

Fifty Years of Behavioral/Lifestyle Interventions for Overweight and Obesity: Where Have We Been and Where Are We Going?

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Objective: This paper reviews the literature pertaining to the structure and content of intensive lifestyle interventions (ILIs) for overweight/obesity since Richard Stuart described this new treatment approach in 1967. A consensus opinion has formed that behavioral/lifestyle treatment of overweight and obesity should be viewed as a mainstream intervention for the treatment and prevention of type 2 diabetes and medical complications associated with obesity.

Methods: The development of modern ILIs and demonstration of their efficacy are compared by structure, content, and efficacy of four major randomized controlled trials: Diabetes Prevention Program (DPP), Look AHEAD, POUNDS Lost, and CALERIE.

Results: The results of these studies indicated that modification of lifestyle behaviors related to nutrition and physical activity can yield weight loss and prevention or improvement of a variety of medical conditions associated with obesity in a variety of subpopulations.

Conclusions: Recommendations for the structure and length of behavioral/lifestyle interventions have been recently adopted by agencies and institutions that approve reimbursement for medical services. These recommendations represent a giant step in the effort to recognize ILIs as a mainstream approach for the treatment of obesity and comorbid medical conditions. Nevertheless, they do not adequately represent advances made since the publication of the DPP results.

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Introduction

In 1967, Richard Stuart (1) published the first paper to describe the behavioral treatment of overeating, presenting the weight loss results of eight patients with obesity treated during a 12-month period. Four years later (2), he described a “three-dimensional program” of behavioral treatment for obesity with many of the components of modern lifestyle interventions: (1) environmental interventions to strengthen healthy eating and decrease sedentary behavior, (2) structured exercise programs to increase physical activity, and (3) dietary programs to decrease caloric intake. The behavioral intervention was delivered using individual counseling with 16 to 41 sessions over a 12-month period (1). Weight loss was described as being continuous over 12 months, averaging between 0.60 and 0.70 pounds per week (1,2), resulting in average 12-month weight losses between 35 and 40 pounds. Most contemporary professionals were pessimistic about the successful treatment of obesity (2). In the past 50 years, behavioral/lifestyle treatment for obesity has been intensely studied (3) and has gone through many iterations. There were early concerns that weight loss effects were too short-lived (4). Nevertheless, clinical research on this approach has continued. This paper describes

the evolution of this research, starting with a discussion about how obesity came to be regarded as a medical problem.

Where Have We Been?

How obesity became recognized as a medical problem

For much of human history, many people were lean or underweight. Nevertheless, the presence of excess adiposity, even in ancient civilizations, has been well documented (5). By the 18th century, being overweight, or “corpulent,” was associated with health and high social standing, though medical consequences of obesity were recognized (5). During the 20th century, the abundance of food was such that most people could finally achieve a “normal” weight, though stigma was attached to having obesity (6). Obesity was viewed as a cosmetic problem associated with gluttony, laziness, and low self-discipline (7). By 1940, scientists began to note the relationships between obesity, type 2 diabetes, and a variety of cardiovascular disease (CVD) risk factors (8). In 1988, Gerald M. Reaven (9) formally hypothesized a Syndrome X that linked insulin resistance (a feature

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of type 2 diabetes) with a range of medical conditions. Syndrome X became known as the metabolic syndrome (10), which was strongly associated with the presence of overweight and obesity (11). By 2000, most scientists and clinicians had concluded that obesity was best regarded as a medical problem as opposed to a cosmetic problem (7). Also, the human race reached a landmark: more than half of the population had overweight or obesity (12,13). This phenomenon has been called the global epidemic of obesity (14). This paper summarizes the evolution of one approach for the treatment of obesity and related problems: intensive lifestyle intervention (ILI).

