

The impact of individualised nutritional therapy according to DASH diet on blood pressure, body mass, and selected biochemical parameters in overweight/obese patients with primary arterial hypertension: a prospective randomised study

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Abstract

Background and aim: The aim of the study was to assess the impact of individualised nutritional intervention based on the DASH diet (Dietary Approaches to Stop Hypertension) on the nutritional status, blood pressure, and selected biochemical parameters of obese/overweight patients with primary arterial hypertension.

Methods: A total of 131 participants were randomised to the DASH intervention group (DIG; n = 69, 33 males) or the control group (CG; n = 62, 32 males). A three-month nutritional intervention was carried out in the DIG group, while the control group received only standard recommendations. Body weight, height, waist and hip circumference, body composition, blood pressure, serum glucose, and insulin and leptin concentrations were measured at the baseline and after the intervention.

Results: Sixty-four (92.8%) participants in the intervention and 62 (100%) in the control group completed the study. In the DIG group a significant decrease in body mass, systolic and diastolic blood pressure, body fat content, fasting glucose, insulin, and leptin concentrations were observed in comparison to the control group ($p < 0.05$).

Conclusions: The DASH dietary intervention provides significant benefits to overweight/obese patients with primary hypertension.

Key words: primary arterial hypertension, obesity, insulin resistance, nutritional therapy

Kardiol Pol 2018; 76, 1: 158–165

INTRODUCTION

Arterial hypertension is a significant cardiovascular risk factor and a frequent cause of morbidity and mortality in developed countries. Around 973 million adults suffered from arterial hypertension worldwide in 2000, including two thirds

in developed countries [1]. Obesity is one of the principal factors predisposing to arterial hypertension and currently affects 13–23% of European residents, and around 20% of Polish citizens [2]. Because the pathogenesis of hypertension in obesity is not fully recognised, hyperinsulinaemia, insulin

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Received: 19.05.2017

Accepted: 29.08.2017

Available as AoP: 29.09.2017

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resistance, and leptin secretion by adipose tissue are of major importance. Body weight loss is among the first-line therapeutic targets, therefore nutritional intervention should be a vital element of complex treatment also among people with primary hypertension [3]. The aim of the study was to assess the impact of individualised nutritional intervention among obese and/or overweight patients with primary hypertension on nutritional status, blood pressure (BP), and selected biochemical parameters, including glucose, insulin, and leptin serum concentrations.

METHODS

The study was conducted in the outpatient Clinic of Arterial Hypertension of the Cardinal Stefan Wyszyński Institute of Cardiology in Warsaw, Poland. It was a randomised trial, involving non-blinded patients with well-controlled, pharmacologically treated primary arterial hypertension.

Participants

Overall, 131 overweight or obese patients with primary hypertension, treated for at least two years at the Clinic, were enrolled in the study. All the patients were recruited by a specialist in hypertension (medical specialty in hypertension diagnosis and treatment available in Poland). The inclusion criteria were the following: well-controlled BP < 140/90 mm Hg for at least six months, body mass index (BMI) ≥ 25 kg/m², postmenopausal age for women (defined as a time period of at least two years from the last menstrual cycle), and no history of hormone replacement therapy. The exclusion criteria were as follows: coronary artery disease, heart failure, kidney and liver diseases, type 2 diabetes, and failure to meet the inclusion criteria. Any one of the above-mentioned criteria was sufficient to exclude the patient. Physical exercise levels during the study were kept unchanged.

Each participant was randomly assigned to the study group, where individual dietary counselling was provided (dietary intervention group; DIG), or to the control group (CG) with no additional nutritional intervention. Sixty-nine participants (33 men, 36 women) were randomly allocated to the DIG group, and 62 patients (32 men, 30 women) were assigned to the CG group. None of the patients had previously taken a dietician's advice, nor participated in any form of organised nutritional counselling. Among the 69 participants randomised to the DIG group, 64 (92.8%) completed the study. The main reasons for withdrawal of the remaining participants were "lack of time" and "personal reasons". All patients from the CG group completed the study.

The approval of the Local Bioethical Committee at the Institute of Cardiology in Warsaw was obtained (no IK-NP-0021-95/911/05). Written, informed consent was given by each participant.

