Evidence-Based Trends for Achieving Weight Loss and Increased Physical Activity: Applications for Diabetes Prevention and Treatment

Linda M. Delahanty, M S, RD

The prevalence of overweight and obesity in the United States has increased from 43% to 55% in the period between 1960–1962 and 1988–1994. Men and women in most racial/ethnic minority populations have a disproportionately higher prevalence of overweight and obesity and are also at greater risk of developing type 2 diabetes. The relative risk of developing diabetes increases by approximately 25% for each additional unit of body mass index (BMI) >22 kg/m², and it has been reported that 27% of new cases of diabetes are attributable to weight gains of 11 lb or more.

The fact that 25% of the U.S. population and 40% of people with type 2 diabetes had a BMI ≥30 kg/m² in 1988–1994 points to the magnitude of the problem of obesity, particularly as it relates to type 2 diabetes, and the importance of finding effective treatments. Obesity is not only a potent risk factor for developing diabetes, but it also complicates its pharmacological management. Because sedentary lifestyle affects the increasing prevalence of obesity and independently contributes to the risk of developing type 2 diabetes, effective strategies to increase physical activity are also important.

The prevalence of obesity-related comorbid conditions in individuals with type 2 diabetes and the increased mortality associated with obesity in type 2 diabetes make weight-loss research in this population a useful model for studying both weight-loss interventions and the health effects of weight loss. Weight loss and increased physical activity decrease insulin resistance, improve glucose tolerance and glycemic control, lower blood pressure, reduce risk of cardiovascular disease, and are particularly important for diabetes prevention and treatment. Current recommendations for weight loss and physical activity are to lose 5–10% of initial body weight and to accumulate at least 30 minutes of moderate physical activity over the course of most days of the week.

People with type 2 diabetes have experienced more difficulty losing weight than have their overweight spouses. However, a weight loss of as little as 10 lb or 5% of body weight has resulted in improved metabolic control. In addition, modest weight losses of at least 15 lb have been associated with significant improvements in glycemic control, fasting blood glucose, insulin levels, HDL cholesterol, and triglyceride levels at 1 year in people with type 2 diabetes, whereas those who gained weight had significant worsening of glycemic control.

Weight-Loss Strategies in Type 2 Diabetes Before 1994

A meta-analysis of 89 studies involving 1,800 subjects with type 2 dia-
Diabetes reviewed five different types of weight-loss strategies (diets, behavioral programs, exercise, anorectic drugs, and surgery) and combinations of these strategies and found that, aside from surgery, dietary strategies alone produced the greatest weight losses. The average weight loss with a diet-alone strategy was 20 lb, and the average decrease in glycated hemoglobin was 2.6 percentage points. However, most of the data analyzed were limited to 6 months post-intervention, and 72% of the studies used a pre-test/post-test design instead of an experimental design.

The main types of diet strategies analyzed were the very-low-calorie diet (VLCD), the protein-sparing modified fast (PSMF), a calorie-restricted diet based on the American Diabetes Association (ADA) exchange list system, and others. Although all diets showed a large improvement in fasting blood glucose levels, the exchange approach had the smallest impact on weight loss, and the PSMF had the largest impact. It is important to note, however, that the meta-analysis included only three studies on the calorie-restricted exchange-based diet and four studies on PSMF diets.

This meta-analysis reviewed the literature up to 1994. It revealed that, at that time, most of the diet research focusing on both weight and glycated hemoglobin outcomes used the VLCD, which may explain the large weight-loss effects seen in this diet category.

Exercise alone had little effect on weight or other diabetes-related outcomes in the short term. However, the analysis did not include longitudinal outcome data. Although the combination of diet, behavioral therapy, and exercise was associated with a small effect on weight, this combined strategy had a large positive and significant effect on glycated hemoglobin.

Since 1994, there has been an expansion in the variety of diet approaches used in the treatment of obesity and diabetes, and there has been substantially more research on the roles of diet and exercise in achieving long-term weight loss. A review of emerging evidence-based research on effective lifestyle treatments for overweight and obesity can inform us about future directions for research and clinical practice for the prevention and treatment of type 2 diabetes.