Evolution of behavioral/lifestyle interventions for obesity-related medical problems

In 1980, Albert Stunkard (15) published one of the first modern texts on obesity. A variety of treatments were described: diets, exercise, drugs, psychoanalysis, self-help, gastric bypass, and behavior modification. Stunkard described behavior modification as a “treatment modality that has aroused much initial enthusiasm” (15). In 1972, Stuart and Davis published the first treatment guide for intensive lifestyle modification for weight management (16). Over the next 25 years, more than 70 randomized controlled trials (RCTs) were published that validated this approach as effective for weight management, and the length of treatment increased from ~8 weeks in the 1970s to more than 20 weeks (17). The initial descriptions of behavioral treatment of obesity (1) used an individual therapy format, but by the mid-1990s, most ILIs utilized group therapy to deliver the intervention. Most experts concluded that at least 2 years of ILI was needed to prevent weight regain (3). The health benefits of weight loss had been established, and the National Institutes of Health (NIH) initiated a series of large-scale, multisite RCTs that investigated the efficacy of lifestyle interventions for weight loss and prevention of obesity-related problems.

The process of refining and maximizing the effectiveness of lifestyle interventions began with the design and implementation of the Diabetes Prevention Program (DPP) in 1994. The next section summarizes the evolution and effectiveness of ILIs over the past 2 decades, based on four important studies (DPP, Look AHEAD [Action for Health in Diabetes], POUNDS Lost [Preventing Obesity Using Novel Dietary Strategies], CALERIE [Comprehensive Assessment of Long term Effects of Reducing Intake of Energy]) that investigated the effect of ILIs on weight changes and health outcomes. While there are many other studies that could be highlighted, these four studies developed ILIs that built upon each other. For example, the ILI design of Look AHEAD was based primarily on the lifestyle intervention tested in the DPP study (18). The ILIs of the POUNDS Lost and CALERIE studies were designed using the content and structure of the Look AHEAD and DPP interventions (19). Table 1 describes the designs, participant characteristics, and outcomes of these four studies.

DPP. The methods of DPP (20) were first reported in 1999 and the primary results were published in 2002 (21). A description of DPP’s ILI was provided in 2002 (22). DPP found that modest (~7%) average reductions of body weight that were sustained (~5%) for 3.2 years could significantly delay the onset of type 2 diabetes in adults who were at high risk for developing diabetes, now called prediabetes (21). After completion of the initial DPP trial, the DPP Observation Study was initiated, and participants were followed for 10 years. Over the course of those 10 years, the participants in the original ILI gradually regained weight that had been lost. Their final average weight

loss was ~2% below baseline, however. An important finding was that in the initial ILI group, the onset of type 2 diabetes was significantly delayed in comparison to the original placebo group (23), and CVD risk factors were significantly improved (24). Thus, the DPP study found that prevention of diabetes and improvement of CVD risk factors with ILI can persist for 10 years. The cost of the ILI was \$1,826 during the first year and averaged \$305 each year afterward (25). The ILI was also found to be cost-effective in comparison to placebo medication after 10 years of follow-up (25,26).

Look AHEAD. Planning for Look AHEAD began in the early 2000s. A description of the Look AHEAD ILI was published in 2006 (18), and a series of papers were published during the next 8 years, with the 8-year weight loss outcomes reported in 2014 (27). The study recruited adults with overweight and obesity who had been diagnosed with type 2 diabetes. In comparison to a control group, the primary findings of Look AHEAD (28) were as follows: (1) ILI resulted in significantly greater weight loss after 1 year (~9%) and after 8 years (~5%) of long-term treatment; (2) weight changes were associated with a wide variety of improved health indicators, ranging from improved CVD risk factors to improved quality of life, but did not reduce the incidence of CVD events such as heart attacks and stroke; (3) improvement of health indicators was sustained for 8 years; and (4) overall medical costs of the ILI arm were significantly lower. During the first year, the ILI cost was \$2,865, and it averaged \$1,120 during years 5 to 9 (29). Average weight loss was robust, with equal success over a variety of subgroups.

POUNDS Lost. Planning for POUNDS Lost began in the mid-2000s, and the primary outcome paper was published in 2009 (30). This RCT compared four macronutrient diet prescriptions for weight loss, differing in terms of the percentages of carbohydrates, proteins, and fats that were prescribed using diets with four different macronutrient compositions. The same ILI was used in all four treatment arms. The study included medically healthy adults with overweight and obesity. The study duration was 2 years, and no differences in weight changes were observed across the four diets. All four macronutrient diets required caloric restriction and were associated with ~8% weight loss after 1 year and ~6% weight loss after 2 years. Improvement of CVD risk factors was observed after 2 years of ILI. Early adherence, e.g., attendance and self-monitoring, was significantly associated with short-term and long-term weight loss (31).

