

## Weight reduction is feasible

# Six-month results of a clinically controlled, randomized intervention study with overweight adults

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The changed living conditions and associated behaviors in the western world have in many cases overridden previously successful basic biological principles. The consequence, which is visible to everyone and a source of suffering for many, is a loss of health literacy and responsibility, which can be clearly seen in the dramatic increase in obesity and its consequences [22, 24]. There appears to be only one comprehensive and effective solution to the problem of obesity: The permanent change in dietary and activity behavior towards an energetically balanced lifestyle while at the same time improving the quality of nutrition.

Against this background, various intervention approaches for weight reduction were compared in terms of their effectiveness in a controlled, randomized study. The aim of the study was, on the one hand, to demonstrate the feasibility of weight and fat mass reduction using a model approach to energy balance. Secondly, to gather scientific and practical experience in the care of overweight adults in order to develop a standardized intervention program for the treatment of obesity and its associated risk factors.

### Methodology

#### **Test subjects**

522 interested, Of overweight potential participants, 202 participants were screened in accordance with the inclusion/exclusion criteria defined in the study protocol<sup>1</sup> (clinical examinations, clinical trials).

ECG, exercise ECG, laboratory status). Subsequently, 30 participants were randomly assigned to one of the three intervention groups (Fig. 1):

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- Group 1: diet-induced weight loss (D group),
- Group 2: weight loss induced by diet and exercise (D+S group),
- Group 3: weight loss induced by health education (GU group).

Four of the allocated participants dropped out at the beginning of the study as they were not satisfied with their group allocation. Three further participants dropped out of the study for personal reasons. The personal and anthropometric data of the study participants are shown in Table 1. A statistical comparison of the personal characteristics showed no differences for the respective subjects in the intervention groups. The planned sixmonthly examination was carried out for 83 participants at the end of 24 weeks. All participants took part in the study voluntarily and with written consent. They did not receive any remuneration financial or inducements (success or participation fee). The study was conducted with the unthinkable vote of the ethics committee of the medical faculty of the Freiburg University Hospital.

### Health classes, diet and sports program

All participants were informed in detail about the basic procedure, the content and objectives of the intervention and the importance of weight reduction.

 Table 1: Personal and anthropometric data of the randomized participants (total sample; data as mean values ± standard deviation)

	Total group	Teaching group	Diet group	(diet + sport) group
Ν	90	30	30	30
Age (Y)	47,5 ± 7,52	49,2 ± 7,72	45,6 ± 7,01	47,6 ± 7,63
Size (cm)	169 ± 8,8	169 ± 10,0	168 ± 8,3	170 ± 8,2
Weight (kg)	89,8 ± 10,89	91,0 ± 11,44	88,3 ± 11,77	90,0 ± 9,52
BMI (kg/m) <sup>2</sup>	31,5 ± 2,26	32,0 ± 2,18	31,2 ± 2,20	31,2 ± 2,39
Fat content (%)	40,5 ± 6,40	40,9 ± 6,28	40,1 ± 6,17	40,6 ± 6,76
Fat mass (kg)	$36,5 \pm 6,29$	37,1 ± 6,16	35,5 ± 5,75	$37,0 \pm 6,96$
Power (watt/kg)	1,8 ± 0,36	1,7 ± 0,35	1,8 ± 0,34	1,8 ± 0,41

 $<sup>^1\</sup>mathrm{Age}$  35-65 years, BMI 27-35 kg/m², symptom-free exercise capacity >75 watts, stable weight  $\pm$  3 kg in the last 3 months), expressed interest in the presented 12-month intervention program with randomization principle, no alcohol abuse, no contraindications or illnesses that prohibit or restrict acute exercise or training, no insulindependent diabetes, no liver or kidney disease with restriction of protein intake, no thyroid d i s e a s e or intake of thyroid or hormone preparations, no intake of psychotropic drugs, no lipometabolic disorders treated with medication

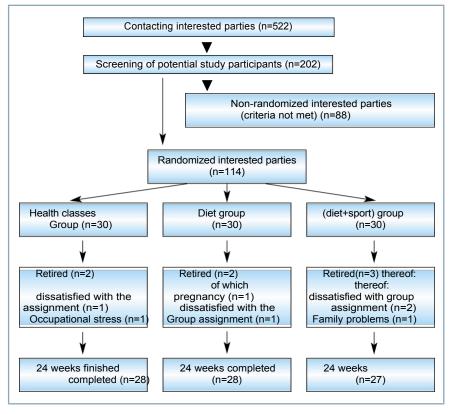


Fig. 1: Flow chart showing participant selection and adherence up to the six-month point.

reduction. The target criterion agreed with them was to reduce their individual BMI by 2.5 units. This was to be achieved by specifically changing the daily energy balance.