Evidence-Based Recommendations for Lifestyle Treatment of Overweight and Obesity

In 1998, evidence-based clinical guidelines were published on the most appropriate and effective treatments for overweight and obesity. These guidelines reviewed the research from 1980 to 1997 and found evidence to recommend the following practice guidelines.

1. Low-calorie diets can reduce body weight by an average of 8% over 3–12 months.
2. Although VLCDs produce greater initial weight loss than low-calorie diets, the long-term (>1 year) weight loss is not different than that associated with low-calorie diets.
3. Lower-fat diets without targeted calorie reduction help promote weight loss by producing a reduced calorie intake. However, low-fat diets coupled with total calorie reduction produce greater weight loss than do lower-fat diets alone.
4. Physical activity, i.e., aerobic exercise, in overweight obese adults results in modest weight loss independent of the effect of calorie reduction through diet.
5. The combination of a low-calorie diet and increased physical activity produces greater weight loss than do either diet or physical activity alone.
6. No single behavior therapy seems superior to any other in its effect on weight loss. Multimodal strategies seem to work best, and those interventions with the greatest intensity seem to be associated with the greatest weight loss.
7. Behavior therapy used in combination with other weight-loss approaches provides additional benefits in achieving weight loss in the short term (1 year), but not in 3–5 years without continued intervention.
8. Long-term follow-up of patients undergoing behavior therapy shows a return to baseline weight in the great majority of subjects in the absence of continual behavioral intervention.

Evidence-Based Research on Lifestyle Interventions for Diabetes Prevention

Since 1997, additional research has demonstrated the long-term effectiveness of weight loss and increased physical activity on diabetes prevention. The Malmo study had previously found that a weight loss of 2.3–3.7% over 6 years normalized glucose tolerance in >50% of subjects with impaired glucose tolerance (IGT) and resulted in remission in >50% of people with type 2 diabetes. The Da Qing IGT and Diabetes Study randomly assigned a large group of men and women by clinic to either a control group or one of three treatments—diet, exercise, or diet plus exercise. The results of this 6-year study showed that the diet, exercise, and diet-plus-exercise interventions were associated with 31, 46, and 42% reductions in the risk of developing diabetes, respectively.

The Finnish Diabetes Study focusing on prevention randomly assigned 522 overweight subjects to either a lifestyle intervention group or a control group. The intervention group received individual counseling aimed at achieving a weight loss of ≥5%, a reduction in total fat intake to <30% of calories, a reduction in saturated fat intake to <10% of calories, an increase in fiber intake to >15 g per 1,000 calories, and an increase in activity level to at least 30 minutes per day.

To accomplish these goals, each subject in the intervention group met with a nutritionist for seven sessions in the first year and for one session every 3 months thereafter. In addition, these subjects received supervised progressive individualized circuit-type resistance training and individual guidance on ways to improve aerobic capacity and cardiorespiratory fitness. After 1 year, 86% of subjects reported exercising more than 4 hours per week, and after 2 years, the intervention group had lost an average of 3.5 kg, and the control group had lost an average of 0.8 kg. These lifestyle changes reduced the risk of developing diabetes by 58% after a mean follow-up of 3.2 years.

The Diabetes Prevention Program (DPP) was a randomized, clinical trial comparing the safety and efficacy of intensive lifestyle change, metformin, and placebo in the prevention of type 2 diabetes in people with IGT. The DPP followed 3,234 ethnically diverse participants at high risk for diabetes from 27 centers (45% were minorities). Subjects randomly assigned to the lifestyle intervention had goals of losing at least 7% of their body weight and increasing activity to at least 150 minutes per week over 3–6 years. The intensive-lifestyle participants achieved a mean weight loss...
One of the most successful DPP exercise campaigns involved the use of pedometers to increase motivation and adherence and challenged participants to strive to reach 10,000 steps a day. This strategy could be easily incorporated into clinical practice settings at a low cost.

