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Weight loss/maintenance as an effective tool for controlling type 2 diabetes: novel methodology to sustain weight reduction

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Summary

The type 2 diabetes epidemic closely parallels the obesity epidemic. Although weight loss is frequently initiated successfully, most patients regain substantial amounts of weight within the first year after completing a weight loss programme. Several studies have shown success over time with weight loss and type 2 diabetes prevention and/or remission. These include the Diabetes Prevention Program and the Look AHEAD study. Novel approaches to weight management have recently found their way onto the internet.

With advances in medicine, there has been more patient success in the weight maintenance field. We review the Weight Management System that permits daily counselling to patients who have been losing or maintaining weight. The Weight Management System is a method that combines four fundamental elements: (1) remote daily weight monitoring by the system and the health professional; (2) daily feedback from the system and, when necessary, the health professional; (3) customized information for the needs and desires of the particular patient; and (4) a proprietary algorithm to detect early signs of weight regain. Recent beta testing of this system has confirmed Dr Rena Wing's statistics and has opened up a novel approach to long-term weight management and diabetes prevention. Copyright © 2012 John Wiley & Sons, Ltd.

Keywords obesity; yo-yo dieting; Look AHEAD study; weight regain; behaviour modification; red alert; internet; weight maintenance

Introduction

It is widely agreed that the United States and many other countries are experiencing an epidemic of obesity [1,2]. Further, obesity and overweight are now affecting a majority of US adults [3–5]. Many reasons have been cited for this positive energy balance. An abundance of readily available food and lack of physical expenditure top the list [6,7]. The supply and size of food portions have increased over time [8,9]. Concomitantly with the advent of enhanced technologies, labour intensity has decreased. The nature of body weight regulation is complex but appears to be more biased in protecting against weight loss than weight gain [6]. There is relatively little control or reason for the body to protect against weight gain, and indeed, the degree of societal obesity currently present is a new phenomenon. Managing obesity in the United States is costly, amounting to \$100bn including \$52bn in direct health costs [10]. Type 2 diabetes and the metabolic syndrome are linearly associated with increased obesity [11]. The risk of type 2 diabetes is quite dramatic even with modestly overweight patients [12,13]. The risk of type 2 diabetes is also well documented in the nurses' health studies [13].

Our purpose is to present the rationale for weight loss and long-term maintenance of weight loss. We will first review the evidence that weight loss can prevent the development of type 2 diabetes, using data from the Diabetes Prevention Program (DPP). We will then present evidence that weight loss ameliorates and reverses the hyperglycaemia of type 2 diabetes and improves clinical parameters and outcomes using the Look AHEAD study. We will briefly describe the follow-up weight regain that occurred in these studies. A description of behavioural modification modalities for weight loss success follows with a survey of pharmacologic agents and meal replacement methods.

Preventing regain of weight is a *sine qua non* for success in any weight loss programme [14]. Failure to maintain weight loss has been the biggest problem in our societal quest to conquer obesity. Yo-yo dieting is self-defeating and does not improve morbidities [15]. After reviewing the weight regain data, we examine the modalities required for sustained weight loss. Finally, we present some of the novel cost-effective technologies that can enhance weight maintenance and that are applicable to large populations via use of the internet and modern computer/personal digital assistants technologies.

Diabetes Prevention Program study

The DPP was federally funded and lasted from 1996 to 2001 with 3234 participants. The DPP's primary goal was to prevent or delay the development of type 2 diabetes in persons with impaired glucose tolerance. The programme was a lifestyle intense programme with the following goals: (1) equal or greater than 7% loss of body weight and maintenance of weight loss; (2) dietary fat goals – less than 25% of calories from fat; (3) calorie intake goal of 1200 to 1800 calories per day; and (4) greater than 150 min per week of physical activity to a modest degree. Patients were originally divided into four groups: placebo, metformin, intense lifestyle and troglitazone (Rezulin). The troglitazone arm was dropped when the Food and Drug Administration recalled the drug over concerns of liver toxicity.

After 1 year, the results of this study were very positive [16]. By the end of the study after 3 years, a 31% decrease in the incidence of diabetes occurred in the metformin arm of the study and a 58% reduction with the lifestyle group [16]. Over the 3 years, lifestyle and metformin were effective and cost effective [17]. Also of note was the subtle regain of weight over the 3-year period. Weight

loss was most impressive at the end of year one; by the end of year three, weight regain was almost 30% of what was initially lost. An ongoing extension study of DPP, the Diabetes Prevention Outcome Study, is a long-term follow-up of the DPP, designed to determine whether the delay in diabetes seen during the original DPP study could be sustained [18]. There still appears to be beneficial effect for both the lifestyle group and the metformin group, but the numbers do not seem as robust. The authors believe that, in the lifestyle group, diabetes can be delayed for 4 years as opposed to the original thought of 11-year prevention after the first 3 years. The metformin group delay in preventing diabetes went from 3 to 2 years. This is not a surprising finding as both metformin and lifestyle groups concomitantly regained weight. They also had an increase in levels of HA_{1C} from years 1 to 4; the lifestyle group went from 5.8 to 6 years, the metformin group level went from 5.9 to approximately 6 years, while the control also increased from 5.9 to 6.1 years [16]. The overall suggestion is that the weight regain diminished the clinical advantages that were originally seen in these studies.

