Influence of combined botanical extract preparation on blood lipids, glucose metabolism, leptin and homocysteine. Results from double-blind randomized clinical trial

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S u m m a r y

Obesity is associated with possible complications like hyperlipidemia, hypertension, coronary heart disease and diabetes. The aim of this study was to evaluate the effect of composite herbal extracts on blood lipids, glucose metabolism, leptin and homocystein.
Design: randomised, double-blind, *placebo*-controlled clinical trial on 51 overweight, healthy subjects. Preparation of nutrifin® support in a form of tablets, which is a botanical water extract composed of green tea extract, bean peels and asparagus was used.
Results: changes in lipoprotein, glucose, insulin, leptin and homocysteine failed to produce statistically significant difference. Alteration of lipid profile including: changes of total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides were: –9.4%, –18.7%, +11.8%, –13.4% for nutrifin® support group and –8.0%, –12.2%, +1.4% and 14.8% for *placebo* group, respectively. Differences between groups were not significant. The change in total cholesterol and LDL cholesterol strongly correlated with start values of total cholesterol and LDL cholesterol. The correlation coefficients were –0.92 and –0.91 ($p<0.001$) in active extract group, respectively.
Conclusions: Most of researched changes in blood parameters in both groups were not significant, but the reduction in total cholesterol and LDL cholesterol was strongly correlated with lipids levels at the start of the study.

Key words: dietary supplement, lipids, cholesterol, glucose, insulin, leptin, homocysteine

INTRODUCTION

Obesity is becoming a great cause of concern in many countries. The problem is also associated with possible complications like hyperlipidaemia, hypertension, coronary heart disease and diabetes. Lipids and lipoproteins present in serum play an important role in development of atherosclerosis and thereby in etiology of circulatory diseases. Factors associated with coronary heart disease are: hypercholesterolemia, low HDL cholesterol level, high triglycerides levels and obesity itself [1-4].

It has been suggested that many natural products, for example green tea, could influence lipid profile. Thereby new dietary supplements have been developed. Components should be searched among digestion enzymes such as lipases from the catechins of tea extracts and α-amylase from kidney bean extract. The same components may improve blood lipid profile and in combination with antiobesity agents can potentate this effect. Other extracts may stimulate fatty acids oxidation through the activity of guarana, caffeine and tea extracts. This is due to catechins mostly obtained from tea, proved in *in vitro* and animal models [2-9].

The aim of this study was to evaluate the influence of composite herbal extract called nutrifin® support (by Finzelberg GmbH & Co. KG) on selected serum biochemical parameters including lipids, lipoprotein a, glucose, insulin, leptin and homocysteine.

MATERIALS AND METHODS

The study was performed from 2 October till 29 November 2003 at Eugeniusz Piasecki University School of Physical Education. Fifty one patients aged 25 to 64 were scheduled for the first visit (V1, screening and starting visit) before randomization. They signed written consent and the study was approved by local bioethics committee. The inclusion criteria were Body Mass Index 25–35 kg/m^2 and no chronic disease. All patients were asked to be fasting at visit and their blood was collected for biochemical estimations. Total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, leptin, homocysteine, glucose and insulin were measured in sera of all subjects (Cormay Elisa kit, Poland).

After the first visit patients were randomized in double-blind manner. Patients in group A received active preparation of nutrifin® support in tablets, which is a botanical water extract composed of green tea extract, bean peels and asparagus. Two coated tablets, each containing 900 mg of actives: asparagus extract (*Asparagus officinalis*), green tea extract (*Camelia sinensis*), and bean pods extract (*Phaseolus vulgaris*) were dispensed daily. The extract from green tea contained about 30 mg of caffeine, 120 mg of epigallocatechin gallate (EGCG) and 150 mg of other polyphenols. Group B received *placebo*, which was identical in size, color and taste. Both groups received 4 tablets per day. Then the patients were scheduled for the

second visit (V2, 28 days from the starting point) and final, third visit (V3, 56 days from the start). On every visit all above-mentioned procedures were repeated, during the first and second visits new part of active preparation or *placebo* was dispensed. On the second and third visits remaining tablets were collected. The nutrifin® support was designed to reduce weight and change biochemical profile, but patients were also asked to maintain their lifestyle.

