Weight-Loss and Maintenance Strategies

The most important component of an effective weight-management program must be the *prevention* of unwanted weight gain from excess body fat. The military is in a unique position to address prevention from the first day of an individual's military career. Because the military population is selected from a pool of individuals who meet specific criteria for body mass index (BMI) and percent body fat, the primary goal should be to foster an environment that promotes maintenance of a healthy body weight and body composition throughout an individual's military career. There is significant evidence that losing excess body fat is difficult for most individuals and the risk of regaining lost weight is high. From the first day of initial entry training, an understanding of the fundamental causes of excess weight gain must be communicated to each individual, along with a strategy for maintaining a healthy body weight as a way of life.

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INTRODUCTION

The principle of weight gain is simple: energy intake exceeds energy expenditure. However, as discussed in Chapter 3, overweight and obesity are clearly the result of a complex set of interactions among genetic, behavioral, and environmental factors. While hundreds, if not thousands, of weight-loss strategies, diets, potions, and devices have been offered to the overweight public, the multi-factorial etiology of overweight challenges practitioners, researchers, and the overweight themselves to identify permanent, effective strategies for weight loss and maintenance. The percentage of individuals who lose weight and successfully maintain the loss has been estimated to be as small as 1 to 3 percent (Andersen et al., 1988; Wadden et al., 1989).

Evidence shows that genetics plays a role in the etiology of overweight and obesity. However, genetics cannot account for the increase in overweight observed in the U.S. population over the past two decades. Rather, the behavioral and environmental factors that conspire to induce individuals to engage in too little physical activity and eat too much relative to their energy expenditure must take most of the blame. It is these factors that are the target of weight-management strategies. This chapter reviews the efficacy and safety of strategies for weight loss, as well as the combinations of strategies that appear to be associated with successful loss. In addition, the elements of successful weight maintenance also will be reviewed since the difficulty in maintaining weight loss may contribute to the overweight problem. A brief discussion of public policy measures that may help prevent overweight and assist those who are trying to lose weight or maintain weight loss is also included.

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PHYSICAL ACTIVITY

Increased physical activity is an essential component of a comprehensive weight-reduction strategy for overweight adults who are otherwise healthy. One of the best predictors of success in the long-term management of overweight and obesity is the ability to develop and sustain an exercise program (Jakicic et al., 1995, 1999; Klem et al., 1997; McGuire et al., 1998, 1999; Schoeller et al., 1997). The availability of exercise facilities at military bases can reinforce exercise and fitness programs that are necessary to meet the services' physical readiness needs generally, and for weight management specifically. For a given individual, the intensity, duration, frequency, and type of physical activity will depend on existing medical conditions, degree of previous activity, physical limitations, and individual preferences. Referral for additional professional evaluation may be appropriate, especially for individuals with more than one of the above extenuating factors. The benefits of physical activity (see Table 4-1) are significant and occur even in the absence of weight loss (Blair, 1993; Kesaniemi et al., 2001). It has been shown that one of the benefits, an increase in high-density lipoproteins, can be achieved with a threshold level of aerobic exercise of 10 to 11 hours per month.

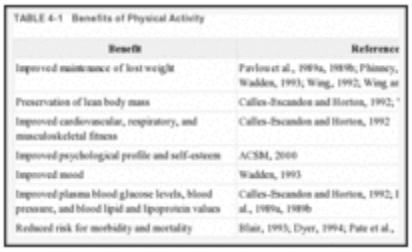

TABLE 4-1 Benefits of Physical Activity

Benefit	Reference
Improved maintenance of lost weight	Pavlou et al., 1989a, 1989b; Phinney, Wadden, 1993; Wing, 1992; Wing et
Preservation of lean body mass	Cullen-Escamilla and Horton, 1992;
Improved cardiovascular, respiratory, and musculoskeletal fitness	Cullen-Escamilla and Horton, 1992
Improved psychological profile and self-esteem	ACSM, 2000
Improved mood	Wadden, 1993
Improved plasma blood glucose levels, blood pressure, and blood lipid and lipoprotein values	Cullen-Escamilla and Horton, 1992; I al., 1989a, 1989b
Reduced risk for morbidity and mortality	Blair, 1993; Dyer, 1994; Pate et al.,

Benefits of Physical Activity.

For previously sedentary individuals, a slow progression in physical activity has been recommended so that 30 minutes of exercise daily is achieved after several weeks of gradual build-up. This may also apply to some military personnel, especially new recruits or reservists recalled to active duty who may be entering service from previously very sedentary lifestyles. The activity goal has been expressed as an increase in energy expenditure of 1,000 kcal/wk (Jakicic et al., 1999; Pate et al., 1995), although this quantity may be insufficient to prevent weight regain. For that purpose, a weekly goal of 2,000 to 3,000 kcal of added activity may be necessary (Klem et al., 1997; Schoeller et al., 1997). Thus, mental preparation for the amount of activity necessary to maintain weight loss must begin while losing weight (Brownell, 1999).

For many individuals, changing activity levels is perceived as more unpleasant than changing dietary habits. Breaking up a 30-minute daily exercise "prescription" into 10-minute bouts has been shown to increase compliance over that of longer bouts (Jakicic et al., 1995, Pate et al., 1995). However, over an 18-month period, individuals who performed short bouts of physical activity did not experience improvements in long-term weight loss, cardiorespiratory fitness, or physical activity participation in comparison with those who performed longer bouts of exercise. Some evidence suggests that home exercise equipment (e.g., a treadmill) increases the likelihood of regular exercise and is associated with greater long-term weight loss (Jakicic et al., 1999). In addition, individual preferences are paramount considerations in choices of activity.

When strength training or resistance exercise is combined with aerobic activity, long-term results may be better than those with aerobics alone (Poirier and Despres, 2001; Sothern et al., 1999). Because strength training tends to build muscle, loss of lean body mass may be minimized and the relative loss of body fat may be increased. An added benefit is the attenuation of the decrease in resting metabolic rate associated with weight loss, possibly as a consequence of preserving or enhancing lean body mass.

As valuable as exercise is, the existing research literature on overweight individuals indicates that exercise programs alone do not produce significant weight loss in the populations studied. It should be emphasized, however, that a large number of such studies have been conducted with middle-aged Caucasian women leading sedentary lifestyles. The failure of exercise alone to produce significant weight loss may be because the neurochemical mechanisms that regulate eating behavior cause individuals to compensate for the calories expended in exercise by increasing food (calorie) intake. While exercise programs can result in an average weight loss of 2 to 3 kg in the short-term (Blair, 1993; Pavlou et al., 1989a; Skender et al., 1996; Wadden and Sarwer, 1999), outcome improves significantly when physical activity is combined with dietary intervention. For example, when physical activity was combined with a reduced-calorie diet and lifestyle change, a weight loss of 7.2 kg was achieved after 6 months to 3 years of follow-up (Blair, 1993). Physical activity plus diet produces better results than either diet or physical activity alone (Blair, 1993; Dyer, 1994; Pavlou et al., 1989a, 1989b; Perri et al., 1993). In addition, weight regain is significantly less likely when physical activity is combined with any other weight-reduction regimen (Blair, 1993; Klem et al., 1997). Continued follow-up after weight loss is associated with improved outcome if the activity plan is monitored and modified as part of this follow-up (Kayman et al., 1990).

While studies have shown that military recruits were able to lose significant amounts of weight during initial entry training through exercise alone, the restricted time available to consume meals during training probably contributed to this weight loss (Lee et al., 1994).

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BEHAVIOR AND LIFESTYLE MODIFICATION

The use of behavior and lifestyle modification in weight management is based on a body of evidence that people become or remain overweight as the result of modifiable habits or behaviors (see Chapter 3), and that by changing those behaviors, weight can be lost and the loss can be maintained. The primary goals of behavioral strategies for weight control are to increase physical activity and to reduce caloric intake by altering eating habits (Brownell and Kramer, 1994; Wilson, 1995). A subcategory of behavior modification, environmental management, is discussed in the next section. Behavioral treatment, which was introduced in the 1960s, may be provided to a single individual or to groups of clients. Typically, individuals participate in 12 to 20 weekly sessions that last from 1 to 2 hours each (Brownell and Kramer, 1994), with a goal of weight loss in the range of 1 to 2 lb/wk (Brownell and Kramer, 1994). In the past, behavioral approaches were applied as stand-alone treatments to simply modify eating habits and reduce caloric intake. However, more recently, these treatments have been used in combination with low-calorie diets, medical nutrition therapy, nutrition education, exercise programs, monitoring, pharmacological agents, and social support to promote weight loss, and as a component of maintenance programs.

