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overweight  
obesity



Scientific  
documentation

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# Clinical Experience of Using a Calorie Reduced Meal Replacement

*The proportion of overweight people in our population is growing in spite of all efforts to stop this development (14, 16, 17). Numerous weight reduction programs try to offer help. Only few of them reliably show success, are evaluated and meet the demands of a continuous quality control. But beside all that it is no matter of controversy that success is only possible by a long-lasting change of eating- and activity-behaviour towards an energetically balanced lifestyle by amelioration of the food quality, at the same time (2, 9). Today, a successful intervention for weight reduction needs to offer more than the ban of a fatty food and the recommendation of more physical activity.*

## The Rational Goal: Successful Weight Reduction

**P**rograms and strategies for weight reduction have to meet the standards of the Guidelines for treatment and prevention of obesity (DAG Guidelines) concerning success and quality, as written down by the German Obesity Society (9). Apart from weight reduction, this always requires an improvement in risk factors, in a healthy lifestyle (physical activity and nutrition) and in quality of life. To reach this goal, ambitious programs, as a rule, run over a period of at least 6 months and are supervised by an interdisciplinary team of physicians with dietary knowledge, psychologists and teachers with knowledge of group behaviour as well as of sports and diet instructors. This allows individual health concepts and assistance in transporting dietary and activity advices into every day practice (2).

When considering the spontaneous weight development of a normal person and the expected weight gain of 400 - 600 g within 12 months (10), weight reduction is realized quite successfully in obese patients. Based on the demands of the M.O.B.I.L.I.S education program, 52 percent of the participants show a weight reduction of 5 percent and more of their initial

body weight, in the final check up after 12 months (2). Even if this does not prove the lasting success of the program, it shows that by lifestyle



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intervention adult obese persons may realize similar effects as are seen by a 12-months pharmacological intervention (15). It is scientifically proven but rather discouraging knowledge of weight reduction programs' success that only a very small number of obese persons can be mobilized to take part in an intervention program (6). Thus the goal and the advices of obesity treatment reflect more the study situation with highly motivated and well-cared participants than the results obtained in reality. Compared to the experience of obesity treatment in practice the objectives seem to be too high and can only partly be realized.

### Is Success Predictable?

Weight loss in the first weeks is one decisive factor for the later and long-term weight reduction (6, 11). Therefore it is important to look very early for possible predictors of treatment success and to influence them favourably. Predicting the medium- and long-term success

decisively, the initial weight loss supports not only the willingness to continue an ongoing program but apart from the psychological feasibility it also reflects the biological effectiveness of the chosen therapeutic program within the given individual conditions (11). It is proven fact that the substitution of the usual food by a calorie reduced meal replacement improves the initial weight reduction and the metabolic adaptation to lifestyle changes (9). Even if the meal replacement is not necessarily part of an intervention program, the advantages and disadvantages of such meal replacements for weight reduction should be carefully and critically discussed with the participants of an intervention program according to the DAG Guidelines (dietary measures in obesity, grade 3: meal replacement) (2). This requires the premise that such a product can be recommended to the participants on the basis of controlled clinical studies on obesity treatment. This is true for Almased®, a soy-milk-honey-product which has a proven effect on body composition and metabolism (5, 7). Corresponding to its favourable calorie balance and optimisation of nutrients quality the use of Almased® as dietary assistance enables a weight reduction of more than 3 kg in the first 6 weeks and of about 9 kg in the course of 6 months (5, 7). This is a positive result concerning discussion and assessment of intervention success, because a weight loss of 4 kg within the first 3 months is said to be a reliable predictor to reach the planned, but difficult goal of at least 5 percent reduction of the initial weight after 12 months (11).

### Ingredients and Postprandial Response of Almased®

According to its ingredients Almased® is a high protein food ▷

▷ on the basis of soy-yoghurt-honey. The amount of protein is 53.3 g%; 83 percent being soy-protein-isolate, 17 percent milk protein. The amount of carbohydrates per 100 g food is 30.5 g. For reasons of nutrition physiology and preventive medicine, it is important that Almased® has a tested property of a very low glycemic index (gi = 27) and a very low glycemic load (gl of one consumption unit = 3.2) (4). Almased®'s high content of biological available isoflavonoids is also proven (19). The ingredient yoghurt powder supplies essential amino acids, active lactic acid bacteria and lactic acid. The later ones favourably influence the distribution of intestinal bacteria and the function of the intestinal mucous membrane. The honey in Almased® guarantees the products lack of side effects and its good taste. Apart from soy, skim milk and honey, Almased® contains no other ingredients.