Procedures

Systolic blood pressure (SBP) and diastolic blood pressure (DBP) measurements were carried out by the specialist in hypertension as part of a routine medical examination. The auscultatory Korotkoff method was applied, and a classic mercury sphygmomanometer with valid certification was used. All the measurements were performed three times in a sitting position, after 10 min of rest (with a 2-min interval) [4]. The mean values were calculated accordingly.

The nutritional status of each participant was assessed using the body weight, height, waist circumference, and body composition parameters.

Body weight, height, and waist and hip circumferences were measured according to World Health Organisation (WHO) recommendations [5]. Body weight was measured with a medical scale, without shoes and heavy outer garments, with accuracy to the nearest 0.1 kg. The scale was calibrated before each measurement. Height measurements were made with a stadiometer, without shoes, with an accuracy of 0.5 cm. Waist circumference was measured with a tailor's measuring tape, at the midpoint between the last ribs and the iliac crest. Hip circumference was measured using the same tape, with 0.5 cm precision, at the greater trochanters level. Based on the measurements, the BMI was calculated with the subsequent qualification to overweight (BMI 25–30 kg/m²) or obese (BMI ≥ 30 kg/m²) category. The waist-to-hip ratio (WHR) was also calculated, and the visceral obesity was defined as the value of > 1 for men, and > 0.8 for women [5].

The body composition measurements were performed using the bioelectrical impedance method. The relative (%) and absolute (kg) contents of body fat were determined with the STA/BIA RJL — Akern 101/S (Italy) device, using a variable frequency current (5, 50, and 100 kHz). A tetrapolar arrangement was applied with two electrodes placed on the wrists and two on the ankles [6]. The measurement was performed after a night's rest, on an empty stomach. The participants were asked to reduce their physical activity on the day preceding the measurements, to decrease the potential loss of systemic water. All measurements were performed twice — at baseline and at the end of the study.

Each participant in the DIG group was provided with an individualised, three-month diet plan. Individual counselling was preceded by a lecture, in groups of four to six patients. Risk factors of hypertension, as well as principles of the DASH diet (Dietary Approaches to Stop Hypertension) were discussed, and special emphasis was put on excessive weight reduction [7]. Each patient from the DIG group received a personalised nutritional plan and three subsequent individual appointments were made at four-week intervals to monitor compliance. All recommendations were also given to participants in writing.

Table 1. Baseline characteristics of study participants

	DIG	CG	Total
N	64	62	126
Female	47.0 (30%)	48.0 (30%)	49.2 (60%)
Age [years]:	61.34 ± 7.90	58.11 ± 8.52	59.75 ± 8.37
Males	58.93 ± 7.97	55.62 ± 8.10	57.22 ± 8.14
Females	63.47 ± 7.33	60.77 ± 8.14	62.20 ± 7.84
Weight [kg]	89.31 ± 16.16	93.38 ± 14.43	91.31 ± 15.41
BMI [kg/m ²]	32.61 ± 4.46	33.08 ± 4.27	32.84 ± 4.36
Regular use of hypertensive drugs	100%	100%	100%
Smoking	10.94 (7%)	16.13 (10%)	13.5 (17%)
Alcohol drinking:	31.25 (20%)	24.19 (15%)	27.7 (35%)
≤ 2 serv./day	28.12 (18%)	20.9 (13%)	24.6 (31%)
> 2 serv./day	3.13 (2%)	3.22 (2%)	3.1 (4%)

BMI — body mass index; CG — control group; DIG — dietary intervention group

Statistical analysis

Statistical analysis was performed using the Statistica v. 10.0 programme for Windows (Stat-Soft, Inc.). The normality of quantitative variables distribution was verified by the Kolmogorov-Smirnov test. The homogeneity of variances was checked by Levene's test. All dependent variables were interval ones and resembled normal distribution. Student's t-test was used to compare quantitative variables between the groups. In the case of unplanned multiple comparisons, the Bonferroni procedure was applied. To determine the relationship between variables, the Pearson's correlation coefficient and stepwise regression analyses were performed. The χ^2 test was used to compare nominal variables.

Pearson's χ^2 test for baseline sociodemographic variables with subsequent multiple Bonferroni comparisons for anthropometric and biochemical parameters showed no statistically significant differences between the DIG and the CG groups ($p > 0.05$). It was then assumed that the groups were homogeneous, and consequent analyses concerned the entire study group ($n = 126$). A p value of less than 0.05 was considered as statistically significant in all tests.