Self-Monitoring and Feedback

Self-monitoring of dietary intake and physical activity, which enables the individual to develop a sense of accountability, is one of the cornerstones of behavioral treatment. Patients are asked to keep a daily food diary in which they record what and how much they have eaten, when and where the food was consumed, and the context in which the food was consumed (e.g., what else they were doing at the time, what they were feeling, and who else was there). Additionally, patients may be asked to keep a record of their daily physical activities. Self-monitoring of food intake is often associated with a relatively immediate reduction in food intake and consequent weight loss (Blundell, 2000; Goris et al., 2000). This reduction in food intake is believed to result from increased awareness of food intake and/or concern about what the dietitian or nutrition therapist will think about the patient's eating behavior. The information obtained from the food diaries also is used to identify personal and environmental factors that contribute to overeating and to select and implement appropriate weight-loss strategies for the individual (Wilson, 1995). The same may be true of physical activity monitoring, although little research has been conducted in this area. Self-monitoring also provides a way for therapists and patients to

evaluate which techniques are working and how changes in eating behavior or activity are contributing to weight loss. Recent work has suggested that regular self-monitoring of body weight is a useful adjunct to behavior modification programs (Jeffery and French, 1999).

Other Behavioral Techniques

Some additional techniques included in behavioral treatment programs include eating only regularly scheduled meals; doing nothing else while eating; consuming meals only in one place (usually the dining room) and leaving the table after eating; shopping only from a list; and shopping on a full stomach (Brownell and Kramer, 1994).

Reinforcement techniques are also an integral part of the behavioral treatment of overweight and obesity. For example, subjects may select a positively reinforcing event, such as participating in a particularly enjoyable activity or purchasing a special item when a goal is met (Brownell and Kramer, 1994).

Another important component of behavioral treatment programs may be cognitive restructuring of erroneous or dysfunctional beliefs about weight regulation (Wing, 1998). Techniques developed by cognitive behavior therapists can be used to help the individual identify specific triggers for overeating, deal with negative attitudes towards obesity in society, and realize that a minor dietary infraction does not mean failure. Nutrition education and social support, discussed later in this chapter, are also components of behavioral programs.

Behavioral treatments of obesity are frequently successful in the short-term. However, the long-term effectiveness of these treatments is more controversial, with data suggesting that many individuals return to their initial body weight within 3 to 5 years after treatment has ended (Brownell and Kramer, 1994; Klem et al., 1997). Techniques for improving the long-term benefits of behavioral treatments include: (1) developing criteria to match patients to treatments, (2) increasing initial weight loss, (3) increasing the length of treatment, (4) emphasizing the role of exercise, and (5) combining behavioral programs with other treatments such as pharmacotherapy, surgery, or stringent diets (Brownell and Kramer, 1994).

Recent studies of individuals who have achieved success at long-term weight loss may offer other insights into ways to improve behavioral treatment strategies. In their analysis of data from the National Weight Control Registry, Klem and coworkers (1997) found that weight loss achieved through exercise, sensible dieting, reduced fat consumption, and individual behavior changes could be maintained for long periods of time. However, this population was self-selected so it does not represent the experience of the average person in a civilian population. Because they have achieved and maintained a significant amount of weight loss (at least 30 lb for 2 or more years), there is reason to believe that the population enrolled in the Registry may be especially disciplined. As such, the experience of people in the Registry may provide insight

into the military population, although evidence to assert this with authority is lacking. In any case, the majority of participants in the Registry report they have made significant permanent changes in their behavior, including portion control, low-fat food selection, 60 or more minutes of daily exercise, self-monitoring, and well-honed problem-solving skills.

Eating Environments

A significant part of weight loss and management may involve restructuring the environment that promotes overeating and underactivity. The environment includes the home, the workplace, and the community (e.g., places of worship, eating places, stores, movie theaters). Environmental factors include the availability of foods such as fruits, vegetables, nonfat dairy products, and other foods of low energy density and high nutritional value. Environmental restructuring empha-sizes frequenting dining facilities that produce appealing foods of lower energy density and providing ample time for eating a wholesome meal rather than grabbing a candy bar or bag of chips and a soda from a vending machine. Busy lifestyles and hectic work schedules create eating habits that may contribute to a less than desirable eating environment, but simple changes can help to counter-act these habits.

Commanders of military bases should examine their facilities to identify and eliminate conditions that encourage one or more of the eating habits that promote overweight. Some nonmilitary employers have increased healthy eating options at worksite dining facilities and vending machines. Although multiple publications suggest that worksite weight-loss programs are not very effective in reducing body weight (Cohen et al., 1987; Forster et al., 1988; Frankle et al., 1986; Kneip et al., 1985; Loper and Barrows, 1985), this may not be the case for the military due to the greater controls the military has over its “employees” than do nonmilitary employers.

Eating habits that may promote overweight:

1.

Eating few or no meals at home

2.

Opting for high-fat, calorie-dense foods

3.

Opting for high-fat snack foods from strategically placed vending machines or snack shops combined with allowing insufficient time to prepare affordable, healthier alternatives.

4.

Consuming meals at sit-down restaurants that feature excessive portion sizes or “all-you-can-eat” buffets

Simple changes that can modify the eating environment:

1.

Prepare meals at home and carry bag lunches

2.

Learn to estimate or measure portion sizes in restaurants

3.

Learn to recognize fat content of menu items and dishes on buffet tables

4.

Eliminate smoking and reduce alcohol consumption

5.

Substitute low-calorie for high-calorie foods

6.

Modify the route to work to avoid a favorite food shop

Physical Activity Environment

Major obstacles to exercise, even in highly motivated people, include the time it takes to complete the task and the inaccessibility of facilities or safe places to exercise. Environmental interventions emphasize the many ways that physical activity can be fit into a busy lifestyle and seek to make use of whatever opportunities are available (HHS, 1996). Environmental changes may be needed to encourage female participation in exercise programs, such as accommodation of the need for more after-exercise “repair time” by women and worksite facilities that are more “user friendly,” such as measured indoor walking routes and lunchtime low-level aerobics classes (Wasserman et al., 2000). The availability of safe sidewalks and parks and alternative methods of transportation to work, such as walking or bicycling, also enhance the physical activity environment. Establishing “car-free” zones is an example of an environmental change that could promote increased physical activity.

Nutrition Education

Management of overweight and obesity requires the active participation of the individual. Nutrition professionals can provide individuals with a base of information that allows them to make knowledgeable food choices.

Nutrition education is distinct from nutrition counseling, although the contents overlap considerably. Nutrition counseling and dietary management tend to focus more directly on the motivational, emotional, and psychological issues associated with the current task of weight loss and weight management. It addresses the *how* of behavioral changes in the dietary arena. Nutrition education on the other hand, provides basic information about the scientific foundation of nutrition that enables people to make informed decisions about food, cooking methods, eating out, and estimating portion sizes. Nutrition education programs also may provide information on the role of nutrition in health promotion and disease prevention, sports nutrition, and nutrition for pregnant and lactating women. Effective nutrition education imparts nutrition knowledge and its use in healthy living. For example, it explains the concept of energy balance in weight management in an accessible, practical way that has meaning to the individual's lifestyle, including that in the military setting.

Written materials prepared by various government agencies or by nonprofit health organizations can be used effectively to provide nutrition education. However, written materials are most effective when used to reinforce informal classroom or counseling sessions and to provide specific information, such as a table of the calorie content of foods. The format of education programs varies considerably, and can include formal classes, informal group meetings, or teleconferencing. A common background among group members is helpful (but seldom possible).

Educational formats that provide practical and relevant nutrition information for program participants are the most successful. For example, some military weight-management programs include field trips to post exchanges, restaurants (fast-food and others), movies, and other places where food is purchased or consumed (Vorachek, 1999).

The involvement of spouses and other family members in an education program increases the likelihood that other members of the household will make permanent changes, which in turn enhances the likelihood that the program participants will continue to lose weight or maintain weight loss (Hart et al., 1990; Hertzler and Schulman, 1983; Sperry, 1985). Particular attention must be directed to involvement of those in the household who are most likely to shop for and prepare food. Unless the program participant lives alone, nutrition management is rarely effective without the involvement of family members.

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DIET

Weight-management programs may be divided into two phases: weight loss and weight maintenance. While exercise may be the most important element of a weight-maintenance program, it is clear that dietary restriction is the critical component of a weight-loss program that influences the rate of weight loss. Activity accounts for only about 15 to 30 percent of daily energy expenditure, but food intake accounts for 100 percent of energy intake. Thus, the energy balance equation may be affected most significantly by reducing energy intake. The number of diets that have been proposed is almost innumerable, but whatever the name, all diets consist of reductions of some proportions of protein, carbohydrate (CHO) and fat. The following sections examine a number of arrangements of the proportions of these three energy-containing macronutrients.

