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Efficacy of 12 Weeks Supplementation of a Botanical Extract-based Weight Loss Formula on Body Weight, Body Composition and Blood Chemistry in Healthy, Overweight Subjects – A Randomised Double-blind Placebo-controlled Clinical Trial

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Abstract
Objective: The aim of this study was to evaluate the efficacy and safety of composite extracts in reducing weight, as the main outcome measure. Secondary measures of the study were body composition change. Design: Randomised, double blind, placebo-controlled clinical trial. Setting: Tertiary university clinic. Subjects: hundred and five subjects, 5 of them withdrawn consent, 2 drop-outs not related to study preparation. Intervention: two tablet per meal concept supposed to generate a "psychological" therapy-like approach during 12 weeks supported by measured physical activity. The tablets 1 (one hour before meals, comprises extracts of Asparagus, Green tea, Black tea, Guarana, Mate and Kidney beans) and 2 (taken half an hour after meals, comprises extracts of Kidney bean pods, Garcinia cambogia, and Chromium yeast) are taken twice daily with two main meals. Results: A significant change of the Body Composition Improvement Index (BCI) was observed in the active extract group compared to placebo ($p = 0.012$). Weight, BMI, waist-to-hip ratio was not statistically different between groups. Body fat loss was greater in active group ($p = 0.011$) compared to placebo. A weight loss parameter corrected for exercise was introduced and found to be higher in active group ($p = 0.046$) than in placebo, meaning that the formula was more efficacious, due to a concurrently performed exercise program – a recommended strategy for life style modification. Conclusions: A significant change of the Body Composition Improvement Index and the decrease in body fat was statistically significant in active extract subjects compared to placebo. A change in some outcome measures like: weight, BMI failed to produce significant difference between groups.

Key words: dietary supplement, weight reduction, obesity, body composition

List of uncommon abbreviations:
BCI - Body Composition Improvement; EGCG - epigallocatechin gallate; FFM - Fat-Free Mass; FM - Fat Mass; HCA - hydroxicitric acid; SKF – skinfold; WHR – Waist-to-Hip Ratio; WL – Weight Loss; WL/Ex - Weight Loss to Exercise ratio

Introduction

In industrialized countries, the incidence of people who are overweight and obese continues to increase. Approximately 25% to 33% of the US population is overweight, Body Mass Index (BMI > 25-30 kg/m^2). Another 30% is obese (BMI >30 kg/m^2). [23] Over the last decade there has been a trend of increasing prevalence of obesity and obesity-related comorbitity and mortality [9, 19]. Examples of conditions that are associated with obesity and overweight are hyperlipidaemia, hypertension, coronary heart disease and diabetes.

Obesity has been characterized as a long-term energy imbalance. Energy balance is defined as the difference between total energy or caloric intake and energy expenditure. If food energy intake is greater than energy expenditure, the body will store the excess energy as fat. [3] There are basically two opportunities for inducing weight loss, reducing energy intake and increasing energy expenditure. Energy intake is regulated by many factors, e.g. energy density, palatability, variety, glycemic index and portion size. [7]

A desirable dietary supplement should be simultaneously designed to increase thermogenesis, lipolysis, loss of body water, and positively impacting digestion enzymes. Such conception is a complex agent that acts in many directions. The chosen components may directly impact the activity of digestion emzyms, like lipases through the catechins of tea extracts, and alpha-amylase through Kidney bean extract. These same components may also improve the blood lipid profile. Other extracts may stimulate oxidation of fatty acids through the activity of caffeine from Guarana and the teas extracts. Hydroxycitrate is discussed to be effective in easing hunger and decrease the 24h energy intake. The trace element Chromium is known to play an important role in the glucose tolerance factor and can improve carbohydrate metabolism.

The aim of this study was to evaluate the efficacy and safety of composite extracts in reducing weight, as the main outcome measure. Secondary measures of the study were body composition change.