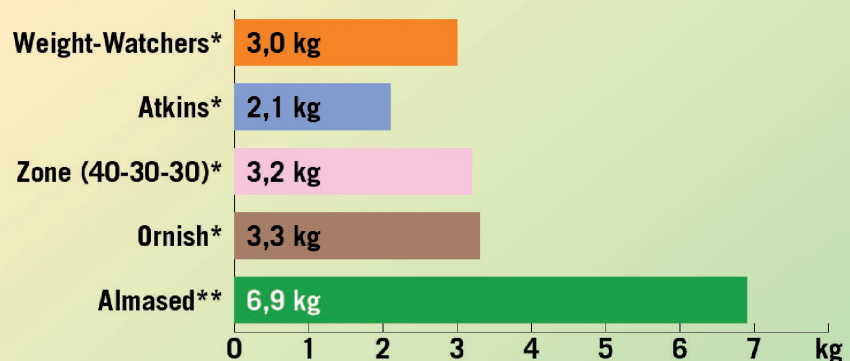
Comparing the blood glucose kinetic and the chronological development of insulin and ghrelin after consumption of Almased® with the reaction to a high carbohydrate breakfast or a standardized glucose intake (50 g in 200 ml liquid), the hormonal response is more favourable and significantly lower from the metabolic point of view after the consumption of Almased® (4). In comparison to the ghrelin levels after the intake of glucose or the consumption of breakfast, the plasma ghrelin levels are -35 percent of the initial values after consumption of Almased® (breakfast: -27 percent; glucose control: -18 percent) and in contrast to the carbohydrate meal remain unchanged on this lower level, even after two hours. After consumption of Almased® it can be supposed that the postprandial ghrelin- and insulin-development favourably influence the appetite regulating system. Such an effect could be a specific advantage of the soy-honey-skim milk-product Almased® in weight intervention and in the treatment of insulin resistance in persons with an increased metabolic risk.

## The Use of Almased® in Controlled Clinical Trials

Using Almased® as meal replacement in the intervention of overweight and obesity the Freiburg study group obtained experience and results which allow statements

1. Which results can be expected from a lifestyle intervention supported by meal replacement with Almased® within 6 months?
2. Can such results be stabilized in the course of 1 year and how do they compare to other non-pharmaceutical interventions (diets)?

### Comparison of diets Weight loss after 12 month (average values)



\* Dansinger ML et al. Comparison of the Atkins, Ornish, Weight Watchers and Zone diets for weight loss and heart disease reduction. JAMA 2005; 293:43-53

\*\* Berg A. et al. Gewichtsreduktion durch Lebensstilintervention. Ernährungsumschau 52 (2005) Heft 8: 310-314

Graph 1: Results of weight reduction after 12 months with different dietary regimen in overweight adults.

on the efficacy in weight reduction, change of body composition and correspondingly changes of metabolic risk factors (3, 4, 5, 7, 8, 12, 20). Data on body composition has been determined by conclusion about the whole body volume in analogy to the hydrostatic body density measurement with the Bod Pod device; the body fat mass as well as the fat free body mass have been calculated (5). By means of standardised clinical-chemical analysis at baseline and after intervention, laboratory parameters have been taken in the fasting-resting setting to identify the metabolic regulation (blood glucose, plasma insulin, plasma leptin), the atherogen risk (total, HDL-, LDL-cholesterol and triglycerides) and the inflammatory risk (plasma fibrinogen, serum-hs-CRP, serum-interleukin-6) (5). In the context of the published original data the different analyses allow evaluated answers to the following questions:

3. From which moment can one expect improvements in the metabolic risk profile?
4. Can positive results be expected in postmenopausal women?
5. Are their advantages without simultaneous weight loss?