Based on glucose and insulin levels, the insulin resistance was calculated according to HOMA formula:

$$HOMA_{IR} = \text{Insulin } (\mu U/ml) \text{ x Glucose (mmol/l)}/22.5$$

Data were stored in Excel files and analyzed with SigmaStat v 3.1. software (Systat Software Inc., 2004, USA). Values are presented as means ± SD (standard deviation). The normal distribution was checked with Kolgomorov-Smirnof test. Due to the fact that only several subgroups of data were normally distributed, all the data were analyzed with the use of distribution-free tests. The Wilcoxon Rank Sum test was used to compare the same parameters measured at the first and the third visits. The difference in change of anthropological and biochemical parameters on several visits (paired) was estimated in Friedman Repeated Measures Analysis of Variance on Ranks with Pairwise Multiple Comparison Tukey Test. Correlations were estimated by Spaerman's test (Rs). Differences between groups A and B concerning parameters change during the study were analyzed with Mann-Whitney test, where other is not specified. P value less than 0.05 was considered significant.

RESULTS

From 51 patients only 42 completed the study according to the protocol. Nine patients did not show up on scheduled visits (6 from group A and 3 from group B) or resigned from the study. Among the other patients 5 violated the protocol being not fasting at least at one visit and were withdrawn from this study. For further analyses 19 patients from nutrifin® support group and 18 from *placebo* group were included.

The group receiving nutrifin® support and *placebo* were compared. Changes in biochemical parameters in both groups from the starting to the finishing visit are presented in Tables 1 and 2 (NS – not statistically significant). In both groups changes were noticed. They seemed to be more favorable for nutrifin® support group (increase in HDL-cholesterol and HDL/LDL ratio, Lipoprotein a). The relative changes and differences between both groups are presented in Table 3 and are not significant.

Table 1.

Changes of main parameters during 3 visits in nutrifin® support group. In parenthesis – Tukey contrast test to indicate visits with statistical difference

nutrifin® support group (n=18)	**visit 1**	**visit 2**	**visit 3**	**Friedman test p [Tukey test]**
cholesterol [mg/dl]	201.0±28.1	202.8±23.5	195.6±13.7	0.68
LDL [mg/dl]	124.2±27.1	123.7±23.1	114.4±13.1	0.092
HDL [mg/dl]	57.4±9.5	60.4±8.0	63.5±9.6	**0.011 [V1:V3]**
HDL/LDL (1/1)	0.49±0.15	0.51±0.14	0.57±0.12	**0.002 [V1:V3. V2:V3]**
triglycerides [mg/dl]	96.7±42.2	93.8±35.0	88.2±34.7	0.35
Lp(a) [mg/dl]	10.7±12.6	9.6±12.3	8.9±11.0	**<0.001 [V1:V3]**
homocysteine [mmol/l]	12.5±4.4	12.6±4.0	14.2±4.2	0.061
leptin [ng/ml]	22.4±12.6	22.3±12.6	21.8±13.8	0.52
glucose [mg/dl]	100.6±17.2	95.4±12.9	94.4±10.3	**0.03 [V1:V3]**
insulin [μIU/ml]	8.3±3.0	12.3±9.5	9.5±4.6	**0.019 [V1:V2]**

Table 2.

Changes of main parameters during 3 visits in placebo group. In parenthesis – Tukey contrast test to indicate visits with statistical difference

***placebo* group (n=19)**	**visit 1**	**visit 2**	**visit 3**	**Friedman test p [Tukey test]**
cholesterol [mg/dl]	205.1±20.7	192.0±20.6	195.3±15.1	0.08
LDL [mg/dl]	117.5±30.0	110.7±23.2	108.5±20.5	**0.007 [V1:V2. V1:V3]**
HDL [mg/dl]	64.8±19.3	67.8±15.9	67.4±14.8	**0.04** [NS]
HDL/LDL (1/1)	0.70±0.69	0.68±0.35	0.66±0.26	**0.08 [V1:V2. V1:V3]**
triglycerides [mg/dl]	114.0±40.3	104.3±31.6	96.6±24.2	**<0.001 [V1:V2. V1:V3]**
Lp(a) [mg/dl]	12.6±13.4	9.9±9.6	9.3±8.5	**0.005 [V1:V3]**
homocysteine [mmol/l]	8.6±2.5	9.5±2.8	12.2±4.0	**<0.001 [V3:V2. V3:V1]**
leptin [ng/ml]	20.7±11.3	21.0±10.3	18.7±8.8	0.13
glucose [mg/dl	95.0±16.3	90.2±11.2	92.0±15.2	0.53
insulin [μIU/ml]	8.7±3.2	10.4±4.9	8.6±3.0	0.17

Table 3.