CALERIE. The CALERIE study was a multisite RCT that compared caloric restriction to a control group over 2 years (32). The study began in 2007 and included healthy adults who had either normal weight or overweight (BMI 22-28). A description of the intensive lifestyle intervention of CALERIE was published in 2011 (19). In comparison to a control group, primary outcomes (33) were as follows: (1) ILI resulted in significantly greater average weight loss after 1 year (~11%), which was sustained (~10%) after 2 years; (2) improvement of health indicators (CVD risk factors, quality of life, metabolic measures) was observed for ILI; and (3) some biomarkers for aging were improved.

Summary. Over the past 2 decades, the methodology for delivering highly effective ILIs for overweight and obesity in adults has advanced, exemplified by the four multisite, NIH-sponsored clinical trials highlighted in this section. Several important conclusions regarding ILIs are warranted from the findings of these four studies:

TABLE 1 Designs, participant characteristics, and outcomes of DPP, Look AHEAD, POUNDS Lost, and CALERIE

	DPP	Look AHEAD	POUNDS Lost	CALERIE
<i>Study description</i>				
Number of participants	3,819	5,145	811	218
Number of clinics	27	16	2	3
Number of Tx arms	3	2	4	2
Intervention types	Lifestyle, metformin, placebo	Lifestyle, diabetes support and education (control)	Hi prot/L fat, Hi prot/A fat, Lo prot/L fat, Lo prot/A fat	Calorie restriction, <i>Ad lib</i> (control)
BMI mean (M) and lowest BMI (L)	M = 34 L = 25	M = 36 L = 25	M = 33 L = 25	M = 25 L = 22
Age mean (M) and age range (R)	M = 50 y R = 25-74 y	M = 59 y R = 45-74 y	M = 51 y R = 30-70 y	M = 39 y R = 21-50
% Males (M) and females (F)	M = 32% F = 68%	M = 41% F = 59%	M = 36% F = 64%	M = 30% F = 70%
Pre-Tx screening for psychological problems	Yes	Yes	Yes	Yes
Pre-Tx screening for barriers	Yes	Yes	Yes	Yes
Completion of 2-3 wk baseline self-monitoring	Yes	Yes	Yes	Yes
<i>Inclusion/exclusion criteria</i>				
Medical condition: inclusion	Pre-diabetes	Type 2 diabetes	None	None
Medical condition: exclusion	Type 2 diabetes; CVD; cancer; renal disease; pulmonary disease; chronic infection	Recent CVD; cancer; renal disease; pulmonary disease; chronic infection	Diabetes; CVD	Diabetes, CVD, cancer
<i>Outcomes</i>				
Weight loss: 6 mo/(% ≥ 5%)	WL = 7%; % ≥ 5% = Un	WL = Un; % ≥ 5% = Un	WL = 7%; % ≥ 5% = Un	WL = 10%; % ≥ 5% = 91%
Weight loss: 1 y/(% ≥ 5%)	WL = 7%; % ≥ 5% = 60%	WL = 9%; % ≥ 5% = 68%	WL = 7%; % ≥ 5% = Un	WL = 12%; % ≥ 5% = 94%
Weight loss: 2 y/(% ≥ 5%)	WL = 5%; % ≥ 5% = Un	WL = 6%; % ≥ 5% = 47%	WL = 4%; % ≥ 5% = 31%-37%	WL = 11%; % ≥ 5% = 91%
Weight loss: 8 y/(% ≥ 5%)	WL = N/A	WL = 5%; % ≥ 5% = 50%	WL = N/A; % ≥ 5% = N/A	WL = N/A; % ≥ 5% = N/A
Improved metabolic outcomes	Yes	Yes	Yes	Yes
Improved CVD risk factors	Yes	Yes	Yes	Yes
Improved QOL	Yes	Yes	Un	Yes

All outcome data, with the exception of data related to POUNDS Lost, pertain to comparisons with a control arm. All comparisons were statistically significant, $P < 0.05$. All data pertaining to changes in weight or improved health reflect within-group changes from baseline that were statistically significant, $P < 0.05$. Effect sizes for these statistically significant differences ranged from small (Cohen's $d > 0.20$) to large (Cohen's $d > 0.80$).
DPP, Diabetes Prevention Program; Look AHEAD, Action for Health in Diabetes; POUNDS Lost, Preventing Obesity Using Novel Dietary Strategies; CALERIE, Comprehensive Assessment of Long term Effects of Reducing Intake of Energy; Tx, treatment; L, low; A, average, prot, protein; WL, average weight loss; % ≥ 5%, percent subjects who lost ≥ 5% weight; Un, unavailable; QOL, quality of life; CVD, cardiovascular disease.

