

Prevention and Treatment of Obesity **Evidence-based Guideline of the DDG**

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Preliminary Remarks

This guideline reflects the state of knowledge as of December 2005. The guidelines commission plans to actualize the guideline every two to three years. If new scientific knowledge becomes available that decisively changes the treatment recommendations made in this guideline before the planned update, the relevant information will be prepared on short notice by the guidelines commission.

The multidisciplinary preparation of the evidence-based guideline on the Prevention and Treatment of Obesity in Germany was carried out through the participation of the following institutions:

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Table of Abbreviations

ADA	American Diabetes Association
AGA	Working Group on Obesity in Childhood and Adolescence
AHA	American Heart Association
ÄZQ	German Agency for Quality in Medicine
EASD	European Association for the Study of Diabetes
NIH	National Institutes of Health
NHLBI	National Heart, Lung, and Blood Institute
SIGN	Scottish Intercollegiate Guidelines Network
WHO	World Health Organization

1 Introduction

Obesity is a chronic disease associated with limited quality of life and high morbidity and mortality risks that require long-term medical attention (WHO, 2000, level IV). Care shortages and cost increases are to be expected in health care systems worldwide with increasing frequency of obesity. Efforts to control this problem have already had an effect on the development of treatment guidelines in Scotland, England, France, U.S.A. and other countries.

Guidelines are systematically developed recommendations that are meant to help therapists and patients decide on the appropriate health care in a given case. The recommendations in the guidelines do not include unproven and unnecessary measures in the treatment of the defined diseases.

The goals of the present evidence-based guideline on the prevention and treatment of obesity in Germany are to increase the awareness of obesity as a health problem, to provide therapists and patients guidance and to make disease specific information und recommendations on the prevention and treatment of obesity available to all people in the health care sector, as well as in health politics.

Methodical Procedure in the Development of the Obesity Guideline

In the preparation of the present guideline, a special effort was made to ensure that the requirements of evidence-based medicine were fulfilled. National und international quality criteria for good guidelines, such as those from the Scottish Intercollegiate Guidelines Network (SIGN, 1999) or that jointly compiled by the German Agency for Quality in Medicine (ÄZQ) and the guidelines commission of the German Association of the Scientific Medical Societies (AWMF) (German Agency for Quality in Medicine, 2005), served as a basis for this guideline.

Selection of the Experts

The managing committees of the four participating professional societies appointed recognized and clinically experienced experts and representatives of relevant organizations to the expert committee.

Literature search

- The search terms to be used were agreed upon by consensus among the experts, general practitioners and patient representatives.
- Comprehensive, systematic, computer-assisted searches in the scientific literature (English und German, clinical studies, meta-analyses) databases of Medline, Cochrane Library, Embase, ERIC and PsycInfo were performed for the period January 2002 to June 2005. Afterwards, a final selection of the literature was made by hand. Moreover, a secondary search in existing guidelines, recommendations, expert opinions and the references found in these texts was also performed. Access to older scientific literature was made possible through an existing database that was established for the first version of the guideline.
- The search results were verified for their relevance by specialists (scientists and doctors in the expert committee, nutrition scientists).
- Classification of the selected studies according to their study design and their scientific validity into evidence classes I to IV (Table 1).

- Discussion of the contents of the guideline drafts and informal consensus in the expert committee.
- Presentation of the revised drafts for public discussion in the Internet (websites of the four medical societies).
- Consideration of suggestions for modifications received by the expert committee and preparation of the final version.

Table 1: Classification of published papers based on their scientific validity into levels of evidence and weighting with strengths of recommendation (modified according to SIGN, 1999)

Levels of evidence	
Ia	Evidence based on meta-analyses of randomized, controlled studies
Ib	Evidence based on at least one randomized, controlled study
IIa	Evidence based on at least one well-planned, nonrandomized, controlled study
IIb	Evidence based on at least one well-planned, nonrandomized, and not controlled clinical study
III	Evidence based on well-planned, nonexperimental, descriptive studies, such as e.g. comparative, correlation or case-control studies
IV	Evidence based on reports from expert committees or expert opinions and/or clinical experience of recognized authorities

2 Definition and Classification of Overweight and Obesity

2.1 Definition and Classification of Overweight and Obesity

Obesity is defined as abnormal increase in body fat.

The basis for calculating weight classification is the Body Mass Index (BMI). The BMI is the quotient of the weight divided by the square of the height (kg/m^2). Overweight is defined as a BMI $\geq 25 \text{ kg}/\text{m}^2$ and obesity as BMI $\geq 30 \text{ kg}/\text{m}^2$ (Table 2) (WHO, 2000, level IV).

Table 2: Weight classification of adults on the basis of BMI (according to WHO, 2000, level IV)

Category	BMI	Risk of concomitant diseases of overweight
Underweight	< 18.5	low
Normal weight	18.5 – 24.9	average
Overweight	≥ 25.0	
Pre-obese	25 – 29.9	slightly increased
Obese class I	30 – 34.9	increased
Obese class II	35 – 39.9	high
Obese class III	≥ 40	very high

2.2 Significance and Measurement of Fat Distribution

In addition to the extent of overweight, which is determined by the BMI, the fat distribution pattern also determines metabolic and cardiovascular health risk. The visceral fat mass correlates especially tightly with cardiovascular risk factors and complications (Despres et al., 2001, level IV). A simple way to evaluate visceral fat is to measure the waist circumference (Lean et al., 1995, level III).

For women, a waist circumference $\geq 88 \text{ cm}$ or for men, $\geq 102 \text{ cm}$ is indicative of abdominal obesity (WHO, 2000, level IV; EASO, 2002, level IV). The waist circumference of people with a BMI $\geq 25 \text{ kg}/\text{m}^2$ should always be measured.

Table 3: Waist circumference and risk for obesity-associated metabolic and cardiovascular complications (according to Lean et al., 1995, level III)

Risk of metabolic and cardiovascular complications	Waist circumference (in cm)	
	Men	Women
increased	≥ 94	≥ 80
clearly increased	≥ 102	≥ 88

3 Causes of Overweight and Obesity

- Familial disposition, genetic causes
- Modern lifestyle (lack of exercise, improper diet such as frequent snacking, high consumption of energy-dense food, fast foods, sugar-containing soft drinks, alcoholic beverages)
- Chronic stress
- Eating disorders (e.g. binge eating disorder, bulimia, sleep-related eating disorder)
- Endocrine diseases (e.g. hypothyroidism, Cushing's syndrome)
- Medications (e.g. some antidepressants, neuroleptic and antidiabetic drugs, glucocorticoids, beta-blockers)
- Other causes (e.g. immobilization, pregnancy, surgery in the hypothalamic region, quitting smoking)

4 Obesity as a Health Problem

4.1 Prevalence of Obesity

The prevalence of obesity (BMI ≥ 30) has been continuously increasing in Germany for many years. In 2003 about 70% of all adult men and about 50% of all women had a BMI ≥ 25 ; between 20 and 25% had a BMI ≥ 30 and were thus obese (Mensink et al., 2005, level III). A continuous increase in the prevalence of obese children and adolescents has also been observed in recent years (Koletzko et al., 2002, level III).