The American College of Sports Medicine Position Stand suggests that physical activity is underutilized in the management of type 2 diabetes and recommends the following strategies to improve physical activity levels: 1) ensure appropriate exercise and equipment to avoid injury; 2) set specific, realistic step-wise goals for which success and progress can be monitored; 3) set an exercise schedule in advance and stick to it; 4) consider getting an exercise partner; 5) encourage self-rewards for reaching exercise goals; 6) identify alternate exercise activities to reduce boredom; and 7) help patients understand the difference between failure and setback. The methods and results of the diabetes prevention studies described above suggest that these strategies are the critical action steps that need to be integrated into clinical practice for the prevention and treatment of type 2 diabetes.

Medical Nutrition Therapy Guideline for Type 2 Diabetes

The clinical practice guidelines for medical nutrition therapy (MNT) for people with type 2 diabetes outline goals and desired outcomes for glycemic control, lipids, blood pressure, weight change, exercise, and diet in the short (4–6 weeks after MNT) and long term. The desired outcomes for weight loss are 1.5–3 kg (3–6 lb) in the first 4–6 weeks and 4.5–9 kg (10–20 lb) in the long term.

The MNT process involves selecting an appropriate meal-planning approach and educational materials based on an individual assessment of a person’s ability or willingness to learn, motivation to make changes in eating habits, clinical and nutrition goals, diabetes medications, activity level, and lifestyle. The selection of a meal-planning approach considers type of diabetes, literacy, and the degree of emphasis desired on weight loss, metabolic control, structure, and complexity.

### Table 1. Expanded Meal-Planning Approaches for Weight Loss in Type 2 Diabetes

<table>
<thead>
<tr>
<th>Approach</th>
<th>Examples</th>
<th>Weight-Loss Emphasis</th>
</tr>
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</table>
| **Guidelines**    | • Healthy Food Choices (guidelines section)  
                   • The First Step in Diabetes Meal Planning  
                   • Individualized goal-setting       | Moderate             |
| **Meal-Planning**| 1. Menus                           |                      |
|                   | • Individualized menus             | Moderate-High        |
|                   | • Month of Meals books             | Moderate             |
|                   | 2. Exchanges                       |                      |
|                   | • Healthy Food Choices (poster section)  
                   • Exchange Lists for Meal Planning | Moderate-High        |
|                   | 3. Counting                        |                      |
|                   | • Calorie counting                 | High                 |
|                   | • Fat-gram counting                | High                 |
|                   | • Fat-gram/calorie counting        | High                 |
|                   | 4. Meal Replacements               |                      |
|                   | • Formula drinks or bars           | High                 |
|                   | • Prepackaged meals                | High                 |
| **Lifestyle-Change**| • Facilitating Lifestyle Change: A Resource Manual  
                   • The Complete Weight Loss Workbook  
                   • The Learn Program for Weight Control | High                 |

Adapted from Ref. 20.

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Green Pastors\textsuperscript{20} describes three categories of meal-planning approaches—guidelines, lifestyle-change, and meal-planning (Table 1). Within these categories, the types of meal-planning approaches can have a low, moderate, or high emphasis on weight loss.

The two guidelines approaches she describes as having at least a moderate degree of emphasis on weight loss are Healthy Food Choices (guidelines section) and The First Step in Diabetes Meal Planning. Healthy Food Choices focuses on the importance of portion control and provides suggestions for making lower-fat and higher-fiber food choices, all of which could help with weight loss. The First Step in Diabetes Meal Planning is a modified food guide pyramid that lists suggested number of servings from each of six food categories—grains/beans/starchy vegetables; vegetables; fruits; milk; meat and others; and fats/sweets/alcohol—and provides tips for lower-fat, higher-fiber food choices within each category.\textsuperscript{20}

Individualized goal-setting is another approach that can have a moderate emphasis on weight loss. This strategy focuses on identifying three to five specific goals for exercise or dietary change based on an assessment of a person’s usual eating habits and lifestyle. Individualized goal-setting is commonly used by practitioners as a stepped approach to reducing fat and calorie intake, improving activity, and promoting weight loss, particularly for those with established eating habits, fragile motivation, or in need of a simplified approach.