Changes in main outcome measures between first and third visit in group A and B

parameter	change in group A between V3 and V1	change in group B between V3 and V1	Mann-Whitney test P
cholesterol [mg/dl]	–5.4±21.7	–9.8±16.6	0.59
LDL [mg/dl]	–9.8±21.5	–9.1±20.2	0.87
HDL [mg/dl]	6.1±7.3	2.6±9.2	0.34
HDL/LDL (1/1)	0.08±0.09	–0.04±0.56	0.89
triglycerides [mg/dl]	–8.5±19.2	–17.3±20.0	0.16
Lp(a) [mg/dl]	–1.8±2.4	–3.3±5.9	0.74
homocysteine [mmol/l]	1.8±3.5	3.7±3.5	0.13
leptin [ng/ml]	–0.62±5.44	–2.02±6.26	0.90
glucose [mg/dl]	–6.3±11.9	–2.9±16.3	0.64
insulin [μIU/ml]	1.2±3.7	–0.1±2.5	0.39

In both groups there was selected a subgroup of patients with hypercholesterolemia at the starting point of the study. The inclusion criterium was total cholesterol over 200 mg/dl at the first visit. The results of this subgroup are presented in Table 4. In this analysis the biochemical parameters were even more favorable for nutrifin® support group, but reached only borderline significance in HDL change. When expressing alteration of lipid profile in percentage of start values, the changes of total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides were: –9.4%, –18.7%, +11.8%, –13.4% for nutrifin® support group and –8.0%, –12.2%, +1.4% and 14.8% for *placebo* group, respectively.

Table 4.

Changes in main outcome parameters in patients with hypercholesterolemia (>200 mg/dl) at the start of the study

parameter	change in group A between V3 and V1 n=10	change in group B between V3 and V1 n=11	Mann-Whitney test p
cholesterol [mg/dl]	–18.9±15.3	–16.6±16.2	0.81
LDL [mg/dl]	–23.2±16.5	–14.4±16.0	0.22
HDL [mg/dl]	6.8±6.5	0.93±6.6	0.06
HDL/LDL (1/1)	0.13±0.08	0.06±0.13	0.19
triglycerides [mg/dl]	–13.0±21.4	–16.9±17.4	0.38
Lp(a) [mg/dl]	–2.1±2.2	–2.4±6.2	0.17
homocysteine [mmol/l]	2.3±4.0	3.9±4.2	0.55
leptin [ng/ml]	–2.11±3.13	–3.73±6.54	0.94
glucose [mg/dl]	–9.4±13.0	–1.3±12.2	0.31
insulin [μIU/ml]	1.2±4.4	–0.3±2.6	0.55
$HOMA_{IR}$	0.03 ± 1.09	–0.11 ± 0.50	0.92

In order to search the additional relationships between values, the correlations were estimated. They are presented in Table 5 for group A (nutrifin® support) and in Table 6 for group B (*placebo*). Lipid profile was correlated with change from baseline of selected parameters, because the lipid status could be of importance, separating patients with potential influence of researched botanical extract.

Table 5.

Correlations between start parameters (first visit) and changes in lipids group A (active preparation). Presented data are correlation coefficients (Rs), in parenthesis – p value

