), total cholesterol (TC), LDL, and global mood state (MOOD by Profile of Mood States) before and after the 12-week lifestyle intervention.

Results: Twenty-nine subjects completed the program (91% completion rate), suggesting that the program was easy to follow and not overly restrictive. Results show that the overall lifestyle program led to significant changes in Body Weight & Body Fat. Participants lost an average of ½ pound Body Weight loss per week. The Body Fat loss of ½ pound per week (2% drop in BF% - indicating 100% fat loss in this group of moderately overweight subjects).



Both, $p \leq 0.05$ compared to pre value

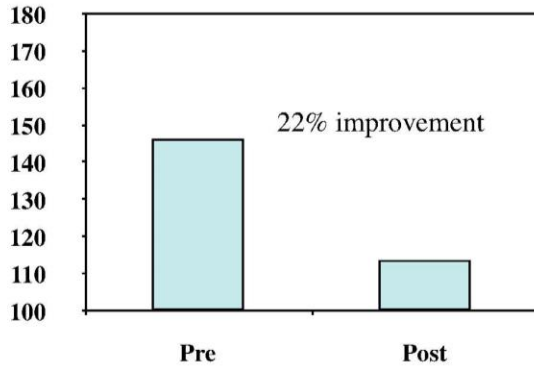
In addition, body composition test revealed that Citruslim[®] supplementation with diet and exercise program help to reduce fat mass significantly (-2.4kg). There were no significant change in lean mass or resting metabolic rate.



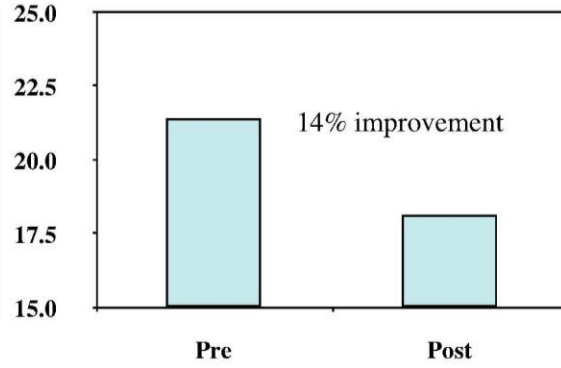
Fat Mass, $p \leq 0.05$ compared to pre value

Supplementation with Citruslim[®] in conjunction with diet and exercise helps participants to manage stress level. We have seen stress reduce by 14%. Global Mood State Score also improved by 22% indicating reduction in tension by 27%, reduction in depression by 52%, reduction in Anger by 42%, increased in vigor by 27%, reduction in fatigue by 48%, and reduction in confusion by 14%.

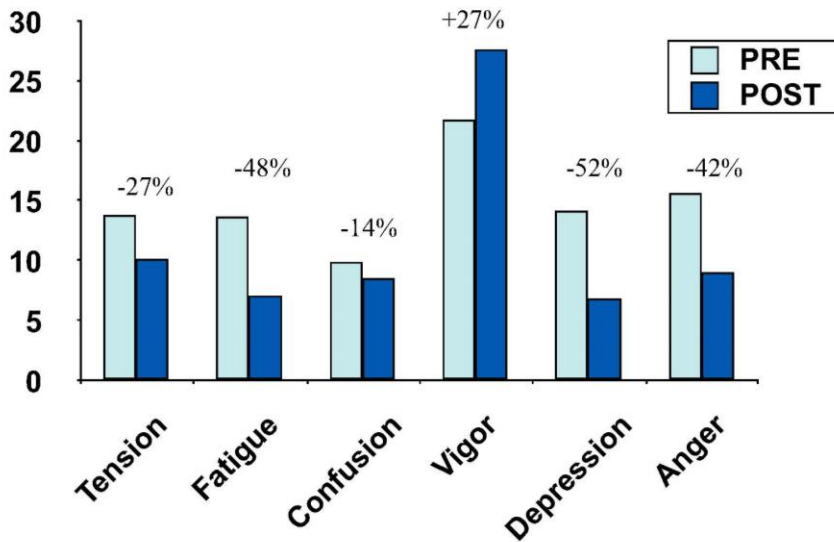
Global Mood State (POMS)