Nutritionally Balanced, Hypocaloric Diets

A nutritionally balanced, hypocaloric diet has been the recommendation of most dietitians who are counseling patients who wish to lose weight. This type of diet is composed of the types of foods a patient usually eats, but in lower quantities. There are a number of reasons such diets are appealing, but the main reason is that the recommendation is simple—individuals need only to follow the U.S. Department of Agriculture's Food Guide Pyramid. The Pyramid recommends that individuals eat a variety of foods, with the majority being grain products (e.g., bread, pasta, cereal, rice), eat at least five servings per day of fruits and vegetables; eat only moderate amounts of dairy and meat products; and limit the consumption of foods that are high in fat or sugar or contain few nutrients. In using the Pyramid, however, it is important to emphasize the portion sizes used to establish the recommended number of servings. For example, a majority of consumers do not realize that a portion of bread is a single slice or that a portion of meat is only 3 oz.

A diet based on the Pyramid is easily adapted from the foods served in group settings, including military bases, since all that is required is to eat smaller portions. Even with smaller portions, it is not difficult to obtain adequate quantities of the other essential nutrients. Many of the studies published in the medical literature are based on a balanced hypocaloric diet with a reduction of energy intake by 500 to 1,000 kcal from the patient's usual caloric intake. The U.S. Food and Drug Administration (FDA) recommends such diets as the “standard treatment” for clinical trials of new weight-loss drugs, to be used by both the active agent group and the placebo group (FDA, 1996).

Meal Replacement

Meal replacement programs are commercially available to consumers for a reasonably low cost. The meal replacement industry suggests replacing one or two of the three daily meals with their products, while the third meal should be sensibly balanced. In addition, two snacks consisting of fruits, vegetables, or diet snack bars are recommended each day. Using this plan, individuals consume approximately 1,200 to 1,500 kcal/day.

A number of studies have evaluated long-term weight maintenance using meal replacement, either self-managed (Flechtner-Mors et al., 2000; Heber et al., 1994; Rothacker, 2000), with active dietary counseling, or with behavior modification programs (Ashley et al., 2001; Ditschuneit and Flechtner-Mors, 2001; Ditschuneit et al., 1999) compared with traditional calorie-restricted diet plans. The largest amount of weight loss occurred early in the studies (about the first 3 months of the plan) (Ditschuneit et al., 1999; Heber et al., 1994). One study found that women lost more weight between the third and sixth months of the plan, but men lost most of their weight by the third month (Heber et al., 1994). All of the studies resulted in maintenance of significant weight loss after 2 to 5 years of follow-up. Hill's (2000) review of Rothacker (2000) pointed out that the group receiving meal replacements maintained a small, yet significant, weight loss over the 5-year program, whereas the control group gained a significant amount of weight. Active intervention, which included dietary counseling and behavior modification, was more effective in weight maintenance when meal replacements were part of the diet (Ashley et al., 2001). Meal replacements were also found to improve food patterns, including nutrient distribution, intake of micronutrients, and maintenance of fruit and vegetable intake.

Long-term maintenance of weight loss with meal replacements improves biomarkers of disease risk, including improvements in levels of blood glucose (Ditschuneit and Fletchner-Mors, 2001), insulin, and triacylglycerol; improved systolic blood pressure (Ditschuneit and Fletchner-Mors, 2001; Ditschuneit et al., 1999); and reductions in plasma cholesterol (Heber et al., 1994).

Winick and coworkers (2002) evaluated employees in high-stress jobs (e.g., police, firefighters, and hospital and aviation personnel) who participated in worksite weight-reduction and maintenance programs that used meal replacements. The meal replacements were found to be effective in reducing weight and maintaining weight loss at a 1-year follow-up. In contrast, Bendixen and coworkers (2002) reported from Denmark that meal replacements were associated with negative outcomes on weight loss and weight maintenance. However, this was not an intervention study; participants were followed for 6 years by phone interview and data were self-reported.

Unbalanced, Hypocaloric Diets

Unbalanced, hypocaloric diets restrict one or more of the calorie-containing macronutrients (protein, fat, and CHO). The rationale given for these diets by their advocates is that the restriction of one particular macronutrient facilitates weight loss, while restriction of the others does not. Many of these diets are published in books aimed at the lay public and are often not written by health professionals and often are not based on sound scientific nutrition principles. For some of the dietary regimens of this type, there are few or no research publications and virtually none have been studied long term. Therefore, few conclusions can be drawn about the safety, and even about the efficacy, of such diets. The major types of unbalanced, hypocaloric diets are discussed below.

High-Protein, Low-Carbohydrate Diets

There has been considerable debate on the optimal ratio of macronutrient intake for adults. This research usually compares the amount of fat and CHO; however, there has been increasing interest in the role of protein in the diet (Hu et al., 1999; Wolfe and Giovannetti, 1991). Studies have looked for the effects of a higher protein diet (CHO/protein ratio ~1.0) compared with a higher CHO diet (CHO/protein ratio ~3.0). Although the high-protein diet does not produce significantly different weight loss compared with the high-CHO diet (Layman et al., 2003a, 2003b; Piatti et al., 1994), the high-protein diet has been reported to stimulate greater improvements in body composition by sparing lean body mass (Layman et al., 2003a; Piatti et al., 1994).

High-protein, low-CHO diets were introduced to the American public during the 1970s and 1980s by Stillman and Baker (1978) and by Atkins (Atkins, 1988; Atkins and Linde, 1978), and more recently, by Sears and Lawren (1998). Some of these diets are high in fat (> 35 percent of kcal), while others have moderate levels of fat (25–35 percent of kcal). While most of these diets have been promoted by nonscientists who have done little or no serious scientific research, some of the regimens have been subjected to rigorous studies (Skov et al., 1999a, 1999b). There remains, however, a lack of randomized clinical trials of 2 or more years' duration, which are needed to evaluate the potent beneficial effect of weight loss (accomplished using virtually any dietary regimen, no matter how unbalanced) on blood lipids. In addition, longer studies are needed to separate the beneficial effects of weight loss from the long-term effects of consuming an unbalanced diet.

Authors of books aimed at the lay public have proposed advantages of high protein diets, including that eating a high-protein, low-CHO diet produces a “near-euphoric” state of maximal physical and mental performance (Sears and Lawren, 1998). These claims are unsupported by scientific data.

Although these diets are prescribed to be eaten ad libitum, total daily energy intake tends to be reduced as a result of the monotony of the food choices, other prescripts of the diet, and an increased satiety effect of protein. In addition, the restriction of CHO intake leads to the loss of glycogen and marked diuresis (Coulston and Rock, 1994; Miller and Lindeman, 1997; Pi-Sunyer, 1988). Thus, the relatively rapid initial weight loss that occurs on these diets predominantly reflects the loss of body water rather than stored fat. This can be a significant concern for military personnel, where even mild dehydration can have detrimental effects on physical and cognitive performance. For example, small changes in hydration status can affect a military pilot's ability to sense changes in equilibrium.

Results of several recent studies suggest that high-protein, low-CHO diets may have their benefits. In addition to sparing fat-free mass (Piatti et al., 1994) and producing greater weight and fat losses than high-CHO diets (Skov et al., 1999b), high-protein diets have been associated with decreases in fasting triglycerides and free fatty acids in healthy subjects and with the normalization of fasting insulin levels in hyperinsulinemic, normoglycemic obese subjects (Baba et al., 1999; Skov et al., 1999b). Furthermore, a 45-percent protein diet reduced resting energy expenditure to a significantly lesser extent than did a 12-percent protein diet (Baba et al., 1999). The length of these studies that examined high-protein diets only lasted 1 year or less; the long-term safety of these diets is not known.

Low-Fat Diets

Low-fat diets have been one of the most commonly used treatments for obesity for many years (Astrup, 1999; Astrup et al., 1997; Blundell, 2000; Castellanos and Rolls, 1997; Flatt, 1997; Kendall et al., 1991; Pritikin, 1982). The most extreme forms of these diets, such as those proposed by Ornish (1993) and Pritikin (1982), recommend fat intakes of no more than 10 percent of total caloric intake. Although these stringent diets can lead to weight loss, the limited array of food choices make them difficult to maintain for extended periods of time by individuals who wish to follow a normal lifestyle.

