

Efficacy of Lifestyle Behavior Change Programs in Diabetes

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Evidence that a comprehensive lifestyle behavior change program targeting eating and physical activity, and ultimately weight loss, can alter the course of diabetes progression is growing. This report summarizes data from major clinical trials primarily, describes key features of behavior change programs, and comments on existing challenges regarding the adequacy, sustainability, and feasibility of behavior change programs for weight loss and diabetes prevention.

Introduction

In the latter part of the 1990s, against a backdrop of sobering statistics regarding obesity and diabetes prevalence [1,2] a foundation was laid for examining lifestyle behavior change methods targeting a well-established trio of risk factors in the progression of diabetes: weight, eating habits, and level of physical activity [3–6]. Effective behavior change methods and programs for diabetes risk reduction and prevention have matured in the same research environment as effective behavior change programs for obesity, with many leading investigators producing important findings in both areas [7,8]. Research advances in the current decade continue to underscore the primary role of weight loss for metabolic control in diabetes [9••,10,11], and the important contribution of physical activity to sustaining weight loss over time [9••]. The independent influence of physical activity on reducing risk for diabetes has also been asserted [12] but its contribution is confounded by the fact that state-of-the-art lifestyle behavior change programs always use a combined approach [9••,12].

Behavior Change Technology

In 2007, there is little doubt that an established behavioral technology for the induction of clinically meaningful weight loss as well as the short-term maintenance (< 5 years) of weight loss for diabetes prevention exists [13,14]. Yet it is equally true that skepticism and controversy continue regarding whether one can achieve such behavior change and weight loss milestones in the context of current medical care, health care reimbursement, and other economic and political realities. Perhaps the biggest barrier is the perception among many health care providers and the general public that even the most well-intentioned individuals will ultimately fail at long-term weight management efforts.

This report attempts not only to review the evidence base for lifestyle behavior change programs aimed at weight loss and diabetes prevention, but to highlight key issues to be considered regarding continuity and integration in overall prediabetes to diabetes care.

Behavior Change for Diabetes Prevention: Essential Elements and Phases of Delivery

State-of-the-art behavior change programs for weight control in general, and diabetes prevention in particular, commence by imparting a core, instrumental knowledge base in three areas: nutrition, physical activity, and behavior modification [15,16]. They aim to teach the learner the behavioral bottom line on “what it takes” to achieve better, healthier eating and physical activity habits as well as come to terms with the personal energy balance equation (“calories in and calories out”) that will produce weight loss. Effective behavior change programs occur in a treatment context, either one-on-one or group-based, and the participant is asked to reflect on their personal reasons for joining (eg, critical events, medical triggers, family and social context). Participants are also asked to commit to the program for a period of months and are seen most frequently, often weekly or bimonthly, during this induction phase.

Subsequent to core nutrition, physical activity, and behavioral learning sessions, the focus turns increasingly to adherence issues and concerns. Participants are asked to grapple with common and unique personal barriers through problem solving and other forms of skill building. Behavioral weight control programs are engineered

so that an individual experiences weight loss at a safe, reasonable rate of no more than 1 to 2 lb per week, while building a safe, reasonable, progressive physical activity regimen that is critical for long-term weight control. This process of trial and error learning while self-monitoring eating, activity, and weight change over a period of time is a hallmark of the behavioral approach.

Essential behavior-modification techniques include self-monitoring and goal setting (eg, calories, fat, weight, physical activity); stimulus control (ie, changing cues in the environment so that healthy behavior is more likely and unhealthy behavior is less likely); cognitive restructuring and relapse prevention (challenging/countering negative thoughts about one's ability to persist at lifestyle behavior over time, ie, "How do I keep going when I feel so frustrated?"); skill building for stress management; and maximizing social support to persevere at what is being framed as a lifelong effort [16,17].

Weight Loss Maintenance and Beyond

The major focus of behavioral technology in 2007 is to help individuals delay, prevent, or minimize post-treatment regain. This, in addition to exploring the best methods for engaging individuals in weight loss efforts beyond the initial weight loss program, even inducing new bouts of weight loss after a period of regain, is a critical new research frontier [17–19]. Although continued contact can provide the support and accountability that many people engaged in long-term weight management efforts seem to need, it is equally true that "treatment fatigue" may produce increased attrition rates over time [15,19]. In addition, the degree to which the initial imprint of successful weight loss, even in the face of regain, continues to delay or prevent the onset of diabetes is not entirely clear, although the long-term follow-up in the Diabetes Prevention Study (DPS) and the Diabetes Prevention Program (DPP) will provide important evidence by the end of this decade.

