An Investigation into the Alleged Lipolytic Abilities of a "Fat Burning" Formula - A Randomized, Double-Blind, Placebo-Controlled Study.

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ABSTRACT

Obesity is now considered a worldwide disease and a major cause of death. The annual cost of dealing with obesity and its associated diseases – diabetes, cardiovascular disease and cancer costs billions of dollars every year.

'Imbalance in the energy equation' is believed to be the major cause of obesity. A simple solution, therefore, would seem to be to right this equation. However, that hasn't proven to be as simple as it may sound in theory. A number of anti-obesity drugs with different modes of action have also been tried; none have been really effective.

In such a backdrop, we decided to investigate an all-natural propriety, "fat-burning" supplement – Lean Optimizer™ – that has being touted in popular literature as quite effective.

For this, a randomized, double-blind, placebo-controlled study to investigate the efficacy of Lean Optimizer™ from HFL, Inc. in reducing body mass index – a measure of obesity – was undertaken. Additionally, we also measured the change in body weight that accompanied the use of Lean Optimizer™.

Participants were randomly assigned to one of the two groups – a test group or a control group. The test group received the recommended dosage of the fat-loss supplement while participants from the control group received a placebo (dicalcium phosphate) (2 capsules, three times a day). The duration of the study was 20 weeks.

The results of our study showed that participants supplemented with Lean Optimizer™ showed significant reductions in BMI and body weight.

Furthermore, participants of the study reported feeling more 'energetic' throughout the day. This despite the fact that most experienced appetite suppression with significant reductions in calorie intake.

Lean Optimizer™ appears to be quite safe for use in the general population and therefore, should be considered on a large scale – especially when combined with a healthy diet and exercise program.

A future study to compare this formulation with other anti-obesity drugs or similar supplements is recommended.

BACKGROUND

Using body mass index (BMI) for reference, the National Health and Nutrition Examination Survey (NHANES) concluded – in 2009-2010 – that a third (33%) of US citizens aged 20 and older were overweight, another third (35.7%) obese and 6.3% were extremely obese – making for a total of 75% of the population with weight problems **(Fryar, Carroll, & Ogden, 2012)**.

The world-wide figures are similar as well. So much so, that researchers are now calling obesity a pandemic **(Yarnell, Oscar-Berman, Avena, Blum, & Gold, 2013)**. According to an estimate, more than 200 countries reflect

overweight and obesity trends similar to the US **(Gortmaker et al., 2011)**. The prevalence of obesity in low and middle income countries is slowly on the rise while that in countries with higher incomes is the greatest.

BMI is calculated by dividing weight in Kg by height in meter squared; the formula **(Fryar et al., 2012)** is expressed as under:

$$BMI = W\,(Kg)/H\,(m)^2$$

BMI greater than or equal to 25.0 kg/m^2 and less than 30.0 kg/m^2 is considered overweight while equal to greater than 30.0 kg/m^2 is considered obese. Extremely obese is when the BMI is greater than or equal to 40.0 kg/m^2 **(Fryar et al., 2012)**.

Effects of Obesity on Human Health

Notwithstanding the reduced wellbeing and fitness scores associated with obesity, there is a very realistic connection between obesity and metabolic diseases as well – diabetes type 2, cardiovascular disease, cancer, etc. Slowly but surely, obesity is replacing smoking as the number one killer in the industrialized world **(Yarnell et al., 2013)**.

Furthermore, the health care costs of dealing with the ill-effects of obesity and related conditions has reached epic proportions as well. An estimated $100 billion are being spent annually to deal with the menace **(Sturm, 2002; Skidmore & Yarnell, 2004)**.

Primary Cause/s of Obesity

Imbalance (in the 'energy equation') between calorie intake and expenditure of calories is considered to be a prime cause of obesity. Lack of enough physical activity, by decreasing expenditure of stored energy (in the form of fat) and excess consumption of refined, high calorie foods or a combination of these two factors may contribute to the development of obesity. Other causes pathologies – like hypothyroidism – contribute to a significantly miniscule % of cases of obesity.

Although a number of approaches have been tried – none have been proved to be really effective over long periods of time. While increasing physical activity (PA) and decreasing food consumption may be the best way to deal with obesity, patient compliance over long periods of time is very difficult to sustain **(Volkow & O'Brien, 2007)**.