Subjective Stress

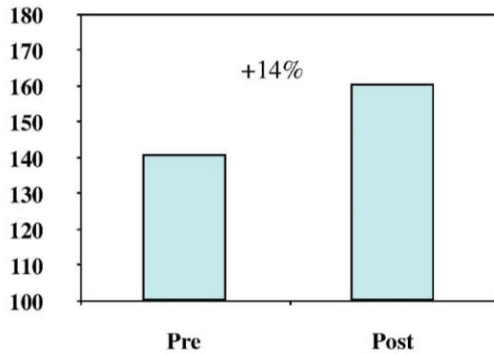


Both, $p \leq 0.05$ compared to pre value

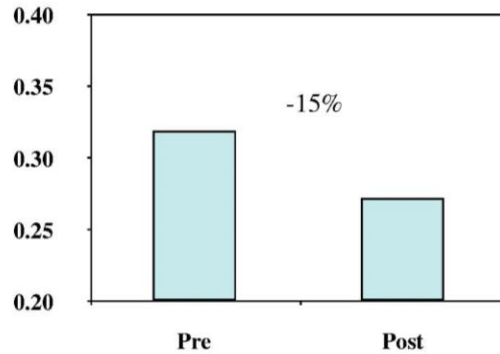


Cortisol level is at normal range level the entire 12 weeks period indicating the modulation of cortisol according to the body's need. There is also possible no change in systemic levels due to HSD control in adipose tissue. Testosterone level is elevated to high normal level (+14%), which may contribute to increased vigor and reduced fatigue level. These results suggest that supplementation with CitruSlim[®] may help to maintain normal levels of cortisol (low) and testosterone (high) and thus promote an overall "anabolic" hormonal state (versus a "catabolic" state characterized by elevated cortisol and suppressed testosterone) during the CitruSlim[®] weight loss program.

Testosterone (pg/mL)



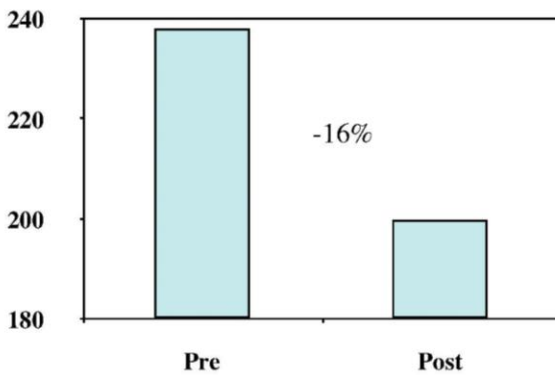
C:T Ratio (x100)



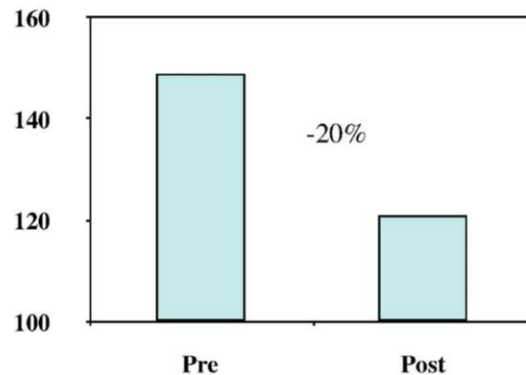
Both, $p \leq 0.05$ compared to pre value

Supplementation with Citruslim[®] help reduce total cholesterol by 16% and LDL by 20%.

Total Cholesterol (mg/dL)



LDL (mg/dL)



Both, $p \leq 0.05$ compared to pre value

Conclusions: These data indicate that a weight loss dietary regimen in conjunction with aerobic and resistance exercise and a daily Citruslim[®] supplement prevents the expected decline in fat-free mass and resting metabolic rate – and results in favorable changes in body composition, metabolic hormones, mood, and cardiovascular parameters. The low attrition rate suggests that effective weight loss and lifestyle regimens need not be overly restrictive, and thus, may be expected to result in superior long-term adherence and, possibly, better maintenance of weight loss.