Material and Method

The study was performed from May 2004 to November 2004 according to prospectively designed protocol. The research was performed on 105 patients, 23 males and 82 females. Subjects who completed the protocol were age 21 to 55 and had a BMI of between 25.2 and 39.6. Every patient was informed about the scope and procedure of the research and signed the written consent before entering the study. Patients had to complete 5 visits, 1 screening visit and 4 scheduled visits; scheduled as follows: screening Visit 1 - Day -7, Visit 2 - Day 1, Visit 3 - Day 29 ± 2, Visit 4 - Day 57 ± 2 and Visit 5 - Day 85 ± 2. The screening visit consisted of multiple laboratory tests, physical examinations and inclusion/exclusion criteria. Patient, who did not report significant disease, were without acute current disease, and who had laboratory test values within double normal value were considered healthy and eligible for the study. Performed screening tests included: blood urea nitrogen (BUN), creatinine, sodium, potassium, chloride, uric acid, calcium, total protein, albumin, globulin, albumin/globulin (A/G) ratio, total bilirubin, alkaline phosphatase, gamma-glutamyl transpeptidase, aspartate aminotransferase, alanine aminotransferase, lactate dehydrogenase, hematology, urine analysis, C-Reactive Protein, and pregnancy test if appropriate. They were repeated at visit 5 and served also as safety parameters. Other blood chemistry for metabolic aspects included: total cholesterol, LDL, HDL, Triglycerides, HDL/LDL ratio, Lipoprotein (a), Fasting Insulin, Fasting glucose. All estimations were performed as routine diagnostics in laboratory with internationally recognized quality certificates. Most important exclusion criteria were: losing more than 5 kg in past 3 months, dietary irregularity, alcohol abuse, diabetes mellitus, thyroid, kidney or hepatic disease, psychiatric disorders (especially depression, eating disorders, medication). Smoking was not exclusion criteria, but the smoking was monitored during the trial.

Eligible patients were randomised on visit 2 into groups receiving placebo or active tablets (nutrifin® appeal PLUS), both were manufactured and specially prepared to be identical regarding size, colour and taste (both preparations were supplied by Finzelberg, GmbH & Co. KG). Basically, the here researched weight loss strategy is built on a "two tablet per meal concept (2-tabs-a-meal)", supposed to generate a "psychological" therapy-like approach towards weight management and helps to increase compliance in conjunction with a exercise program. The supplementation comprises of tablets 1 and 2 taken twice daily with two main meals. Patients received randomisation number and appropriate tablets, neither the subjects nor the research team knew about the tablets' content. The components of the researched extract composition are presented below. Randomised visits consisted of anthropometrical measurement, lipid profile, fasting insulin and glucose estimation, preparation dispense (visits 2, 3 and 4) and collection (visits 3, 4 and 5). The compliance of patients was measured based on the consumption rate of the extract preparation and assumed 70% of tablets consumed as the minimum compliance level. The remained tablets were calculated and collected. All patients were instructed and asked to maintain 1500 kcal daily diet prepared as a brochure specially for this trial and adapted to polish conditions. The last visit, Visit 5, included additionally multiple laboratory tests for safety assessment. Adverse Events were recorded at every visit, with the relation to study preparation noted, e.g. none, unlikely, possible, probable, and definitive. The active phase of the study lasted 84 days ± 2 days.

The anthropometric measurements included weight, height, Body Mass Index (BMI = weight in kg/height^2 in m), waist, hip circumference, Waist-to-Hip Ratio (WHR). The percentage of body fat was estimated by 4-Skinfold method, measurement were made with Harpenden caliper (Batty, UK). All measurements were performed before blood sample collection in fasting stage. The 4 sites are subscapular, suprailiac, triceps, and biceps for both gender according to method of Durnin and Womersley (1974). Based on percentage of body fat and weight, the Fat Mass (FM) and Fat-Free Mass (FFM) were calculated. Consequently, Body Composition Improvement index (BCI) was estimated as the sum of positive changes: Fat Mass decrease (as positive value) and Fat-Free Mass increase (as positive value).