TABLE 2 Key ILI components used in four studies: DPP, Look AHEAD, POUNDS Lost, and CALERIE

Component	DPP	Look AHEAD	POUNDS Lost	CALERIE
Emphasis	Individual	Group	Group	Individual
Group counseling	No	Yes	Yes	Yes
Individual counseling	Yes	Yes	Yes	Yes
Used DPP core	Yes	Yes	Yes	Yes
Diet prescription	CR + reduced FI	CR	CR	CR
Exercise goal	150 min/wk	175 min/wk	90 min/wk	N/A
Weight loss goal	7%	10%	N/A	Individualized
Core ILI duration	24 weeks	1 year	2 years	2 years
Follow-up duration	10 years	8 years	2 years	2 years
Use of MR	No	Yes	No	Yes
Use of toolbox	Yes	Yes	Yes	Yes
Use of CTS	Yes	Yes	Yes	Yes
Weight loss math models	No	No	No	Yes
C/RG during FU	Yes	Yes	No	No
Y1 # indiv sess	24	12	6	20
Y1 # group sess	0	30	30	16
Y1 # total sess	24	42	36	36
Y2 # indiv sess	0	12	6	12
Y2 # group sess	16-24	12-18	12	12
Y2 # total sess	16-24	24-30	18	24
Y3 + # indiv sess	0	12	N/A	N/A
Y3 + # group sess	16-24	8-18	N/A	N/A
Y3 + # total sess	16-24	20-30	N/A	N/A

DPP, Diabetes Prevention Program; Look AHEAD, Action for Health in Diabetes; POUNDS Lost, Preventing Obesity Using Novel Dietary Strategies; CALERIE, Comprehensive Assessment of Long term Effects of Reducing Intake of Energy; indiv, individual; MR, meal replacement; CR, caloric restriction; FI, fat intake; C/RG, campaign/ refresher groups, FU, follow-up, sess, session; Y3+, year 3 and beyond; CTS, computer tracking system; ILI, intensive lifestyle intervention.

(1) Modest but clinically meaningful weight loss and improved health can be achieved; (2) the types of adults who were responsive were very diverse; (3) weight losses and health improvements were sustained for 2 to 8 years after beginning the initial ILI; (4) variability of results (% achieving 5% weight loss; Table 1) was observed across studies; (5) no significant adverse effects were reported, even in adults without obesity; and (6) initial costs of clinic-based ILI exceeded \$1,000 per year, though these cost estimates may be higher than those of most ILIs (34).

Evolution of ILI components: DPP, Look AHEAD, POUNDS Lost, and CALERIE

Table 2 summarizes some of the components of the ILIs tested in the four studies. The ILI of the DPP study established the essential elements of studies that followed. As illustrated in Table 2, the studies following DPP introduced additional components to the intervention.

Duration of core ILI. One difference across the studies is that the number of sessions and the overall duration of the core ILI curriculum systematically increased over time.

Group versus individual counseling. The initial study of a behavioral/lifestyle intervention for obesity (1) utilized individual counseling. Over the next 30 years, studies used group counseling more often (17). By the initiation of DPP, some ILIs used only

individual counseling, some only group counseling, and occasionally some used both. Two of the ILIs summarized in Table 2 emphasized individual counseling, and the other two emphasized group counseling to deliver the core curriculum. The DPP's ILI exclusively used individual counseling (during the first 6 months), and the other three studies used a combination of individual and group counseling, with ratios ranging from two group sessions and two individual sessions per month (CALERIE) to seven group sessions and one individual session every 2 months (POUNDS Lost).