4.2 Comorbidities and complications of overweight and obesity (according to WHO, 2000, level IV)

- Disorders of carbohydrate metabolism (e.g. insulin resistance, impaired glucose tolerance, diabetes mellitus type 2)
- Dyslipoproteinaemia (low HDL cholesterol, hypertriglyceridaemia, increased small, dense LDL particles)
- Hyperuricaemia/gout
- Disorders of haemostasis (increase in coagulation and inhibition of fibrinolysis)
- Chronic inflammation (e.g. elevated CRP)
- Arterial hypertension, left ventricular hypertrophy
- Cardiovascular diseases (e.g. coronary heart disease, stroke, heart failure)
- Carcinoma (women: e.g. endometrium, cervix, ovaries, breast, kidney, colon; men: e.g. prostate, colon, gall bladder, pancreas, liver, kidney, oesophagus)
- Hormonal disorders (e.g. hyperandrogenaemia in women, polycystic ovarian syndrome, low testosterone level in men, reduced fertility)
- Pulmonary complications (e.g. dyspnoea, impaired ventilation, hypoventilation and sleep apnoea syndromes)
- Gastrointestinal diseases (e.g. cholecystolithiasis, acute and chronic cholecystitis, fatty liver, non-alcoholic-fatty-liver-disease (NAFLD), reflux)
- Degenerative diseases of the locomotor system (e.g. coxarthrosis, osteoarthritis, spinal disorders)

- Elevated risk for surgical and narcosis complications
- General symptoms (e.g. increased sweating, joint pain, exertional dyspnoea)
- Limitations in the activities of daily living (ADL)
- Reduced quality of life
- Elevated risk of accidents
- Elevated risk of complications during pregnancy (e.g. eclampsia, gestational diabetes) and before and after the delivery (e.g. increased rate of caesarean sections, after-bleeding)
- Psychosocial consequences with increased depression and anxiety, social discrimination, loss of self-esteem, social isolation

4.3 Metabolic Syndrome

Overweight or obesity is regarded as the most important cause of metabolic syndrome, which is also associated with a high risk of atherosclerosis. For people with metabolic syndrome, the risk for cardiovascular complications is increased by about threefold (Lakka et al., 2002, level III; Sattar et al., 2003, level III). The diagnosis of metabolic syndrome is made according to the proposal of the AHA/NHLBI (Grundy et al., 2005, level IV) that is based upon the criteria listed in Table 4. If three of the five criteria apply, metabolic syndrome is present. Additional definitions for metabolic syndrome also exist (Alberti et al., 2005, level IV; Ford et al., 2005, level III).

Table 4: Criteria for the diagnosis of metabolic syndrome according to AHA/NHLBI (Grundy et al., 2005, level IV)

Large waist circumference	Men	≥ 102 cm
	Women	≥ 88 cm
Elevated triglyceride (fasting)	≥150 mg/dl (1.7 mmol/L)	
	or	
Taking medication for the treatment of elevated triglycerides		
Low HDL cholesterol (fasting)	Men	< 40 mg/dl (1.0 mmol/L)
	Women	< 50 mg/dl (1.3 mmol/L)
or		
Taking medication for the treatment of low HDL cholesterol		
High blood pressure	≥ 130 mm Hg systolic blood pressure	
	or	
	≥ 85 mm Hg diastolic blood pressure	
	or	
Taking medication for the treatment of existing high blood pressures		

Elevated fasting blood glucose

 ≥ 100 mg/dl (5.6 mmol/L)

or

Taking medication for the treatment of
elevated fasting blood glucose

4.4 Mortality and Life Expectancy

Large prospective studies have shown that increasing BMI is coupled to an increasingly shorter life expectancy (Fontaine et al., 2003, level III; Peeters et al., 2003, level III).

The mortality risk of obese people diminishes in old age (Calle et al., 1999, level III). The effect of obesity on mortality has decreased in the last 30 years (Flegal et al., 2005, level III).

5 Recommendations for Preventing Obesity

5.1 Indication and Goals

The necessity for preventive measures has been established based upon the following findings:

- With increasing duration and degree of obesity, the treatment becomes increasingly more difficult, complex and expensive (Weintraub et al., 1992, level IIa)
- The health sequelae of obesity are not always reversible after weight loss (Pi-Sunyer, 1993, level IV)
- In the meantime, the prevalence of obesity in most industrialized nations has become so high that not all affected persons can be offered appropriate treatment (WHO, 2000, level IV)

Weight stabilization is a primary prevention goal at the population level since the average body weight of adults up to the age of 65 years is continually rising (Mensink et al., 2005, level III). For a BMI between 25 and 29.9, weight stabilization or moderate weight loss is a desirable goal in order to prevent the development of comorbidities and obesity.

5.2 Recommendations for Obesity Prevention

There are only a few studies which address the question which preventive measures are suitable and effective. Children and parents from families with elevated obesity risk could be a logical target group for prevention measures. Studies show that effective support programmes for children which lead to long-term weight reduction are especially those that include the parents of the children in the target group for behaviour modification (Epstein et al., 1994, level Ib). Prevention programmes for adults that aim at a healthy lifestyle and controlling cardiovascular risk factors were only minimally or not at all effective in regards to body weight (Taylor et al., 1991, level III; Luepker et al., 1996, level III; Hoffmeister et al., 1996, level III). Fundamentally, a healthy lifestyle with regular physical exercise (Jakicic et al., 2001, level IV) and a diet following the recommendations of the German Nutrition Society (DGE, 2003, level IV), which means moderate amounts of fat and high amounts of polysaccharides and dietary fibre, is regarded as a good preventive for increase in weight.

To achieve a balanced energy intake, preferably foods with lower energy density, that is with high water and dietary fibre contents, but lower sugar and fat contents should be selected. Sporting activity, particularly endurance training, leads to an increase in fatty acid oxidation in the muscles and

hence contributes to avoidance of obesity. Prevention of obesity, however, requires additional measures that go beyond a healthy diet. It represents a task involving all of society that must aim at changing adipogenic life conditions.