The researched composition of extracts was based on a "two tablet per meal twice per day concept". This concept is chosen to generate a "psychological" therapy-like approach towards weight management and requires the participant to be actively involved in their weight management thus increasing compliance. Further, patients were asked to increase exercise by initiating a walking program which was recorded in a patients' diary as time spent every day on walking. Tablet 1, taken one hour before meals, was designed to inhibit digestion enzymes, act as a mild diuretic, and excert a thermogenic effect. It contains extracts of Asparagus, Green Tea, Black Tea, Guarana, Mate and Kidney beans. Tablet 2, taken half an hour after meals should impact the fat synthesis, glucose metabolism, ease hunger, and act as mild diuretic. It is comprised of extracts of Kidney Bean pods, Garcinia Cambogia, and Chromium as Chromium yeast.

Statistics

Data were stored in Clinical File Records and an electronic database (MsAccess, Microsoft Corp, USA). Statistical analysis was performed with SigmaStat v3.10. software (Systat Software Inc, 2004, USA). Values are presented as means ± SD (Standard Deviation). The normal distribution was checked with Kolgomorov-Smirnof test. Because only some subgroups of data had no normal distribution, all data were analysed with distribution-free tests. For comparison between subgroups Mann-Whitney test was used. The comparison between the same parameters measured during visits 2 and 5 were done using the Wilcoxon Rank Sum test. The difference in changing anthropological and biochemical parameters during visits 2, 3, 4 and 5 (paired) was estimated in Friedman Repeated Measures Analysis of Variance on Ranks with Pairwise Multiple Comparison Tukey Test, unless otherwise indicated. Because of no normal distribution in some

measured parameters paired data in parallel nutrifin® appeal PLUS group and placebo were analysed with One Way Analysis of Variance with Repeated Measures (RM ANOVA) after transformation of data to normal distribution. Correlations were estimated by Spaerman's test (Rs). P values less than 0.05 were considered significant.

The study was approved by the local bioethics committee in accordance to Good Clinical Practice rules (GCP). Every patient was informed about the aim and study design and signed written consent.

Results

Seven patients were withdrawn from the study and did not complete the five visit protocol, two because of events not correlated with the study preparation and 5 who withdrew their consent. The study was completed by 21 males and 77 females. The overall compliance was 94.3%, as measured by planned dosage. Patients randomised to groups of active extract or placebo, who completed the protocol, were equal at the start of the study, with the exception of a small difference in age (Table 1).

Patients in the active extract group had a higher decrease in weight, BMI, waist and WHR, but differences considering all 98 patients were not significant. The decrease in body fat estimated by skinfolds was statistically significant. (Table 2)

Patient in both groups (active extract and placebo) additionally were given an exercised (walking) program which was self-monitored and tracked via a pedometer. Assuming, that additional exercise to the previous lifestyle, could contribute to change of weight, BMI or percentage of body fat, correction for exercise was introduced. The weight loss (WL) per hour walk or exercise (Ex) (ratio, WL/Ex), BMI decrease per hour walk or exercise (BMI/Ex), body fat decrease estimated by Skinfolds per hour walk or exercise (SKF-fat/Ex) were calculated. Results are presented in Table 3.

Based on percentage of body fat, fat mass (FM), fat-free mass (FFM) and Body Composition Improvement (BCI) were calculated by adding the FM decrease to the FFM increase. The results are presented in Table 4 and Figures 1-3.

No changes in laboratory safety parameters were observed between the start and end of the study in both groups. The systolic and diastolic blood pressure decreased in both groups and the difference was statistically significant in both groups, but not significant between groups. The overall number of adverse events in active and placebo groups differ in an insignificant manner (n = 3 and n = 5 respectively for none/unlikely relation; n = 8 and n = 2 respectively for possible/probable). Specific symptoms limited to gastrointestinal tract (e.g. discomfort) occurred in 8 patients from active group and no patient from placebo (p = 0.002, Fisher's Exact test).