A plethora of anti-obesity drugs have been tried – orlistat, sibutramine, rimonabant and the likes – however, these are not as effective as initial research reported and their use invariably requires some amount of dietary restriction **(Elfhag, Rossner, Barkeling, & Rooth, 2005; Hauptman, Lucas, Boldrin, Collins, & Segal, 2000; Kiortsis, Tsouli, Filippatos, Konitsiotis, & Elisaf, 2008)**. Hence, long-term compliance is an issue with the use of these drugs.

Supplements containing herbal or naturally-derived ingredients are usually aimed towards increasing basal metabolic rate and thus burn fat; these have also been tried and recommended by fitness professionals and researchers alike for fighting obesity. However, although 'natural', these have the potential to cause adverse effects – some severe. A case in study are the ephedra alkaloids which have now been banned **(Health News, 2000; Am J Health Syst Pharm, 1997; CDC, 1996)**. Other 'natural' drugs like synephrine extract, which have similar actions may not be as effective or indeed as safe as are made out by manufacturers or promoters **(Bent, Padula, & Neuhaus, 2004)**.

The search for effective and long-lasting therapeutic solutions to obesity, therefore, remains a top pharmacological concern.

In such a backdrop, we decided to investigate a propriety fat-burning supplement – Lean Optimizer™ – that has been touted – in popular literature – as being quite effective.

STUDY DESIGN

A randomized, double-blind, placebo-controlled study to investigate the efficacy of Lean Optimizer™ from HFL, Inc. in reducing body mass index – a reliable measure of obesity – was undertaken.

METHODOLOGY AND PARTICIPANTS

120 adults (of age more than 20 years) and BMI of more than or equal to 25.0 kg/m^2 (78 men and 42 women) were shortlisted. This was done after inviting members of the local community to join the research study.

Participants were randomly assigned to one of the two groups – a test group and a control group; 60 in each group. All participants underwent BMI test before commencement of the study and at the end of week 20. We also recorded baseline body weights of participants.

The test group received the recommended dosage of the fat-loss supplement (2 capsules, three times a day) while participants from the control group received a placebo (dicalcium phosphate). The duration of the study was 20 weeks. A one week off was planned after every 4 week of 'being on the supplement'. In effect, we used 4x4 week 'cycles' of Lean Optimizer™ with a week off between the cycles.

Additionally, study subjects were also instructed to follow a simple exercise program of alternate day walking sessions. These were of an incremental nature – increasing in both intensity and duration as the weeks went by. Participants were also instructed to follow a 'wholesome food plan' containing minimal amount of refined and processed foods.

Before commencing the study, BMI and body weight of each individual was ascertained and recorded. These results are displayed in **table1**.

Table1. Baseline reading of BMIs

BMI (in $kg/m^{2)}$	Test Group	Control Group
≥25 and <30 (overweight)	25	29
≥30 and <40 (obese)	28	23
≥40 (extremely obese)	7	8
Total	60	60

Table2. Baseline reading of body-weight

Weight in lbs.	Test Group	Control Group
180-200	35	30
201-300	23	29
>300	2	1
Total	60	60

According to BMI, 25 from the test group were found to be overweight, 28 obese and 7 extremely obese with a BMI of over 40 kg/m^2. The corresponding figures for the control group were: 29 overweight, 23 obese and 8 extremely obese.

As far as body weight goes, 35 in the test groups were recorded with a body weight within range of 180-200lbs, 23 between 201-300lbs and 2 weighed more than 300lbs. The control group recorded somewhat similar bodyweights – 30 participants with bodyweight between 180-200lbs, 29 between 201-300lbs and 1 with a bodyweight of more than 300lbs.

RESULTS

As opposed to participants receiving placebo, those receiving Lean Optimizer™ showed significant reductions in BMI. As shown in **table3**, improvements in BMI were seen in 37 of the 60 participants. Also, an interesting statistic was that this positive change was observed evenly over different levels of BMI – overweight, obese or extremely obese. Bodyweight improvements (**table4**) were seen in 23 of the participants who received Lean Optimizer™; longer-term supplementation we believe could reduce this number even further.

