Weight reduction through lifestyle intervention

One-year results of a clinically controlled randomized trial in overweight adults.

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The need to repeatedly point out the importance of obesity and its direct link to lifestyle arises from the fact that the proportion of overweight people in our population continues to increase despite all efforts [1, 2]. Obesity is more than just a cosmetic problem, as it is epidemiologically proven that overweight people are a risk group for atherosclerotic and metabo- lic diseases that requires therapy [3, 4].
In turn, Germany is being overrun by a wave of weight-loss programs. About 200 such programs are currently offered by various institutions. However, only a few programs offer reliable success, and only a few have been evaluated and meet the criteria of continuous quality management. Despite all this, there is no doubt that only a lasting change in dietary and activity behavior towards an energetically balanced lifestyle and a simultaneous improvement in dietary quality can lead to lasting success [5].

Against this background, the Department of Rehabilitative and Preventive Sports Medicine at the University Hospital of Freiburg has already in October 2003
[6] reported on the first successes of a controlled and randomized study on the reduction of increased body weight in adults. After the publication of the half-year results in the past, the one-year results should now show that the feasibility of weight and fat mass reduction according to the calorie balance approach is possible with a reasonable effort for the participants. is not possible. The scientific and practical results obtained in this way should also serve as a basis for the creation of a standardized training program for the therapy of obesity and its associated risk factors [7].

Methodology

The individual sub-areas of metho-dics have already been described in detail in the previous publication [6].

Participant

After information sessions on the topic of obesity, the study participants were selected according to defined inclusion and exclusion criteria (age: 35-65 yrs; BMI: 27-35 $^{kg/m2}$;
Symptom-free power >75 watts; stable weight behavior in the past 3 months; expressed interest in the intervention program with randomization; no medicated lipid metabolic-

In the study, 202 potential participants were pre-screened (clinical status, stress ECG, laboratory status) and 30 participants were randomly assigned to one of the three intervention groups: **Group 1:** diet-induced weight loss (D group), **Group 2:** weight loss induced by diet and supervised exercise (D+S group), **Group 3:** health education induced weight loss (GU group).

7 participants dropped out during the first 24 weeks of the intervention; there were no further dropouts during the second half of the intervention, so that the scheduled one-year examination could be conducted for 83 participants after completion of 48 weeks. The personal and anthro-pometric data of the persons included in the study are shown in Table 1; there were no differences for the respective participants in the intervention groups formed in this way. The start and end of the project was the month of December for all groups. All participants took part in the study voluntarily and with written informed consent; participants did not receive a success or participation fee. The study was conducted with consent.

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

	Total group	Teaching group	Diet group	(Diet + Sport) Group
N	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 ($^{kg/m2}$)	31,5 ± 2,26	32,0 ± 2,18	31,2 ± 2,20	31,2 ± 2,39
Fat mass (% kg)	40,5 ± 6,40	40,9 ± 6,28	40,1 ± 6,17	40,6 ± 6,76
Fat mass (kg)	36,5 ± 6,29	37,1 ± 6,16	35,5 ± 5,75	37,0 ± 6,96
Power (Watt/kg)	1,8 ± 0,36	1,7 ± 0,35	1,8 ± 0,34	1,8 ± 0,41

The study was performed with the approval of the Ethics Committee of the Medical Faculty of Freiburg University Hospital.

Intervention Program

All participants were informed in detail about the basic procedure, the contents and goals of the intervention as well as the importance of weight reduction; a targeted reduction in the individual BMI value by 2.5 units was agreed with all participants as a target criterion for the planned intervention. This was to be achieved by changing the energy balance. The instruments used for this purpose are described in detail in the initial publication [6]. The aim of the intervention in all groups was to teach and implement a healthy diet and physical activity behavior in self-responsibility. In the "Diet" and
"Diet and Sport", a commercially available nutritional supplement based on soy yogurt and honey (Almased®) with a low glycemic index (GI = 27, testing according to WHO/FAO 1998 [Berg A., personal communication 2004]) and low glycemic load (GL = 3.2 based on a usual portion size of 40 g). This use was justified on the one hand with the protection against a possible protein deficit and for the preservation of the muscle mass with calorie restriction, on the other hand however also as motivation assistance and entrance into the nourishing change. The amount of food supplements consumed over the period of the overall intervention is documented in dependence on the respective intervention phases in Figure 1. The compliance check for the respective consumption quantities showed that 80% of the body weight-related daily recommendation was achieved in the first twelve weeks. The "diet and exercise" group additionally received a duration-oriented, guided exercise program of 2 x 60 minutes per week with the aim of achieving a weekly exercise program as a leisure activity in the 7th-24th week.
energy consumption of approx. 2,500 kcal/week, corresponding to 30 METh/week. In the second half During the first year of the intervention, the participants were required to maintain the learned or recommended activity status on their own.