Primary Prevention of Diabetes and Beyond

A behavioral weight loss program for diabetes prevention can be distinguished from standard diabetes support and education, or medical nutrition therapies, which traditionally have focused on short-term counseling of those already diagnosed with diabetes as opposed to diabetes prevention through weight loss. It is not within the scope of this report to discuss important advances in the field of nutrition, diabetes education, or ecologic approaches to diabetes self-management and care [20,21]. However, it should be noted that if effective behavioral technologies for weight management are shown to be at the heart of diabetes prevention programs [9••,10] and an integral part of diabetes care over time, then the integration of treatment models for prediabetes, newly diagnosed diabetes, and chronic diabetes care across multiple areas of

behavioral science research and intervention are needed [8]. In fact, the case of diabetes care has been presented as one of the priority conditions to be targeted for innovative health care quality improvement in this century [22].

The Look AHEAD (Action for Health in Diabetes) trial [23] was designed to be an extension of primary prevention trials by examining the long-term cardiovascular outcomes (12 years of follow-up) of a 4-year intensive behavioral weight loss program in participants who are already diagnosed and medically treated for type 2 diabetes. The trial compares a standard diabetes education approach to an even more rigorous, goal-based weight loss and physical activity regimen than was used in the DPP. The study is intended to provide the most definitive results of the long-term health consequences of intentional weight loss.

Moving Toward a Core Curriculum for Diabetes Prevention: Dose and Access

Several recent articles describe the most effective intervention approaches available [11,16,24]. The DPP website (<http://www.bsc.gwu.edu/dpp/manuals.htmlvdoc>) contains all of the participant materials and guidelines for delivery of the 16-session core curriculum.

What many in the field most interested in public health impact would like to determine is how a Cadillac model can be translated into a less costly, yet still dependable Honda. Can effective behavior change treatments possibly be delivered in four, eight, or 12 sessions? Can some sessions be combined or spared? What level of professional training and practice is required to be an effective interventionist? Finally, is there any place to go and get this kind of treatment reliably?

Although the evidence reviewed here gives direction, many questions remain unanswered. The behavior change literature has not determined a definitive "minimal effective dose" of behavior change treatment for diabetes prevention. However, it should be asserted that just as with efficacious pharmacotherapy, things such as dose, exposure, adherence, and access to a regimen over time do matter.

If weight loss in the range of 5% to 10% has been determined to be related to corresponding decreases in blood glucose [13,14] and behavior change technologies produce 1- to 2-lb weight losses per week, then a 200-lb (91-kg) individual needs a minimum of 10 weeks to learn from the experience of achieving a simple 5% weight loss. Just one or two sessions of counseling about the importance of weight loss for diabetes prevention is not likely to do the job, yet that may be all that is available in the health care system at present. The problem of "weight loss failure" in diabetes care stems at least in part from the economic and political reality that evidence-based effective treatments are rarely available; thus, most patients must figure out a way to do it on their own.

Weight Loss Induction and Maintenance: Getting Off to a Good Start Is Important

To summarize, the evidence to date suggests that most effective behavior change treatments for obesity, prevention of regain, and diabetes prevention are likely to begin with a defined program of core treatment sessions, and occur in the context of a face-to-face treatment relationship [13,14,18]. If an initial effective dose of treatment helps participants get off to a good start then further empiric investigations can refine the optimal combinations of key elements and variable rates of follow-up [8,10] necessary for clinically meaningful diabetes outcomes.

DPS and DPP: Methods, Adherence, and Outcomes

Since the publication of the major outcomes of the DPS in Finland [13] and the DPP in the United States [14], more recent data have characterized the nature of demographic, psychosocial, and behavioral factors related to achieving weight loss and physical activity goals as well as the relationship of specific behavior change adherence variables to diabetes outcomes. Although the methods of lifestyle intervention treatment and the number of sessions delivered in the first year of treatment differed considerably between the trials in the two countries, the resulting reduction in diabetes risk was identical: 58% among the lifestyle compared with control groups in the Finnish sample as well as the ethnically diverse US sample. Both studies terminated a year early because the efficacy of the lifestyle treatment compared with the control condition was clear.

Table 1 presents a comparison of the lifestyle intervention baseline characteristics, treatment methods, treatment adherence, weight loss, and diabetes outcomes. It also highlights common elements between the two effective treatments.

The most apparent difference between the two structured, one-on-one interventions is attendance rate. In the first year of treatment of the DPS core curriculum there were seven preplanned treatment sessions compared with 16 in the DPP. Face-to-face sessions in the DPS were held every 3 months thereafter, whereas in-person sessions in the DPP were held, at a minimum, monthly. In fact, DPP participants attended a mean of 23.6 plus or minus 7.1 sessions during the first full year of treatment and approximately half that many sessions during the second year of treatment [10]. Actual rates of attendance were not reported in the DPS papers.

Weight loss was greater in the DPP compared with the DPS at both the 1-year (6.8 vs 4.5 kg) and 3-year treatment mark (4.3 vs 3.5 kg), which is likely a result of the stronger dose of behavior change intervention delivered in the US intervention. However, as noted earlier, the risk of diabetes was reduced in both trials by 58% at an average 3.2 years of follow-up. Such results raise

important questions regarding just how much weight loss is needed to produce a diabetes prevention effect as well as the independent contribution of changes in physical activity [12].