6 Treatment of Overweight and Obesity

6.1 Indications

Indications for the treatment of overweight or obese people are:

- BMI \geq 30 or
- Overweight with a BMI between 25 and 29.9 and concomitant presence of
 - overweight-related health problems (e.g. hypertension, type 2 diabetes) or
 - abdominal fat distribution or
 - diseases that are worsened by overweight or
 - high psychological strain

6.2 Therapeutic Goals

Treatment goals must be realistic and adapted to the individual's conditions. Because obesity can be regarded as a chronic disease with a high tendency for recurrence, an equally important aspect is the assurance of long-term weight control after weight loss. Here the emphasis should be placed on stabilizing the weight or the moderate weight loss of 5 to 10% rather than achieving the ideal or normal weight (SIGN, 1996, level IV). The following treatment goals can be defined individually:

- Reduction of obesity-related morbidity
- Reduction of obesity-related mortality
- Increasing the quality of life

These therapeutic goals serve the:

- Long-term lowering of body weight
- Improvement in health behaviour (energy-balanced diet, regular exercise)
- Strengthening of self-management and stress management capabilities

6.3 Preconditions for Treatment

A successful therapy requires an adequately motivated and cooperative patient. Empowerment and personal responsibility are the keys to long-term successful weight management. This calls for comprehensive information on the patient, his/her illness, the complications and treatment. In order to evaluate the individual health risk and to undertake an optimal treatment plan, a careful medical history and specific examinations are necessary before beginning treatment (Hauer, 1997, level IV).

Medical history information

- Motivation
- Weight history, previous treatment attempts

- Dietary habits and eating behaviour
- Psychosocial history
- Exercise
- Family history (obesity, hyperlipoproteinaemia, atherosclerosis, in particular coronary heart disease and stroke)

Examinations

- Height und weight, waist circumference, blood pressure, bioimpedance analysis* (tetrapolar bioimpedance analysis)
- Clinical examination
- Fasting blood sugar, oral glucose tolerance test*
- Total, HDL and LDL cholesterols, triglycerides
- Uric acid
- Creatinine, electrolytes*
- TSH, other endocrinological parameters* (e.g. dexamethasone inhibition test to exclude Cushing's syndrome)
- Microalbuminuria or albumin/creatinine ratio in urine
- ECG, ergometry*, echocardiogram*, 24-h blood pressure measurement*, sleep apnoea screening*
- Upper abdomen sonography*, Doppler sonography*
- Except for clinical studies, it is currently not indicated to have the following determined: leptin, ghrelin, adiponectin, etc.

* Optional examinations. These serve to diagnose comorbidities and to recognize contraindications for therapeutic measures.

For well-founded suspicion of a syndromic (e.g. Prader-Willi Syndrome) or other monogenetic forms (e.g. MC-4 receptor gene defect) of obesity, molecular genetic diagnostics may be advisable, as long as the tests were not already performed in childhood or adolescence (AGA, 2002, level IV). For this purpose, a specialized centre should be contacted.

6.4 Treatment

6.4.1 Basic programme

The foundation for weight management should be a basic programme that includes the elements medical nutrition, exercise and behaviour therapies. A programme for weight management should be made up of two phases. In the first phase, weight reduction is of immediate importance. The purpose of the second phase is weight maintenance and implementing the long-term change in diet to a balanced, varied diet such as is recommended by the German Nutrition Society; this means moderate amounts of fat, high amounts of polysaccharides and dietary fibre and an energy content that facilitates the stabilization of body weight (DGE, 2003, level IV).

6.4.2 Medical nutrition therapy

Medical nutrition therapy comprises different levels or strategies and may begin at any level. The entry level is determined after assessing the individual risk profile and considering the individual circumstances. The patient's complete situation should be considered when planning a dietary change therapy to improve the short and long-term compliance. The patient must be well-informed on the principles of dietary change (SIGN 1996; WHO 2000, level IV). The desired energy deficit can be achieved through the following levels:

Level 1: Reduction of Fat Intake Only

The daily energy deficit should be about 500 kcal. The fat intake is reduced to about 60 grams per day and the consumption of carbohydrates is not limited. An average weight loss of 3.2 to 4.3 kg over a period of six months is possible. The higher the starting weight and previous fat consumption, the greater the loss of weight (Astrup et al., 2000, level Ia; Popitt et al., 2002, level Ib). Furthermore, this concept is suitable for attaining long-term stabilization of body weight after weight loss (Toubro et al., 1997, level Ib).

Level 2: Moderately energy-reduced varied diet

Here an energy deficit of 500 to 800 kcal per day is the goal. In addition to a limited fat intake, the consumption of carbohydrates and protein are reduced. Through the increased consumption of plant-derived products, a reduction in energy density while simultaneously maintaining a sensation of satiation is achieved. Thus, an average of 5.1 kg over 12 months can be successfully lost (Hauner et al., 2004, level Ib). This type of diet is largely free of side effects and is also effective over the long-term. It is still the standard therapy for obesity (Anderson et al., 2001, level Ia).

For calculating resting energy expenditure (BMR = basal metabolic rate), the following formula can be used (Müller et al., 2004):

For **BMI >25 to <30**, the BMR is calculated as follows:

$$\text{BMR (MJ/d)} = 0.045 \times \text{body weight (kg)} + 1.006 \times \text{sex} - 0.015 \times \text{age (years)} + 3.407$$

For **BMI ≥ 30**, the BMR is calculated as follows:

$$\text{BMR (MJ/d)} = 0.05 \times \text{body weight (kg)} + 1.103 \times \text{sex} - 0.016 \times \text{age (years)} + 2.924$$

Sex: female = 0; male = 1

For converting kJ to kcal, multiply by the factor 0.239.

Level 3: Meal replacement with formula products

Formula products can be used flexibly in a meal replacement strategy. For this diet, one to two main meals per day are replaced by formula products (protein drink or bar, etc; ca. 200 kcal per meal). For a daily energy intake of 1200 to 1600 kcal, an average weight loss of 6.5 kg after three months is to be expected (Heymsfield et al., 2003, level Ia; Noakes et al., 2004, level Ib). In a long-term study from Ditschuneit et al., an average loss of weight of 10.4 kg was possible after 27

months (Ditschuneit et al., 1999, level Ib). Overweight patients with type 2 diabetes also benefited from this concept (Williams et al., 1998, level Ib; Ash et al., 2003, level Ib).