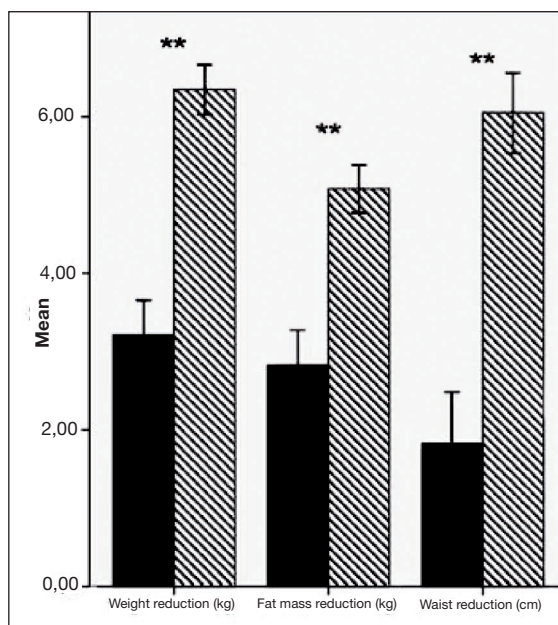
**To 1:** In comparison to usual education programs with a weight reduction of about 0.25 kg/week (6) meal replacement with Almased® (see: application advice) leads to significant more favourable improvements concerning body weight and fat-free body mass; 0.4 kg/week or 9 kg within half a year are possible (5). Independent from gender and without side effects, the weight reduction on the part of the fat-free body mass (1) leads to an improvement of the body composition and to a reduction of the visceral body fat mass. Based on comparative measurements by ct (computertomography) one can suppose that a 9 cm-reduction of waist circumfe- ▷

ence decreases the visceral fat mass about more than 2.5 kg within 6 months (18). This result is important concerning the reduction of the cardiovascular and the metabolic risk (14,16).

To 2: Meanwhile, one-year (7) and two-years-results (3) are available. They allow the statement that the reduction in body weight and body fat mass, which is reached by a flexible use of a meal replacement, can be stabilized for further 6 to 18 months. This applies for the changes of body composition and of waist circumference, too. The clinical-chemical data on metabolic fitness stabilize with the reached weight reduction and so do the athero-gen risk factors on a now more favourable level (3). In case of a very strong compliance and adherence the one-year-success (according to the intention to treat-analysis) of a weight reduction with Almased® is significantly better than with usual dietary means (6) (see graph 1).

To 3: According to our results we suppose that after a short period already – here evaluated for a 6 week period – the use of Almased® as meal replacement (2 times a day) leads to a clear improvement in body composition and these changes are accompanied by a significant reduction of the metabolic risk factors insulin and leptin (12). It is also documented that comparable changes of body composition and risk factors cannot be reached by a fat- and calorie-reduced diet (see graph 2).

To 4: Concerning the efficacy of a lifestyle intervention with the additional use of Almased® in postmenopausal women (8), the recently published results impressively show that the expected results are not diminished by age.



Graph 2: Results of body weight reduction in kg, fat mass reduction in kg and waist circumference in cm after 6 weeks of lifestyle intervention in overweight and obese adults (12): Black bars: usual calorie- and fat reduced diet, n=29, hatched bars: meal replacement with Almased®, n=59. (\*\*Significant to group difference p<0.01)

Although postmenopausal women have a significantly more unfavourable body composition and more pronounced metabolic and athero-gen risk factors, they can positively influence their risk factors by a lifestyle intervention with the additional use of Almased® and the resulting weight reduction. The initially existing disadvantages in anthropometrical values of postmenopausal women are almost alleviated by the reached changes of body composition (see table 1); this observation is also valid for initially existing differences in the

metabolic risk and in the frequency of syndrome X.

To 5: By using Almased® health advantages are not only due to meal replacement for calorie reduction but also to the use of Almased® as additional meal in the frame of an exercise program. This is demonstrated by very recent results looking at the changes of body composition and the endocrine-metabolic regulation in men aging 50 years and more, who have completed a 12-weeks lifestyle intervention with strength training. A controlled randomised exercise study with 40 men in the age of 55.7 (±4.57) years and a BMI of 28.2 (±2.07) kg/m<sup>2</sup> showed that, in the frame of a strength-exercise orientated prevention program, an improvement in body composition (see table 2) was reached apart from the expected changes of muscle strength and of motor competence (13).