In the control group, however, the numbers (BMI and bodyweight) didn't change much – all participants still qualified as either overweight, obese or extremely obese. Although some improvement within the group; this was credited to the 'alternate-day walking program' and healthy food intake.

Table3. Post-study reading of BMIs

BMI (in kg/m$^{2)}$	Test Group	Control Group
≥25 and <30 (overweight)	15	32
≥30 and <40 (obese)	20	25
≥40 (extremely obese)	2	3
Total	37	60

Table4. Post-study reading of body-weight

Weight in lbs.	Test Group	Control Group
180-200	15	27
201-300	16	27
>300	2	1
Total	33	55

Table5. Post-study overall results

BMI (in $kg/m^{2)}$	Test Group	Control Group
Average Initial BMI	$33kg/m^2$	$31kg/m^2$
Average Initial weight	226 lbs	238 lbs
Average Final BMI	$28kg/m^2$	$30kg/m^2$
Average Final weight	194 lbs	233.5 lbs
Average Weight Loss	**32 lbs**	**4.5 lbs**

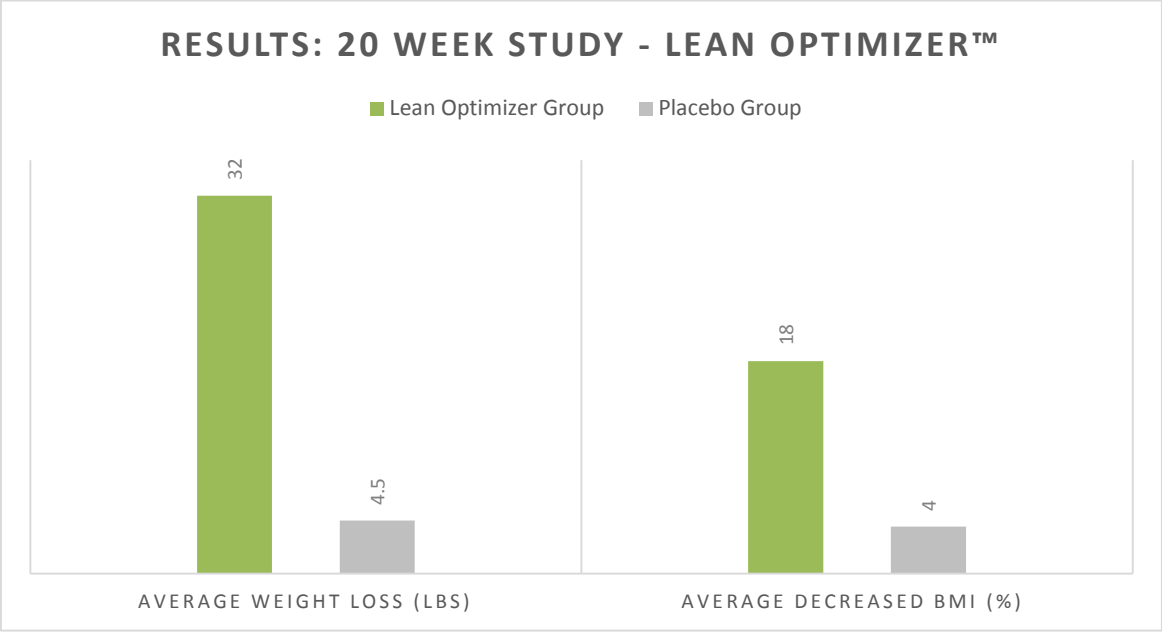

Table5, additionally summarizes the comparison between the test and control group – both in terms of improvements in BMI and loss of body weight in pounds. While the average improvement in BMI amongst participants receiving the supplement was a phenomenal 5kg/m^2 with an average weight loss of 32lbs, control group participants didn't reflect much improvements in either BMI or body weight.

Lean Optimizer™, on an average caused a loss of 32lbs of body weight over a period of 20 weeks.

Most participants, when questioned about it – after the completion of the study – said they felt 'euphoria' when on the supplement. Most reported feeling more 'energetic' throughout the day. This despite the fact that most participants experienced appetite suppression with significant reductions in calorie intake.