Discussion

According to the best current knowledge, the treatment of obesity requires changes in eating habits and energy expenditure, accompanied by other approaches tailored to the individual patient's needs. There are many problems related to such therapy, including motivation, lifestyle, understanding, activity, pressure from mass media, and achieving long-lasting results. Nowadays it seems to be possible to find herbal formulations which maintain their original characteristics and which undergo microbiological and analytical tests. Thus, it is reasonable to assess the validity of phytotherapeutic products in the adjuvant treatment of overweight subjects. [20] Many diet supplements targeted at weight management are combination products rather than single agents. Thus it is difficult to evaluate the effectiveness of single agents when com-

Table 1. Comparison between randomized patients to active extract and placebo group.

Parameter	Active extract (n = 47)	Placebo (n = 51)	p value (Wilcoxon test)
Age (years)	43.8 ± 8.6	40.2 ± 8.8	**0.031**
Males/Females (n/n)*	11/36*	10/41*	* 0.83
Weight (kg)	86.6 ± 13.2	88.3 ± 18.5	0.99
BMI (kg/m^2)	31.4 ± 3.7	31.5 ± 4.5	0.99
Tabacco use (cigaret/day)	6.0 ± 9.0	4.2 ± 7.7	0.38
Caffeine Intake (cups/day)	2.2 ± 1.5	2.8 ± 1.5	0.085
Meals/day	2.7 ± 0.6	2.8 ± 0.7	0.50
Waist (cm)	100.3 ± 12.3	98.2 ± 13.0	0.43
Hip (cm)	106.1 ± 16.4	107.7 ± 11.7	0.72
W/H Ratio	0.93 ± 0.08	0.91 ± 0.07	0.38
Body fat by SKF (%)	36.4 ± 6.5	36.0 ± 6.9	0.72

* Chi-square test

Table 2. Changes in selected parameters between start visit 5 and end visit 2 in both groups.

Change between V5 and V2 (raw or %)	**Active extract (n = 47)**	**Placebo (n = 51)**	**P (Wilcoxon test)**
Weight (kg)	-2.0 ± 2.6	-1.5 ± 3.5	0.27
BMI (kg/m^2)	-0.74 ± 0.95	-0.63 ± 1.02	0.30
Waist (cm)	-1.32 ± 4.50	-0.15 ± 4.20	0.13
Hip (cm)	-0.26 ± 14.2	-1.16 ± 3.20	0.06
W/H Ratio (1/1)	0.0 ± 0.04	0.01 ± 0.04	0.71
Body fat by SKF (%)	-1.75 ± 1.53	-1.02 ± 1.59	**0.011**
Total cholesterol (mg/dl)	-9.8 ± 42.0 (-15.4 ± 44.4)	-6.1 ± 26.9 (-8.3 ± 26.8)	0.77 (0.71)
LDL (mg/dl)	-10.2 ± 34.8 (-13.8 ± 36.5)	-5.4 ± 19.6 (-6.7 ± 17.3)	0.83 (0.97)
HDL (mg/dl)	2.5 ± 9.8 (2.0 ± 9.6)	0.7 ± 7.7 (0.8 ± 7.9)	0.56 (0.56)
Triglycerides (mg/dl)	-11.7 ± 84.2 (-17.6 ± 76.4)	9.6 ± 137.0 (-0.9 ± 60.0)	0.82 (0.68)
HDL/LDL ratio (1/1)	0.04 ± 0.13 (0.05 ± 0.11)	0.03 ± 0.13 (0.03 ±0.10)	0.57 (0.54)
Lipoprotein (a) (g/l)	0.029 ± 0.096	0.025 ± 0.121	0.85 (0.85)
Fasting Insulin (μU/ml)	-0.3 ± 16.5 (0.5 ± 11.4)	1.2 ± 7.1 (0.3 ± 5.1)	0.94 (0.86)
Fasting glucose (mg/dl)	2.7 ± 21.0 (3.5 ± 11.4)	-1.3 ± 9.8 (-0.5 ± 8.3)	0.08 (0.07)