More modest reductions in fat intake, which make a dietary regimen easier to follow and more acceptable to many individuals, can also promote weight loss (Astrup, 1999; Astrup et al., 1997, 2000; Blundell, 2000; Castellanos and Rolls, 1997; Flatt, 1997; Kendall et al., 1991; Shah and Garg, 1996). For example, Sheppard and colleagues (1991) reported that after 1 year, obese women who reduced their fat intake from approximately 39 percent to 22 percent of total caloric intake lost 3.1 kg of body weight, while women who reduced their fat intake from 38 percent to 36 percent of total calories lost only 0.4 kg.

Results of recent studies suggest that fat restriction is also valuable for weight maintenance in those who have lost weight (Flatt 1997; Miller and Lindeman, 1997). Dietary fat reduction can

be achieved by counting and limiting the number of grams (or calories) consumed as fat, by limiting the intake of certain foods (for example, fattier cuts of meat), and by substituting reduced-fat or nonfat versions of foods for their higher fat counterparts (e.g., skim milk for whole milk, nonfat frozen yogurt for full-fat ice cream, baked potato chips for fried chips) (Dywer, 1995; Miller and Lindeman, 1997). Over the past decade, pursuit of this latter strategy has been simplified by the burgeoning availability of low-fat or fat-free products, which have been marketed in response to evidence that decreasing fat intake can aid in weight control.

The mechanisms for weight loss on a low-fat diet are not clear. Weight loss may be solely the result of a reduction in total energy intake, but another possibility is that a low-fat diet may alter metabolism (Astrup, 1999; Astrup et al., 2000; Castellanos and Rolls, 1997; Shah and Garg, 1996). Support for the latter possibility has come from studies showing that the short-term adherence to a diet containing 20 or 30 percent of calories from fat increased 24-hour energy expenditure in formerly obese women, relative to an isocaloric diet with 40 percent of calories from fat (Astrup et al., 1994).

Over the past two decades, fat consumption as a percent of total caloric intake has declined in the United States (Anand and Basiotis, 1998), while average body weight and the proportion of the American population suffering from obesity have increased significantly (Mokdad et al., 1999). Several factors may contribute to this seeming contradiction. First, all individuals appear to selectively underestimate their intake of dietary fat and to decrease normal fat intake when asked to record it (Goris et al., 2000; Macdiarmid et al., 1998). If these results reflect the general tendencies of individuals completing dietary surveys, then the amount of fat being consumed by obese and, possibly, nonobese people, is greater than routinely reported. Second, although the proportion of total calories consumed as fat has decreased over the past 20 years, grams of fat intake per day have remained steady or increased (Anand and Basiotis, 1998), indicating that total energy intake increased at a faster rate than did fat intake. Coupled with these findings is the fact that since the early 1990s, the availability of low-fat and nonfat, but calorie-rich snack foods (e.g., crackers, candy, cookies, cake, frozen desserts) has grown dramatically. However, total energy intake still matters, and overconsumption of these low-fat snacks could as easily lead to weight gain as intake of their high-fat counterparts (Allred, 1995).

Two recent, comprehensive reviews have reported on the overall impact of low-fat diets. Astrup and coworkers (2002) examined four meta-analyses of weight change that occurred on intervention trials with ad libitum low-fat diets. They found that low-fat diets consistently demonstrated significant weight loss, both in normal-weight and overweight individuals. A dose-response relationship was also observed in that a 10 percent reduction in dietary fat was predicted to produce a 4- to 5-kg weight loss in an individual with a BMI of 30. Kris-Etherton and colleagues (2002) found that a moderate-fat diet (20 to 30 percent of energy from fat) was more

likely to promote weight loss because it was easier for patients to adhere to this type of diet than to one that was severely restricted in fat (< 20 percent of energy).

High-Fiber Diets

Most low-fat diets are also high in dietary fiber, and some investigators attribute the beneficial effects of low-fat diets to the high content of vegetables and fruits that contain large amounts of dietary fiber. The rationale for using high-fiber diets is that they may reduce energy intake and may alter metabolism (Raben et al., 1994). The beneficial effects of dietary fiber might be accomplished by the following mechanisms: (1) caloric dilution (most high-fiber foods are low in calories and low in fat); (2) longer chewing and swallowing time reduces total intake; (3) improved gastric and intestinal motility and emptying and less absorption (French and Read, 1994; Leeds, 1987; McIntyre et al., 1997; Rigaud et al., 1998; Schonfeld et al., 1997; Vincent et al., 1995); and (4) decreased hunger and enhanced satiety (Pasman et al., 1997a, 1997b, 1997c). Dietary fiber is not a panacea, and the vast majority of controlled studies of the effects of dietary fiber on weight loss show minimal or no reduction in body weight (LSRO, 1987; Pasman et al., 1997b, 1997c).

Many individuals and companies promote the use of dietary fiber supplements for weight loss and reductions in cardiovascular and cancer risks. Numerous studies, usually short-term and using purified or partially purified dietary fiber, have shown reductions in serum lipids, glucose, or insulin (Jenkins et al., 2000). Long-term studies have usually not confirmed these findings (LSRO, 1987; Pasman et al., 1997b). Current recommendations suggest that instead of eating dietary fiber supplements, a diet of foods high in whole fruits and vegetables may have favorable effects on cardiovascular and cancer risk factors (Bruce et al., 2000). Such diets are often lower in fat and higher in CHOs.

Very-Low-Calorie Diets

Very-low-calorie diets (VLCDs) were used extensively for weight loss in the 1970s and 1980s, but have fallen into disfavor in recent years (Atkinson, 1989; Bray, 1992a; Fisler and Drenick, 1987). FDA and the National Institutes of Health define a VLCD as a diet that provides 800 kcal/day or less. Since this does not take into account body size, a more scientific definition is a diet that provides 10 to 12 kcal/kg of “desirable” body weight/day (Atkinson, 1989). The VLCDs used most frequently consist of powdered formulas or limited-calorie servings of foods that contain a high-quality protein source, CHO, a small percentage of calories as fat, and the daily recommendations of vitamins and minerals (Kanders and Blackburn, 1994; Wadden, 1995). The servings are eaten three to five times per day. The primary goal of VLCDs is to produce relatively rapid weight loss without substantial loss in lean body mass. To achieve this goal, VLCDs usually provide 1.2 to 1.5 g of protein/kg of desirable body weight in the formula or as fish, lean meat,

or fowl. Fisler and Drenick (1987) reviewed the literature and concluded that about 70 g/day of protein is needed to ensure that nitrogen balance is achieved within a short period of time on a VLCD.

VLCDs are not appropriate for all overweight individuals, and they are usually limited to patients with a BMI of greater than 25 (some guidelines suggest a BMI of 27 or even 30) who have medical complications associated with being overweight and have already tried more conservative treatment programs. Additionally, because of the potential detrimental side effects of these diets (e.g., gallstone formation, nutritional deficiencies, cardiac arrhythmias), medical and nutritional monitoring is important while individuals are on the diet.

On a short-term basis, VLCDs are relatively effective, with weight losses of approximately 15 to 30 kg over 12 to 20 weeks being reported in a number of studies (Anderson et al., 1992, 1999; Apfelbaum et al., 1987; Atkinson, 1989; Fisler and Drenick, 1987; Kanders and Blackburn, 1994). However, the long-term effectiveness of these diets is somewhat limited. Approximately 40 to 50 percent of patients drop out of the program before achieving their weight-loss goals. In addition, relatively few people who lose large amounts of weight using VLCDs are able to sustain the weight loss when they resume normal eating. In two studies, only 30 percent of patients who reached their goal were able to maintain their weight loss for at least 18 months. Within 1 year, the majority of patients regained approximately two-thirds of the lost weight (Apfelbaum et al., 1987; Kanders and Blackburn, 1994). In a more recent study with longer followup, the average regain over the first 3 years of follow-up was 73 percent. However, weight tended to stabilize over the fourth year. At 5 years, the dieters had maintained an average of 23 percent of their initial weight loss. At 7 years, 25 percent of the dieters were maintaining a weight loss of 10 percent of their initial body weight (Anderson et al., 1999, 2001).

It appears that VLCDs are more effective for long-term weight loss than hypocaloric-balanced diets. In a meta-analysis of 29 studies, Anderson and colleagues (2001) examined the long-term weight-loss maintenance of individuals put on a VLCD diet with behavioral modification as compared with individuals put on a hypocaloric-balanced diet. They found that VLCD participants lost significantly more weight initially and maintained significantly more weight loss than participants on the hypocaloric-balanced diet (see Table 4-2).