It is noticeable that in spite of an unchanged body weight significant improvements in the fasting insulin and the HOMA-index could be measured suggesting additional health benefits. Furthermore an improvement in metabolic fitness and a significant increase in sexual satisfaction of the exercising participants could be documented. It is also remarkable that these health benefits are influenced by nutritional factors and that the daily con-

variable	premenopausal (n=22)		postmenopausal (n=50)	
	baseline Mean ± SD	after 48 w. Mean ± SD	baseline Mean ± SD	after 48 w. Mean ± SD
age (years)	43.7 ± 6.4 <sup>a</sup>		58.2 ± 5.1 <sup>a</sup>	
height (cm)	166 ± 6		163 ± 6	
weight (kg)	85.5 ± 8.6	78.8 ± 9.7 <sup>§</sup>	87.1 ± 11.1	80.4 ± 0.7 <sup>§</sup>
BMI (kg/m <sup>2</sup> )	31.0 ± 2.4 <sup>a</sup>	28.6 ± 3.1 <sup>§</sup>	32.9 ± 3.7 <sup>a</sup>	30.3 ± 3.7 <sup>§</sup>
waist circumference (cm)	99 ± 7 <sup>a</sup>	92 ± 9 <sup>a §</sup>	104 ± 9	98 ± 10 <sup>a §</sup>
hip circumference (cm)	112 ± 6	106 ± 10 <sup>§</sup>	116 ± 8 <sup>a</sup>	111 ± 8 <sup>§</sup>
fat mass (kg)	37.4 ± 6.9 <sup>a</sup>	32.0 ± 9.0 <sup>§</sup>	42.5 ± 8.6 <sup>a</sup>	35.9 ± 8.3 <sup>§</sup>
fat-free mass (kg)	48.2 ± 4.6 <sup>b</sup>	46.7 ± 4.5 <sup>§</sup>	44.6 ± 5.1 <sup>b</sup>	44.5 ± 5.2

Table 1: Change of body composition in overweight and obese pre- and postmenopausal women after participation in a 1-year lifestyle intervention program (8)

<sup>a</sup> = p < .05 in comparison pre-postmenopausal  
<sup>b</sup> = p < .01 in comparison pre-postmenopausal  
<sup>§</sup> = p < .01 before-after-comparison within the group

▷ **sumption of 50 g Almased® in the evening significantly reinforces the health benefits (13).**

## Benefits in the Metabolic Condition

The different studies of lifestyle and weight intervention with

	before intervention	after 12 weeks
<b>Fat mass (%)</b>	24,1 ± 3,9	22,9 ± 3,7**
<b>Fat-free mass (%)</b>	75,9 ± 3,9	77,1 ± 3,7**
<b>Waist circumference (cm)</b>	97,9 ± 7,2	96,7 ± 6,3*

\* = significant change, \*\* = highly significant change

**Table 2: Improvement of body composition in men over 50 years of age by a 12-weeks strength-oriented health program (13)**

Almased® show the reproducible result: a highly significant decrease of the plasma leptin levels can be expected (related to weight reduction as  $\Delta\text{leptin}/\Delta\text{body weight}$  in the sector of 1.7 ng/ml/kg) (5, 12). This is accompanied by a significant decrease in the fasting blood glucose and plasma insulin levels; in case of initially elevated values at the baseline of the study, normal values of fasting glucose and plasma insulin and thus of the HOMA index are reached after intervention (3, 5). The intervention also leads to a significant decrease in total and LDL-cholesterol as well as in triglycerides. In correspondence to the atherogen lipid profile improvements in the inflammatory profile (hs-CRP, IL-6) can be observed, if the values were increased at baseline (3, 5).

By improvement of the body composition and reduction of the body fat mass lifestyle intervention with additional use of Almased® promotes favourable alterations of the metabolic status and regression in the systemically detectable factors of the syndrome X. It has become evident that persons who are overweight and show signs of the syndrome X benefit extraor-

dinarily from the intervention, even if they had only an average weight reduction (3, 5, 8, 13). This is true, too, for patients with a diagnosed diabetes mellitus type 2 that needs treatment. In an intervention study with 51 type-2-diabetic patients the consumption of daily 50 g Almased® over 26 weeks significantly improved the fasting blood glucose from

167 to 127 mg/dl in average, the fasting insulin from 20.7 to 10.6  $\mu\text{U}/\text{ml}$  and the HbA<sub>1c</sub> from 8.2 to 7.3 percent (20).