Also, none of the participants receiving Lean Optimizer™ experienced any untoward effects. Initial 'unease' was reported to settle a few days into the supplementation, as well as transient insomnia.

DISCUSSION

Contents of Lean Optimizer™ are green coffee bean extract, theobromine, dandelion root, l-tyrosine, yerba mate, 5-hydoxytryptamine (HTP), Bladderwrack, higenamine HCl, Dendrobium extract, 3,5-diiodo-L-thyronine, Forskolin extract, Chlorella chlorophyll and guggulsterones.

Additionally, it contains chromium picolinate, vitamin C (ascorbic acid), vitamin B_6 (pyridoxal hydrochloride) and potassium. Enough scientific evidence exists that most of the ingredients of Lean Optimizer™ are beneficial in obesity.

A literature review of the effects of supplementation with green coffee bean extract by Chacko et al., reports of its benefits in obesity, including high-fat diet induced obesity **(Chacko, Thambi, Kuttan, & Nishigaki, 2010)**. Most of the actions of green coffee bean extract are credited to its chlorogenic acid. Additionally, green coffee bean has also been shown to be protective against different types of cancers, liver disease, type II diabetes and the risk of coronary heart disease **(Gortmaker et al., 2011; Sartippour et al., 2002; Moyers & Kumar, 2004; Chacko et al., 2010; Sueoka et al., 2001)**.

Similarly, other herbal products like yerba mate **(Arcari et al., 2009; Kang et al., 2012)** , Bladderwrack **(Harv Womens Health Watch., 1999)**, higenamine HCl – a β_1-adrenergic agonist with the ability to stimulate adrenergic system, Dendrobium moniliforme which reduces deposition of fats around organs and protects organs from fat-induced damage **(Lee et al., 2012)** may provide for the overall fat-burning abilities of Lean Optimizer™.

Theobromine and 3,5-diiodo-L-thyronine, through their conversion into thyroxin, optimize the levels of thyroid hormones in the body and hence may contribute significantly towards enhancing basal metabolic rate and energy expenditure **(Tvarijonaviciute, Jaillardon, Ceron, & Siliart, 2013; CASTEX & SCHTEINGART, 1959)**.

There is evidence that the other herbal contents like Forskolin extract, Chlorella chlorophyll **(Chon, Sung, Hwang, & Park, 2009; Hidaka, Okamoto, & Arita, 2004)** and guggulsterones may also help fight obesity.

5-hydoxytryptamine (5HTP) in addition to acting as a mood elevator is believed to optimize endogenous release of growth hormones **(Giordano, Foppiani, Marugo, Minuto, &**

Barreca, 1973) – thus maintaining or improving lean muscle may one of the actions carried out by 5HTP.

CONCLUSION

In our study, Lean Optimizer™ seemed to cause a significant improvement in anthropometric parameters in those supplemented with it. Improved BMI and reduction in body weight, across all levels of overweight and obesity, was observed.

Furthermore, our findings suggest that the dose required to cause such drastic improvements are both well-tolerated and safe for use and should be considered for use in the general population on a larger scale.

FURTHER RESEARCH

Our outcomes suggest that the ingredients of Lean Optimizer™ may work synergistically to cause significant improvements in BMI and reduction in body weight. This is contradictory to prevalent literature where some of the ingredients, on their own, have been shown to be not that effective. We suggest, a larger scale and longer-term study be undertaken to addresses these issues.

One potential conclusion for the synergy of the ingredients utilized and positive outcome with Lean Optimizer™, is the potential improvements seen in hormones. Lean Optimizer™ primary benefit might be in its ability to improve key hormones which help control the metabolism; more specifically Thyroid, Leptin, Cortisol and Insulin. With slight improvements in any or all these hormones, may cause dramatic improvements in weight loss, especially adipose tissue.

Also, the improvements in anthropometric measures may reduce the risk of metabolic diseases like diabetes mellitus and cardiovascular disease. We also surmise that some contents of Lean Optimizer™ may also help reduce plasma levels of cholesterol and glucose.

Thus, more elaborate studies to look into the likely preventive and therapeutic effects of Lean Optimizer™, especially in hormone manipulation and improvement – as well as diabetes and cardiovascular diseases, should be undertaken.

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