



## Complete Summary

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### GUIDELINE TITLE

Treatment of obesity.

### BIBLIOGRAPHIC SOURCE(S)

Finnish Medical Society Duodecim. Treatment of obesity. In: EBM Guidelines. Evidence-Based Medicine [Internet]. Helsinki, Finland: Wiley Interscience. John Wiley & Sons; 2006 Sep 20 [Various].

### GUIDELINE STATUS

**Note:** This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

## COMPLETE SUMMARY CONTENT

SCOPE  
METHODOLOGY - including Rating Scheme and Cost Analysis  
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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT  
CATEGORIES  
IDENTIFYING INFORMATION AND AVAILABILITY  
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## SCOPE

### DISEASE/CONDITION(S)

Obesity

### GUIDELINE CATEGORY

Counseling  
Evaluation  
Management  
Treatment

### CLINICAL SPECIALTY

Family Practice  
Internal Medicine  
Nutrition

## **INTENDED USERS**

Dietitians  
Health Care Providers  
Nurses  
Physicians

## **GUIDELINE OBJECTIVE(S)**

Evidence-Based Medicine Guidelines collect, summarize, and update the core clinical knowledge essential in general practice. The guidelines also describe the scientific evidence underlying the given recommendations.

## **TARGET POPULATION**

Patients who are obese

## **INTERVENTIONS AND PRACTICES CONSIDERED**

### **Evaluation**

1. Assess the need for treatment using body mass index (BMI)

### **Counseling/Treatment**

1. Basic treatment (lifestyle counseling regarding behaviour, diet, and exercise)
2. Basic treatment plus a very low calorie diet
3. Drug (orlistat, sibutramine, rimonabant)
4. Surgical treatment (gastroplasty, gastric banding, or gastric bypass)
5. Follow-up

**Note:** Guideline developers considered but did not specifically recommend guar gum, ephedrine, ephedrine plus caffeine, dietary supplements containing ephedra, or chitosan.

## **MAJOR OUTCOMES CONSIDERED**

- Morbidity associated with obesity
- Efficacy of treatment
  - Weight loss
  - Maintenance of weight loss
  - Amount of weight regained
  - Prevention of progression of obesity
  - Effect of treatment on comorbidities
- Adverse effects or complications associated with treatment

## METHODOLOGY

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Hand-searches of Published Literature (Primary Sources)  
Hand-searches of Published Literature (Secondary Sources)  
Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

The evidence reviewed was collected from the Cochrane database of systematic reviews and the Database of Abstracts of Reviews of Effectiveness (DARE). In addition, the Cochrane Library and medical journals were searched specifically for original publications.

### **NUMBER OF SOURCE DOCUMENTS**

Not stated

### **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Weighting According to a Rating Scheme (Scheme Given)

### **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

#### **Levels of Evidence**

- A. Strong research-based evidence. Multiple relevant, high-quality scientific studies with homogenic results.
- B. Moderate research-based evidence. At least one relevant, high-quality study or multiple adequate studies.
- C. Limited research-based evidence. At least one adequate scientific study.
- D. No research-based evidence. Expert panel evaluation of other information.

### **METHODS USED TO ANALYZE THE EVIDENCE**

Review of Published Meta-Analyses  
Systematic Review

### **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

### **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Not stated

### **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

Not applicable

## **COST ANALYSIS**

Cost analyses were reviewed.

In a cost-utility analysis, the net cost per quality-adjusted life years (QALY) was 6,289 Great Britain pound GBP for gastric bypass (Roux-en-Y), 10,237 GBP for vertical banded gastroplasty, and 8,527 GBP for silicone adjustable gastric banding as compared with non-surgical management. Gastric bypass appears to have a modest net cost per QALY gained compared to vertical banded gastroplasty (742 GBP/QALY), when silicone adjustable gastric banding has a large net cost per QALY gained compared to gastric bypass (256,856 GBP/QALY).

## **METHOD OF GUIDELINE VALIDATION**

Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Not stated

# **RECOMMENDATIONS**

## **MAJOR RECOMMENDATIONS**

**Note:** This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

The levels of evidence [A-D] supporting the recommendations are defined at the end of the "Major Recommendations" field.