Green Pastors described one type of lifestyle-change approach with a high emphasis on weight loss for people with diabetes: Facilitating Lifestyle Change: A Resource Manual.\textsuperscript{20,21} This manual focuses on using self-monitoring, problem-solving, and goal-setting to promote lifestyle change and improve eating habits and activity level. Other types of manuals that use the lifestyle-change approach are The Complete Weight Loss Workbook\textsuperscript{22} and The Learn Program for Weight Control,\textsuperscript{23} both of which have been used in weight reduction programs to achieve successful weight outcomes.\textsuperscript{24,25}

Meal-planning approaches have traditionally included menus, such as individualized menus or Month of Meals, exchange lists, and counting methods, each of which can have an emphasis on weight loss. Individualized menus are based on a person’s food preferences and treatment goals and specify the portions and types of foods to be consumed at meals and snacks. The five Month of Meals books each contain 28 days of complete menus for breakfast, lunch, dinner, and snacks providing 1,200, 1,500, or 1,800 calories per day.

Exchange lists includes the Exchange Lists for Meal Planning, which divides foods into three food groups—carbohydrate, meat and meat substitutes, and fat—and can be used as a basis for teaching the calorie and fat content of foods. This category also includes a simplified exchange list approach, from Healthy Food Choices.\textsuperscript{20}

Counting methods include calorie counting, fat-gram counting, or a combination fat-gram and calorie counting. These approaches teach flexibility and control over food choices but do not guarantee carbohydrate consistency.

Another type of meal-planning approach that should be considered and added to the meal-planning options is the meal-replacement approach. This involves using formula shakes or bars or prepackaged meals to control portions and simplify food decisions. Typically, formula drinks or bars are used to replace two meals and one snack per day to achieve weight loss and to replace one meal per day for weight maintenance. The relative effectiveness of each of the different meal-planning approaches that can be used to achieve a low-calorie diet has not been adequately studied. However, since 1997, evidence has been accumulating regarding the role of meal replacements as a viable meal-planning approach for the treatment of obesity. Typically, dietitians and other health care practitioners have felt somewhat uncomfortable with this approach to weight loss. However, a review of recent evidence\textsuperscript{25–32} now requires a reassessment of the effectiveness and appropriateness of meal replacement as a strategy for weight reduction in the prevention and treatment type 2 diabetes.

Evidence-Based Research on Meal Replacements

Table 2 summarizes some of the more recent research on the effectiveness of the meal-replacement approach. The studies by Rothacker and associates\textsuperscript{26,27} and others\textsuperscript{28,29} demonstrate that using meal replacement formula drinks can promote effective weight loss for periods as long as 4–5 years. The studies by M etz and Pi-Sunyer\textsuperscript{30–32} used prepackaged meals for periods of time from 10 weeks up to 1 year.

Two of the three studies using prepackaged meals analyzed results for patients with type 2 diabetes. After 1 year of using prepared meal plans, patients with type 2 diabetes had greater weight losses; better improvements in glucose, glycated hemoglobin levels, and quality of life; and better adherence to diet recommendations.\textsuperscript{32}

Most of the meal-replacement studies involved very little nutrition counseling or follow-up provided to the groups receiving the alternate meal-planning approach. Since the alternate approaches typically require more education and skills, the true effectiveness of these approaches may have been underestimated. However, the study by Ashley et al.,\textsuperscript{25} which evaluated the use of meal-replacement formula drinks, did adequately represent the alternate meal-planning approaches and found that the integration of meal replacements into a dietitian-led group behavioral weight-loss program significantly improved weight-loss outcomes.

Although most of the studies using meal-replacement formula drinks were not done on patients with type 2 diabetes, more recent studies have focused on the application of this approach to people with type 2 diabetes. Yip et al.,\textsuperscript{33} randomly assigned 75 patients with type 2 diabetes treated only with oral agents to one of three treatment groups: a calorie-restricted, exchange-based diet; two meal replacements per day (Ultra SlimFast) with a portion-controlled meal; or two meal replacements per day (Sugar-Free Ultra SlimFast) with a portion-controlled meal.

After 12 weeks, the meal-replacement groups lost more weight and had significantly lower fasting glucose levels than the exchange-diet group. Insulin, total cholesterol, LDL cholesterol, and hemoglobin A1c levels were reduced in both groups, and there were no adverse side effects reported. This demonstrated the safety and efficacy of these meal replacements in patients with type 2 diabetes.