The participants in the "health education" group were additionally motivated in the form of group and individual counseling sessions to reduce their weight by changing their lifestyle. The given everyday conditions were taken into account. The direct contact persons were an adult educator specializing in health and the investigator accompanying the study. The aim of the consultations was to impart and practically implement healthy eating and exercise habits on a selfresponsible basis. To this end, teaching materials from the German Society for Nutrition (DGE), the German Society for Sports Medicine and Prevention (DGSP) and selected commercially available brochures on the topic of "Promoting health through nutrition and sport" were used. At intervals of 6 weeks, a total of 5 clinical visits and 3 group sessions of 90 minutes each and 2 in-person sessions were conducted.

Ernährungs-Umschau 50 (2003) Issue 10 individual consultations of 20 minutes each.

The participants in the "diet" group were to achieve their BMI target value by following a calorie-reduced diet. According to an individual, body-weight-related scheme, а commercially available high-protein food supplement based on soy, yoghurt and honey (Almased<sup>®</sup>; 100 g contains 54.1 g protein, of which 45.0 g soy protein and 8.3 g milk protein, 31.5 g carbohydrates and 0.6 g fat with a calorific value of 96 kcal; calculated on the individual's normal weight, e.g. 70 kg, 45-50 g Almased is consumed as a unit of consumption per meal) in the first few weeks. For the first 6 weeks of the intervention, two of the planned three daily meals were consumed (saving approx. 1400 kcal), in the following 18 weeks one of the usual three daily meals (saving approx. 700 kcal). In addition, the participants were informed about a "healthy" and active lifestyle and instructed to reduce the fat content of the freely selectable meals. The person in charge of the diet group was the accompanying investigator. As in the health education group, the participants in the diet group were also instructed to reduce the amount of fat in the freely selectable meals

A total of 5 clinical visits were carried out every six weeks.

In addition to the contents of the "diet" group, the people in the "diet and exercise" group were required to take part in an endurance-oriented, regular and supervised exercise program of 2 x 60 minutes per week. The aim was to achieve a weekly energy turnover of approx. 2,500 kcal/week, corresponding to 30 METh/week, after an introductory phase of 6 weeks in the second part of the intervention (week 7-24) through supervised and selfperformed leisure activities. The participants in the group

"Diet and sport" were also informed about a "healthy" and active lifestyle and encouraged to reduce the fat content of the freely selectable foods. The reference persons for the "diet and exercise" group were a sports instructor and the accompanying investigator. In this group too, in addition to the weekly sports lessons, a total of 5 clinical visits were carried out every six weeks over a period of 24 weeks.

over a period of 24 weeks.

### Anthropometric and performance-physiological status

At the beginning of the study and after 24 weeks of intervention, the body composition and physical performance of the participants were examined. In conclusion to the whole body volume, the body fat percentage was determined and the body fat mass as well as the fat-free body mass was calculated in analogy to the hydrostatic body density measurement using BodPod® technology [17]. The BodPod® technology enables the exact determination of body volume in a closed system using pressure sensors via the proportion of individually displaced air volume. In addition, the participants' abdominal and hip circumferences were measured for indirect assessment of abdominal, visceral and subcutaneous fat distribution [25]. Physical performance was documented for all participants at the beginning and after the intervention phase using standardized bicycle ergometry [4] (semi-sitting, three-minute exercise levels of 25 watts each, starting at 50 watts) in a defined exercise protocol. The activity and nutritional behavior of the participants was pro