Level 4: Formula diets

Through the use of formula diets with a total caloric value of 800 to 1200 kcal/day, it is possible to lose 0.5 to 2 kg/week (NIH, 1998, level IV) over a period of up to 12 weeks. Very low calorie diets (<800 kcal/d) should only be used for people with BMI ≥ 30 kg/m² and who should lose weight quickly for medical reasons. A formula diet should always be accompanied by an increase in physical activity. After 12 weeks at the most, a change to a moderately hypocaloric varied diet for weight maintenance should be made. Co-supervision by specialists is advisable due to the elevated side effect risks. A minimum of 2.5 L liquid per day must be drunk.

Other types of diets for weight reduction:

With low carbohydrate diets, such as the Atkins diet, rapid weight loss is possible with good compliance in the beginning. However, after 12 months, there is no difference in the course of weight loss between the Atkins diet and a balanced hypocaloric varied diet (Foster et al., 2003, level Ib; Stern et al., 2004, level Ib; Dansinger et al., 2005, level Ib). Due to the limited selection of food and other disadvantages (no reduction in LDL cholesterol level; long-term data not available), this concept is only suitable for initial weight loss and not for long-term weight loss.

Diets with low glycaemic index:

Diets with low glycaemic index (GI) focus on the increased consumption of slowly absorbed carbohydrates that are associated with low postprandial blood sugar and insulin levels. Currently available data do not indicate that a diet with low GI is superior to a diet with high GI (Raben, 2002, level Ia; Sloth et al., 2004, level Ib; Raatz, 2005, level Ib). However, long-term studies addressing this question have not been conducted.

Extremely one-sided diets (e.g. total fasting, fasting cures, Schroth cure, Mayr cure, pineapple diet etc.) should not be recommended due to their medical risks and lack of long-term success.

6.4.3 Exercise therapy

Increased physical activity contributes to weight loss and even more strongly to weight maintenance through the higher energy demand. This effect is largely proportional to the energy consumed (Jakicic et al., 2003, level III).

- To measurably reduce weight, an additional energy consumption of 2500 kcal/week is necessary. This corresponds to at least five hours additional physical activity per week (Pavlou et al., 1989, level IIa; Jakicic et al., 2001, level IV; Jeffery et al., 2003, level III).
- Physical activity is particularly suitable for weight maintenance after weight reduction. To stabilize the weight, three to five hours per week of increased activity with an energy consumption of at least 1500 kcal are required (Klem et al., 1997, level II; Jakicic et al., 2001, level IV).
- Increasing daily activity has a beneficial effect on weight stabilization similar to that achieved in structured exercise programmes (Andersen et al., 1999, level Ib).

It is unclear which exercise frequency, duration and intensity are best for weight maintenance. The training intensity should be based on cardiovascular training and reach about 75% of the maximum heart rate or a calculated heart rate in which the resting heart rate is included (e.g. Karvonen formula) if there are no contraindications. The combination of endurance training with muscle-building training increases strength and halves the loss of fat-free mass; however, it does not increase the loss of fat (Ballor et al., 1991, level Ia; Jakicic et al., 2001, level IV).

6.4.4 Behaviour therapy

Behaviour therapy can bolster the patient's motivation to comply with the nutrition and exercise recommendations. Behaviour modification techniques are primarily recommended for weight management programmes aimed at long-term weight reduction or stabilization (Jeffery et al, 2000, level IV; Westenhöfer, 2001, level IV).

The most important elements are:

- Self-observation of eating, drinking and exercise habits, for example with a diet diary or exercise protocol
- Gradual introduction of flexible, controlled eating habits (in contrast to rigid behaviour control)
- Learning stimulus control techniques to decrease eating impulses
- Use of positive reinforcement (e.g. praise) in order to strengthen new eating habits and prevent relapse
- Social support
- Relapse prophylaxis and management

6.4.5 Weight reduction programmes

6.4.5.1 Commercial weight reduction programmes

Commercial weight reduction programmes usually combine an initial, very low-calorie diet with formula products, increase in physical activity and behaviour modification training with the goal of a long-term change in diet. Most programmes do not have systematic evaluations. For clearly overweight patients (BMI ≥ 30), the 6-month Optifast programme shows good initial weight loss of about 15 to 25% while taking into account contraindications; however, the majority of the participants regain more than 50% of the weight lost within one to two years (Tsai et al., 2005, level IIb). In Germany, a further development is offered as the Optifast52 programme. The Weight Watchers programme enables moderately obese people to attain an average weight reduction of 3 to 4.5 kg (Heshka et al., 2003, level Ib; Dansinger et al., 2005, level Ib).

6.4.5.2 Other evaluated programmes

The DGE programme "Ich nehme ab" ("I am losing weight"), is a strongly behaviour therapy-oriented self-management programme. Through this programme, a moderate reduction of the body weight is to be attained and above all, balanced eating habits established. It was conceived for moderately overweight people without comorbidities. When the programme is applied with adviser support, an average weight loss of 2.3 kg in women and 4.1 kg in men was achieved after one year. At the same time, the participants improved the nutritional composition of their diets (Scholz et al., 2005, level Ib).

6.4.6 Adjuvant drug therapy

The indication for additional pharmacotherapy for weight loss can be made under the following preconditions (National Task Force on the Prevention and Treatment of Obesity; 1996, level IV):

- Patients with BMI ≥ 30 , who did not have satisfactory success with the basic programme; this is defined as weight loss $\leq 5\%$ over three to six months or regaining the weight during this period.
- Patients with BMI ≥ 27 , who additionally have grave risk factors and/or comorbidities and for whom the basic therapy was not successful.
- The drug therapy should be continued only if a weight loss of at least 2 kg is achieved within the first four weeks.

6.4.6.1 Medications with weight-reducing potential

Two weight-reducing substances (anorexigenic drugs) are currently authorized for marketing.

Sibutramine:

In randomized, controlled studies in obese patients, the selective serotonin and noradrenaline reuptake inhibitor sibutramine led to a average weight reduction of 2.8 or 4.4 kg for an intervention period of 3 or 12 months, respectively (Padwal et al., 2003, level Ia; McTigue et al., 2003, level Ia; Arterburn et al., 2004, level Ia). In obese people with type 2 diabetes, an average weight loss of 4.5 kg was observed in comparison to placebo (Norris et al., 2005b, level Ia, Vettor et al., 2005, level Ia). Sibutramine can also be prescribed intermittently (Wirth & Krause, 2001, level Ib). The most important side effects are dry mouth, constipation, dizziness, sleep disorders, and moreover, an increase in blood pressure (by more than 10 mm Hg in 4% of the drug takers) and the heart rate by 3 to 5 beats. Important contraindications are hypertension ($> 145/90$ mm Hg), CHD, glaucoma and cardiac arrhythmia.