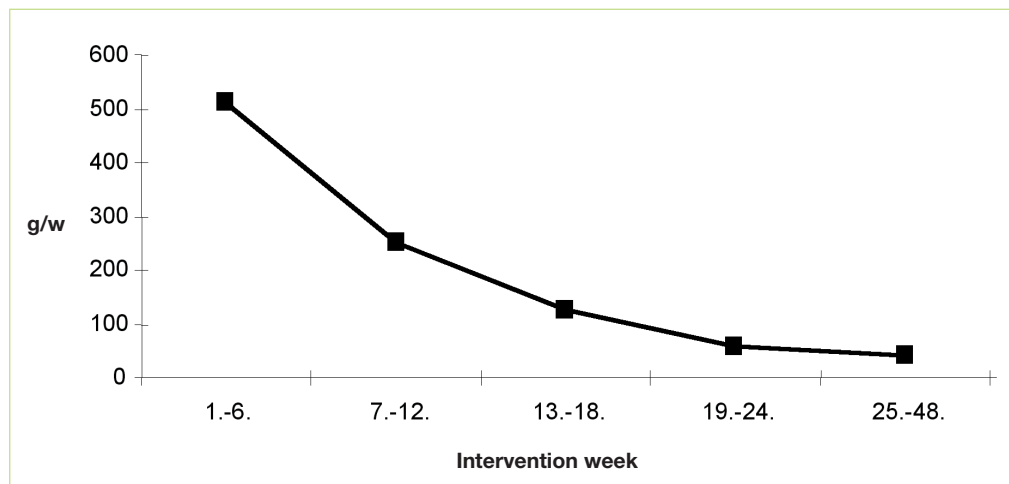
## Application Advice for the Use of Almased®

Never did any side effect happen if Almased® was used as meal replacement

There was no sign that Almased® as meal replacement restricted the lessons to learn concerning eating behaviour nor became a lasting habit of the participants (2, 3, 5, 7).

If Almased® was used for weight reduction, 80 percent of the participants stated that the meal replacement was a noticeable treatment support, 15 percent saw only a partly usefulness of the meal replacement and 5 percent none at all (3, 5, 7). The existing controls after 2 and 3 years showed also that the optional treatment with Almased® as meal replacement was occasionally used for the stabilisation of body weight, for example in situations with higher food and calorie intake (3).

To reach a BMI target value with the aid of a meal replacement by a negative energy balance the following body weight oriented scheme should be used (1 meal replacement contains 0,5 g Almased® per kg body weight; in practice about 35-45 g or 7-9 heaped teaspoons): In the first 6 intervention weeks 2 of the planned



**Graph 3: Typical timetable of the quantity of consumed Almased® used as meal replacement in a guided 12-months lifestyle intervention in overweight and obese adults (n = 55). Figures: average value in gram of the product (consumption/week), cited according to Berg A et al. 2005, Ernährungs Umschau 52:310-314**

placement in clinical controlled trials for weight reduction (3, 5, 7, 8). Moreover the protocols of the participants' activity and eating behaviour showed that the dietary aid in the education programs was not misunderstood and not used as an excuse instead of the desired changes of the activity and eating behaviour.

3 meals should be replaced (saving of about 1,400 kcal), in the following weeks until the BMI target value is reached, 1 of the usual 3 meals is replaced (saving of about 700 kcal) (3, 5); the typical timetable of the quantity of Almased® consumption in an intervention program is shown in graph 3. Of course participants ▷

- ▷ receive information on a healthy and active lifestyle and are requested to reduce the amount of fat in the freely chosen food.

## Conclusion

Weight reduction by lifestyle intervention is possible and can be planned. It is important to continue the once followed course. This requires accompanying interdisciplinary measures. The success of weight reduction is greater if the initial weight loss is supported by a meal replacement. Concerning the use of Almased® in more than 500 patients, clinical controlled studies and experience document that a considerable reduction of weight and fat mass is possible without negative effects on the fat free body mass, if Almased® is used as meal replacement with an reasonable effort for overweight and obese people and with a good compliance.

The obtained results and experience justify the statement that the use of Almased® makes sense in the intervention of overweight and obesity from a clinical and medical point of view and can be recommended in standardised intervention programs. Respecting the generally valid contraindication against a planned weight reduction by a negative calorie balance (pregnant women, nursing mothers, chronically ill people or persons with acute health problems, young people) the use of Almased® in the initial phase of weight reduction and in the stabilisation of the lower body weight is favourable from a metabolic point of view and with no harm to health.