	Teaching group		Diet group = 28		(diet+sport) group= = 27	
	before	after	before	after	before	after
Weight (kg)	91,2 ± 11,6	84,9 ± 10,8 °	89,3 ± 12,4	80,4 ± 12,0 °	92,1 ± 10,7	83,1 ± 11,4 °
BMI (kg/m ) <sup>2</sup>	32,8 ± 2,37	29,9 ± 2,37 °	31,5 ± 2,16	28,3 ± 2,52 °	31,4 ± 2,62	28,3 ± 3,17 °
Fat content (%)	40,8 ± 6,49	36,0 ± 8,52 °	39,8 ± 6,24	33,2 ± 7,72 °	40,0 ± 6,70	32,6 ± 9,62 °
Fat mass (kg)	36,9 ± 6,27	30,4 ± 7,60 °	35,2 ± 5,84	26,3 ± 6,06 °	36,7 ± 7,16	27,3 ± 9,37 °
Fat-free mass (kg)	54,2 ± 10,60	54,6 ± 11,16	54,1 ± 11,63	54,1 ± 12,36	55,4 ± 9,42	55,8 ± 10,23
Abdominal circumference (cm)	104 ± 9,5	98 ± 9,5 °	104 ± 10,6	95 ± 10,3 °	105 ± 8,4	97 ± 10,0 °
Hip circumference (cm)	110 ± 6,9	107 ± 7,6 <sup>b</sup>	110 ± 6,9	104 ± 6,0 °	111 ± 7,3	104 ± 8,4 °

Tab. 2a: Initial and intervention values in body weight and body composition for the different intervention groups (data as mean values ± standard deviation at the beginning of the program and after 24 weeks of participation)

Paired comparison (before/after) with p <0.05, 0.01, 0.001 as "a, b, c"

documented in a tocolary. Participant satisfaction and acceptance of the program were also evaluated using a questionnaire.

### Metabolic status and risk factor profile

Using standardized and previously described clinical-chemical analysis methods [10], all participants were tested at the beginning and after the intervention phase in a fasting state (between 8 and 9 a.m., after a 12-hour fasting period, (in the morning between 8 a.m. and 9 a.m., after a 12hour fasting period, as a cubital venous blood sample) to assess metabolic regulation (blood glucose, plasma insulin, serum leptin) and atherogenic cholesterol, (total. HDL, LDL triglycerides) and inflammatory risk (plasma fibrinogen, serum hs- CRP, serum interleukin 6).

#### Statistical evaluation

The statistical analysis was performed using SPSS 11.0.1. For the intraindividual comparisons between the The Wilcoxon test was used to compare the pre-intervention status and the status after 24 weeks within the groups. Analyses of variance were performed to test the hypothesis of whether the differences (before/after intervention) differed between the groups. Non-normally distributed variables (CRP, insulin, IL-6) were previously normalized by logarithmic transformation.

### Results

### Adherence and acceptance of the program

Of the 90 people who took part in the study, 83 were successful over 24 weeks with the programs assigned to them and the associated six-month examination. The majority of participants (83 %) were very satisfied or satisfied with the program, and all participants (100 %) stated that they were satisfied with the program and the

to recommend the therapy modules to others or to use them again. In the two diet-supported groups, 80% of participants described the the nutritional supplements they used as a noticeable therapeutic aid, 15% of the participants were only partially convinced and 5% were not convinced of the benefits of the nutritional supplements. In the sportsdiet accompanied group, the participants felt that the training program was the most important therapeutic component.

### Weight loss and anthropometric variables

All therapy groups showed a significant reduction in body weight and BMI at the end of the 24-week intervention (Tab. 2a). In a group comparison, the diet-supported groups performed significantly better (Tab. 2b). The agreement made with the participants at the start of the intervention as a therapy goal was achieved by 12 of the 28 participants in the GU group.

(43%), in the D group by 20 of the 28 (71%) and in the (D+S) group by 16 of the 27 participants (59%).

circumference (cm)

Hip circumference	-3,0 [-5,1; -1,0]	-6,3 [-7,8; -4,9]
(cm)		

Tab. 2b: Changes in body weight and body composition for the different different intervention groups (data as mean values with 95% confidence interval for difference 24-week value minus initial value)

	Teaching group n = 28	Diet group n = 28	(Diet + Sport) Group n = 27	Differences in group comparis on (p- value)
Weight (kg)	-6,2 [-7,8; -4,6]	-8,9 [-10,4; -7,4]	-8,9 [-10,5; -7,4]	0,017
BMI (kg/m) <sup>2</sup>	-2,2 [-2,7; -1,6]	-3,1 [-3,6; -2,6]	-3,0 [-3,6; -2,5]	0,016
Fat content (%)	-4,8 [-6,3; -3,4]	-6,6 [-8,1; -5,0]	-7,3 [-9,1; -5,5]	0,075
Fat mass (kg)	-6,6 [-8,4; -4,8]	-8,8 [-10,5; -7,2]	-9,4 [-11,2; -7,6]	0,053
Fat-free mass (kg)	0,4 [-0,3; 1,1]	-0,1 [-0,9; 0,8]	0,4 [-0,5; 1,3]	0,628
Abdominal	-6,1 [-8,3; -4,0]	-9,1 [-11,3; -6,8]	-8,3 [-11,0; -5,5]	0,186