Values between brackets ( ) represent means ± SD and p-value after exclusion of subjects who were not fasting at visit 2 and/or 5

Table 3. Weight loss, BMI decrease and body fat decrease in active extract and placebo groups corrected by exercise.

parameter	**Active extract**	**Placebo**	**P (Wilcoxon test)**
WL/Ex (g/hour)	-54.2 ± 72.8 (*Me = -30.7*)	-30.1 ± 68.0 (*Me = -14.1*)	**0.046**
BMI/Ex	-0.0623 ± 0.0810 Me = -0.0361	-0.0325 ± 0.0723 Me = -0.0263	0.07
SKF-fat/Ex	-0.0408 ± 0.0509	-0.0205 -± 0.0372	0.07

Me – median value

Table 4. Changes in Fat Mass (FM), Fat-Free Mass (FFM) and Body Composition Improvement index (BCI) during the study.

Parameter	Active extract (n = 47)		Placebo (n = 51)		P (Wilcoxon test)
		P (Friedman test)		p (Friedman test)	
FM change (V2-V5)	-2.2 ± 1.9	-	-1.5 ± 2.0	-	0.066 (0.084)*
FM change (V2-V4)	-1.8 ± 1.7		-1.3 ± 1.7		0.13 (0.13)*
FFM change (V2-V5)	0.2 ± 1.5	-	-0.2 ± 1.9	-	0.32
FFM change (V2-V4)	0.0 ± 1.4		-0.3 ± 1.7		0.61
BCI (V2-V5)	2.4 ± 2.3	**(0.003) V2-V3 period versus V2-V5 period**	1.3 ± 2.5	(0.383)	**0.012 (0.031)***
BCI (V2-V4)	1.8 ± 2.1		1.0 ± 2.3		0.085 (0.088)*
BCI (V2-V3)	1.0 ± 1.7		0.4 ± 1.8		0.15 (0.083)*

* additionally t-Student test when data normally distributed
V2, V3, V4, V5 – Visits 2,3,4 and 5

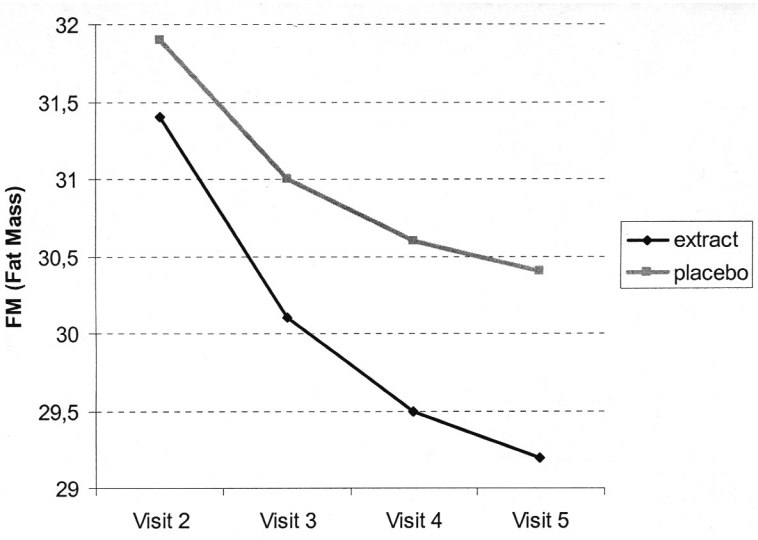

Fig. 1. Difference between Fat Mass (FM) in active extract and placebo groups during the study.