RESULTS

A summary of the participants' baseline characteristics is presented in Table 1. There were no statistically significant differences between the two groups ($p > 0.05$). Blood pressure values remained within the recommended range, ($< 140/90$ mm Hg) both in the DIG and the CG groups. All the patients were overweight or obese ($BMI \geq 25$ kg/m²), with the predominant visceral obesity pattern, as indicated by waist circumference of > 94 cm for men, and > 80 cm for women. All the patients reported regular intake of antihypertensive drugs. 17% of the participants were smokers, while regular

consumption of alcohol (more than two drinks per day) was declared by 3.1% ($n = 4$) of the participants (Table 1).

Table 2 presents the baseline and the on-intervention of biochemical parameters for both groups. A significant decrease in the majority of the measured parameters was observed in the DIG group, except for glucose, serum insulin concentration, and HOMA. However, all these parameters remained within the normal range during the study, at the baseline, and at the endpoint. The average fasting glycaemia was 5.43 ± 0.69 mmol/L, and remained within the normal range. The average serum insulin concentration (normal range 4–16 μ U/mL) was distributed around the upper limit, and it was 15.76 ± 10.73 μ U/mL. The HOMA index (insulin resistance) was 3.86 ± 2.87 . In the CG groups, no significant changes in any tested parameters were observed at the endpoint ($p > 0.05$) (Table 2).

Due to the fact that analysed parameters differed only in the DIG group, all the parameters were further compared, taking into consideration the gender of the participants (Table 3).

In the DIG group, a statistically significant decrease of several parameters was noted. These changes were similar for both sexes; however, a slightly greater decrease of waist circumference was demonstrated among men. A statistically significant reduction of fasting blood glucose and serum leptin concentrations was also found, along with a reduction of HOMA index values ($p < 0.05$). In contrast, no significant decrease in the insulin concentration was found.

Final analysis involved correlations between selected parameters within the DIG group (Table 4). A positive correlation between the BMI change and the serum insulin or leptin changes, as well as changes of the HOMA index, were observed. Moreover, positive correlations between WHR changes and the serum insulin concentration change, as well

Table 2. Clinical and biochemical parameters in the CG and DIG group at the baseline (p0) and the outcome (p1) time points

Parameters	Period	DIG (n = 64)			CG (n = 62)			p**
		X ± SD	Δ	p*	X ± SD	Δ	p*	
SBP [mm Hg]	p0	130.84 ± 5.06	-4.63	0.000	130.06 ± 6.39	-0.84	1.000	0.000
	p1	126.22 ± 5.17			129.22 ± 6.21			
DBP [mm Hg]	p0	85.16 ± 3.67	-2.64	0.000	83.10 ± 3.71	+1.74	0.09	0.002
	p1	82.52 ± 3.28			84.84 ± 3.69			
Body mass [kg]	p0	89.69 ± 16.31	-4.09	0.000	93.38 ± 14.43	+0.65	1.000	0.000
	p1	85.60 ± 15.96			94.02 ± 14.96			
BMI [kg/m ²]	p0	32.61 ± 4.46	-1.50	0.000	33.08 ± 4.27	+0.30	1.000	0.005
	p1	31.11 ± 4.28			33.38 ± 4.49			
Waist circumference [cm]	p0	105.30 ± 11.46	-4.76	0.000	103.82 ± 11.25	+0.95	1.000	0.000
	p1	100.55 ± 11.07			104.77 ± 11.74			
WHR	p0	0.93 ± 0.09	-0.08	0.000	0.95 ± 0.08	0.00	1.000	0.000
	p1	0.85 ± 0.13			0.94 ± 0.09			
Relative body fat content [%]	p0	36.29 ± 9.59	-1.71	0.040	36.05 ± 9.97	+0.26	1.000	0.000
	p1	34.58 ± 7.90			36.31 ± 10.73			
Absolute body fat content [kg]	p0	32.21 ± 8.67	-3.10	0.000	33.62 ± 11.13	+0.71	1.000	0.000
	p1	29.12 ± 8.19			34.33 ± 11.87			
Glucose [mmol/L]	p0	5.55 ± 0.70	-0.28	0.000	5.31 ± 0.65	+0.27	1.000	0.000
	p1	5.27 ± 0.66			5.59 ± 1.10			
Insulin [μU/mL]	p0	17.50 ± 13.35	-1.84	0.091	13.95 ± 6.71	+2.13	0.346	0.008
	p1	15.66 ± 10.37			16.06 ± 10.31			
HOMA	p0	4.35 ± 3.32	-0.57	0.032	3.35 ± 1.77	+0.67	0.078	0.038
	p1	3.78 ± 2.73			4.02 ± 2.71			
Leptin [μg/L]	p0	22.23 ± 15.96	-3.63	0.000	22.42 ± 16.31	+0.57	1.000	0.000
	p1	18.59 ± 14.26			21.75 ± 16.42			