Conversely, further analysis of the DPP adherence data exploring the relative contribution of changes in weight, diet, and activity [9••] has demonstrated weight loss to be the dominant predictor of reduced diabetes risk. For every kilogram of weight loss there was a 16% reduction in risk, adjusted for changes in diet and activity. A decreased percentage of total energy from fat and increased physical activity also appeared to be related to sustained weight loss. One may conclude from these data that there is in fact a dose-response relationship between weight loss and diabetes prevention, kilogram for kilogram.

Extending the Efficacy of Behavior Change Treatments: Use of Pharmacologic and Internet Therapies

There is sizable recent literature on US Food and Drug Administration–approved pharmacologic agents, approved for long-term use in obesity: sibutramine and orlistat [25–28]. Studies looking at the effects of sibutramine as an augment to dietary or behavior change interventions suggest that weight outcomes and patient satisfaction with outcomes may be increased. However, an adverse effect of this drug is increased blood pressure and increased heart rate; thus, it cannot be used without close medical monitoring [29]. The most recent orlistat trial [30] also indicated a beneficial weight loss and weight maintenance effect, as well as specific improvements in diabetes and cardiovascular risk factors, over a 2-year period.

An exciting recent study by Wing et al. [18] examined a group of participants who had already lost a very significant amount of weight (mean = 19.3 kg) over the previous 2 years and randomized them to either control (newsletter), face-to-face, or Internet intervention designed specifically to address behaviors related to weight regain. Over the next 18 months (consisting of monthly contacts), a self-regulation program based on daily self-weighing reduced the percentage of participants who regained 2.3 kg or more to 45.7% in the face-to-face behavior change group (absolute weight gain; 2.5 ± 6.7 kg), and 54.8% in the Internet group (weight gain; 4.7 ± 8.6 kg), compared with 72.4% in the control group (weight gain; 4.9 ± 6.5 kg).

Participants in both intervention groups were given a bathroom scale and were taught to use it in a manner similar to a home glucose monitor, adjusting energy-balance behaviors according to the daily feedback they were receiving from the home scale. Participants in both groups were also asked to submit their weekly weights either through an automated phone system (face-to-face group) or via a Web-based form (Internet group).

Table 1. DPS and DPP lifestyle intervention methods and outcomes

	DPS*	DPP†
Mean reported follow-up, y	3.2	3.2
Baseline cohort		
<i>n</i>	265	1079
Mean age, y	55 ± 7	50.6 ± 11.3
BMI	31.4 ± 4.5	33.9 ± 6.8
Female, %	66	68
Race/ethnicity	Heterogeneous	Homogeneous
Lifestyle methods	Core:	Core:
	7 sessions over 6 mo, face to face	16 sessions over 24 wk, face to face
	3-d food records 4 times per year	Weekly food records first half of year
	Exercise prescription/free gym access	Voluntary supervised activity
	Post-Core:	Post-Core:
	Every 3 mo (interim phone/mail contact)	Every 1 mo (interim phone/mail contact)
	Voluntary group sessions (frequency not reported), expert lectures, cooking classes, supermarket visits	Voluntary group sessions 3 times per year, nutrition, activity, behavioral, motivational topics and campaigns
	Voluntary walking/hiking groups	Voluntary supervised activity sessions
	Ongoing free gym access	Optional structured meal plans to boost weight loss
	Optional VLCD groups for 2- to 5-wk periods to boost weight loss	
Weight, activity, dietary behavior change goals	≥ 5% weight loss	≥ 7% weight loss
	30 min/d of moderate-vigorous physical activity	150 min/wk of moderate-vigorous physical activity
	Total fat < 30% of energy intake	Total fat < 25% of energy intake
	Saturated fat < 10% of energy intake	If no weight loss, give calorie goal
	Fiber ≥ 15 g per 1000 kcal	
Year 1 loss, kg	4.5 (<i>n</i> = 256)	6.8 (<i>n</i> = 1023)
Year 3 loss, kg	3.5 (<i>n</i> = 231)	4.3 (<i>n</i> = 970)
Diabetes outcomes	58% risk reduction in lifestyle versus control	58% risk reduction in lifestyle versus control

*Finland (5 clinic sites).

†United States (27 clinic sites).

BMI—body mass index; DPP—Diabetes Prevention Program; DPS—Diabetes Prevention Study; VLCD—very low calorie diet.

Conclusions

Behavior change technology for weight management in obesity, prediabetes, and diabetes is becoming more compelling and there is hope that comprehensive programs of care can alter the course of disease progression. Getting participants off to a good start through regular contact and solid behavioral teaching is critical. Studies of combination methods and use of the Internet also show promise, but it appears that results are most optimal when a face-to-face behavioral treatment context is already established. Ultimately, all individuals at risk for diabetes need a “place to go” where they can receive a continuum of adequate, reliable, behavioral care that is engineered for effective outcomes.

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