### **Assessment of the Need of Treatment**

- Overweight (mild obesity): body mass index (BMI) 25 to 30 kilograms (kg)/m<sup>2</sup>
  - Usually no treatment is indicated.
  - Treatment (Glenny & O'Meara, 1997; Avenell, Broom, & Brown, 2004) [A] is indicated in central obesity, metabolic syndrome (see Finnish Medical Society Duodecim guideline "Metabolic Syndrome [MBS]"), or non-insulin-dependent diabetes.
  - In children even mild obesity should be treated.
- Moderate obesity: BMI 30-35 kg/m<sup>2</sup>
  - Treatment (Glenny & O'Meara, 1997; Avenell, Broom, & Brown, 2004) [A] is always indicated if the patient has diabetes, hypertension, hyperlipidaemia, or other associated disease (Douketis et al., 1999) [B].

- A young obese person with good health should be treated. The treatment of middle-aged persons is decided individually according to the available resources.
- Severe obesity: BMI >35 kg/m<sup>2</sup>
  - Must always be treated

### Selecting the Method of Treatment

1. Basic treatment consisting of a gradual and permanent change in living habits by counselling and guidance.
  - Well suited for patients with mild and moderate obesity and for the majority of patients with severe obesity; **should always be included in other forms of conservative treatment**
2. Basic treatment and a very low calorie diet
  - Well suited for morbid and severe obesity
  - A choice in moderate obesity if the basic treatment has been unsuccessful and there is a strong indication for reducing weight (associated diseases)
3. Drugs (orlistat, sibutramine, rimonabant)
  - Do not automatically help all patients
  - An alternative especially if other approaches have been failed
  - Life-style counselling must also be included.
4. Surgical treatment
  - Suitable only for selected patients with morbid obesity (see criteria below).

### Basic Treatment

#### Organisation

- **Group treatment** is less costly and as effective as individualised treatment
  - At least 10 meetings are arranged with about one-week intervals.
  - The group leader is a nurse or a dietician with special training in the treatment of obesity.

#### Goals that Can Be Measured

- **The optimal rate of weight reduction is 0.5 kg/week.** As the adipose tissue contains about 30 MJ (7,000 kcal)/kg, a daily reduction of 2,100 kJ (500 kcal) in the energy intake will result in this rate of weight reduction.
- The goal is to reduce weight by 5 to 10%, which already results in significant benefit in the treatment of diseases associated with obesity.
- A permanent result is always aimed at. This means that the changes in living habits must be permanent.
- In growing children, weight should be kept constant so that the growth of height corrects the relative weight.
- There are many treatments with no proven efficacy. Appetite-suppressant drugs may result in a moderate weight reduction but the effect is transient.

### Aims and Contents of Counselling

- Changes in knowledge and attitudes
  - Human energy consumption is reduced if the body weight is reduced. In order to sustain the weight that has been achieved **the changes in living habits must be permanent.**
- Changes in meals (Miller, Koceja, & Hamilton, 1997) [**A**]
  - Find out the present contents of meals.
  - Reduce intake by about 2,000 kJ (500 kcal) daily.
  - The main emphasis is on the reduction of fat intake (Pirozzo et al., 2002) [**B**].
  - Remember alcohol as a cause of obesity.
  - Small daily changes are effective in the long run.
  - Keep three daily meals.
- Changes in physical exercise (Miller, Koceja, & Hamilton, 1997) [**A**]
  - The advice depends on the degree of obesity.
  - Exercise during daily activities should be encouraged (climbing up stairs, walking or cycling to work).
- Changes in eating behaviour
  - The most common goal is to change behaviour, not to "hunt kilograms."
  - Identify the circumstances that trigger eating.
  - Grocery shopping with a pre-planned list
  - Reduce temptations (no food in sight!).
  - Do nothing else when eating (such as watch TV, read magazines).
  - Eat slowly.