Orlistat:

Orlistat, which is a gastrointestinal tract lipase inhibitor, led to an additional average weight loss of 2.8 kg in comparison to placebo in obese patients (Padwal et al., 2003, level Ia; McTigue et al., 2003, level Ia; Hutton & Fergusson, 2004, level Ia). In obese type 2 diabetic patients on oral antidiabetic drug therapy, an additional average weight loss of 1.9 kg was observed and in insulin-treated diabetic patients, the additional weight loss was 2.6 kg (Hollander et al., 1998, level Ib; Kelley et al., 2002, level Ib; Norris et al., 2005b, level Ia). In people with impaired glucose tolerance, orlistat reduced the conversion to type 2 diabetes (3.0% vs. 7.6%) (Torgersen et al., 2004, level IIa). Frequent side effects are soft stools, higher stool frequency, meteorism and steatorrhea. Between 5 and 15% of the patients showed a decreased absorption of fat-soluble vitamins, whose clinical significance is unclear.

Rimonabant:

Rimonabant is a specific cannabinoid-1 receptor antagonist that was recently approved as a centrally acting weight loss agent. In randomized, controlled trials in overweight subjects (BMI ≥ 27 kg/m²) with and without comorbidities (dyslipidaemia, type 2 diabetes), 20 mg rimonabant reduced body weight by an average of 3.9 to 6.7 kg over a 12-month treatment period (van Gaal et al., 2005; Despres et al., 2005; Pi-Sunyer et al., 2006; Scheen et al., 2006; Curioni and André, 2006). The

most important side effects are dizziness, nausea, depressive symptoms and anxiety. Important contraindications include psychiatric diseases, in particular depressive and anxiety disorders.

Records on the clinical use of sibutramine, orlistat and rimonabant are available for only a limited duration of two or four years; thus, longer use cannot be recommended. For all substances, prospective studies with cardiovascular outcomes are not available. The benefit of combinations of these active substances has not been adequately studied.

Substances such as diuretics, growth hormones, amphetamines and thyroxine cannot be recommended for the treatment of obesity due to their unproven effects or dangerous side effects. Metformin and acarbose show weak weight-reducing effects of 0.5 - 2 kg on the average (Knowler et al., 2002, level Ib; Van de Laar et al., 2005, level Ia). Selective inhibitors of serotonin reuptake can be used in the treatment of depression that is related to obesity; they are not suitable as the only treatment for obesity (Royal College of Physicians, 1998, level IV).

6.4.6.2 Dietary supplements, special foods

For isolated dietary supplements or functional foods, such as green tea, MCT fats, calcium and nuts, a weak or transient, but not clinically significant effect on body weight has been observed in some studies, while other studies showed no weight-reducing effect at all (Pittler et al., 2004, level Ia; St-Onge, 2005, level Ia). None of the named and also none of the other dietary supplements and special foods on the market can be recommended as supportive products for weight loss.

6.4.7 Surgical Therapy

The indication for surgical intervention can be made for patients with

- Obese class III (BMI \geq 40) or
- Obese class II (BMI \geq 35) with important comorbidities (e.g. diabetes mellitus type 2)

after failure of conservative therapy (National Institute of Health Consensus Development Conference, 1991, level IV; Sauerland et al., 2005, level IV). Obesity surgical intervention should be performed in specialized facilities that, if possible, offer the whole spectrum of obesity-specific surgical techniques.

Patient selection must be made according to strict criteria in which the risk-benefit assessment must be clearly positive (National Institute of Health Consensus Development Conference, 1991, level IV; Sauerland et al., 2005, level IV). Strict standards must be applied to the surgical risk associated with this elective surgery; in no case may the risk exceed the risks known from similar elective surgeries. The patients must be sufficiently motivated and must completely comprehend the surgical procedure, its risks and long-term consequences (informed consent). Normally, several consultations are required. A patient's lack of compliance can lead to life-threatening complications after obesity surgical interventions (Sauerland et al., 2005, level IV).

Before making the diagnosis, the patient should have attempted conservative treatment according to defined quality criteria for at least 6 to 12 months. A psychological or psychosomatic therapy preceding surgical treatment does not appear to be fundamentally required; for patients with suspected depression, psychosis, addiction or eating disorder such as binge eating, a psychiatrist or psychotherapist must be consulted. If psychotherapy seems to be promising for a patient with an eating disorder, this should be first attempted before surgical therapy. Eating disorders, in particular binge

eating syndrome, are not fundamentally contraindications for obesity surgical measures (Busetto et al., 2005, level III).

The decision which surgical procedure, restriction or a combination of restriction and malabsorption, is appropriate for a given case, is dependent on BMI, the individual risk, the comorbidities and the patient's wishes (Sauerland et al., 2005, level IV). Decision criteria are not evaluated. For patients with good compliance and BMI < 50, restrictive procedures (adjustable stomach band or possibly gastric banding) could be appropriate (Husemann, 2003, level IV). For patients with BMI \geq 50 kg/m², usually a combination procedure such as stomach bypass, duodenal switch, or possibly a biliopancreatic diversion is used since greater and more stable weight loss can be achieved (Sjöström et al., 2004, level IIa). Whenever possible, laparoscopy is preferred (Sauerland et al., 2005, level IV).

Perioperative complications occur in 5 to 15% of the patients and mostly concern wound healing impairment (3 to 12%) or cardiovascular problems such as thrombosis (1 to 9%) or pulmonary embolism (0.2 to 1.5%). Perioperative mortality is about 1% (Husemann, 2003, level IV). In recent US American analyses on large collectives, a hospital mortality of 0.1 to 0.2% (Santry et al., 2005, level III) and however, also a 30-day mortality of 2.0% were reported, in which the rate for men was double that of women (Flum et al., 2005, level III). Due to possible late complications, interdisciplinary long-term aftercare of the patients must be ensured. Most complications are related to local anatomical problems in the operated area and to chronic malnourishment as a result of malabsorption.

The efficacy of obesity surgical measures is substantiated through numerous clinical studies. Depending on the method employed, the weight reduction lies between 21 to 38 kg after one year and 15 to 28 kg after 10 years (Sjöström et al., 2004, level IIa). The loss of excessive body weight (EWL) for stomach bands is 41 to 54%, for stomach bypass 62 to 75% and for biliopancreatic diversion or duodenal switch 66 to 74% (Buchwald et al., 2004, level IIa; Maggard et al., 2005, level IIa).