Another study\textsuperscript{34} compared SlimFast (220 calories, 33 g carbohydrate, 5 g dietary fiber, 14 g protein, and 3 g fat) to a standard breakfast (376 calories, 59 g carbohydrate, 7.3 g dietary fiber, 22.5 g protein, and 8.4 g fat) by measuring insulin and glycemic responses.
## Table 2. Effectiveness of Meal Replacement as a Meal-Planning Approach for Weight Loss

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Design</th>
<th>Treatment</th>
<th>Duration</th>
<th>Weight Outcome (M R)</th>
<th>Weight Outcome (Control)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rothacker et al.26</td>
<td>75 women</td>
<td>RCT</td>
<td>1,200-calorie low-fat diet with sample menus and exchange lists vs. 1–3 M Rs per day supplemented with fruits and vegetables</td>
<td>12 weeks and 1 year</td>
<td>-6.3 kg</td>
<td>-3.8 kg</td>
<td>Literature on the diets was given, but no counseling was provided.</td>
</tr>
<tr>
<td>Rothacker et al.27</td>
<td>108 women, 50 men</td>
<td>Matched controls</td>
<td>2 M Rs per day for 3 months, 1–2 M Rs per day until weight goal achieved, then either 1 M R per day or daily weight check to maintain weight</td>
<td>5 years</td>
<td>-4.2 kg</td>
<td>-6.5 kg</td>
<td>M R given free and if weight regain of &gt;1–2 kg, resume 2 M Rs per day.</td>
</tr>
<tr>
<td>Ditshunet28</td>
<td>79 women, 21 men</td>
<td>RCT for phase 1 only</td>
<td>1,200–1,500 calories per day using personalized sample menus, food exchange lists, recipes, and food diaries with follow-up monthly versus similar self-selected diet except that 2 of 3 main meals and 2 snacks were replaced with M Rs</td>
<td>3 months</td>
<td>-7.8%</td>
<td>-1.5%</td>
<td>No attrition</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Phase 2 single-arm intervention</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>All subjects seen monthly; all replaced 1 meal and 1 snack with M R daily</td>
<td></td>
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</tr>
<tr>
<td>Flechtner-Mors29</td>
<td>60 women, 15 men</td>
<td>Single-arm intervention, Follow-up to phase 1 and 2 above</td>
<td>1,200–1,500 calories with 1 meal and 1 snack per day replaced with M R</td>
<td>4 years</td>
<td>-8.4%</td>
<td>-3.2%</td>
<td>75% of the original cohort participated.</td>
</tr>
<tr>
<td>Ashley25</td>
<td>113 women</td>
<td>RCT</td>
<td>Dietitian-led group (26 1-h sessions using The Learn Program for Weight Control and 1,200 calories per day) versus same dietitian-led group using 2 M Rs per day versus doctor/nurse office visits using 1,200 calories, The Learn Program for Weight Control, and 2 M Rs per day (26 10- to 15-minutes sessions)</td>
<td>1 year</td>
<td>-9.1% (dietitian)</td>
<td>-4.1%</td>
<td>65% of original group completed 1 year.</td>
</tr>
<tr>
<td>Metz20</td>
<td>314 women, 246 men</td>
<td>RCT</td>
<td>Exchange-based self-selected diet versus nutrient-fortified prepackaged meal plan</td>
<td>10 weeks</td>
<td>-4.8 kg</td>
<td>-2.8 kg</td>
<td>Nutrition counseling only at week 0 and week 2.</td>
</tr>
<tr>
<td>Pi-Sunyer31</td>
<td>102 women, 100 men with type 2 diabetes</td>
<td>RCT</td>
<td>Exchange-based self-selected diet, sample menus, and recipes versus nutrient-fortified prepackaged meal plan</td>
<td>10 weeks</td>
<td>-3.4 kg</td>
<td>-2.9 kg</td>
<td>Nutrition counseling only at week 0 and week 2.</td>
</tr>
<tr>
<td>Metz32</td>
<td>302 adults with hypertension and dyslipidemia, 119 adults with type 2 diabetes</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>RCT</td>
<td>Exchange-based self-selected diet versus prepackaged meal plan</td>
<td>1 year</td>
<td>-5.8 kg</td>
<td>-1.7 kg</td>
<td>The frequency of nutrition counseling for each group is unclear.</td>
</tr>
</tbody>
</table>

M R, meal replacement; RCT, randomized controlled trial
and calculating the area under the curve. Although the carbohydrate content of the two meals was not similar, there was no exaggerated post-prandial hyperglycemia with SlimFast when compared with the mixed meal.