Anthropometric-performance-physiological status and behavior.

At the beginning of the study and after 48 weeks of intervention, the participants were tested for their body composition and physical performance. In conclusion to the whole body volume, the body fat percentage was determined and the body composition was calculated for all participants using BodPod® technology [8]. In addition, the abdominal and hip circumferences of the participants were measured to indirectly assess abdominal and visceral as well as subcutaneous fat distribution [9]. Physical performance was assessed for all participants at baseline and postintervention using standardized bicycle ergometry [10]. Activity behavior was documented in a protocol at the beginning and end of the intervention; participants' satisfaction and acceptance of the program were also evaluated via a questionnaire.

Metabolic status and risk factor profile

Using standardized and previously described clinical chemistry analysis procedures [11], laboratory parameters were determined in all participants at baseline and after the intervention in the fasting resting state to assess metabolic regulation and atherogenic and inflammatory risk.

Statistical analyses

SPSS 11.0.1 was used for statistical analysis. For the intrain- dividual comparisons between the status before intervention and the status after 48 weeks within the groups, the Wilcoxon test for connected samples was used. Analyses of variance were performed to test the hypothesis whether the differences (before/after intervention) differed between the groups.

Results

Adherence and acceptance of the program

Following the previously published mid-year results [6], there were no further dropouts; of the 90 people included in the study, 83 participants could be conclusively examined. 83 % of the participants were very satisfied or satisfied with the program; all participants stated that they would recommend the program to others. 80% of the participants in the diet-supported groups described the dietary supplement used as a therapy aid that was noticeable to them. In the first six weeks of the intervention, the diet-supported groups consumed an average of 516 g of the recommended nutritional supplement per participant and week, and 250 g of the supplement in the 7th to 12th weeks (Fig. 1).

Activity behavior

In the course of the year, the sales-oriented program was successful in all

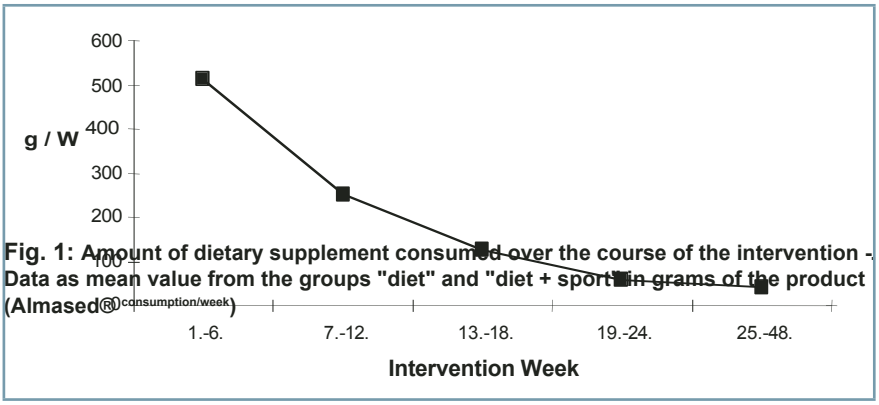

Fig. 1: Amount of dietary supplement consumed over the course of the intervention - Data as mean value from the groups "diet" and "diet + sport" in grams of the product (Almased® consumption/week)

groups a significant change in activity behavior could be achieved ($p<0.05$). In the activity protocols collected at the same time of year (beginning of December), a mean increase in leisure time activity of 5.7 METh/week was secured. In practice, this corresponds approximately to a one-hour physical load in the 125-watt intensity range and a regular additional energy consumption of about 430 kcal/week. In accordance with the behavior learned in the group-specific program, this increased activity in the (D+S) group was mainly due to sports activities, while in the other groups it was due to increased everyday activities.