*Student t test; significance of change between p0 and p1; **Student t test; significance of change between p1 (CG) and p1 (DIG); Δ — mean change between p0 and p1; BMI — body mass index; CG — control group; DBP — diastolic blood pressure; DIG — dietary intervention group; SBP — systolic blood pressure; SD — standard deviation; WHR — waist-to-hip ratio; X — mean value

as the HOMA index, were demonstrated. Nevertheless, there was no significant relationship between the relative and the absolute body fat content change on the one hand, and the systolic or the DBP on the other (Table 4).

DISCUSSION

For people with arterial hypertension, the primary goal of therapy is to reduce morbidity and mortality caused by cardiovascular events. Despite pharmacological interventions, regular physical activity and diet plan modifications should be recommended in most cases. Different forms of therapeutic patient education (TPE) have been introduced in health care systems, but they have often been arbitrarily designed and poorly delivered. TPE should be managed by trained health care providers and designed to enable participants to deal with the treatment of medical conditions, prevent avoidable complications, as well as maintain or even improve the quality of life [8]. A therapeutic effect of TPE is expected in addition

to that of all other interventions (pharmacological, physical therapy, etc.). TPE may also contribute to reducing economic costs of long-term care, both to patients and to society. In our study, a three-month dietary intervention based on the DASH recommendations was carried out. A motivating approach was employed, and special efforts were made to adapt the dietary recommendations to the individual expectations in the DIG group, with all applicable restrictions. Our study also followed previous projects concerning dietary education of patients with arterial hypertension [9].

Blumenthal et al. [10] proved that for overweight or obese persons with above-normal BP, the DASH diet is an effective anti-hypertensive intervention, while the addition of exercise and weight loss to the DASH diet resulted in even more pronounced BP reductions, greater improvements in vascular and autonomic function, as well as reduced left ventricular mass. In a meta-analysis by Neter et al. [11], it was demonstrated that weight loss results in a reduction of both SBP and DBP.

Table 3. Changes in anthropometric, clinical, and biochemical parameters in the DIG group (n = 64)

Parameter	Period	Men (n = 30)			Women (n = 34)			P**
		X ± SD	Δ	p ^a	X ± SD	Δ	P*	
SBP [mm Hg]	p0	131.67 ± 5.56	-5.33	0.000	130.12 ± 4.54	-4.00	0.000	0.237
	p1	126.33 ± 5.49			126.12 ± 4.95			
DBP [mm Hg]	p0	85.20 ± 3.70	-2.70	0.000	85.12 ± 3.69	-2.59	0.002	0.913
	p1	82.50 ± 3.07			82.53 ± 3.49			
Body mass [kg]	p0	85.8 ± 15.08	-3.53	0.000	92.37 ± 16.68	-4.20	0.000	0.361
	p1	82.31 ± 14.60			88.17 ± 16.60			
BMI [kg/m ²]	p0	32.76 ± 3.50	-1.48	0.000	32.48 ± 5.21	-1.52	0.000	0.851
	p1	31.28 ± 3.53			30.96 ± 4.90			
Waist circumference [cm]	p0	111.87 ± 8.82	-5.25	0.000	99.51 ± 10.43	-4.32	0.000	0.251
	p1	106.62 ± 8.74			95.19 ± 10.18			
Relative body fat content [%]	p0	29.79 ± 4.75	-0.61	0.215	42.02 ± 9.14	-2.68	0.077	0.208
	p1	29.18 ± 6.15			39.34 ± 6.01			
Absolute body fat content [kg]	p0	30.12 ± 7.57	-2.35	0.000	34.06 ± 9.25	-3.76	0.001	0.253
	p1	27.77 ± 8.25			30.30 ± 8.07			
Glucose [mmol/L]	p0	5.55 ± 0.60	-0.25	0.030	5.56 ± 0.79	-0.30	0.007	0.730
	p1	5.30 ± 0.69			5.25 ± 0.64			
Insulin [μU/mL]	p0	16.92 ± 11.02	-1.10	0.520	18.02 ± 15.27	-2.50	0.079	0.522
	p1	15.82 ± 10.67			15.52 ± 10.26			
HOMA	p0	4.17 ± 2.76	-0.38	0.394	4.51 ± 3.78	-0.73	0.018	0.512
	p1	3.79 ± 2.71			3.78 ± 2.79			
Leptin [μg/L]	p0	13.48 ± 8.78	-1.96	0.001	29.94 ± 16.97	-5.11	0.002	0.054
	p1	11.52 ± 8.69			24.83 ± 15.37			