TABLE 4-2 One through Five-Year Maintenance of Initial Weight Loss of Individu
Very-Low-Calorie Diets or Hypocaloric-Balanced Diets

Diet	1 year	2 years	3 years	4 years	5 years
Very-low-calorie diet	16.1	9.7	7.8	7	6.2
Hypocaloric-balanced diet	7.2	4.2	3.5	2.8	2

SOURCE: Adapted from Anderson et al. (2001).

TABLE 4-2

One through Five-Year Maintenance of Initial Weight Loss of Individuals (%) Placed on Either Very-Low-Calorie Diets or Hypocaloric-Balanced Diets.

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SUPPORT SYSTEMS

Almost any kind of assistance provided to participants in a weight-management program can be characterized as support services. These can include emotional support, dietary support, and support services for physical activity. The support services used most often are structured in a standard way. Other services are developed to meet the specific needs of a site, program, or the individual involved. With few exceptions, almost any weight-management program is likely to be more successful if it is accompanied by support services (Heshka et al., 2000). However, not all services will be productively applicable to all patients, and not all can be made available in all settings. Furthermore, some weight-loss program participants will be reluctant to use any support services.

Counseling and Psychotherapy Services

Psychological and emotional factors play a significant role in weight management. Counseling services are those that consider psychological issues associated with inappropriate eating and that are structured to inform the patient about the nature of these issues, their implications, and the possibilities available for their ongoing management. This intervention is less elaborate, intense, and sustaining than psychotherapy services. For example, it should be useful to help patients understand the existence and nature of a sabotaging household or the phenomenon of stress-related eating without undertaking continuing psychotherapy. A counselor or therapist can provide this service either in individual or group sessions. These counselors should, however, be sufficiently familiar with the issues that arise with weight-management programs, such as binge eating and purging. Short-term, individual case management can be helpful, as can group sessions because patients can hear the perspective of other individuals with similar weight-management concerns while addressing their individual concerns (Hughes et al., 1999; Perri et al., 2001; Wadden and Sarwer, 1999).

Psychotherapy services, both individual and group, can also be useful. However, the costs of this type of service limits its applicability to many patients. Nevertheless, the value for individual patients can be substantial, and the option should not be dismissed simply because of cost. Concerns about childhood abuse, emotional linkages to sustaining obesity (fat-dependent personality), and the management of coexisting mental health problems are the kinds of issues that might be addressed with this type of support service. The individual therapist can structure the format of the therapy but, as with counseling services, the therapist should be familiar with weight-management issues.

Patient-Led Groups

Nonprofessional patient-led groups and counseling, such as those available with organized programs like Take Off Pounds Sensibly and Overeaters Anonymous, can be useful adjuncts to weight-loss efforts. These programs have the advantages of low cost, continuing support and encouragement, and a semi-structured approach to the issues that arise among weight-management patients. Their disadvantage is that, since the counseling is nonprofessional in nature, the programs are only as good as the people who are involved. These peer-support programs are more likely to be productive when they are used as a supplement to a program with professional therapists and counselors. In Overeaters Anonymous, a variant of these groups is a sponsor-system program that pairs individuals who can help one another.

Commercial Groups

Certain commercial programs like Weight Watchers and Jenny Craig can also be helpful. Since commercial groups have their own agenda, caution must be exercised to avoid contradictions between the advice of professional counselors and that of the supportive commercial program. Since the counselors in commercial programs are not likely to be professionals, the quality of counseling offered by these programs varies with the training of the counselors.

Other Community Resources

Many communities offer supplemental weight-management services. Educational services, particularly in nutrition, may be provided through community adult education using teaching materials from nonprofit organizations such as the American Heart Association, the American Diabetes Association, and government agencies (FDA, National Institutes of Health, and U.S. Department of Agriculture). Many community hospitals have staff dietitians who are available for out-patient individual counseling (Pavlou et al., 1989a). However, the military's TRICARE health services contracts would need to be modified to include dietitian services from community hospitals or other community services since these contracts do not currently include medical nutrition therapy (and therefore dietitian counseling).

Family Support

The family unit can be a source of significant assistance to an individual in a weight-management program. For example, program dropout rates tend to be lower when a participant's spouse is involved in the program (Jeffery et al., 1984). With simple guidance and direction, the involvement of the spouse as a form of reinforcement (rather than as a source of discipline and monitoring) can become a resource to assist in supporting the participant. However, individual family members (or the family as a group) can become an obstacle when they express reluctance to make changes in food and eating patterns within the household. Issues of family conflict become more complex when the participants are children or adolescents or when spouses are reluctant to relinquish status quo positions of control.

Internet Services

A variety of Internet- and web-related services are available to individuals who are trying to manage their weight (Davison, 1997; Gray and Raab, 1999; Riva et al., 2000). As with any other Internet service, the quality of these sites varies substantially (Miles et al., 2000). An important role for weight-management professionals is to review such sites so they can recommend those that are the most useful. The use of e-mail counseling services by military personnel who travel frequently or who are stationed in remote locations has been tested at one facility; initial results are promising (James et al., 1999a). The use of web-based modalities by qualified counselors or facilitators located at large military installations would extend the accessibility of such services to personnel located at small bases or stationed in remote locations.

Physical Activity Support Services

Support is also required for military personnel who need to enhance their levels of physical fitness and physical activity. All branches of the services have remedial physical fitness training programs for personnel who fail their fitness test, but support is also needed for those who need to lose weight and for all personnel to aid in maintaining proper weight. Support services should include personnel, facilities, and equipment, and should provide practical advice on how to begin and progress through physical training routines (including proper use of training equipment and how to prevent musculoskeletal injuries), as well as advice on when and how to eat in conjunction with physical activity demands.

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PRESCRIPTION AND OVER-THE-COUNTER DRUGS AND SUPPLEMENTS

Success in the promotion of weight loss can sometimes be achieved with the use of drugs. Almost all prescription drugs in current use cause weight loss by suppressing appetite or enhancing satiety. One drug, however, promotes weight loss by inhibiting fat digestion. To sustain weight loss, these drugs must be taken on a continuing basis; when their use is discontinued, some or all of the lost weight is typically regained. Therefore, when drugs are effective, it is expected that their use will continue indefinitely. For maximum benefit and safety, the use of weight-loss drugs should occur only in the context of a comprehensive weight-loss program. In general, these drugs can induce a 5- to 10-percent mean drop in body weight within 6 months of treatment initiation, but the effect can be larger or smaller depending on the individual. As with any drug, the occurrence of side effects may exclude their use in certain occupational contexts. Current convention recommends the use of weight-loss drugs in

otherwise healthy individuals who have a BMI ≥ 30, or in individuals with a BMI between 27 and 30 with an existing comorbid condition (e.g., hypertension, diabetes, heart disease). Recognition that weight-related diseases, such as diabetes and hypertension, occur in individuals with BMI levels below 25, and that weight loss improves these conditions in these individuals, suggests that indications for weight-loss drugs need to be individualized to the specific patient.

A number of hormonal and metabolic differences distinguish obese people from lean people (Leibel et al., 1995; Pi-Sunyer, 1993), suggesting that genetic factors play a role in weight. Weight loss alters metabolism in obese individuals, limiting energy expenditure and reducing protein synthesis. This alteration suggests that the body may attempt to maintain an elevated body weight.

The facts that genetics might play a role in hormonal and metabolic differences between people and that weight loss alters metabolism imply that obesity is not a simple psychological problem or a failure of self-discipline. Instead, it is a chronic metabolic disease similar to other chronic diseases and it involves alterations of the body's biochemistry. Like most other chronic diseases that require ongoing pharmacotherapy to prevent the recurrence of symptoms, obesity management and relapse prevention may someday be accomplished through this form of treatment. The following sections provide a brief review of the mechanisms of action, efficacy, and safety of prescription agents that have been approved for weight loss and the various over-the-counter substances that are promoted for weight loss.

Mechanisms of Action of Obesity Drugs

Obesity drugs act by a variety of mechanisms (see Box 4-1), but all must either reduce energy intake and/or increase energy output (Arch, 1981; Aronne, 1998; Astrup et al., 1998; Bray et al., 1996; Bross and Hoffer, 1995; Cole et al., 1998; Hanotin et al., 1998a, 1998b; Heal et al., 1998; Hollander et al., 1998; Jonderko and Kucio, 1989; Kogon et al., 1994; McNeely and Benfield, 1998; Rolls et al., 1998; Scalfi et al., 1993; Sjostrom et al., 1998; Tonstad et al., 1994; Troiano et al., 1990; van Gaal et al., 1998). Energy intake may be curbed by reducing hunger or appetite or by enhancing satiety.