Cardiovascular Fitness

Over the course of the year, the ergome-tested maximum physical performance remained unchanged. Body weight related performance increased significantly ($p <0.05$) in all groups by an average of 10% (GU: +7.5%; D: +9.8%; D+S: +11.2%).
All groups also showed a favorable change in circulatory and exercise regulation with the weight loss achieved. Heart rate at rest decreased by a mean of 7 beats/min ($p <0.01$) and by 5 beats/min ($p <0.05$) during exercise (75-watt level). Systolic blood pressure improved only in the diet-supported groups by an average of 10 mmHg ($p <0.01$) at rest and under exercise; for the sports-supported (D+S) group, diastolic blood pressure also decreased by an average of 8 mmHg ($p <0.001$) at rest and under exercise, and lactate decreased by 0.36 mmol/l ($p <0.001$) under exercise (75-watt level).

Weight loss and anthropo-metric variables

A significant ($p <0.001$) reduction in body weight and BMI was shown for all therapy groups at the end of the 48-week total intervention period (Table 2). As in the six-month study, the diet-supported groups performed better in the group comparison by approximately 2 kg weight difference and 0.5 BMI units. The agreement reached with the participants at the beginning of the intervention (weight reduction by 2.5 BMI units) was achieved in the GU group only in exceptional cases. Assessed on the basis of the guidelines of the German Obesity Society (DAG)
[12], 40% of the participants in the GU group, 60% in the D group and 62% in the (D+S) group achieved the goal of a weight reduction of at least 5% of the initial weight according to intention-to-treat criteria at the 1-year follow-up. For all groups, more than 80% of the observed weight reduction can be explained by the decrease in fat mass. The reduction in lean body mass was not significant in all groups and accounted for less than 20 % of the weight reduction. As in the six-month study, a significantly greater reduction in hip circumference was found in the group comparison for the diet-supported groups ($p = 0.038$).

Metabolic regulation

In all groups, there was a significant reduction in serum leptin levels (Table 3) and fasting glucose levels after the overall intervention. With initially elevated levels, the (D+S) group also experienced a significant decrease in plasma insulin. In contrast to the baseline study, the (x+s) values in fasting blood glucose and plasma insulin were within the clinical-chemical normal range for all groups at the end of the year.

Risk Factor Profile

After the intervention phase, there was a highly significant reduction in total and LDL cholesterol in all groups (Table 3). LDL cholesterol levels were on average 14% lower than at baseline. Impressive was the significant increase in HDL chole-sterol in the range of 12% or 4-9 mg/dl on average. In contrast to the atherogenic lipid profile, the changes in the inflammatory profile were not uniform and were significantly improved only in one case. In the group comparison, however, no significant differences were found within the individual groups.

Discussion

Against the background of the demand to develop feasible and practical intervention models for the successful treatment of overweight in adults [12, 13], the annual results presented here show that the effective reduction of an increased body weight, defined as a weight reduction of at least 5% of the initial weight, is possible for the majority of participants (depending on the group allocation up to 62%) after 12 months. Moreover, this result can be achieved via the desired reduction in body fat mass without detriment to fat-free mass [14]. The set goal of demonstrating the feasibility of the ge-

Tab. 2: Initial and intervention values in body weight and body composition for the different intervention groups - given as mean values ± standard deviation at the beginning of the program and after 48 weeks of participation.

	Teaching group 28		Diet group = 27		(Diet+Sport) group = =	
	before	after	before	after	before	after
Weight (kg)	91,2 ± 11,6	86,2 ± 12,6***	88,2 ± 11,28	81,1 ± 11,8***	92,1 ± 10,7	85,5 ± 11,6***
BMI (kg/m^2)	32,8 ± 2,37	30,3 ± 2,84***	31,3 ± 2,09	28,8 ± 2,80***	31,4 ± 2,62	29,2 ± 3,28***
Fat percentage (%)	40,8 ± 6,49	38,0 ± 8,12**	40,4 ± 5,45	36,3 ± 7,34***	40,0 ± 6,70	36,3 ± 8,91***
Fat mass (kg)	36,9 ± 6,27	32,6 ± 8,04***	35,5 ± 5,75	29,5 ± 7,54***	36,7 ± 7,16	31,3 ± 9,28***
Fat-free mass (kg)	54,2 ± 10,60	53,6 ± 11,17	52,8 ± 9,32	51,6 ± 9,39	55,4 ± 9,42	54,2 ± 9,50*
Abdominal girth (cm)	104 ± 9,5	98 ± 9,5***	104 ± 10,5	95 ± 10,3***	105 ± 8,4	97 ± 9,2***
Hip circumference (cm)	110 ± 6,9	108 ± 6,7	110 ± 6,3	104 ± 8,4***	111 ± 7,3	106 ± 9,5***