Diet and exercise goals/prescriptions. A strategy that was consistent across the four studies was a diet prescription that restricted caloric intake below baseline caloric intake (usually by about 500-750 kcal). The DPP study also prescribed strategies to reduce fat intake. Prescriptions for physical activity have generally been expressed as minutes of exercise above routine activity. As shown in Table 2, the exercise prescription varied considerably across the four studies (90-175 min/wk), including no exercise prescription in the CALERIE study.

Duration of the ILI. As shown in Table 2, the trend toward increasing length of ILI treatment (17) persisted into the 21st century, ranging from 24 weeks for the core DPP ILI and 2 years for the ILIs of the POUNDS Lost and CALERIE studies.

Use of meal replacements. In recent years, ILIs have tended to use meal replacements or provision of prepared foods to facilitate adherence to a calorically restricted diet. Two of the four studies, Look AHEAD and CALERIE, used meal replacements. In Look AHEAD, a meal replacement program was encouraged for much of the first 5 months; after that, meal replacements were used to assist participants who were having difficulty following the prescribed diet. In CALERIE, specially prepared foods were provided for the first 4 weeks. After that, prepared foods or meal replacements were provided for those who struggled to maintain a 25% calorically restricted diet.

Toolbox strategies. All four ILIs employed strategies to individualize the intervention to address specific lifestyle problems that were encountered by participants (19,35).

Computer tracking system (CTS). In the past 2 decades, computer technology has rapidly advanced. All four of these studies utilized some form of CTS to monitor progress and/or adherence. As might be expected, the sophistication of this computer technology improved over the course of these four studies (19,36). Methodology for using CTS data to define adherence to an ILI has also been described (37).

Mathematical models of weight loss. Most modern ILIs have monitored changes in body weight over time to evaluate progress toward weight loss (18,22). Several investigators, e.g., Pieper et al. (38) and Thomas et al. (39), have developed mathematical models of weight loss over time that can be applied to individuals who differ in sex, height, and weight during 2 years of treatment. By comparing actual weight loss to the weight loss predicted by these models (19), the counselor can evaluate whether weight loss is progressing as expected versus being too slow or too fast. Toolbox strategies can be applied to address deviation from expected weight loss trajectories. Of the four studies, only the CALERIE study employed this strategy.

Use of campaigns/refresher groups during follow-up. Individual and group counseling can be used during follow-up, but this strategy is expensive and time consuming. Another approach is to develop “open” groups that can be attended by anyone who has completed year 1. Two studies, DPP and Look AHEAD, used this approach and coined the terms “campaigns” and “refresher groups” (18,20). These special open groups were limited to approximately 4 to 8 weeks and focused on specific themes, e.g., resistance training or nighttime eating/snacking. These special groups were conducted two to three times per year and were used as one component of weight maintenance strategies. In contrast, the POUNDS Lost and CALERIE studies continued individual and group counseling sessions during year 2 and did not use campaigns or refresher groups.

Total number of individual and group counseling sessions. For the DPP ILI, it was common to schedule at least 15 individual or group sessions within the first 6 months of the intervention, with a tapering of total sessions over the next 6 months to several years. Examination of the lower sections of Table 1 illustrates how this strategy was employed in each of the four studies. Each of the ILIs following the DPP study utilized more scheduled sessions and included a combination of group and individual counseling.

Summary. Tables 1 and 2 illustrate that from DPP to CALERIE, there was a trend toward increased intensity of the intervention that was accompanied by increased efficacy, as indicated by improved average weight loss. Over the 15 years summarized in Tables 1 and 2, ILIs became more sophisticated, e.g., by using computer technology to track behavioral and weight changes and to provide feedback about adherence. Thus, by 2010, the efficacy of clinic-based ILIs had been established; but they were costly, inconvenient, and not sustainable as a public health initiative (40–42).