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## Literature

- Ballor DL, Poehlman ET. Exercise-training enhances fat-free mass preservation during diet-induced weight loss: a meta-analytical finding. *Int J Obes Relat Metab Disord* 1994;18:35-40.
- Berg A, Berg A jr, Frey I, König D, Predel HG. Ergebnisse zu M.O.B.I.L.I.S. - einem Bewegungsorientierten Schulungsprogramm für adipöse Erwachsene. *DAB* (2007; zur Publikation akzeptiert)
- Berg A, König D, Deibert P, Landmann U, Frey I, Kloock B, Gollhofer A. Anti-atherogenic effects of a 1-yr intervention program in 50-65 yrs-old overweight women (2007; zur Publikation eingereicht)
- Berg A, König D, Deibert P, Landmann U, Frey I, Kloock B, Gollhofer A. Favorable metabolic properties of a soy-honey-yoghurt product for meal replacement in overweight subjects with atherogenic risk (2007; zur Publikation eingereicht)
- Berg A, Frey I, Deibert P, Landmann U, König D, Schmidt-Trucksäß A, Rücker G, Kreiter H, Berg A jr und Dickhuth HH. Gewichtsreduktion ist machbar - Halbjahresergebnisse einer klinisch kontrollierten, randomisierten Interventionsstudie mit übergewichtigen Erwachsenen. *Ernährungs Umschau* 2003;50:386-92
- Dansinger ML, Gleason JA, Griffith JL, Selker HP, Schaefer EJ. Comparison of the Atkins, Ornish, Weight Watchers, and Zone diets for weight loss and heart disease risk reduction: a randomized trial. *JAMA* 2005; 293:43-53
- Deibert P, König D, Schmidt-Trucksäß A, Zaenker KS, Frey I, Landmann U, Berg A. Weight loss without losing muscle mass in pre-obese and obese subjects induced by a high-soy-protein diet. *Int J Obes Relat Metab Disord*. 2004; 28:1349-52
- Deibert P, König D, Vitolins MZ, Landmann U, Frey I, Zahradnik HP, Berg A. Effect of a weight loss intervention on anthropometric measures and metabolic risk factors in pre-versus postmenopausal women. *Nutr J* 2007; 6:31
- Deutsche Adipositas-Gesellschaft. Leitlinie zur Therapie der Adipositas. [www.adipositas-gesellschaft.de](http://www.adipositas-gesellschaft.de). 2006
- Droyvold WB, Nilsen TI, Kruger O, Holmen TL, Krokstad S, Midthjell K, Holmen J. Change in height, weight and body mass index: Longitudinal data from the HUNT Study in Norway. *Int J Obes*. 2006; 30:935-9
- Finer N, Ryan DH, Renz CL, Hewkin AC. Prediction of response to sibutramine therapy in obese non-diabetic and diabetic patients. *Diabetes Obes Metab*. 2006; 8:206-13
- König D, Deibert P, Frey I, Landmann U, Berg A. Effect of meal replacement on metabolic risk factors in overweight and obese subjects. *Ann Nutr Metab* (2007; zur Publikation akzeptiert)
- Landmann U, Kloock B, König D, Berg A. Sport und Salutogenese - körperliche Aktivität als Gesundheitsfaktor. *Blickpunkt „der mann“* 2007; 5 (4):10-15
- Mokdad AH, Bowman BA, Ford ES, Vinicor F, Marks JS, Koplan JP. The continuing epidemics of obesity and diabetes in the United States. *JAMA* 2001;286:1195-200.
- Padwal RS, Majumdar SR. Drug treatments for obesity: orlistat, sibutramine, and rimonabant. *Lancet*. 2007; 369:71-7
- Peeters A, Barendregt JJ, Willekens F, Mackenbach JP, Al Mamun A, Bonneux L; NEDCOM, the Netherlands Epidemiology and Demography Compression of Morbidity Research Group. Obesity in adulthood and its consequences for life expectancy: a life-table analysis. *Ann Intern Med*. 2003; 138:24-32
- RKI. Themenheft 16, Übergewicht und Adipositas, Berlin: Robert Koch-Institut. 2003
- Ross R, Dagnone D, Jones PJ et al. Reduction in obesity and related comorbid conditions after diet-induced weight loss or exercise-induced weight loss in men. A randomized, controlled trial. *Ann Intern Med*. 2000;133:92-103
- Zänker KS, Daftary GV, Gottschalk G, Adlercreutz H. Genistein and Daidzein: Mode of action and bioavailability as chemopreventive agents in soy-enriched diet. *Ger J Ophthalmol*. 2001; 33:37-44
- Zänker KS, Erxleben-Neis J, Gottschalk G, Schweig N. Diabetes Typ 2 mellitus und Krebs – eine ernährungsorientierte Interventionsstudie. *Dtsch Zschr Onkologie* 2005; 37:114-121