parameter GROUP A	change in Cholesterol	change in LDL	change in HDL	change in HDL/LDL	change in triglycerides	change in Lp(a)	change in homocysteine
At VISIT 1							
cholesterol [mg/dl]	–0.92 (0.000)	–0.88 (0.000)	NS	0.55 (0.02)	NS	NS	NS
LDL [mg/dl]	–0.86 (0.000)	–0.91 (0.000)	NS	0.63 (0.005)	NS	NS	NS
HDL [mg/dl]	NS	NS	NS	NS	NS	NS	NS
HDL/LDL (1/1)	0.65 (0.002)	0.74 (0.000)	NS	–0.59 (0.009)	NS	NS	NS
triglycerides [mg/dl]	NS	NS	NS	NS	NS	NS	NS
Lp(a) [mg/dl]	NS	NS	NS	NS	NS	–0.82 (0.000)	0.48 (0.043)
homocysteine [mmol/l]	NS	NS	NS	NS	NS	NS	NS
leptin [ng/ml]	0.67 (0.002)	0.62 (0.005)	NS	NS	NS	NS	NS
glucose [mg/dl]	NS	NS	NS	NS	NS	NS	NS
insulin [μIU/ml]	NS	NS	NS	NS	NS	NS	NS
$HOMA_{IR}$	NS	NS	NS	NS	NS	NS	NS

Interestingly higher levels of total cholesterol and LDL cholesterol at the start of the study correlated with higher decrease in these parameters in patients mainly from group A. This is presented in Figures 1 and 2.

Table 6.

Correlations between start parameters (first visit) and changes in anthropologic and biochemical parameter in group B (placebo). Presented data are correlation coefficients (Rs), in parenthesis – p value

parameter GROUP B	change in cholesterol	change in LDL	change in HDL	change in HDL/LDL	change in triglycerides	change in Lp(a)	change in homocysteine
At VISIT 1							
cholesterol [mg/dl]	–0.54 (0.016)	NS	Ns	NS	NS	NS	NS
LDL [mg/dl]	NS	NS	NS	NS	NS	NS	NS
HDL [mg/dl]	NS	NS	–0.64 (0.003)	NS	–0.47 (0.041)	NS	NS
HDL/LDL (1/1)	NS	NS	–0.57 (0.01)	NS	–0.48 (0.037)	NS	NS
triglycerides [mg/dl]	NS	NS	NS	NS	–0.71 (0.000)	NS	NS
Lp(a) [mg/dl]	NS	NS	NS	NS	NS	–0.45 (0.05)	NS
homocysteine [mmol/l]	NS	NS	NS	NS	NS	NS	NS
leptin [ng/ml]	NS	NS	NS	NS	NS	NS	NS
glucose [mg/dl]	NS	NS	NS	NS	–0.60 (0.007)	NS	NS
insulin [μIU/ml]	NS	NS	NS	NS	NS	NS	0.47 (0.039)
$HOMA_{IR}$	NS	NS	NS	NS	NS	NS	NS

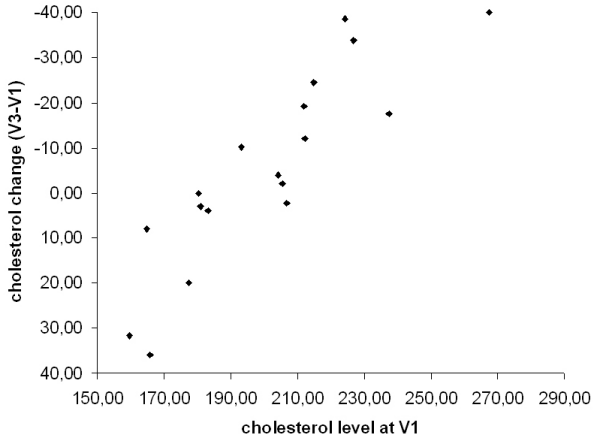

Figure 1. Group A correlation between cholesterol level at the first visit and change of cholesterol between first and third visit

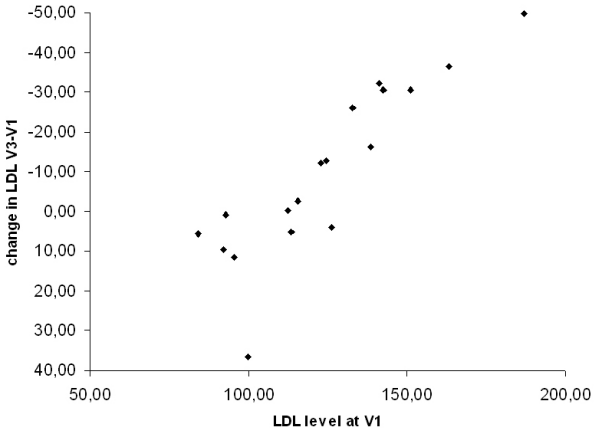

Figure 2. Group A correlation between LDL level at the first visit and change of LDL between first and third visit