BOX 4-1

Summary of Potential Mechanisms of Action of Obesity Drugs. Reductions in food intake
Reduction in hunger and/or appetite

Some obesity drugs may reduce the preference for dietary fat or refined CHOs (Blundell et al., 1995; Bray, 1992b; Foltin et al., 1995; Leibowitz, 1995; Wurtman et al., 1987). For example, the drug orlistat reduces the absorption of fat, which results in energy loss in the feces; other drugs not approved for obesity treatment reduce CHO absorption (Heal et al., 1998; McNeely and Benfield, 1998; Sjostrom et al., 1998; van Gaal et al., 1998). These drugs may produce sufficiently adverse effects, such as oily stools or increased flatus, so that patients reduce consumption of high-fat foods in favor of less energy-dense foods (McNeely and Benfield, 1998; Sjostrom et al., 1998; van Gaal et al., 1998).

Obesity drugs also may increase activity levels or stimulate metabolic rate. Drugs such as fenfluramine or sibutramine were reported to increase energy expenditure in some studies (Arch, 1981; Astrup et al., 1998; Bross and Hoffer, 1995; Heal et al., 1998; Scalfi et al., 1993; Troiano et al., 1990), but not in others (Schutz et al., 1992; Seagle et al., 1998). Fluoxetine, although not approved for obesity treatment, has been shown to increase resting metabolic rate (Bross and Hoffer, 1995). Ephedrine and caffeine, which act on adenosine receptors, may increase metabolic rate, reduce body-fat storage, and increase lean mass (Liu et al., 1995; Stock, 1996; Toubro et al., 1993). With one exception (orlistat), all currently available prescription obesity drugs act on either the adrenergic or serotonergic systems in the central nervous system to regulate energy intake or expenditure (Bray, 1992b). These adrenergic and serotonergic agonists increase secretion of norepinephrine, serotonin, and/or dopamine, or inhibit neuronal reuptake. Table 4-3 summarizes the mechanism of action of pharmacological agents used for treating obesity, which are discussed in detail below.

TABLE 4-3 Prescription Pharmacological Agents for Weight-Loss Treatment and

Drug Class	Drug
Adrenergic (DEA[a] II)	Amphetamine[b,c] Methamphetamine[b,c]
Adrenergic (DEA[a] III)	Benzphetamine Phendimetrazine
Adrenergic (DEA[a] IV)	Diethylpropion[d] Mazindol[e] Phentermine
Adrenergic over-the-counter	Phenylpropanolamine[c]
Serotonergic	d,l-fenfluramine[e] d-norfenfluramine[e] SSRI anti-depressants[f]
Combined adrenergic and serotonergic	Sibutramine

TABLE 4-3

Prescription Pharmacological Agents for Weight-Loss Treatment and Mechanisms of Action.

Efficacy and Safety of Currently Available Prescription Obesity Drugs

Adrenergic and Serotonergic Agents

Efficacy. Phentermine, an adrenergic agent, is the most commonly used prescription drug for obesity and has one of the lowest costs of all prescription agents. Weight loss is comparable with that of other single agents (Silverstone, 1992). Diethylpropion, phendimetrazine, and

benzphetamine are other adrenergic agents that stimulate central norepinephrine secretion and produce weight loss similar to that of phentermine (Griffiths et al., 1979; Silverstone, 1992). The categorization of phendimetrazine and benzphetamine as Drug Enforcement Agency Schedule III drugs may have limited their use, although little evidence exists to suggest that they have a higher abuse potential than does phentermine. Diethylpropion was reported to have a higher reinforcement potential in nonhuman primates than that of the other Schedule III and IV adrenergic drugs (Griffiths et al., 1979).

No currently available agents for treating obesity are exclusively serotonergic. Fluoxetine and sertraline are selective serotonin reuptake inhibitors that produce weight loss (Bross and Hoffer, 1995; Goldstein et al., 1993, 1995; Ricca et al., 1997; Wadden et al., 1995), but they do not have FDA approval for use in obesity treatment. Fluoxetine produced good weight loss after 6 months, but 1-year results were not different from those of placebo treatment (Goldstein et al., 1993). Sertraline also produced short-term weight loss (Ricca et al., 1997; Wadden et al., 1995).

Sibutramine inhibits reuptake of both norepinephrine and serotonin in central nervous system neurons. At doses of 15 mg/day, the drug produced a 1-year weight loss of 6 to 10 percent (Astrup et al., 1998; Bray et al., 1996; Hanotin et al., 1998b; Seagle et al., 1998). Blood pressure rose slightly in normotensive subjects, but fell in hypertensive subjects (Heal et al., 1998). Decreases in fasting blood glucose, insulin, waist circumference, waist-hip ratio, and computerized tomography-estimated abdominal fat were greater with sibutramine than with placebo (Heal et al., 1998). The greater weight losses observed in the sibutramine group compared with the placebo group may be responsible for the greater improvements in other parameters.

Safety. Common complaints with the use of centrally active adrenergic and serotonergic obesity drugs include dry mouth, fatigue, hair loss, constipation, sweating, sleep disturbances, and sexual dysfunction (Atkinson et al., 1997; Bray, 1998). Sibutramine can increase blood pressure and pulse rate in occasional patients and may cause dizziness and increased food intake (Cole et al., 1998; Hanotin et al., 1998a, 1998b). Mazindol may cause penile discharge (van Puijenbroek and Meyboom, 1998).

Drugs Affecting Absorption: Lipase and Amylase Inhibitors

Efficacy. Orlistat binds to lipase in the gastrointestinal tract and inhibits absorption of about one-third of dietary fat (Hollander et al., 1998; James WP et al., 1997; McNeely and Benfield, 1998; Sjostrom et al., 1998; Tonstad et al., 1994; van Gaal et al., 1998; Zhi et al., 1994). Thus, consumption of over 100 g of fat/day should result in about 30 g or more of fat reaching the colon. Average weight loss on orlistat is about 8 to 11 percent of initial body weight at 1 year (James WP et al., 1997; Sjostrom et al., 1998).

Compared with the effects of a placebo, orlistat treatment resulted in greater improvements in total cholesterol, low-density lipoprotein (LDL) cholesterol, LDL/high-density lipoprotein ratio, and concentrations of glucose and insulin (Hollander et al., 1998; James WP et al., 1997; McNeely and Benfield, 1998; Sjostrom et al., 1998; Tonstad et al., 1994; van Gaal et al., 1998). Although weight loss may be responsible for some of the observed improvements, orlistat lowered LDL independently of its effect on weight loss.

Acarbose is an alpha glucosidase inhibitor that inhibits or delays absorption of complex CHOs (Wolever et al., 1997). This drug is approved by FDA for the treatment of diabetes mellitus, but not for weight loss. Although it produces modest weight loss in animals, it has minimal or no effect on humans.

Safety. Adverse side effects of orlistat include abdominal cramping, increased flatus formation, diarrhea, oily spotting, and fecal incontinence (Hollander et al., 1998; James WP et al., 1997; McNeely and Benfield, 1998; Sjostrom et al., 1998; Tonstad et al., 1994; van Gaal et al., 1998; Zhi et al., 1994). These adverse effects may serve as a behavior modification tool to reduce the level of fat in the diet and presumably to reduce energy intake. Orlistat has been shown to produce small reductions in serum levels of fat-soluble vitamins. The manufacturer recommends that a vitamin supplement containing vitamins A, D, E, and K be prescribed for patients taking orlistat.

Drugs Approved for Other Conditions

A variety of drugs currently on the market for other conditions, but not approved by FDA for obesity treatment, have been evaluated for their ability to induce weight loss. Metformin (Lee and Morley, 1998), cimetidine (Rasmussen et al., 1993; Stoa-Birketvedt, 1993), diazoxide (Alemzadeh et al., 1998), bromocriptine (Cincotta and Meier, 1996), nicotine (Grant et al., 1997; Jensen et al., 1995; Nides et al., 1994), bupropion (Croft et al., 2000; Gadde et al., 1999), and topiramate (Rosenfeld et al., 1997) have produced modest weight loss. Additional studies are needed to support these findings.

Drugs Used in Combination

Efficacy. Although chronic diseases often require treatment with more than one drug, few studies have evaluated combination therapy for obesity. Private practitioners have used various combinations in an off-label fashion. The available data suggest that combination therapy is somewhat more effective than therapy with single agents. Combinations such as phentermine and fenfluramine or ephedrine and caffeine produce weight losses of about 15 percent or more of initial body weight compared with about 10 percent or less with single drug use. However, due to reported side-effects of cardiac valve lesions and pulmonary hypertension, fenfluramine and dexfenfluramine are no longer available.

