Weight reduction through lifestyle intervention

One-year results of a clinically controlled randomised 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, because it is epidemiologically proven that overweight people are a risk group for atherosclerotic and metabolisms [3, 4].
In turn, Germany is being overrun by a wave of weight-loss programmes. About 200 such programmes are currently offered by different institutions. However, only a few programmes offer reliable success, and only a few have been evaluated and fulfil the criteria of continuous quality management. Despite all this, there is no doubt that only a permanent change in dietary and activity behaviour 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 randomised 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.
The scientific and practical results obtained in this way should also serve as a basis for the creation of a standardised training programme for the treatment of obesity and its associated risk factors [7].

Methodology

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

Participant

After information sessions on the topic of overweight, the following criteria were defined for inclusion and exclusion (age: 35-65 years; BMI: 27-35 kg/m2);
Symptom-free performance >75 watts; stable weight behaviour in the last 3 months; expressed interest in the intervention programme with randomisation; no medically treated lipometabolic disorders.

In the study, 202 potential participants were pre-screened (clinical status, stress ECG, laboratory status) and 30 participants each 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:** weight loss induced by health education (GU group).

7 participants dropped out in the first 24 weeks of the intervention; there were no further dropouts in the second half of the intervention, so that the planned one-year examination could be carried out for 83 participants after completion of 48 weeks.

The data of the people included in the study are shown in table 1; there were no differences between the participants in the intervention groups formed in this way. The project started and ended in December for all groups. All participants took part in the study voluntarily and with written consent; the participants did not receive a success or participation fee.

Tab. 1: Personal and anthropometric data of the randomised 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 project was carried out with the approval of the ethics committee of the medical faculty of the Freiburg University Hospital.

Intervention programme

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 upon 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 are described in detail in the first publication [6]. The aim of the intervention in all groups was to teach and implement a healthy diet and exercise behaviour in self-responsibility.

In the groups "diet" and "Diet and Sport" available food supplement based on soy yoghurt and honey (Almased®) with a low glycaemic index (GI = 27, testing according to WHO/FAO 1998 [Berg A., personal communication 2004]) and low glycaemic load (GL = 3.2 based on a usual portion of 40 g) were used [illegible] justified on the one hand as protection against a possible protein deficit and to maintain muscle mass in the case of calorie restriction, and on the other hand as a motivational aid and introduction to the dietary 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 sport" group additionally received a duration-oriented, guided sport programme of 2 x 60 minutes per week, with the aim of achieving a weekly exercise programme as a leisure activity in the 7th-24th week. Corresponding to an energy consumption of approx. 2 500 kcal/week, corresponding to 30 METh/week.

In the second half of the year of the intervention, the participants were encouraged to maintain the learned or recommended activity status on their own.

Anthropometric-performance-physiological status and behaviour

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 total body volume, the body fat percentage was determined for all participants using BodPod® technology [8] and the body composition was calculated. In addition, the abdominal and hip circumferences of the participants were measured to indirectly assess the abdominal, visceral and subcutaneous fat distribution [9]. Physical performance was assessed for all participants at baseline and after the intervention using standardised bicycle ergometry [10]. Activity behaviour was documented in a protocol at the beginning and end of the intervention; satisfaction and acceptance of the participants with the programme were also evaluated via a questionnaire.

Metabolic status and risk factor profile

Using standardised 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 the 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 of whether the differences (before/after intervention) differed between the groups.

Results

Adherence and acceptance of the programme

After the already published mid-year results [6], there were no further drop-outs; 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 programme; all participants stated that they would recommend the programme to others. 80 % of the participants in the diet-supported groups described the dietary supplements used as a noticeable therapy aid for them. In the first six weeks of the intervention, the diet-supported groups consumed an average of 516 g of the recommended dietary supplement per participant and week, and 250 g of the dietary supplement in the 7th to 12th week (Fig. 1).

Activity behaviour

In the course of the year, the behaviour-oriented programme was successful in all

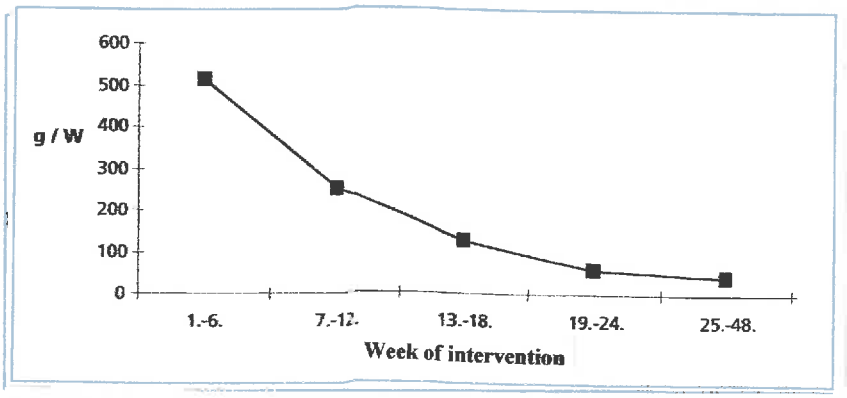

Fig.1: Amount of dietary supplement consumed over the course of the intervention. Data as mean value for the group's "diet" and diet+sport" in grams per week (g/w)

groups, a significant change in activity behaviour was 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 roughly to a one-hour physical load in the 125-watt intensity range and a regular additional energy consumption of approx. 430 kcal/week. According to the behaviour learned in the group-specific programme, this increased activity in the (D+S) group was mainly due to sporting activities, and in the other groups to increased everyday activities.