Ernährungs-Umschau 50 (2003) Issue

Assessed according to the guidelines of the German Obesity Society (DAG) [12], 71 % of the participants in the GU group, 89 % in the D group and 93 % in the (D+S) group achieved the goal of a 5 % weight reduction. For all groups, the observed weight reduction could be explained by the simultaneous decrease in fat mass (Tab. 2b). The correlation analysis shows a high biological dependency between weight loss (x) and the corresponding reduction in fat mass (y) in all groups ( $r^2_{GU group} = 0.85$ ; r D group<sup>2</sup> = 0.74; r D+S group<sup>2</sup> = 0.75). A

	Teaching group n = 28		Diet group n = 28		(diet+sport) group n = 27	
	before	to	before	to	before	to
Total chol. (mg/dl)	223 ± 27,4	202 ± 28,3 °	225 ± 30,4	196 ± 23,1 °	221 ± 34,8	198 ± 32,6 °
HDL-Chol. (mg/dl)	58 ± 19,3	51 ± 13,5 <sup>b</sup>	59 ± 14,1	52 ± 10,4 <sup>b</sup>	59 ± 14,0	54 ± 15,6 <sup>ь</sup>
LDL-Chol. (mg/dl)	130 ± 25,8	117 ± 24,8 °	128 ± 25,6	114 ± 15,2 <sup>ь</sup>	127 ± 29,2	112 ± 26,3 °
Triglycerides (mg/dl)	127 ± 68,4	137 ± 55,2	145 ± 66,8	131 ± 59,3	137 ± 62,8	136 ± 84,2
Glucose (mg/dl)	95 ± 14,1	90 ± 9,9 ª	92 ± 9,4	90 ± 9,1	98 ± 14,4	91 ± 10,5 °
Insulin (µU/ml)	8,8 ± 3,92	7,4 ± 3,98	11,7 ± 8,92	6,3 ± 3,97 <sup>b</sup>	13,8 ± 11,35	7,8 ± 5,90 °
Leptin (ng/ml)	36,5 ± 29,2	27,8 ± 20,7 <sup>b</sup>	37,9 ± 26,7	22,5 ± 13,9 °	$33,9 \pm 24,2$	21,3 ± 16,3 °
hs-CRP (mg/dl)	0,27 ± 0,22	0,23 ± 0,16	$0,32 \pm 0,32$	0,21 ± 0,18 ª	$0,27 \pm 0,23$	0,18 ± 0,16 <sup>ь</sup>
IL-6 (pg/ml)	1,8 ± 1,25	1,7 ± 2,30	2,4 ± 2,61	1,5 ± 0,96 ª	2,0 ± 1,30	1,9 ± 1,56
Fibrinogen (mg/dl)	371 ± 59,6	373 ± 65,8	394 ± 117	362 ± 51,8	360 ± 70,1	366 ± 75,5

Tab. 3a: Initial and intervention values in the metabolic status and the risk factor profile for the different intervention groups (data as mean values ± standard deviation at the beginning of the program and after 24 weeks of participation)

Paired comparison (before/after) with p <0.05, 0.01, 0.001 as "a, b, c"

A reduction in lean body mass was not observed in any group. For the diet-supported groups, however, the greater the weight reduction, the greater the reduction in the percentage of fat and the absolute fat mass (Tab. 2b). Interestingly, this also appears to be significantly reflected in a reduction in hip circumference in the group comparison.

#### Cardiovascular fitness

The intervention significantly (p = 0.023) improved the geometrically tested maximum physical performance by 5 % from 155 watts to 163 watts only in the D group. However, this change is not significant in the group comparison. For all groups

As expected, the weight loss achieved resulted in favorable changes in heart rate, blood pressure and lactate regulation. For example, the heart rate at rest and during exercise increased in all groups by 8-10 beats/min (p <0.001), the systolic blood pressure by an average of 10 mmHg (p <0.01) and for the (D+S) group also the lactate value under stress (75 watt level) by 0.24 mmol/l

### Metabolic regulation

(p <0.01).