Results of tests using combinations of phentermine with selective serotonin reuptake inhibitors (mainly fluoxetine or sertraline) have been reported in abstracts or preliminary reports (Dhurandhar and Atkinson, 1996; Griffen and Anchors, 1998). These combinations produced weight losses somewhat less than that of the combination treatment of ephedrine-caffeine, but greater than that of treatment with single agents (Dhurandhar and Atkinson, 1996).

Safety. Anchors (1997) used the combination of phentermine and fluoxetine in a large series of patients and suggested that this combination is safe and effective. Griffen and Anchors (1998) reported that the combination of phentermine-fluoxetine was not associated with the cardiac valve lesions that were reported for fenfluramine and dexfenfluramine.

Alternative Medicines, Herbs, and Diet Supplements

In 1994, Congress passed the Dietary Supplement Health and Education Act, which exempted dietary supplements (including those promoted for weight loss) from the requirement to demonstrate safety and efficacy. As a result, the variety of over-the-counter preparations touted to promote weight loss has exploded. Dietary supplements include compounds such as herbal preparations (often of unknown composition), chemicals (e.g., hydroxycitrate, chromium), vitamin preparations, and protein powder preparations. With the exception of herbal preparations of ephedrine and caffeine, none of these compounds have produced more than a minimal weight loss and most are ineffective or have been insufficiently studied to determine their efficacy. Furthermore, while little is known about the safety of many of these compounds, there are a growing number of adverse event reports for several of them. Table 4-4 summarizes the current safety and efficacy profile of a number of alternative compounds promoted for the purpose of weight loss.

TABLE 4-4 Alternative Medicines, Herbs, and Supplements Used for Weight Loss

Name/Compound	Descript
Bladderwrack	Fucus vesiculosus
Chitosan	Polymer of glucosamine derived
Chromium	Cr—an essential element
CLA	Conjugated linoleic acid
DHEA	Dehydroepiandrosterone
Ephedrine fat-burning stack	Ephedrine with caffeine and aspir and willow bark
Garcinia cambogia	Contains hydroxycitrate (HCA)
Germander	Teucrium chamaedrys
HMB	β-Hydroxy-β-methylbutyrate
Ofestra (Lawson et al., 1997)	Mixture of hexa-, hepta-, and oct

TABLE 4-4

Alternative Medicines, Herbs, and Supplements Used for Weight Loss.

The combination of ephedrine and caffeine to treat obesity has been reported to produce weight losses of 15 percent or more of initial body weight (Daly et al., 1993; Toubro et al., 1993). Both drugs are the active ingredients in a number of herbal weight-loss preparations. Weight loss is maximal at about 4 to 6 months on this combination, but body-fat levels may continue to

decrease through 9 to 12 months, with increases in lean body mass (Toubro et al., 1993). This observation suggests that the combination may be a beta-3 adrenergic agonist (Liu et al., 1995; Toubro et al., 1993).

Reports of cardiovascular and cerebrovascular events following use of ephedrine and caffeine to treat obesity have reached sufficient frequency that FDA and the Federal Trade Commission have begun to investigate the safety of this combination and have issued warnings to consumers. In addition, FDA has proposed new regulations for the labeling of products containing ephedrine, which would require warning statements for potential adverse health effects. Use of ephedrine alone or in combination with caffeine has been associated with a wide range of cardiovascular, cerebrovascular, neurological, psychological, gastrointestinal, and other symptoms in adverse events reports (Haller and Benowitz, 2000; Shekelle et al., 2003). Some prospective studies do not support the concept that there are major adverse events with ephedrine and caffeine (Boozer et al., 2001, 2002; Greenway, 2001; Kalman et al., 2002), but these studies were conducted using healthy individuals selected using careful exclusion criteria.

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FUTURE DRUGS FOR THE TREATMENT OF OBESITY

Body weight, body fat, energy metabolism, and fat oxidation are regulated by numerous hormones, peptides, neurotransmitters, and other substances in the body. Drug companies are devoting a large amount of resources to find new agents to treat obesity. Potential candidates include cholecystokinin, cortiocotropin-releasing hormone, glucagon-like peptide 1, growth hormone and other growth factors, enterostatin, neurotensin, vasopressin, anorectin, ciliary neurotrophic factor, and bombesin, all of which potentially either inhibit food intake or reduce body weight in humans or animals (Bray, 1992b, 1998; Ettinger et al., 2003; Okada et al., 1991; Rudman et al., 1990; Smith and Gibbs, 1984). Neuropeptide Y and galanin are central nervous system neurotransmitters that stimulate food intake (Bray, 1998; Leibowitz, 1995), so antagonists to these substances might be expected to reduce food intake. Beta-3 adrenergic receptor agonists reduce body fat and increase lean body mass in animals (Stock, 1996; Yen, 1995), but human analogs have not been identified that are effective and safe in humans. Several types of uncoupling proteins have been identified as being involved with the regulation of energy metabolism and body fat (Bao et al., 1998; Bouchard et al., 1998; Chagnon et al., 2000; Pérusse et al., 1999), but no agents based on these proteins have yet been produced to treat obesity.

As discussed in Chapter 3, seven single gene defects have been reported to produce obesity in humans (Pérusse et al., 1999). The leptin gene is defective in ob/ob mice, and leptin administration has been shown to be highly effective in reducing body weight in these mice (Campfield et al., 1995; Halaas et al., 1995; Pelleymounter et al., 1995). A very small number of humans with this gene defect have been identified, and at least one responded to leptin (Clement et al., 1998; Pérusse et al., 1999). Leptin levels are high in most obese individuals (Considine et al., 1996; Phillips, 1998), and preliminary trials of administration of leptin to these individuals show modest effects. Defects in the genes for protein convertase subtilisin/kexin type 1, PPAR-gamma, and pro-opiomelanocortin and in the genes for the receptors for leptin, thyroid hormone, and melanocortin-4R (Bouchard et al., 1998; Chagnon et al., 2000; Pérusse et al., 1999) have been identified in humans. It may be possible in the future to develop gene therapy or products that correct these defects in order to treat obesity.

Summary

Although obesity drugs have been available for more than 50 years, the concept of long-term treatment of obesity with drugs has been seriously advanced only in the last 10 years. The evidence that obesity, as opposed to overweight, is a pathophysiological process of multiple etiologies and not simply a problem of self-discipline is gradually being recognized—obesity is similar to other chronic diseases associated with alterations in the biochemistry of the body. Most other chronic diseases are treated with drugs, and it is likely that the primary treatment for obesity in the future will be the long-term administration of drugs. Unfortunately, current drug treatment of obesity produces only moderately better success than does diet, exercise, and behavioral modification over the intermediate term. Newer drugs need to be developed, and combinations of current drugs need to be tested for short- and long-term effectiveness and safety. As drugs are proven to be safe and effective, their use in less severe obesity and overweight may be justified.

The appropriateness of using weight-loss drugs in the military population requires careful consideration. On average, a 5 to 10 percent weight loss can improve comorbid conditions associated with obesity, but it is not known if this degree of weight reduction by itself would improve fitness or if it could be expected to improve performance in all military contexts. The side effects that are sometimes encountered might also restrict the use of weight-loss drugs in some military contexts. On the other hand, the military is losing or is in danger of losing otherwise qualified individuals who cannot “make weight.” Such people might be able to keep their weight within regulation if they are allowed to take weight-loss drugs for the remainder of their term in the military. The frequency of known side effects of current weight-loss drugs is sufficiently low that the potential for adverse events would not seem to be a reason to avoid the use of these drugs by military personnel.

The use of available dietary supplements and herbal preparations to control body weight is generally not recommended because of a lack of demonstrated efficacy of such preparations, the absence of control on their purity, and evidence that at least some of these agents have significant side effects and safety problems. The occurrence of potential adverse effects (e.g., dehydration, mood alterations) would be of particular concern for military personnel.

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SURGERY

Although it would be expected that very few active duty military personnel would qualify for consideration for obesity surgery, a review of weight-management programs would not be complete without a discussion of this option.

For massively obese individuals (those with a BMI above 35 or 40), the modest weight losses from behavioral treatments and/or drugs do not alter their obese status. For these individuals, obesity surgery may produce massive, long-term weight loss. Recent studies have shown dramatic improvements in the morbidity and mortality of those who are massively obese, and surgery is being recommended with increasing frequency for these individuals (Hubbard and Hall, 1991). Table 4-5 presents the rationale and results of all forms of obesity surgery.