### **Very Low Calorie Diet (VLCD)**

- Reference: (Anderson, Hamilton, & Brinkman-Kaplan, 1992)
- Constituents
  - 1,700 to 2,100 kJ (400 to 500 kcal) of energy, a maximum of 3,300 kJ (800 kcal) daily
  - Protein as needed (at least 50 grams (g) daily)
  - Essential fatty acids, trace elements, and vitamins as needed
- Schedule
  - Ready-made commercial formulas should be used as the only food continuously for 8 to 10 weeks in severe obesity and for a shorter period in milder obesity, but usually for a minimum of 6 weeks.
  - The patient is followed up at 1 to 2 week intervals.
  - Suitable for patients with non-insulin-dependent (type 2) diabetes and hypertension. Insulin treatment is stopped or the dose is reduced considerably, and the dose of sulphonylureas is halved (risk of hypoglycaemia) before starting VLCD. The doses of other drugs need not be reduced.
  - The rate of weight reduction is about 1.5 to 2 kg/week, and the short-term weight reduction is 2 to 2.5 times that on basic treatment.
  - A VLCD alone does not yield permanent results. Basic treatment for permanent life-style changes is applied in the normal fashion.

### **Drug Treatment for Obesity**

- Drugs are not a universal remedy in the management of obesity. They can be tried for patients who have the metabolic syndrome or some other "obesity disease" when lifestyle changes alone have not given sufficient results.
- When prescribing a weight-reducing drug, the patient should also be provided with guidance in lifestyle changes.
- A drug indicated for the treatment of obesity may be used when the patient has body mass index over 30 kg/m<sup>2</sup> (or over 27 to 28 kg/m<sup>2</sup>, if the patient has diabetes or some other disease requiring weight reduction).
- The patient should be informed that the drug treatment for obesity is aimed to last for several years. After discontinuation of the drug, weight will increase again in most cases.
- Stop the drug, if there has not been a significant weight reduction in 3 months (at least 5% of the baseline weight).

### **Orlistat**

- Orlistat is a lipase inhibitor acting in the digestive tract. It partly prevents the absorption of dietary fat. The drug is not absorbed in the bloodstream.
- Weight reduction in patients who have taken 120 mg of orlistat before main meals has been on the average 3 kg more than with placebo at one year (Padwal, Li & Lau, 2003) [**B**]. The proportion of patients who have lost more than 10% of the baseline weight has been 12 percentage points greater with orlistat than with placebo.
- Due to the mode of action of the drug, low-density lipoprotein (LDL) cholesterol concentration will reduce more than would be achieved with the weight reduction alone.
- When using the drug, a concomitant aim is to limit the proportion of dietary energy intake coming from fat to no more than 30%. The snacks should be low-fat. The patient should receive sufficient dietary counselling.
- Common adverse effects include fatty or oily stools, faecal urgency and oily faecal spotting (>1/10 users).

### **Sibutramine**

- A centrally acting appetite suppressant that inhibits the reuptake of serotonin and noradrenalin
- Weight reduction in patients who have taken 15 mg of sibutramine daily has been on the average 4 kg more than with placebo at one year (Padwal, Li & Lau, 2003) [**B**]. The proportion of patients who have lost more than 10% of the baseline weight at one year has been 15 percentage points greater with sibutramine than with placebo.
- The most common adverse effects include insomnia, nausea, dry mouth and constipation. These have occurred in 7% to 20% of patients using sibutramine.
- Because of the effects on blood pressure and heart rate, the drug is not recommended for patients with cardiovascular diseases.

### **Rimonabant**

- A centrally acting appetite suppressant that blocks the endocannabinoid receptor 1. CB1-receptors are also found in fat cells and in the digestive tract.
- Brought to market during the year 2006.

- Weight reduction in patients who have taken 20 mg of rimonabant daily has been on the average 6 kg more than with placebo at one year (Despres, Golay & Sjostrom, 2005; Pi-Sunyer et al., 2006; Curioni & Andre, 2006) [**A**]. The proportion of patients who have lost more than 10% of the baseline weight at one year has varied between 17% and 26% with rimonabant compared to placebo, depending on the study.
- The most common adverse effects include nausea, vertigo, diarrhoea, anxiety, depression, fatigue and insomnia.

## **Surgical Treatment**

### **Criteria**

- Age below 60 years
- BMI at least 35 to 40 kg/m<sup>2</sup>.
- An efficient conservative treatment strategy has been tried.
- The patient is cooperative.
- There is no abuse of alcohol or drugs.