Paired comparison (before/after); * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

Table 3: Baseline and intervention values in metabolic status and risk factor profile for the different intervention groups - mean values ± standard deviation at baseline and after 48 weeks of participation.

	Teaching group 28		Diet group = 28		(Diet+Sport) group= =27	
	before	after	before	after	before	after
Total Chol. (mg/dl)	223 ± 27,4	211 ± 28,3*	225 ± 30,4	209 ± 28,6**	221 ± 34,8	204 ± 32,2***
HDL chol. (mg/dl)	58 ± 19,3	66 ± 18,1**	59 ± 14,1	63 ± 15,2	59 ± 14,0	68 ± 6,9***
LDL chol. (mg/dl)	130 ± 25,8	111 ± 24,5***	128 ± 25,6	115 ± 22,8*	127 ± 29,2	106 ± 26,7***
Triglycerides (mg/dl)	127 ± 68,4	127 ± 62,3	145 ± 66,8	140 ± 62,1	137 ± 62,8	132 ± 60,4
Glucose (mg/dl)	95 ± 14,1	88 ± 7,7**	92 ± 9,4	89 ± 11,7*	98 ± 14,4	87 ± 9,3***
Insulin (µn/ml)	8,8 ± 3,92	8,3 ± 5,05	11,7 ± 8,92	11,0 ± 8,98	13,8 ± 11,35	10,9 ± 7,74*
Leptin (ng/dl)	36,5 ± 29,2	30,2 ± 24,0*	38,0 ± 26,7	30,8 ± 19,8*	33,9 ± 24,2	26,9 ± 19,1**
hs-CRP (mg/dl)	0,27 ± 0,22	0,25 ± 0,19	0,32 ± 0,32	0,21 ± 0,24	0,27 ± 0,23	0,18 ± 0,18**
IL-6 (pg/ml)	1,8 ± 1,25	1,6 ± 1,04	2,4 ± 2,61	1,4 ± 0,77*	2,0 ± 1,30	2,4 ± 2,06
Fibrinogen (mg/dl)	371 ± 59,7	353 ± 46,0	394 ± 118	366 ± 62,3	360 ± 70,1	385 ± 65,1*

Paired comparison (before/after); * p < 0.05; ** p < 0.01; *** p < 0.001.

The aim of this study was to demonstrate the success of a therapeutic lifestyle intervention based on the principle of reduced caloric balance [9]. The scientific and practical experience gained in this study in the care and therapy of overweight adults has already been implemented in a standardized training concept, which has been offered nationwide since the beginning of 2005 under the name M.O.B.I.L.I.S. and the costs of which can also be reimbursed as a supplementary therapeutic service according to § 43.2 SGBV [7].

The results show that although the targets agreed upon at the beginning of the intervention, such as the reduction of the BMI value by 2.5 units, are not achieved for all patients, good results in the reduction and stabilization of body weight through the combination of lifestyle measures are realistic when measured against the DAG criteria [12]. This also justifies a standardized and optimized implementation of the program in terms of a therapeutic schooling measure. The technology used to determine body density by means of the BodPod® [8] also credibly documents that the weight reduction achieved was due to a reduction in fat mass without significant impairment of fat-free mass. The often observed reduction of muscle mass as an undesirable side effect of therapeutic intervention [14, 15] can be largely avoided with the intervention method chosen here.

Compared to the results of the mid-year examination, the body weight increases only slightly; the therapeutic success measured by the BMI and the loss of fat mass is largely maintained. It can only be speculated whether and to what extent the seasonal fluctuations [16], which are known to be independent of the program, are responsible for the observed slight increase in weight.