A highly significant reduction in the serum leptin level was found in all groups after the intervention phase (Tab. 3a); in relation to the respective mean weight loss as  $\Delta$ leptin/ $\Delta$ kg, the leptin reduction of 1.7 ng/ml/kg was particularly pronounced in the D Ernährungs-Umschau 50 (2003) Issue 10

The effects of the intervention were particularly pronounced (Tab. 3b). Once the intervention was completed. there were also significant reductions in fasting blood glucose and plasma insulin levels (Tab. 3a,b). However, the decisive factor for the reduction was the respective initial value at the start of the study. In all groups, the (x+s) values for fasting glucose and plasma insulin were also impressively within the clinical-chemical normal range after the intervention.

#### **Risk factor profile**

In all groups, there was a highly significant reduction in total and LDL cholesterol after the intervention phase (Tab. 3a); however, the low-fat and weight-lowering intervention was also associated with a reduction in LDL cholesterol. group. A reduction in HDL cholesterol in the range of 5-7 mg/dl was observed. Parallel to the atherogenic lipid the profile, changes in proinflammatory profile were also observed. Depending on previously moderately elevated baseline values in the diet-supported groups, there were significant improvements in the values for hs-CRP and IL-6. In the group comparison, however, the changes caused by the intervention in the different groups did not prove to be significantly different (Tab. 3b).

### Discussion

The controlled and randomized study presented here was conducted before the Tab. 3b: Changes in metabolic status and risk factor profile for the different intervention groups (data as mean values with 95% confidence interval for difference 24-week value minus initial value)

	Teaching group n = 28	Diet group n = 28	(Diet + Sport) Group n = 27	Differences in group comparison (p-value)
Total chol. (mg/dl)	-20 [-29; -12]	-29 [-38; -19]	-23 [-32; -14]	0,396
HDL-Chol. (mg/dl)	-7 [-12; -3]	-7 [-11; -2]	-5 [-8; -2]	0,763
LDL-Chol. (mg/dl)	-13 [-19; -7]	-15 [-24; -5]	-15 [-23; -8]	0,897
Triglycerides (mg/dl)	9 [19; 37]	-14 [-38; 11]	-1 [-20; 17]	0,384
Glucose (mg/dl)	-4,6 [-9,9; 0,6]	-2,1 [-5,7; 1,4]	-6,9 [-10,2; -3,7]	0,260
Insulin (µU/ml)	-1,4 [-3,2; 0,3]	-5,4 [-8,8; 2,0]	-5,9 [-9,1; 2,8]	0,139
Leptin (ng/ml)	-8,7 [-14,6; -2,7]	-15,5 [-21,6; -9,3]	-12,5 [-17,4; -7,7]	0,226
hs-CRP (mg/dl)	-0,04 [-0,11; 0,03]	-0,12 [-0,21; 0,02]	-0,09 [-0,15; 0,04]	0,151
IL-6 (pg/ml)	-0,02 [-0,79; 0,75]	-0,91 [-1,92; 0,10],	-0,14 [-0,57; 0,29]	0,309
Fibrinogen (mg/dl)	3 [-12; 17]	-32 [-73; 10]	6 [-16, 28]	0,111

The aim of the study was to develop feasible and practical intervention models for the successful treatment of obesity in adults. The results show that this can be done effectively with different approaches, for example according to the principle of calculated calorie balance, by reducing body fat mass. Scientific and practical experience was also gained in the care of overweight adults and in the treatment of obesity and its associated risk factors.

In line with an agreed therapeutic goal (reduction of the BMI value by 2.5 units), good results were achieved with regard to the reduction and stabilization of body weight through a change in diet, personal behavior and physical activity [6, 8, 18, 21, 25, 27]. The findings on body composition for all three groups show that the proportion of fat in the body mass can be reduced without affecting the fat-free mass. can be reduced with reasonable effort. If - as shown for the dietsupported groups - the restriction of calorie and protein intake to values of less than 1000 kcal per day is avoided by offering a low-fat and highprotein diet, an unphysiological, negative nitrogen balance and the undesirable loss of muscle mass that is usually observed [2, 9, 13] can be avoided even with a weight loss in 0.5 range of kg/week. the Intervention with an programs energy deficit of around 700 kcal/day also appear to be medically justifiable in the long term when observing the body composition. With the supply of a protein source that is favorable for the nitrogen balance [20, 29], the maintenance of fat-free body mass and muscle mass, which is important for basal and energy metabolism, appears to be possible under the conditions investigated here, even without guided or supervised additional physical activity.