Relationship of adherence to ILI components and weight loss

One of the key features of behavioral/lifestyle intervention for obesity is the inclusion of interrelated sessions that are designed to maximize adherence to the components of the program. Enhanced adherence has been found to increase weight loss and health benefits. In the Look AHEAD trial, three behavioral factors were associated with greater weight loss during year 1: (1) session attendance, (2) minutes of self-reported physical activity, and (3) number of meal replacements consumed (35). In the POUNDS Lost study, indicators of adherence during the first 6 months of the ILI were highly correlated (37) and significantly predicted weight loss at 6 and 24 months (31). In a meta-analysis of community-based DPP interventions, Ali et al. (43) reported a strong ($r = 0.90$) correlation between program attendance and weight loss. Thus, attendance to sessions has been a consistent and strong predictor of weight loss. To put this into context, the Look AHEAD study reported attendance to sessions in year 1 to be 84% (35), which translates to approximately 27 sessions attended on average during the first year. The CALERIE study had very high attendance during year 1, with 99% attendance to individual sessions (average = 26 sessions) and 81% attendance to group sessions (average = 18 sessions). Thus, in the CALERIE study, attendance to sessions during the first year averaged 44 sessions.

Where Are We Going?

Recent recommendations about the structure of effective intensive lifestyle interventions

Since the original Stuart paper (1), hundreds of RCTs and smaller clinical studies have investigated the efficacy of multicomponent ILIs (3). What are the key components of effective ILI? This question has been addressed in two recent reviews (3,44). Both reviews concluded that effective ILI for initial weight loss must be at least 20 weeks in duration with at least 14 contacts during this period. There was general agreement about the content and structure of the ILI. The intervention program should include the following: a calorically restricted diet prescription, regular and intense exercise programs, educational presentations, self-monitoring (food intake, physical activity, and body weight), feedback from counselors, individual and/or group counseling, and a variety of components to promote adherence to the ILI (e.g., problem-solving, cognitive restructuring, meal planning, etc.). They also emphasized the potential importance of using meal replacement or structured meal programs. Both reports concluded that ILI could be delivered via face-to-face counseling sessions, telephone contact, or using the internet.

Similar conclusions were derived for weight loss maintenance. Both papers concluded that weight loss maintenance ILI should last at

least 1 year (after conclusion of the core ILI during the first year) and that contact should be at least monthly to every other week. Also, both reports recommended frequent weighing and the development of weight self-regulation skills. They also recommended continued calorically restricted diets and intense and regular exercise (>200 min/wk). Individual and/or group counseling was recommended along with a structured program to prevent relapse. The 2013 Guidelines Committee (3) recommended delivery of ILI for weight maintenance via face-to-face counseling or via telephone, but did not recommend dissemination via the internet or mobile devices.

Recent developments: official recognition of efficacy of ILIs

CDC Diabetes Prevention Recognition Program. Based on the seminal results of the DPP study (21), in 2011, the Centers for Disease Control (CDC) developed a pilot program to formally recognize programs that were similar in content and structure to the ILI of the DPP study (45). This program was named the CDC Diabetes Prevention Recognition Program (DPRP). The final DPRP criteria were published in 2015 (45). Prior to 2015, there were many calls for the development of sustainable, cost-effective programs that might delay the onset of type 2 diabetes, as had been reported in the 2002 DDP paper (40-42,46). The aim of the DPRP was to recognize programs that delivered proven type 2 diabetes prevention lifestyle interventions and therefore promoted the development of sustainable, cost-effective lifestyle interventions that could be implemented in community settings. Starting in 2015, DPRP programs could be conducted using digital/internet-based approaches (47). There are many requirements for DPRP recognition, but for this discussion, several criteria are important. First, participants in the program must be screened to meet *a priori* criteria for prediabetes. Second, the program curriculum (regardless of delivery mode) has to include 16 sessions in the first 6 months that are directly modeled after the original DPP curriculum. Completion of this phase is defined as attending at least nine of the 16 sessions. Third, during months 7 to 12, the program must include at least one session in each of the 6 months that match the prescribed content from 15 acceptable topics. Completion of this phase is defined as attending at least three of the six sessions. Fourth, the duration of the program must be at least 12 months. In 2016, the CDC disseminated a model curriculum (called Prevent T2) that, if adopted, will partially fulfill the requirements for DPP recognition. A recent report (48) reported promising outcomes-based results from the first 4 years of the program.