The significant reductions in abdominal circumference achieved at the half-year point as a sign of the reductions in abdominal visceral fat mass [9] remained almost unchanged at -6.1 cm in the GU group, -9.0 cm in the D and -8.1 cm in the (D+S) group. This represents a considerable improvement in metabo- lic fitness and is also reflected in the normal values of fasting blood glucose and plasma insulance as well as in the significantly lowered leptin levels. Thus, an improvement in the regulation of adipocyte metabolism and a reduction in the risk of type 2 diabetes can be assumed for the participants [17]. A multivariate analysis of the results will have to clarify whether observable differences in the course of the intervention in the individual study periods [6] can be explained by the intake and effect of the nutritional supplements consumed in the first half of the year largely according to specification (see Fig. 2) [18].

As expected, the
with the reduction of body fat mass-se, the lipid profile and the associated atherosclerotic risk also [11, 13]. For all participants, a significant reduction in atherogenic LDL cholesterol of about 14% and a simultaneous significant increase in protective HDL cholesterol of about 12% can be observed. Thus, the changes in the LDL/HDL profile are more favorable than described for usual intervention programs [19]. In all groups, prognostically favorable LDL/HDL ratios of less than 2 were achieved for the now still moderately overweight participants with BMI values of 28-30 $^{kg/m2}$. In contrast to the six-month results [6], there are now no consistent results in the additionally determined pro-inflammatory variables (hs-CRP, IL-6, fibrinogen). The multivariate analysis of the results, which is still pending, must clarify whether the different course of the intervention is due to differences in the lifestyle of the participants,
z. E.g. by consuming the diet aid
or by the individual dietary and activity pattern.

Significant and encouraging improvements for the patient clientele were documented in the leisure time activity behavior recorded via questionnaires [20]. The changes are around +5.7 METh/week and thus correspond to a regular energy consumption of approx. 430 kcal/week. Even if this seems low at first, it can contribute to weight stabilization in the long term. If this activity behavior is maintained, the weekly increase in energy consumption of 430 kcal would be equivalent to 3.4 kg of body weight over the course of the year. Zu-

The changes in activity behavior show that the diet aid is not misunderstood and is not used in the diet-supported groups as an alibi function instead of the necessary change in activity behavior. Similarly, there is no evidence that the consumption of the diet aid negatively affects the learning effect in eating behavior or becomes a permanent habit for the participants. On the contrary, it can be observed that the advantage in the reduction of body fat mass [14, 15] achieved at the beginning of the intervention [6] is maintained throughout the year.

The available one-year results allow the statement that with the lifestyle-oriented training program described here, significant reductions in body weight and body fat mass of more than 0.25 kg/week can be achieved over a period of 6 months and subsequently stabilized over a further 6 months. In this process, weight reduction leads to an improvement in body composition and a reduction in abdomi- nal and thus visceral body fat mass. Accordingly, weight reduction is accompanied by positive

The program is accompanied by changes in metabolic fitness and proatherogenic risk factors. 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 make sense and is recommended for implementation in a standardized training program.

The authors thank Mrs. G. RÜCKER, Freiburg, for the statistical processing of the data and her competent advice.

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Summary

Weight reduction through lifestyle intervention
One-year results of a clinically controlled randomized trial in overweight adults.

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Against the background of developing and evaluating practical intervention models for the successful treatment of overweight in adults, the annual results of a clinically controlled intervention study at the University Hospital of Freiburg, which have already been published, show that the effective reduction of increased body weight is possible for the majority of participants (up to 62% depending on group allocation) even after 12 months. The weight loss achieved can be achieved via the desired reduction in body fat mass without any disadvantages for the fat-free mass. Thus, on the one hand, the feasibility of weight and fat mass reduction as a success of a therapeutic lifestyle intervention according to the principle of reduced calorie balance was demonstrated, and on the other hand, the favorable influence of weight reduction on concomitant atherogenic risk factors was once again proven. Thus, reductions in LDL cholesterol of 14% on average and increases in HDL cholesterol of 12% on average were observed over the course of the year. The theoretical and practical experience gained in this study in the care and therapy of overweight adults has already been implemented in a standardized training concept, which has been offered nationwide under the name M.O.B.I.L.I.S. since the beginning of 2005.

Ernährungs-Umschau 52 (2005), pp. 310-314

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