As a rule, weight loss leads to significant improvement of comorbidities such as type 2 diabetes mellitus, hypertension, dyslipoproteinaemia, obstructive sleep apnoea syndrome (Buchwald et al., 2004, level IIa; Maggard et al., 2005, level IIa) and to reduction of the relative mortality risk by up to 89% (Christou et al., 2004, level IIa). However, prospective outcome studies have not been conducted. In particular, extremely obese patients with type 2 diabetes benefit from this procedure; 64% of the diabetic persons achieve full remission (MacDonald 1997, level III; Dixon et al., 2002, level IIa). For people with impaired glucose tolerance, the rate of conversion to manifest diabetes mellitus can be drastically lowered (Sjöström et al., 2004, level IIa).

Liposuction is a method from plastic surgery that can be employed for the removal of local fat deposits, but which is not suitable for the treatment of obesity. A benefit of this technique for long-term weight loss has not been demonstrated; the risks of this intervention are poorly documented and are not insignificant. Plastic surgical procedures may be necessary after successful weight reduction to remove excess skin and also to correct the risk of chronic skin infections.

6.4.8 Long-term weight stabilization

Long-term results of weight management programmes are critically dependent upon the long-term support concept. The following factors must be considered:

- Because energy consumption during a weight reduction diet declines, a return to the previous lifestyle leads to weight gain (Leibel et al., 1995, level IIa). The energy balance must continually be kept under control so that the body weight remains constant.
- A low-fat diet appears to be well-suited for the prevention of renewed weight gain (Klem et al., 1997, level IIa; Toubro et al., 1997, level Ib).
- Energy consumption is increased through physical activity. The simultaneous maintenance of muscle mass both promotes and makes weight stabilization easier (Ewbank et al., 1995, level IIa; Jakicic et al., 2001, level IV).
- Continuation of the therapist-patient contact has a positive effect on long-term weight stabilization, since the patient receives continual motivation and support, learns to maintain the new eating and exercise habits (Perri et al., 1993, level IV).
- Integration into a self-help group and the support of family members or other reliable or close persons also have positive effects on weight stabilization and prevent relapses (Perri et al., 1993, level IV).
- Regular weight monitoring (once a week) and self-management improve long-term results (Klem et al., 1997, level IIa).

7 Advantages and Disadvantages of Weight Reduction

7.1 Advantages Weight Reduction

Weight reduction in principle improves all above-named comorbidities and complications. Metabolic and cardiovascular sequelae have been studied the most. Numerous studies have documented the following advantages of moderate weight loss (~ 10 kg) (Goldstein, 1992; SIGN, 1996):

Mortality:

- Lowering of total mortality by > 20% (Williamson, 1995, level Ib)
- Lowering of diabetes-associated mortality risks by > 30% (Williamson, 1995, level Ib)
- Lowering of obesity-associated carcinoma deaths by > 40% (Williamson, 1995, level Ib)

Diabetes mellitus type 2:

- Decrease in fasting glucose by 30 to 40 mg/dl (1.7 to 2.2 mmol/L) per 10 kg weight reduction (Anderson, 2001, level Ia)
- Lowering of relative risks for conversion of impaired glucose tolerance to type 2 diabetes by a weight reduction of 2.8 to 5.8 kg in combination with dietary measures and increase in physical activity by 38 to 58% (Tuomilehto et al., 2001, level Ib; Knowler et al., 2002, level Ib; Torgerson et al., 2004, level Ib; Norris et al., 2005, level Ia)

Lipids:

- Lowering of total cholesterol by an average of 10%
- Lowering of LDL cholesterol by 7 to 15%
- Increase in HDL cholesterol by 2 to 8%
- Lowering of triglycerides by 20-30% (SIGN, 1996, level Ib; Anderson et al., 2001, level Ib)

Blood pressure:

- Lowering of blood pressure in patients with hypertension by an average of 7 mm Hg systolic and 3 mm Hg diastolic (MacMahon et al., 1987, level Ia).
- Weight loss decreases the risk for new on-set hypertension (Stevens et al., 2001, level Ib)

Markers of chronic inflammation:

- Lowering of CRP by 26% after a weight reduction of 7.9 kg (Heilbronn et al., 2001, level IIb)
- Significant lowering of IL-6 by 17 to 47% and TNF- α by 31% after an average weight loss of 9.8 kg (Bastard et al., 2000, level Ib; Ziccardi et al., 2002, level IIa)
- Lowering of IL-18 by 30% for an average weight loss of 14 kg (Esposito et al., 2003, level Ib)

Haemostasis:

- Lowering of PAI-1 activity by 21 to 31% for weight losses of 5.4 to 9.5 kg (Rissanen et al., 2001, level Ia)

The changes in the parameters for morbidity usually depend upon the starting values; greater changes are expected with higher starting values.

7.2 Disadvantages of weight reduction

After weight reduction, there is an elevated risk for gall stone diseases. The faster and more pronounced the weight loss, the more frequently gall stones develop (Everhart, 1993, level IV). Drastic weight reduction is often associated with loss in bone density. In Caucasian women who started weight reduction after the age of 50, an elevated incidence of hip fractures was observed (Langlois et al., 1996, level III).

Health drawbacks due to weight cycling could not be confirmed (National Task Force on the Prevention and Treatment of Obesity, 1994, level Ia). There is also no evidence supporting the assumption that diets or weight reduction programmes promote the development of eating disorders (National Task Force on the Prevention and Treatment of Obesity, 2000, level Ia).

8. Medical Care Aspects

The family doctor plays a central role in the long-term care of overweight or obese patients. Obese patients with particular comorbidities or treatment problems should receive additional care in specialized treatment facilities (e.g. medical practices or centres specializing in nutritional medicine or diabetes or outpatient and stationary rehabilitation facilities).

For obese persons with grave concomitant diseases or serious psychosocial problems, initial care by obesity specialists in private practice or in an outpatient obesity centre may be advisable or necessary (SIGN, 1996, level IV; NIH, 1998, level IV). Such institutions should fulfil defined quality criteria for outpatient obesity programmes and be subjected to continuous quality control (Hauner et al., 2000, level IV). Electronic documentation systems such as, for example, the apv programme can support quality management.