Cardiovascular fitness

Over the course of the year, the ergometrically tested maximum physical performance remained unchanged. Body weight-related performance increased significantly ($p <0.05$) by an average of 10% in all groups (GU: +7.5%; D: +9.8%; D+S: +11.2%).

All groups also showed a favourable change in circulation and exercise regulation with the weight loss achieved. The heart rate at rest decreased by an average 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 during 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 during exercise, and lactate levels decreased by 0.36 mmol/l ($p <0.001$) during exercise (75-watt level).

Weight loss and anthropometric variables

For all therapy groups, a significant ($p <0.001$) reduction in body weight and BMI could be shown after the 48-week total intervention (Table 2). As in the six-month study, the diet-supported groups performed better in the group comparison by about 2 kg weight difference or 0.5 BMI units. The agreement reached with the participants at the beginning of the intervention (weight reduction by 2.5 BMI units) was only achieved in exceptional cases in the GU group. 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 in the 1-year study. 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 values after the overall intervention. With initially elevated values, 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

In all groups, there was a highly significant reduction in total and LDL cholesterol after the intervention phase (Tab. 3). The LDL cholesterol values were on average 14% lower than the baseline values. The considerable increase in HDL cholesterol was impressive, averaging 12% or 4-9 mg/dl. In contrast to the atherogenic lipid profile, the changes in the inflammatory profile were not uniform and were only significantly improved in one case. In the group comparison, however, there were no significant differences 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 (up to 62 % depending on the group allocation) after 12 months. Moreover, this result can be achieved through the desired reduction in body fat mass without any disadvantages for fat-free mass [14].

Tab. 2: 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 programme and after 48 weeks of participation

	Teaching group n = 28		Diet group n = 27		(diet+sport) group n =	
	before	after	before	to	before	to
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/m2)	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***

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

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

	Teaching group = 28		Diet group n = 28		(diet+sport) group n =27	
	before	after	before	to	before	to
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*

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

The aim of this study was to show the reduction of weight and fat mass as a success of a therapeutic lifestyle intervention according to the principle of reduced calorie 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 standardised 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 stabilisation of body weight through the combination of lifestyle measures are realistic when measured against the DAG criteria [12]. This also justifies a standardised and optimised implementation of the programme in terms of a therapeutic training measure. The technology used to determine body density by means of the BodPod® [8] also credibly documents that the weight reduction achieved was achieved through a reduction in fat mass without significant impairment of fat-free mass. The often observed reduction in 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 programme, 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 means a considerable improvement in metabolic fitness and is also reflected in the normal values of fasting blood sugar and plasma insulin as well as in the significantly lower leptin levels. It can therefore be assumed that the participants experienced an improvement in the regulation of adipocyte metabolism and a reduction in the risk of type 2 diabetes [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 food supplements consumed in the first half of the year largely according to the guidelines (see Fig. 2) [18].

With the reduction of body fat mass, the lipid profile and the associated atherosclerotic risk are also reduced [11, 13]. For all participants, a significant reduction of the atherogenic LDL cholesterol by approx. 14 % and a simultaneous significant increase of the protective HDL cholesterol by approx. 12 % can be observed. The changes in the LDL/HDL profile are thus more favourable than those described for the usual intervention programmes [19]. In all groups, prognostically favourable 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 uniform 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 eating 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 behaviour 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 stabilisation in the long term. If this activity behaviour 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.

The changes in activity behaviour 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 behaviour. There are also no indications that the consumption of the diet aid negatively affects the learning effect in eating behaviour 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 programme 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 then stabilised over a further 6 months. The weight reduction leads to an improvement of the body composition and to a reduction of the abdominal and thus also the visceral body fat mass.

The programme is accompanied by changes in metabolic fitness and proatherogenic risk factors. Against the background that the results and the participants' assessment of the programme are positive, the form of intervention presented here seems to make sense and is recommended for implementation in a standardised training programme.

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Summary

Weight reduction through lifestyle intervention
One-year results of a clinically controlled randomised 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 the group allocation) even after 12 months. The weight loss achieved can be achieved through 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 favourable influence of weight reduction on accompanying 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 standardised training concept, which has been offered nationwide since the beginning of 2005 under the name M.O.B.I.L.I.S..

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