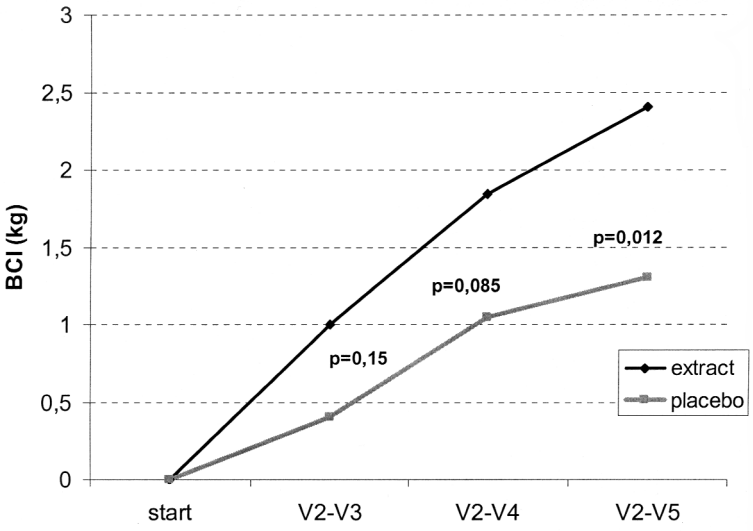

Fig. 2. Difference between Body Composition Improvement index in the active extract and placebo groups during the study.

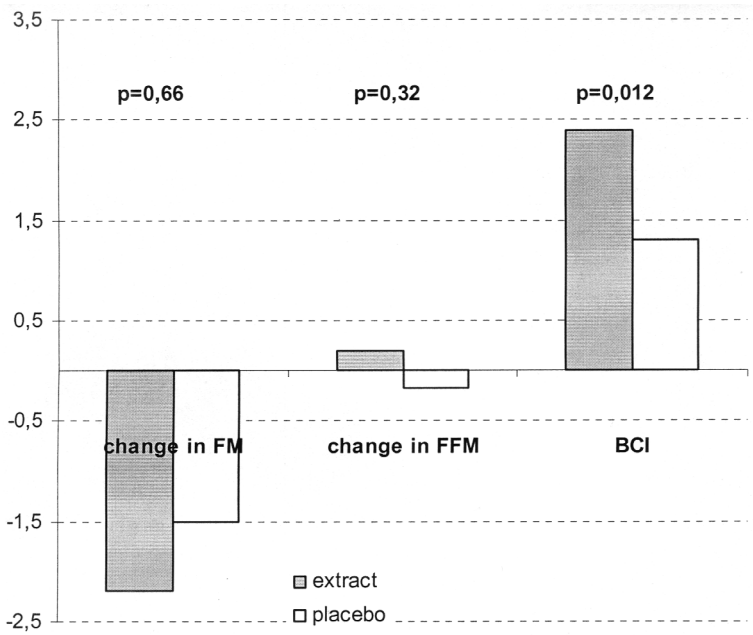

Fig. 3. Differences in changes of FM, FFM and BCI between active extract and placebo group.