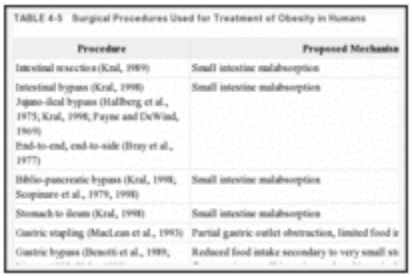

TABLE 4-5 Surgical Procedures Used for Treatment of Obesity in Humans

Procedure	Proposed Mechanism
Intestinal resection (Kral, 1989)	Small intestine malabsorption
Intestinal bypass (Kral, 1998) Jejuno-ileal bypass (Hallberg et al., 1975; Kral, 1998; Payne and DeWind, 1969) End-to-end, end-to-side (Bray et al., 1977)	Small intestine malabsorption
Biliio-pancreatic bypass (Kral, 1998; Scopinaro et al., 1979, 1998)	Small intestine malabsorption
Stomach to ileum (Kral, 1998)	Small intestine malabsorption
Gastric stapling (MacLean et al., 1993)	Partial gastric outlet obstruction, limited food i
Gastric bypass (Benotti et al., 1989,	Reduced food intake secondary to very small st

TABLE 4-5

Surgical Procedures Used for Treatment of Obesity in Humans.

Individuals who are candidates for obesity surgery are those who (1) exhibit any of the complications of obesity such as diabetes, hypertension, dyslipidemia, sleep disorders, pulmonary dysfunction, or increased intracranial pressure and have a BMI above 35, or (2) have a BMI above 40.

Gastric bypass is currently the most commonly used procedure for obesity surgery. Following this procedure, patients lose about 62 to 70 percent of excess weight and maintain this loss for

more than 5 years (Kral, 1998; MacDonald et al., 1997; Pories et al., 1992, 1995; Sugerman et al., 1989). Biliopancreatic bypass, another type of obesity surgery, and its variations produce weight losses comparable or superior to gastric bypass (Kral, 1998). In addition to massive weight loss, individuals who undergo obesity surgery experience improvements in health status relative to hypertension, dyslipidemia, sleep apnea, pulmonary function (oxygen saturation and oxyhemoglobin levels and decreased carbon dioxide saturation) (Sugerman, 1987; Sugerman et al., 1986, 1988), obesity-hypoventilation syndrome, and pseudotumor cerebri, urinary incontinence, and pulmonary dysfunction possibly due to increased intra-abdominal pressure (Sugerman et al., 1995, 1999).

Obesity surgery is, however, considered the treatment of last resort because of the short- and long-term complications associated with the surgery. Perioperative mortality is small but significant (about 0.3 to 2 percent) and appears to vary inversely with the experience of the surgeon (Kral, 1998). Other potential side effects include vomiting, diarrhea, electrolyte abnormalities, liver failure, renal stones, pseudo-obstruction syndrome, arthritis syndrome, and bacterial overgrowth syndromes.

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THE USE OF STRUCTURED MAINTENANCE PROGRAMS

When to Use a Maintenance Program

The long-term success of weight management appears to depend on the individual participating in a specific and deliberate follow-up program. Programs to aid personnel in weight maintenance or prevention of weight gain are appropriate when:

- An individual has successfully achieved his or her weight-loss goal and now seeks to maintain the new weight,
- An individual who is gaining weight has taken a weight-loss readiness assessment and has determined that he or she is not ready for weight loss at this time, or
- An overweight individual is temporarily excluded from a weight-reduction program until a medical, physical, or psychological problem stabilizes.

Components of a Maintenance Program

A comprehensive weight-maintenance strategy has five fundamental components:

1.

It helps the patient select a weight range within which he or she can realistically stay and, if possible, minimize health risks.

2.

It provides an opportunity for continued monitoring of weight, food intake, and physical activity.

3.

It helps the patient understand and implement the principle of balancing the energy consumed from food with routine physical activity.

4.

It helps the patient establish and maintain lifestyle change strategies for a sufficiently long period of time to make the new behaviors into permanent habits (a minimum of 6 months has been suggested [Wing, 1998]).

5.

It considers the long-term use of drugs.

Helping Patients Learn How to Balance Energy

Individuals who have achieved a weight-loss goal generally fall into one of two groups: those who see no point in participating in a maintenance program since they believe they know how to keep the weight off and those who remain open to change and improving their skills in weight management.

The critical role of the health care provider is to motivate the former group to learn the skills necessary for weight management. The skills necessary to:

- Maintain regular exercise for at least 60 min/day or an expenditure of 2,000 to 3,000 kcal/wk (8,368 kJ) (Klem et al., 1997; Schoeller et al., 1997).
- Decrease the amount of energy-dense foods eaten (especially those that are low in nutrients).
- Practice healthy eating by including fruits, vegetables, and whole grains in the diet.
- Understand portion control.
- Access the services of nutrition counselors or other forms of guidance.

Helping Patients Establish Permanent Lifestyle Change Strategies

As mentioned above, individuals who have lost weight need to make permanent lifestyle changes in order to maintain their loss. To assist patients in making these changes, successful maintenance programs will include education on and assistance with the following factors (Foreyt and Goodrick, 1993, 1994; Kayman et al., 1990):

- *Self-monitoring.* Regular weighing and recording of daily food intake and physical activity for the first month or two of the maintenance period and during periods of increased exposure to food (e.g., during the holidays). If weight gain occurs, reinstitution of this practice may help bring weight back into control. Frequent follow-up contact with counselors is also crucial (Perri et al., 1993). Effective follow-up consists of a schedule of regular weekly to monthly contacts by mail, phone, or in person. Support groups may substitute for some of this follow-up with a health care provider, but should not replace it.

- *Physical activity.* Daily physical activity is key to successful weight maintenance; it is the factor cited as the most important in maintaining weight loss by the majority of individuals in the National Weight Loss Registry (Klem et al., 1997). An average of 80 min/day of moderate activity or 35 min/day of vigorous activity is needed to maintain weight (Schoeller et al., 1997).

- *Problem solving.* Learning to identify and anticipate problems that threaten to undermine success is necessary. Problem solving skills allow the individual to craft strategies that will resolve problems as they emerge.

- *Stress management.* Exercise, relaxation, and social support can help reduce stress. Techniques to reduce stress can be critical for some individuals who overeat in response to stress.

- *Relapse prevention.* Relapse, temporary loss of control, and return to old behaviors is common. The key to relapse prevention is learning to anticipate high-risk situations and to devise plans to reduce the damages. Patients need to learn to forgive themselves for a lapse and view it as a “learning experience.” Reestablishing control is crucial.

- *Social influence/support.* Sabotage by family or friends is seen often and may be stressful for the individual who is trying to maintain weight. The skills to recognize intentional or unintentional sabotage may be learned. In extreme cases, a choice may need to be made between the weight-maintenance program or the relationship. Identifying a fresh circle of supporters or starting a support group may be useful.

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PUBLIC POLICY MEASURES

To the extent that the epidemic of obesity can be attributed to changes in our living and working environments (the increased availability of calorie-dense foods and decreased opportunity to expend energy), public policy efforts may help prevent overweight and may assist those who are trying to lose weight or maintain weight loss (Koplan and Dietz, 1999). Some measures that have been suggested and/or tried include the following:

- Increasing choices and decreasing prices of low-calorie (and low-fat) foods (e.g., fruits and vegetables) offered at worksite eating places and in vending machines (French et al., 1997; Hoerr and Louden, 1993)
- Instituting workplace and community programs that include regular monitoring, nutrition and health promotion, overweight prevention education, and exercise classes or groups
- Renovating community spaces to provide more and safer spaces for physical activity
- Modifying work environments or schedules to encourage greater physical activity on and off the job
- Mandating regular physical activity during the workday (IOM, 1998).

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SUMMARY

Apart from the obvious need to increase energy expenditure relative to intake, none of the strategies that have been proposed to promote weight loss or maintenance of weight loss are universally recognized as having any utility in weight management. The efficacy of individual interventions is poor, and evidence regarding the efficacy of combinations of strategies is sparse, with results varying from one study to another and with the individual. Recent studies that have focused on identifying and studying individuals who have been successful at weight management have identified some common techniques. These include self-monitoring, contact with and support from others, regular physical activity, development of problem-solving skills

(to deal with difficult environments and situations), and relapse-prevention/limitation skills. However, an additional factor identified among successful weight managers, and one not generally included in discussing weight-management techniques, is individual readiness, that is, strong personal motivation to succeed in weight management.

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