There now seems to be substantial evidence of improved short-term and long-term weight loss with meal replacements in the treatment of obesity. Moreover, recent research has demonstrated the safety and efficacy of using meal replacements in people with type 2 diabetes to achieve weight loss and improved glycemic control. It is now time for dietitians and diabetes educators to also consider some of the clinical benefits of using meal replacements as a potential strategy for patients who have type 2 diabetes and want to lose weight.

Many patients with type 2 diabetes have already tried more traditional weight-loss approaches and meal-planning strategies without success. The faster weight-loss results and the more significant lowering of fasting blood glucose levels that can result from using meal replacements may inspire and encourage some of these patients who have experienced repeated failure with other approaches.

Indeed, some patients may do better if they have fewer food decisions to make and less variety from which to choose. Meal replacements can simplify the tasks of portion control, food selection, and meal preparation while achieving the goal of reducing calories for weight loss. The cost and convenience features of meal replacements may also be appealing to some, especially those who eat on the run and do not have time to plan ahead or cook low-fat, low-calorie meals.

Certainly meal replacements are not for everyone, as evidenced by the attrition levels reported in some of the research studies. However, those who continue to participate in studies using meal replacements give these products high taste and satiety ratings. In fact, Rolls’ review of factors underlying food selection suggests that satiety is relatively specific to the particular foods consumed and that more is eaten during a meal containing a variety of foods than during a meal of just one food. More recently, McCrory et al. found that dietary variety was associated with increased calorie intake within every food group and that high dietary variety of sweets, snacks, condiments, entrees, and carbohydrates coupled with low variety of vegetables was associated with body fatness.

Wing et al. have studied the various components of food provision to try to determine whether the benefits of food provision are due to the fact that the food is provided free, that it is given to subjects (reducing the barriers associated with shopping for and preparing foods in appropriate portions), or that it shows people exactly what to eat for each meal. Subjects were randomly assigned to receive one of four treatment groups: a standard behavioral treatment program (Group 1); a behavioral program supplemented with either specific meal plans and grocery lists (Group 2); a behavioral program supplemented with food provision on a cost-sharing basis (Group 3); or a behavioral program supplemented with free food provision (Group 4).

After the 6-month program, all treatment contact and food provision was stopped. The groups who received the structured advice about what to eat (whether through meal plans and grocery lists or with food provision) all lost more weight than the group who received the standard behavioral treatment program both at 6-month and 1-year follow-ups. No extra weight-loss benefit was seen by actually giving food to participants.

These studies on food variety and provision suggest that providing patients with examples of what they should eat, either by providing the actual food or by providing specific meal plans, and limiting the food choices (variety) have advantages in producing weight-loss results. For these reasons, we need to consider the use of meal replacements as an effective option in the repertoire of meal-planning approaches to help patients as they try to lose weight to prevent or treat type 2 diabetes.

Look Ahead (Action for Health in Diabetes) is a new multi-center research study designed to evaluate the long-term health effects of weight loss in 5,000 overweight people with type 2 diabetes. Half of the participants will receive a program of group support and education, and half will receive a long-term lifestyle change program aimed at achieving a 10% weight loss and a minimum of 175 minutes of activity per week. Based on an evidence-based review of the literature, the weight-loss intervention will include the use of meal replacements in the hopes that people in this part of the study will have greater success with weight loss and weight maintenance. The experience of using meal replacement as a primary intervention strategy will further expand our knowledge and insights about the efficacy of this approach for patients who have type 2 diabetes and want to achieve long-term weight loss and its health benefits.

References


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Linda M. Delahanty, M.S., R.D., is a clinical nutrition specialist and research dietitian at Massachusetts General Hospital in Boston.