bination products are tested. Lenz et al. performed the meta-analysis of not numerous, but only single agents, tested in randomised, double blind, placebo-controlled clinical trials. [18] In well designed studies of chromium, as a single agent, it failed to produce a statistical significant effect on body weight in all four analysed trials. The dose used in these trials was 200 or 400μg during 8, 9, 10 or 16 weeks. There was a significant difference between start and endpoint in both active and placebo groups, but no between-group difference was noticed. [18] In another review of chromium studies, which is supposed to have major influence on glucose metabolism, fat free mass, ten randomised controlled trials were analysed. [21] Only a small weight reduction was observed (1.2 kg) during 6-14 weeks of treatment. Restrictive diet would be more effective, thus clinical relevance remains uncertain. [21] In a newer extensive meta-analysis of chromium effectiveness in reducing weight 489 patients were included. It revealed significant reduction in body weight (-1.1 kg versus placebo), no significant change in fat free mass, and significant reduction in percentage of body fat (-1.2% versus placebo). Authors also conclude, that effect is rather small and not clinically relevant. [22] In previously cited paper only 1 study of garcinia cambogia was qualified for analysis. It was a 12-week trial of 1500 mg of hydroxicitric acid (HCA) per day (from Garcinia cambogia). It revealed the weight reduction in active and placebo group (3.2 vs 4.1 kg), but failed in between-group results. [18] Another randomised controlled trial with a dose of 1500 mg of HCA for Garcinia cambogia versus placebo (and third group + medium chain triglycerides) revealed weight loss, but not a reduction in fat mass, however, this was a short term study (2 weeks). [16] In a similar study, where daily dose was 900 mg of HCA during 2 weeks, energy intake reduction was observed, but changes in weight and satiety did not reach statistical significance. [25] Soni et al. analysed the toxic influence of HCA on rats and humans in one studies and as meta-analysis. It revealed that HCA could be responsible for adverse events observed rarely in clinical trials, like headache and gastrointestinal discomfort. [24] But the toxic dose for rats is about 2500mg/kg/day and in humans several toxicological studies with 2800 mg and 4667 mg daily were performed. It was not observed, that such doses could have a negative influence or cause adverse events. [24] The dose used in the current study was 1000 mg of HCA. Doses even 3 times higher than in our study are recognized as safe. [24] Some authors report, that the useful dose for therapy could also be 360 mg of hydroxycitric acid (from Garcinia cambogia). [20] In another 12-week randomised, placebo-controlled study of HCA from Garcinia cambogia 135 patients were enrolled. The weight loss was -3.2 kg in the active group and -4.1 kg in placebo group. The repeated measure differences were significant, but not when comparing the two groups. The same is true for fat mass (-1.44% vs 2.16% respectively) and the number of adverse events. [11] The authors compared their own results with other well designed studies. In some of them a statistical differences occurred (studies with 1500 mg of HCA, 1500 mg HCA+600 μg chromium and with 1320 mg of HCA), however, in others no statistical difference was found (two different studies with 1500mg HCA + 300 μg chromium, study with 2400 mg of HCA + 150 mg caffeine and 120 μg chromium). [11] The above mentioned studies of the pure substance (HCA) and in combination with one or more other dietary supplements have confusing results making it impossible to conclude whether HCA is effective, at which doses it should be taken, and if the addition of other supplements potentates its action. The last cited study (HCA+caffeine+chromium) is partially parallel to the current trial, but it revealed no influence. In the herein presented trial weight loss did not reach statistical difference, however the percent of body fat and the body composition index significantly improved. Pittler et al., in a systematic review of double-blind randomised controlled trials, conclude that there was no difference in patients treated with HCA compared to placebo in one trial, but in 2 other trials it seems to be favourable. Other studies were performed with HCA in combination with other supplements and the results are inconclusive. [21]

In an additional well designed randomised, double-blinded, placebo-controlled trial of a combination: 72mg ephedrine alkaloids and 240 mg caffeine, during 8 weeks revealed significant intra-group weight loss (-4.0 vs -0.8 kg), body fat reduction (-2.1 vs. 0.2 %), and a decrease in hip circumference (-4.7 vs -0.4 cm), while blood pressure, and heart rate remained unchanged. [2] It also mildly influenced the lipid profile (decrease of triglycerides), but it is difficult to establish, whether it is a primary or secondary effect of herbal combination or the weight loss. [2] The same site performed a 6 months trial with modified doses: 90 mg of ephedrine alkaloids and 192 mg caffeine. The results indicate a significant reduction in weight (-5.3 vs -2.6 kg), Fat Mass (-4.3 vs -2.7kg), waist and hip circumference, while blood pressure and heart rate remained unchanged. [1] However, this study comprises 167 subjects, thus making it possible to detect sublimate differences. It was also noticed, that some positive changes in LDL and HDL concentrations occurred, but the authors could not exclude, that the origin is secondary, produced by the weight loss itself. [1] The currently studied composition contained 300 mg of caffeine per daily dose. It was also reported, that lower doses could be useful (55-87 mg), but some studies reported up to 800 mg of caffeine per day. [20] Other composite extract (ephedrine alkaloids, caffeine, white willow bark) were evaluated in a randomised double-blind, placebo-controlled trail during 12 weeks among 102 subject with BMI 30-39.9 kg/m^2. Such composition revealed significant between-group difference in weight loss (-2.18 vs -0.53 kg), BMI (-0.87 vs -0.21 kg/m^2), but not in percent of body fat or fat mass. [5] In randomised controlled trial among 288 subjects a dose of 200mg of caffeine daily was evaluated as safe. The FDA allows up to 1600mg daily caffeine as an OTC preparations. [10]