*Student t test — significance of change between p0 and p1; **Student t test significance of the difference between women and men; Δ — mean change between p0 and p1 time points; BMI — body mass index; DBP — diastolic blood pressure; SBP — systolic blood pressure; SD — standard deviation; X — mean value

Table 4. The relationship between anthropometric and biochemical changes

Parameter	r			
	Δ Insulin [μU/mL]	Δ Leptin [μg/L]	Δ Glucose [mmol/L]	Δ HOMA
Δ BMI [kg/m ²]	0.516**	0.472**	0.019	0.515**
Δ WHR	0.265*	0.104	-0.114	0.263*
Δ Relative body fat content [%]	0.010	-0.034	0.142	0,024
Δ Absolute body fat content [kg]	-0.056	0.050	-0.001	0,038
Δ SBP [mm Hg]	-0.159	0.062	0.099	-0.173
Δ DBP [mm Hg]	-0.028	0.061	0.054	-0.136

*p < 0.05; **p < 0.001; r — Pearson's correlation coefficient; BMI — body mass index; DBP — diastolic blood pressure; SBP — systolic blood pressure; WHR — waist-to-hip ratio

Nutritional intervention based on DASH recommendations, with an individualised energy deficit, significantly reduced body weight in our intervention. As expected, BMI, waist and hip circumferences, WHR, and relative and absolute body fat content also decreased. Such results correspond

to other trials performed among both healthy participants and patients with metabolic disorders [12–14]. In our study, weight loss was achieved without additional physical activity, apart from everyday walks, as previously recommended by a physician. When comparing the effects of low-energy diet

combined with aerobic/endurance exercises to a diet alone for obese women, Janssen et al. [15] showed the efficacy of each approach in terms of metabolic risk factors, including body mass and body fat contents. This is also in line with our observations, which supports the role of a well-balanced diet combined with moderate physical activity for obese people trying to lose weight.

Moreover, our study reaffirmed that there is a positive correlation between waist circumference and BP. Many studies have confirmed a strong correlation between obesity — especially the visceral pattern — and arterial hypertension. Research conducted by Siani et al. [16] and Poirier et al. [17] recognised waist circumference as an independent predictor of BP. Participants of the DIG group showed a statistically significant reduction in SBP and DBP when compared to the pre-treatment time period.

In our study, no correlation was demonstrated between changes of anthropometric parameters and BP alterations within the study period. One should notice, however, that all patients took their anti-hypertensive drugs regularly, with a satisfactory clinical effect.

Excessive body weight is often accompanied by an elevated insulin concentration and insulin resistance [18]. Our results support this well-described relation. At the baseline, the participants were found to have hyperinsulinaemia and increased HOMA index. Such findings reflect the insulin resistance phenotype. Furthermore, positive correlations were found between BMI, waist circumference, absolute body fat, and insulin concentration or the HOMA index. Glucose intolerance due to peripheral insulin resistance with subsequent hyperinsulinaemia can also play a vital role in the pathophysiology of hypertension among obese individuals. The association of hypertension and insulin resistance was confirmed in our study — DBP positively correlated with serum insulin concentration and the HOMA index.

When reducing body weight, obesity, and waist circumference, certain metabolic benefits are expected. Many studies demonstrated that reducing body mass decreases insulin resistance and insulin secretion, regardless of the treatment strategy [19–21]. Our findings indicate that in the group of individualised dietary intervention, there was merely a trend towards a lower serum insulin concentration among women, in parallel with a body mass reduction and a body fat content decrease. This change, however, was sufficient to lower the HOMA index along with the fasting glucose concentrations. Furthermore, the positive correlations between BMI and the insulin concentration change, as well as BMI change and the HOMA index, confirmed the metabolic effects of body mass reduction.