DISCUSSION

Many diet supplements targeted at weight management and lipid or carbohydrates metabolism are rather combined products than single agents. Thus, it is difficult to evaluate the effectiveness of single agents when combination products are tested. Lenz et al. performed the meta-analysis of not numerous, but only single agents, tested in randomized, double blind, *placebo*-controlled clinical trials. The majority of results are controversial with regard to anti-obesity effectiveness [10]. Green tea extracts contain up to 25% of xanthine alkaloids, including caffeine and theobromine. They comprise of up to 60% flavonols, including the whole group of catechins as well, especially epigallocatechin gallate (EGCG) which inhibits lipase activity [11, 12]. The green tea extract (rich in catechin polyphenols and to a lesser extent of caffeine) is stimulating the respiration rate of brown adipose tissue [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 shown. The results from controlled studies are optimistic, moderately influencing weight, body composition and blood lipids [13-16]. The studied composition contained 4 x 300 mg green tea extract in a daily dose and produced significant effect in combination with asparagus and bean pods. In *placebo* group some similar but less expressed changes were noticed. This could be a psychological effect, because some patients could have modified their diet or physical activity to reach "better results". When comparing direct changes in nutrifin® support and *placebo* groups, the differences were not significant, but still more favorable for the group A, especially when selecting hypercholesterolemic patients. In Tokunaga et al. study consumption of green tea extract was associated with lower level of total cholesterol but no influence on HDL fraction and triglycerides was

noticed. The effect was dependent on the number of tea cups consumed per day [4]. In a well designed double-blind randomized clinical trial with 240 patients the dose of 150 mg catechins, 75 mg theaflavins and 150 mg other polyphenols from green tea, this agent decreased total cholesterol and LDL cholesterol in participants. The effect on HDL fraction and triglycerides was insignificant. Above-mentioned study included only patients with hypercholesterolemia and the effect of green tea extract depended on the start lipids level [7]. In other human study in normal and obese men, with no criteria of lipid levels similar to our study, green tea extract containing 689.9 mg catechins did not affect the total, LDL and HDL cholesterol [17]. In animal studies the effect was also more dependent on hypercholesterolemic diet and reduced total cholesterol as well as LDL cholesterol in presence of green tea extract consumption [9]. In our study similar correlation was observed, but the number of hypercholesterolemic subjects was small, probably making statistical differences insignificant. But interestingly, lipid profile changed more when dividing patients into hypercholesterolemic (>200 mg/dl) and normocholesterolemic. Thus, the typical beneficent of studied preparation was a hypercholesterolemic patient.

In other green tea-drinking trials, where the dose of cateching ranged from 50 to 850 mg no influence on blood lipids was observed. In Lee et al. study no reduction in lipid profile was observed, but reduction of oxidized LDL cholesterol was noticed [6]. In other study on mice EGCG decreased total cholesterol and triglycerides compared to *placebo* [5]. Catechins from green tea are supposed to have anti-obesity effect and it is possible that the effect on blood parameters is not additional to weight loss [18]. The question is whether the addition of theaflavins and other polyphenols or extraction method is the key point here [7].

The most potential actives in green tea extract are caffeine and catechins. In our study the dose of caffeine and epigallocatechin in green tea extract was 10% and 40%, respectively. Particular interest should be focused on effects of the green tea extract in enhancing thermogenesis and fat oxidation that could not be explained solely on the basis of its caffeine content. In well designed study with green tea extract compared to caffeine and *placebo*, equivalent to that in the extract dose of caffeine solely failed to alter energy expenditure [13]. The dose of caffeine in this study as well as those by Dulloo et al. is far too low to produce thermogenetic effect. Doses of 600-1000 mg of caffeine daily are supposed to produce such effect [19, 20]. We could hypothesize, that the effect observed in our study should be to catechins rather than to caffeine.

Not much is known about the influence of green tea on glucose metabolism. In diabetic mice consumption of green tea improved the glucose tolerance in oral glucose tolerance test [8]. In other study on mice 1% EGCG decreased blood glucose compared to *placebo*, but the difference was not significant [5]. In Kao et al. study on animal model the reduction in insulin levels as well as leptin levels were observed. Changes in leptin concentrations in response to EGCG modify the appetite control pathway and reduce food intake. The consequence could

be the weight reduction [12]. In the study designed similarly to ours, the dose of catechins was 134 mg 3 times per day. Authors observed the reduction in glucose and leptin, but lipid profile was insignificantly affected [18]. In the same study changes in *placebo* group were also observed, which were similar to green tea extract group, but weaker expressed [18]. Similar phenomenon was estimated in our trial.