### **Method**

- Gastroplasty, gastric banding (Schneider, 2000; Chapman et al., 2002; HTA-20030005, 2004; "Newer techniques," 2003; HTA-20031130, 2004) [**B**], or gastric bypass so that the patient can eat only slowly and small amounts at a time. There are several surgical techniques, including laparoscopic procedures.
- The operation is not sufficient alone. Adequate preoperative investigations, patient counselling, and organized follow-up are mandatory.
- The outcome of successful surgical treatment is much better than that of conservative treatment (Colquitt et al., 2005; Clegg et al., 2002; "Special report," 2003; "Gastric restrictive surgery," 2000; "Newer techniques," 2003; Nilsen, 2003) [**A**]: the patients reduce 30 to 40 kg of their weight, and the result is long lasting (Glenny & O'Meara, 1997; Avenell, Broom, & Brown, 2004) [**A**].
- Some patients experience complications after surgery.

### **Related Evidence**

- Guar gum is not effective in weight reduction and causes adverse effects (Pittler & Ernst, 2001) [**A**].
- Ephedrine, ephedrine plus caffeine, or dietary supplements containing ephedra may be effective in producing a modest short-term weight loss as compared to placebo (Shekelle, Morton, & Maglione, 2003; HTA-20030424, 2004) [**C**].
- Chitosan may be more effective than placebo in the short-term treatment of overweight and obesity, but the evidence comes mainly from poor quality studies (Ni Mhurchu, 2005)

### **Definitions:**

### **Levels of Evidence**

- A. Strong research-based evidence. Multiple relevant, high-quality scientific studies with homogenic results.
- B. Moderate research-based evidence. At least one relevant, high-quality study or multiple adequate studies.
- C. Limited research-based evidence. At least one adequate scientific study.
- D. No research-based evidence. Expert panel evaluation of other information.

### **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

### **REFERENCES SUPPORTING THE RECOMMENDATIONS**

[References open in a new window](#)

### **TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

Concise summaries of scientific evidence attached to the individual guidelines are the unique feature of the Evidence-Based Medicine Guidelines. The evidence summaries allow the clinician to judge how well-founded the treatment recommendations are. The type of supporting evidence is identified and graded for select recommendations (see the "Major Recommendations" field).

## **BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

### **POTENTIAL BENEFITS**

Appropriate assessment and treatment of obesity

### **POTENTIAL HARMS**

- The most common adverse effects of orlistat are fatty or oily stools, faecal urgency and oily faecal spotting (>1/10 users).
- The most common adverse effects of sibutramine are insomnia, nausea, dry mouth, and constipation.
- The most common adverse effects of rimonabant include nausea, vertigo, diarrhoea, anxiety, depression, fatigue and insomnia.
- The complications reported from laparoscopic adjustable gastric banding included aspiration pneumonia, band slippage, and rotated or infected access ports. Band migration was more common if the band injections were performed by residents or nurses, rather than senior surgeons.
- Some complications of gastric surgery can occur

## **CONTRAINDICATIONS**

### **CONTRAINDICATIONS**

Because of the effects on blood pressure and heart rate, sibutramine is not recommended for patients with cardiovascular disease.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Getting Better  
Living with Illness

### IOM DOMAIN

Effectiveness  
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Finnish Medical Society Duodecim. Treatment of obesity. In: EBM Guidelines. Evidence-Based Medicine [Internet]. Helsinki, Finland: Wiley Interscience. John Wiley & Sons; 2006 Sep 20 [Various].

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

2004 Jun 22 (revised 2006 Sep 20)

### GUIDELINE DEVELOPER(S)

Finnish Medical Society Duodecim - Professional Association

### SOURCE(S) OF FUNDING

Finnish Medical Society Duodecim

### GUIDELINE COMMITTEE

Editorial Team of EBM Guidelines

## **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

*Primary Author:* Pertti Mustajoki

## **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

Not stated

## **GUIDELINE STATUS**

**Note:** This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

## **GUIDELINE AVAILABILITY**

This guideline is included in "EBM Guidelines. Evidence-Based Medicine" available from Duodecim Medical Publications, Ltd, PO Box 713, 00101 Helsinki, Finland; e-mail: [info@ebm-guidelines.com](mailto:info@ebm-guidelines.com); Web site: [www.ebm-guidelines.com](http://www.ebm-guidelines.com).

## **AVAILABILITY OF COMPANION DOCUMENTS**

None available

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This NGC summary was completed by ECRI on September 2, 2005. This NGC summary was updated by ECRI on December 26, 2006.

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