Peripheral tissue insulin resistance and secondary hyperinsulinaemia are particularly typical for visceral obesity. In our study, visceral obesity was reduced, as indicated by the WHR, due to the dietary intervention, and with subsequent

beneficial metabolic effects. These effects were additionally confirmed by a positive correlation between the WHR and the serum insulin change as well as by the WHR and the HOMA index change.

Restriction of food intake and a modest weight loss can reduce insulin levels with subsequent improvement of skeletal muscle insulin sensitivity. This improvement occurs, first of all, due to the increase in anaerobic glucose metabolism, with only a minimal change in the insulin-stimulated glucose oxidation rate. Normalisation of the insulin curves after beta-cell stimulation with glucose is often observed among patients who are still obese, even after a moderate weight loss. The decrease of insulin resistance due to weight loss is not permanent, and persistent control of energy intake, along with physical activity, should be encouraged [20, 21].

All the participants of our study were obese/overweight people with high serum leptin concentrations. There was, however, a distinct dichotomy, since leptin concentrations were twice as high among women than among men. This finding can be probably explained by the significantly higher body fat content among women.

Positive correlations were observed between the serum leptin concentration and BMI, as well as the relative and absolute body fat content. According to many authors, leptin concentration is directly proportional to body fat content. There is also a positive correlation between serum leptin concentration and BMI [22]. Interestingly, no relationship between arterial BP and serum leptin concentration was found in our study. This was probably due to the effective treatment with anti-hypertensive drugs of all participants. Weight loss was accompanied by a significant reduction of serum leptin concentration, and a significant correlation was also found between the BMI and the serum leptin concentration changes. Our observations are consistent with findings reported by Itoh et al. [23], who studied a group of obese people with hypertension, and after a three-month programme of weight loss showed a positive correlation between insulin, HOMA index, and serum leptin changes.

There are inconsistent results concerning the relationship between leptin, insulin concentration, and insulin resistance; however, most authors recognise such links. It is believed that insulin and leptin can interact and modulate their actions, thus participating in the pathogenesis of arterial hypertension. We support such a view because we demonstrated a positive correlation between leptin and insulin concentrations as well as between leptin concentration and insulin resistance.

In our study, significant weight loss and metabolic benefits were achieved among patients randomised to the DIG group. According to a meta-analysis of 46 studies concerning the efficacy of dietary counselling in weight loss, nutritional interventions provide modest effects, which tend to decrease over time. This is a significant drawback of such strategies in medical practice, thus their long-term effectiveness seems to be restricted [24].

Limitations of the study

There are some limitations of our study. This was a single-centre trial, and most of the participants were residents of a capital city (Warsaw), who had higher education. People with active coronary artery disease, heart failure, kidney and liver diseases, as well as patients with type 2 diabetes were excluded. It should be noted, however, that such diseases are quite common among overweight/obese people suffering from arterial hypertension. Therefore, our results have to be extrapolated to the general population with caution. On the other hand, it is well documented that social determinants including the level of education, income, employment, family and social support play a fundamental role in the health of each individual. Research on the relationship between socioeconomic status and health confirmed that people with a higher level of education benefit from having better access to information about health. They may also have healthier behaviours, such as following a well-balanced diet and being active [25].

CONCLUSIONS

Our prospective randomised trial demonstrated the effectiveness of an individualised dietary intervention based on the DASH diet principles. In light of our results, such an intervention can be considered as part of a complex therapy for overweight/obese patients with arterial hypertension. However, its long-term efficacy requires more research.

It was demonstrated that for overweight/obese participants with primary arterial hypertension the visceral pattern was accompanied by high serum levels of leptin and insulin, as well as insulin resistance. Individualised nutritional therapy according to DASH principles reduces body weight, and waist and hip circumference, as well as body fat content. Dietary intervention decreases the SBP and DBP among people with primary arterial hypertension. Moreover, it reduces leptin concentration and the HOMA index. Thus, our work revealed a beneficial effect of individualised nutritional counselling and therapy based on the DASH diet on some modifiable cardiovascular and metabolic risk factors.

Conflict of interest: none declared

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Cite this article as: Kucharska A, Gajewska D, Kiedrowski M, et al. The impact of individualised nutritional therapy according to DASH diet on blood pressure, body mass, and selected biochemical parameters in overweight/obese patients with primary arterial hypertension: a prospective randomised study. *Kardiol Pol*. 2018; 76(1): 158–165, doi: [10.5603/KP.a2017.0184](https://doi.org/10.5603/KP.a2017.0184).