Table 5: Quality criteria for outpatient obesity programmes (according to Hauner et al., 2000)

	Quality criteria
Spatial requirements	<ul style="list-style-type: none"> • Training classroom • Possibly also a teaching kitchen
Personnel requirements	<ul style="list-style-type: none"> • Physician with nutritional medicine certification (mandatory) • Nutritionist (mandatory) = nutrition scientist/dietician • Psychologist with behaviour therapy certification* • Physical therapist or other occupational group with sports medicine certification*
The therapeutic programme should include	<ul style="list-style-type: none"> • Initial medical examination and consultation • Structured training in groups • Integrated concept of nutritional, exercise and behaviour therapies; if necessary, weight-reducing medications in accordance with the guideline • Length of therapy: 6 to 12 months • Systematic data documentation • Scientific evaluation • Quality management

* For a complete multidisciplinary treatment approach, these qualifications are required. However, to ensure comprehensive care of the obese patients, it is acceptable to have the respective treatment components from exercise therapy (Chapter 6.4.3) and behaviour therapy (Chapter 6.4.4) within a structured treatment approach performed by appropriately trained doctors or nutritionists.

Flow Diagram: Obesity prevention and treatment

Class of the body weight and the endangerment to health	Goal	Measures
Normal weight (BMI 18.5 – 24.9)	→ Weight stabilization	→ If necessary, weight monitoring
Normal weight (BMI 18.5 – 24.9) plus risk factor and/or comorbidities	→ Weight stabilization; for familial predisposition, prevent weight increase > 3 kg. Risk factor management, e.g. quitting smoking, healthier lifestyle	→ Weight monitoring, Risk factor management, treatment of the comorbidities, counselling on healthy lifestyle
Pre-obese (BMI 25 – 29.9)	→ Prevention of weight increase	→ Weight monitoring, Counselling on healthy lifestyle
Pre-obesity (BMI 25 – 29.9) plus risk factor and/or comorbidities or waist circumference w: >80cm m: >94 cm	→ Permanent weight reduction by 5 to 10%	→ Basic programme*, Risk factor management, treatment of the comorbidities, for BMI > 27 kg/m ² after 12 weeks at the earliest, consider additional drug therapy
Obesity class I (BMI 30 – 34.9)	→ Permanent weight reduction by 5 to 10%	→ Basic programme*, Risk factor management, treatment of the comorbidities, for BMI > 27 kg/m ² after 12 weeks at the earliest, consider additional drug therapy
Obesity level I (BMI 30 – 34.9) plus risk factor and/or comorbidities or waist circumference w: >88 cm m: >102 cm	→ Permanent weight reduction by 5 to 10%	→ 1. Basic programme *, risk factor management, treatment of the comorbidities 2. If unsuccessful, after 12 weeks at the earliest, consider additional drug therapy
Obesity class II (BMI 35 – 39.9)	→ Permanent weight reduction by ≥ 10%	→ Basic programme * Counselling on healthy life style
Obesity class II (BMI 35 – 39.9) plus risk factor and/or comorbidities	→ Permanent weight reduction by 10 to 20%	→ 1. Basic programme *, risk factor management, treatment of the comorbidities 2. If unsuccessful, after 12 weeks at the earliest, consider additional drug therapy 3. For unsuccessful conservative therapy, consider surgical therapy
Obesity class III (BMI > 40)	→ Permanent weight reduction by 10 to 30%	→ 1. Basic programme *, risk factor management, treatment of the comorbidities 2. If unsuccessful, after 12 weeks at the earliest, consider additional drug therapy 3. For unsuccessful conservative therapy, consider surgical therapy

* The basic programme includes medical nutrition therapy (Chapter 6.4.2), exercise therapy (Chapter 6.4.3) and behaviour therapy (Chapter 6.4.4).

Internet addresses

www.adipositas-gesellschaft.de

www.a-g-a.de Working Group on Obesity in Childhood and Adolescence (AGA)

www.deutsche-diabetes-gesellschaft.de

www.dge.de

www.dgem.de

www.diabetikerbund.de

www.diabetes-deutschland.de

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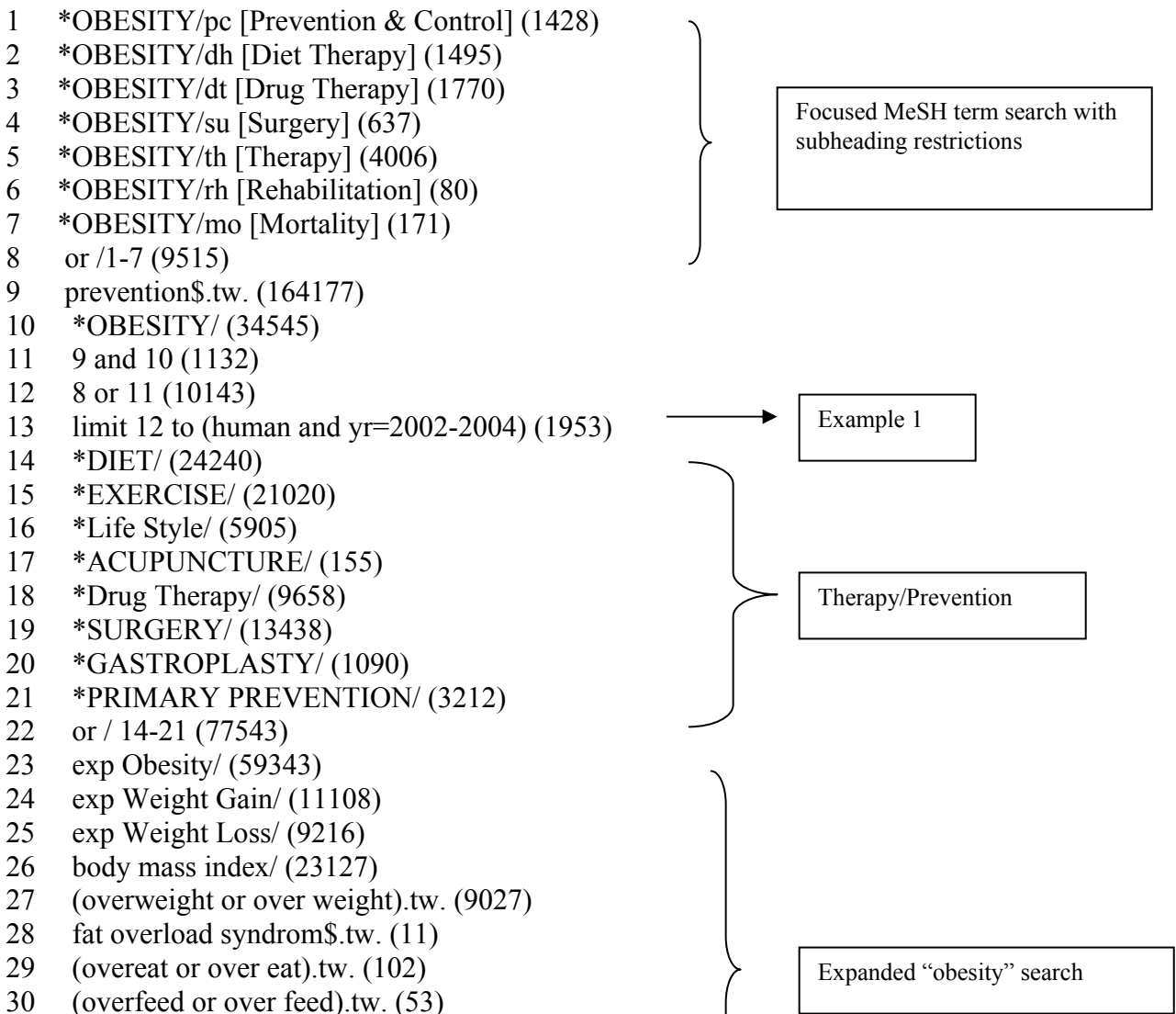
Comments on the literature search