The other group of herbal substance acting as an appetite modulator comprises of plants 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. Other mechanisms are regulatory effect on intestinal functions common to both soluble and insoluble fiber and the barrier effect. The daily consumption of fiber should be about 40 g, much more than in our study with nutrifin® support. Probably this is also a reason why most observations suggest that fiber intake does not result in a positive effect on body weight [21].

Asparagus and kidney bean pods are common food plants, and similarly to tea or its extracts they have a long tradition of use as mild diuretics. Both the roots and 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. Kidney bean (*Phaseolus vulgaris*) extract contains alpha amylase inhibitor [22, 23]. Thus in our study changes observed in biochemical parameters were likely due to green tea extract rather than by asparagus and kidney bean pods.

In observational studies and clinical trials 1% reduction of LDL cholesterol results in about 1.0%–1.5% reduction in relative risk of major cardiovascular events [7]. Even small changes that usually are observed in herbal products trials results in important decrease of cardiovascular events. The mechanism of this effect remains uncertain, direct changes of lipid and glucose metabolism could be involved, but some effect could be indirectly caused by weight loss itself or body composition change. We proved in earlier studies that this preparation positively influenced body composition by reducing fat mass but only in hypercholesterolemic patients [24].

CONCLUSION

1. Changes in serum lipids, lipoprotein, glucose, insulin, leptin and homocysteine failed to produce statistically significant difference in nutrifin® support group compared to *placebo*.

2. The reduction in total cholesterol and LDL cholesterol was strongly correlated with lipids levels at the start, whereby hypercholesterolemic subjects benefited stronger from nutrifin® support herbal preparation.

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WPŁYW ZŁOŻONEGO WYCIĄGU ROŚLINNEGO NA STĘŻENIA LIPIDÓW, GLUKOZY, LEPTYNY I HOMOCYSTEINY WE KRWI. WYNIKI RANDOMIZOWANEGO BADANIA KLINICZNEGO Z PODWÓJNIE ŚLEPĄ PRÓBĄ

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S t r e s z c z e n i e

Otyłość związana jest z takimi powikłaniami jak hiperlipidemia, nadciśnienie tętnicze, choroba wieńcowa czy cukrzyca. Celem badania było określenie wpływu złożonego wyciągu roślinnego na profil lipidowy, metabolizm glukozy, stężenie leptyny i homocysteiny we krwi. **Materiał i metoda**: Wykonano randomizowane badanie kliniczne z podwójnie ślepą próbą wśród 51 otyłych zdrowych osób. Zastosowano suplement diety nutrifin®, który jest wodnym wyciągiem złożonym z liści zielonej herbaty, skóry fasoli i szparagów.
Wyniki: Nie zauważono istotnych statystycznie zmian w stężeniach lipoproteiny, glukozy, leptyny i homocysteiny w grupie osób przyjmujących suplement diety nutrifin® w porównaniu z *placebo*. Zmiany w profilu lipidowym, tzn stężenia całkowitego cholesterolu i frakcji LDL, HDL i triglicerydów wynosiły odpowiednio: –9,4%, -18,7%, +11,8%, –13,4% dla grupy zażywającej nutrifin® –8,0%, –12,2%, +1,4% oraz 14,8% dla *placebo*. Różnice pomiędzy grupami nie były jednak istotne statystycznie. Zmiany stężenia cholesterolu i jego frakcji LDL korelowały silnie z wyjściowymi wartościami badania, osiągając współczynniki korelacji odpowiednio:–0,92 i –0,91 ($p<0,001$) w grupie z aktywnym preparatem.
Wnioski: Większość badanych parametrów nie zmieniała się w zależności od przyjmowania aktywnego preparatu, choć spadek całkowitego cholesterolu i frakcji LDL korelował z poziomem wyjściowym badania.

Słowa kluczowe: suplement diety, lipidy, cholesterol, glukoza, insulina, leptyna, homocysteina