US Preventive Services Task Force (USPSTF) recommendations. The USPSTF makes recommendations about the effectiveness of specific interventions based on evidence and provides a letter grade (A, B, C, D, I) for the quality of the evidence. As a part of the Affordable Care Act, grades of A or B for a service require health insurers to cover, at no cost to the patient, that service, regardless of cost. In 2014 (49), the USPSTF recommended that ILIs for obesity with additional CVD comorbidity were sufficiently efficacious (grade B) to be covered under Affordable Care Act guidelines. The USPSTF recommended at least 5 to 16 sessions over a 9- to 12-month period and specified the content similar to the core curriculum of the DPP ILI. Furthermore, the recommendation is not made for medically healthy patients who also have overweight or obesity, but it is not limited to people diagnosed with prediabetes (impaired fasting glucose). For example, a patient with overweight and one CVD risk

factor, e.g., hypertension or high cholesterol, but who does not meet criteria for prediabetes would qualify for care using the USPSTF recommendations. A recent economic analysis indicated that the recommendations should be cost-effective, especially for adults with overweight or obesity who have at least one CVD risk factor (50).

Medicare diabetes prevention program expanded model. Recently, the Centers for Medicare and Medicaid Services (51) approved the use of ILI for treatment of patients with obesity with Medicare Part B who are diagnosed with prediabetes using blood chemistry tests. This new initiative is scheduled to begin in January 2018. To qualify for reimbursement, the program has to offer 1 year of ILI with 16 sessions in months 1 to 6 and 6 sessions in months 7 to 12. Programs must also be fully recognized by the CDC DPRP. Thus, the new Medicare program will treat patients with overweight or obesity who are also diagnosed with prediabetes.

Summary. These three recent developments mean that at least some patients with obesity can receive ILI treatment and the provider can be reimbursed for the services rendered. Thus, for the first time in the history of medicine in the United States, behavioral/lifestyle interventions for certain cases of obesity have been determined to be sufficiently efficacious to warrant payment by health insurers and the US government. This is a monumental moment in the overall struggle to transition behavioral/lifestyle treatment for overweight and obesity from interventions for overeating to mainstream medical care.

Where do we go from here: some remaining questions

The rapidly increasing prevalence of obesity in the United States and most of the world has been amply documented (13). For years, most people and even most health care providers viewed obesity to be an intractable and essentially untreatable disorder (52). As obesity became recognized as a medical problem that could be treated using behavioral and medical interventions, this perception has gradually begun to change.

As noted in this overview of the history of ILIs, health care researchers have developed one safe and effective method for achieving at least 5% weight loss for most adults with overweight or obesity from all walks of life. This approach is structured to systematically modify lifestyle behaviors related to nutrition and physical activity. As illustrated in Table 2, the common components of successful ILIs have been established. According to several expert panels, successful ILIs need to be intensive (at least 14 sessions over the first 6 months) and should include programs to develop the skills that are necessary to maintain long-term adherence to changed habits pertaining to diet and physical activity.

Recently, two expert panels and government services have endorsed ILIs for the prevention of type 2 diabetes (45,51), and another (49) recommended ILI for the treatment of comorbid CVD conditions associated with obesity. This recognition is both welcome news and a reflection of the many efforts by scientists over the past 50 years. As we pause and reflect, several cautionary observations are warranted:

1. Recent recognition approves ILIs for the prevention of type 2 diabetes and for the treatment of medical conditions that are common comorbidities of obesity. They do not, however,