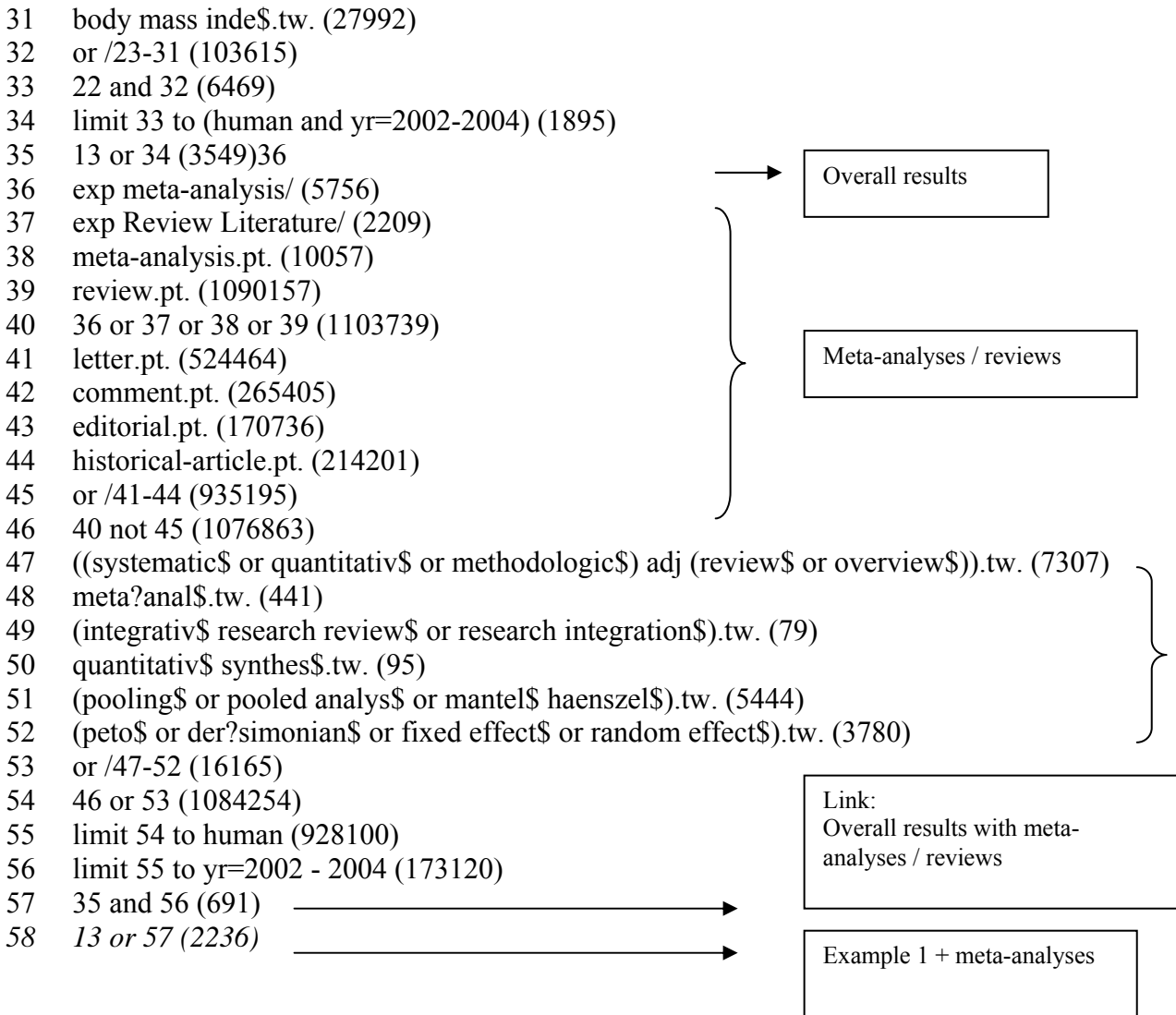
National und international quality criteria for good guidelines, such as those from the Scottish Intercollegiate Guidelines Network (SIGN, 1999) or the jointly compiled “German Instrument for Methodological Guideline Appraisal” by the German Agency for Quality in Medicine and the guidelines commission of the German Association of the Scientific Medical Societies (AWMF and ÄZQ, 2005), served as a basis for this guideline. Access to older scientific literature was made possible through an existing database that was established for the first version of the guideline. Ms. Karla Bergerhoff of the Cochrane Metabolic and Endocrine Disorders Group, Heinrich Heine University in Düsseldorf performed the literature search for the period January 2002 to November or December 2004 according to the strategy shown below. The following databases were searched: Medline (n=2102), Cochrane Library (n=655), Embase (n=1789), ERIC (n=7) und PsycInfo (n=244).

Furthermore, a secondary search was performed on existing guidelines, recommendations, expert opinions and the references appearing in these texts.

The literature search was performed according to the following search strategy:

Database: Ovid MEDLINE(R) < 01.2002 to 12.2004>
Date: December 2004





Legend:

- / = Following an indexed term, this sign denotes that all subheadings of the term were selected.
- \$ = When \$ follows a term, it shows an extension/modification of the search term.
- * = When * precedes the respective term, this denotes a focused MeSH term search.
- expl = Preceding an indexed term, this denotes an expanded MeSH term search.
- pt = Publication type: Indicates a search according to study design.
- tw = Text word: The term is searched for in the title and in the abstract of the study.
- and/or = Denotes an inclusive or exclusive combination with so-called Boolean operators.
- adj = Adjacent: Denotes the search for two terms in one sentence.
- MeSH term = Thesaurus of the National Library of Medicine (MeSH, medical subject headings).