Despite the fact that Green and Black tea extracts contain up to 15% of xanthine alkaloids including caffeine and theobromine they as well comprise of up to 60% flavonols including the whole group of catechins specifically epigallocatechin gallate (EGCG), which inhibit lipase activity. [12, 13] Numerous clinical studies

on the slimming properties of Green and Black teas and their constituents like EGCG have been performed and its efficacy was clearly shown.[8, 12, 13]

The other group of herbal substance, which act to modulating appetite, comprises of plants, which are characterized by the presence of dietary fiber. Asparagus and bean pods contain soluble fiber. Among acting mechanisms the most important is to produce the satiety effect. But most observations suggest, that fiber intake does not result in a positive effect on body weight. [20]

Asparagus and Kidney Bean Pods are common food plants, and as tea or extracts they have a long tradition of use as mild diuretics. Asparagus has been cultivated for over 2,000 years as a vegetable and medicinal herb. Both the roots and the shoots can be used medicinally; they have a restorative and cleansing effect on the bowels, kidneys and liver. The plant is antispasmodic, aperient, cardiac, demulcent, diaphoretic, diuretic, sedative and tonic. The shoots are a good source of protein and dietary fibre. Kidney bean (Phaseolus vulgaris) extract contains alpha-amylase inhibitor [15, 17]

In the current trial a composition of several herbal extracts was used. Theoretically, using a number of antiobesity agents combined at doses comparable to other studies, a higher efficacy was expected. Unfortunately, within a combination it is difficult to estimate, which herbal extract contributed in a significant way to the observed decreased body fat and improvement in body composition.

One major advantage of herbal products is commonly the low incidence of adverse effects, which are related to a gently impact on one's metabolism in comparison to highly potent pharmaceutical products showing more side effects. As an example, in the 4-week study with Orlistat combined with diet and versus Orlistat with diet and exercise, better results were noticed, when the additional exercise was applied. [6] But even in potent chemical substances the reduction of weight (about 4 kg) and BMI (about 2 kg/m^2) was significant, but not exponentially better as compared to the herbal extract combination used in our study. [6] Further, the FFM remained, like in this study, nearly unchanged with most changes occurring due to FM reduction. [6] In another randomised Orlistat study lasting 6 months in patients with type 2 Diabetes Mellitus, the reduction in weight was -10.1kg in Orlistat versus -9.4 kg in placebo. Both groups had a concurrent dietary intervention. [14] In addition to the rather low efficacy of this pharmaceutical preparation many side effects are reported, like diarrhoea and fatty stools, which are more severe if the medication is taken after a high fat meal as well as an interference with absorption of vitamins A, D, E, K, and of beta-carotene. [4]

Conclusions

1. A significant change of the Body Composition Improvement Index (BCI) was observed after the 12-week supplementation in the active extract group compared to placebo.
2. The decrease in body fat measured with 4-skinfold method was statistically significant in active extract subjects compared to placebo.
3. A change (decrease) in main outcome measures (weight, BMI, some anthropometric measurements) was significant in active and placebo group, but failed to produce significant difference between groups.

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