- advocate the use of ILIs for the treatment of comorbidities associated with diagnosed type 2 diabetes (53) or for medically healthy patients with obesity who are likely to progress toward prediabetes and/or the metabolic syndrome (54).
- The content and structure of all three recommendations (CDC DPRP, USPSTF, and Centers for Medicare and Medicaid Services) are modeled using the core curriculum of the DPP ILI. As shown in Table 1, major studies planned after DPP all designed ILIs that were even more intensive than the DPP ILI. Also, they systematically enhanced the duration and structure of the new ILIs; e.g., they added the use of meal replacements and the use of mathematical models of weight loss. We do not know whether adding new components and greater intensity to the DPP ILI will produce greater weight loss and/or superior prevention or treatment of disease (43).
 - All three recent recommendations limit the duration of ILIs to 1 year. They make no recommendation beyond the first year of treatment, despite the fact that the DPP study and most other similar studies of ILIs over the past decade have investigated the impact of lifestyle modification for at least 2 years. There seems to be an implicit assumption in the major studies that sustained weight loss is needed to prevent or treat disease. Furthermore, ILIs of short duration have consistently been found to result in significant weight regain. The necessity of long-term care needs further study. Does longer treatment generate a superior health outcome? The practical and economic implications of this question loom large.
 - There have been many calls (42,55) to translate the strategies of studies such as those of DPP and Look AHEAD into sustainable, lower-cost interventions for the public. This call for real-world interventions (43) has often been translated into the development of internet-based or smart phone applications that follow the core curriculum of DPP. Evidence concerning the efficacy of these translational studies has recently emerged. In a recent review of these studies (47), an expert panel concluded that the weight loss associated with online ILIs with (usually asynchronous) human counseling was lower than that observed in in-person clinical studies such as those summarized in Tables 1 and 2. The panel also noted that limited evidence concerning the efficacy of fully automated online programs indicated very poor efficacy. These programs generally follow the CDC DPRP guidelines, which, as noted earlier, are not as intense as the core curriculum of DPP or of the other studies conducted after DPP (see Table 1). From a population health perspective, this lower efficacy may be tolerable or even desirable, if these sustainable programs reach larger populations than can be accomplished using clinic-based, in-person counseling.

Summary and Future Directions

Over the past 50 years, ILIs for management of weight have progressed from a promising new strategy to accepted mainstream treatment for overweight/obesity and associated medical disorders. This progress comes from the diligence and dedication of the investigators of hundreds of controlled studies (3,17,28,43,46,55).

There is general acceptance that ILIs are best conceptualized as treatment packages that draw synergy from an organized, coordinated set of components (3,35,45,49). This conclusion begs a question: what are the necessary components of effective ILIs? There have been few scientific efforts to dismantle ILIs, but the question calls for speculation. The CALERE ILI resulted in the highest

average weight loss and weight loss maintenance of the four studies summarized in Tables 1 and 2. CALERIE provides the following clues: (1) Computer technology was used to enhance adherence to caloric restriction, (2) participants were screened before enrollment to maximize adherence and retention, (3) increased physical activity was not emphasized, and (4) intense individual and group counseling was continued for 2 years. In another recent study, Martin and colleagues (56) reported the successful use of mathematical models of weight loss without extensive human counseling to induce short-term weight loss. Similar to CALERIE, this study used mathematical models of weight loss to assess adherence and to reinforce consistent behavior change over time. The results of these two studies suggest that ILI components that enhance adherence, especially to changes in nutrition, and guide weight loss over time should be studied as key features of ILIs.

Another question: Who benefits most from ILIs? The answer to this question may also lead to adherence as a potential answer; those with the best adherence are those who respond most positively (31,47,48). As shown in Table 2, all four studies conducted pre-enrollment screening interviews and required 2 weeks of self-monitoring to be eligible for participation. These strategies were designed to identify barriers to adherence and retention. ILIs are generally more effective for older adults (> 65 years) (28,50), possibly because they have more time to adhere to the ILI protocol.

Thus, it seems likely that components designed to enhance adherence (before and during the ILI) may be important components of effective ILIs. An important question for the future is how to enhance adherence while simultaneously lowering the intensity and costs of ILIs to make them sustainable in the real world (43). Artificial intelligence (AI) is often touted as a technical advance that could reduce the use of human counselors and therefore greatly reduce costs and substantially enhance scalability of counseling programs (57). Use of AI as opposed to human counselors raises an important question: Can AI replace the human capacity to think creatively and respond to the limitless contingencies that arise in the weight management counseling environment? The answer to the question appears to be no; AI is not sufficiently advanced to supplant the need for human counseling. For example, a recent report (58) concluded that 21 of 25 (84%) digital diabetes prevention and management programs (addressing modification of diet, activity, and/or weight) used live human counseling as a part of the intervention. In fact, one of the most intensively studied uses of AI in an ILI (59) includes live human counseling in addition to AI (58). Use of streaming media may be another answer to this conundrum, and it is more fully developed than AI. Even the use of streaming appears to necessitate the use of human counseling, however (58). Thus, for the foreseeable future, it is likely that human counselors will be needed to deliver ILIs to maximize adherence (47). Delivery of effective ILI with only minimal human interaction may be possible, however (56). Such speculation is exciting but also requires empirical study; let us look to the future. **O**

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