In addition to the body density

#### Summary

Weight reduction is feasible

Six-month results of a clinically controlled, randomized intervention study with overweight adults

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In a controlled, randomized study, the effectiveness of different intervention approaches for reducing excess body weight was compared. The study involved 30 people in each of three intervention groups (diet vs. diet+exercise vs. health education) over a total period of 12 months; a soy-yoghurt-honeybased food supplement (Almased®) was used for the diet intervention. The sixmonth results now available on body composition (analysis of body fat percentage and lean body mass using BodPod® technology), physical performance, metabolic status and risk factor profile (blood glucose, plasma insulin, serum leptin; total, HDL, LDL cholesterol, triglycerides; plasma fibrinogen, serum hs-CRP, serum interleukin 6) show significant improvements in body composition and health status for all groups. Weight reduction is accompanied by positive changes in metabolic fitness as well as in proatherogenic and pro-inflammatory risk factors. In the diet-led groups, a significantly higher weight loss (on average -8.9 kg) is achieved than through the provision of health and lifestyle content (on average -6.2 kg). The sports offer, on the other hand, is not accompanied by any additional success in weight reduction. No loss of muscle mass as an undesirable side effect can be observed even with weight reductions in the range of 0.5 kg/week when the lowfat but high-protein diet is offered. Intervention programs with an energy deficit o f 700 kcal/day also appear to be medically justifiable in the long term when observing the body composition.

Ernährungs-Umschau 50 (2003), pp. 386-393

The results for abdominal and hip circumference are also used to assess body composition and changes in body fat distribution, so that, based on comparative MRI data in overweight people, it is possible to determine

[25] can also be used to calculate the reductions in abdominal-visceral fat mass achieved here. With an average reduction in abdominal circumference of 6.1 cm in the GU group, 9.1 cm in the D group and 8.3 cm in the (D+S) group, an average reduction in abdominal fat mass of 1.8 kg, 2.7 kg and 2.5 kg respectively can be assumed. Regardless of the respective intervention approach, this means a considerable improvement in metabolic fitness. In addition, the risk of coronary heart disease and type 2 diabetes is reduced. This also applies if the patient is still overweight in the BMI range of 27.7 to 29.9 kg/m after the intervention<sup>2</sup>. Compared to subcutaneous fat, abdominal visceral fat is easier to mobilize and accessible for lipolysis even in the presence of insulin resistance [23, 25]. It is therefore all the more interesting that in the groups with diet-supported intervention, a statistically confirmed increased reduction in hip fat can be observed in the group comparison. Whether this can be assessed as a specific effect of the dietary supplement used remains to be discussed [1].

With the improvement of the body composition and the reduction in body fat mass, a change in metabolic status and a regression in the systemically detectable factors of metabolic syndrome can be expected in the people studied here [10]. This is confirmed on the one hand by the significant reduction in serum leptin levels and on the other hand by the variables of carbohydrate metabolism (fasting glucose, plasma insulin). Interestingly, a greater drop in leptin levels can be observed for the D group than would be expected for the corre- sponding reduction in fat mass. In addition, the blood glucose and plasma insulin levels in the groups with previously moderately elevated baseline values decrease significantly after completion of the intervention, so that the (x+s) values can be measured in the clinicalchemical normal range for all groups. This shows that especially those people who additionally

The intervention can also be beneficial for patients who show signs of metabolic syndrome in addition to being overweight, even if they only lose an average amount of weight [3].

The change in body composition associated with obesity and the unfavorable ratio of the body compartments fat mass and muscle mass have considerable disadvantages for the functional capacity of the biological systems. They also alter the physiological balance of pro- and anti-atherogenic as well as pro- and anti-inflammatory factors [22, 26, 30]. Muscle mass and the energy turnover caused by physical activity have a re- gulatory effect on this process via metabolic anabolic and anti-catabolic factors [3, 5]. Disorders in the bioenergetic system and age- and inactivityinduced sarcopenia, on the other hand, are mutually reinforcing and can be seen as the etiological basis for a variety of chronic degenerative diseases. Sensible intervention programs to reduce obesity should therefore demonstrably change the ratio of fat mass to muscle mass in a favorable way and thus minimize atherogenic and inflammatory risk factors. This is demonstrably the case for the interventional approaches of health education, diet and exercise described here. Both atherogenic factors such as LDL cholesterol and inflammatory factors such as CRP and IL-6 are significantly influenced by the presence of unfavorable input group averages. In the diet group in the atherogenic particular, LDL cholesterol content and its accompanying inflammatory reaction were positively altered. As already mentioned for the symptom of insulin resistance and metabolic fitness, it can also be assumed for this effect that the group of overweight people who already had elevated initial levels of atherogenic and inflammatory risk factors before the intervention benefited to a particular extent [30].

Significant, in the sense of preventive As expected, the positive change in cardiovascular fitness can be

documented as part of the intervention and the weight improvement in the sense of a functional adaptation. ted [4]. In contrast, improvements in maximum absolute performance in watts were only significant for the D group. It should be noted that neither the health classes nor the lifestyle instructions or the sports program were aimed at improving maximum performance. The focus for all participants was on increasing leisure activity and the associated energy turnover through physical exertion. In a positive sense for the participants, it must be remembered that good fitness or genetically determined high aerobic performance  $(VO_{2max})$  does not automatically correlate with increased energy turnover. The decisive factor for energy turnover is not the aerobic capacity per se, but the regular use of the aerobic energy supply during the period of physical exertion [15, 28]. Furthermore, there are

The results of the two diet-supported groups do not differ despite the offer of a guided training program for the (D+S) group. In terms of energy balance, targeted weight reduction can be achieved equivalently both by saving food calories and by the activity-induced additional expenditure of calories [25]. For the (D+S)group, there was а mathematical advantage of approx. 1,000 kcal/week in the energy balance. Thus, an increased weight reduction of approx. 2 kg was to be assumed in the study period compared to the D group. However, this advantage is not confirmed by the available results. However, since the (D+S) group did not follow a defined, isocaloric diet in comparison to the D group, this may be due to an increased calorie intake and/or reduced use of the low-calorie food supplement in the (D+S) group. On the other hand, it may be due to additional, independently performed free-time activity in the sense of the desired lifestyle change for the D group. A final answer to this question will only be possible after the available compliance protocols of all participants have been evaluated. As described above, acute weight reduction through increased activity achieved can only be with quantitative control of the energy and energy intake.

a demonstrably negative energy balance [25]. However, this does not appear to be feasible in a practical intervention approach. Accordingly, preference is usually given to dietary calorie reduction, and increasing physical activity is seen more as a concomitant measure for the rebalancing and improvement of cardio-circulatory, metabolic and psycho-vegetative factors [11].

Taking action against obesity with increased physical activity therefore appears to be particularly promising in the long term, i.e. in prevention and after successful weight reduction, rather than in short-term intervention [19, 31]. However, if not calorically compensated by food, even low, additional daily turnover with regular use, e.g. 2 km walking distance per day corresponding to an energy content of approx. 140 kcal [4] cumulatively leads to a considerable amount of energy, in this case 51,000 kcal per year corresponding to a fat mass of 5.7 kg or an adipose tissue equivalent of approx. 8 kg. This makes it understandable why a low positive fat and energy balance can lead to a considerable disturbance of weight regulation in the long term. Retrospective analyses of obesity confirm interventions also the statement that, in addition to permanent calorie restriction, regular increased physical activity also contributes to the long-term success of therapy [7, 11, 14, 16, 21].

The present results allow the statement that body weight can be reduced significantly and body fat mass in the range of approx. 0.25 kg/week over a period of 6 months with pedagogically oriented health education. In contrast, improvements in body weight and body fat mass in the range of approx. 0.4 kg/week on average can be achieved during this period with diet-supported measures without undesirable side effects on the proportion of fat-free body mass. This success cannot be measurably improved by the offer of an accompanied sports program in the design carried out here. In any case, weight reduction leads to an improvement in body composition and a reduction in abdominal and visceral body fat mass. Correspondingly

### Put up for discussion

Weight reduction is accompanied by positive changes in metabolic fitness and in pro- atherogenic and proinflammatory risk factors. Defined risk persons as a subgroup appear to benefit particularly from the weightreducing measures with regard to a possible reduced risk of disease. In view of the fact that the available results and the participants' assessment of the program are positive, the form of intervention presented here appears to be sensible and recommendable from a medical point of view. A final evaluation of intervention the approaches presented and the therapy goals to be achieved with them is planned after the evaluation of the one-year data.

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