Look AHEAD study

The Look AHEAD study [19] is a multicentre randomized control trial designed to determine whether intentional weight loss reduces cardiovascular morbidity and mortality in overweight individuals with type 2 diabetes. The study started in 2001 and is scheduled to conclude in 2012. A total of 5145 participants have been randomized to lifestyle intervention or enhanced usual care conditions (i.e. diabetes support and education). The intensive lifestyle group was to achieve at least a 7% weight loss and increased participation in physical activity to a minimum of 175 min per week. The intensive lifestyle group used classic weekly behavioural techniques with three groups and one individual session per month of the first 6 months. They were also encouraged to use meal replacement shakes and bars. At month 7, they attended an individual and two group meetings per month and were also offered the potential of using medication to enhance weight loss. From years 2 to 4, treatment was provided mainly on an individual basis that included at least one on-site visit per month and a second contact by telephone, e-mail or letter. Finally after year 4, participants were offered monthly individual visits [18].

Like the DPP study, the first year results of the Look AHEAD study were very impressive with an 8.6% reduction in weight, 26.4% improvement in A_{1C} below 7, a 15.1% improvement in blood pressure – systolic over diastolic 130/80 – and a 6.7% improvement in low-density lipoprotein cholesterol below 100. All these results were statistically significant [20]. Review of the data at 4 years showed statistical improvement although less robust except for the low-density lipoprotein, which was statistically comparably the same [21]. Dr Wing noted that HA_{1C} levels waned a little over time. Despite this, Wing

and associates still expected a positive effect on outcome. Other positive outcomes in the study pertain to the ability to decrease medication use in the intensive lifestyle group.

In summary, the DPP and the Look AHEAD studies clearly show that diabetes can be forestalled and improved upon when the condition already exists. This is not unexpected as there are numerous studies showing physical and metabolic improvements with weight loss [22]. However, when we look at both of these studies, there is a weakening of the data with time. This is typically associated with weight regain (Figure 1). From years 1 to 4, both studies confirm that with regain of weight, metabolic conditions deteriorated. Still to be answered is whether 1, 2, 3 or more years of weight loss and maintenance have an impact on the future course of metabolic states. Until this can be accurately answered, it is prudent to address the main issue of regain in weight.

Behavioural techniques and the accomplishment of weight loss

Weight loss traditionally has been accomplished using behaviour modification, diet, prescription medications and exercise. Fletchtner-Mors et al. [23] have shown persistent improved weight loss when meal replacement and snack replenishment were utilized. This also was the case in the Look AHEAD study. Wadden et al. [24] showed that behavioural therapy with meal replacement and pharmacotherapy has an additive effect with the group having the most substantial weight loss over a 12-month period. However, obesity treatment requires long-term care. Perri et al. [25] showed that patients treated with traditional behavioural therapy did statistically better when maintenance therapy continued past the 6-month weight loss therapy. The use of very low calorie diets (400 to 1000 kcal) has fallen out of use. This is mainly because low calorie diets at 1200 to 1500 calories along with behaviour modification do just as well, with less risk of metabolic aberrations [26].

Problems with weight loss techniques do not stem from the inability to lose weight but from the inability to maintain weight loss for prolonged periods (greater than 2 years). Approximately 20% of overweight individuals are successful at long-term weight loss (as defined by



Figure 1. DPP *versus* Look AHEAD: percent reduction in initial weight over a 4-year period

losing greater than 10% of initial body weight and maintaining this weight loss for at least 1 year). This of course suggests that 80% of patients who are trying to lose weight either fail within the first year or have regained the weight lost. With this reality, a fundamental need is to introduce methods that maintain weight loss on a more or less permanent basis.

Wing et al. created the National Weight Control Registry. This was a registry of 'successful (weight) losers'. This registry was established in 1994 and is a self-selected population of more than 4000 individuals who lost a minimum of 30 lb and maintained it for at least 1 year. Several features of this study helped define long-term success in weight loss. The positive health impact of a 10% weight loss is well documented [27]. Patients studied in the registry [28] varied widely in how they lost weight. Approximately 55% reported receiving some type of help with weight loss (commercial programmes, nutritionists and physicians). Others (44.6%) reported losing the weight entirely on their own. The vast majority (89%) reported using both diet and physical activity for weight loss. Only 10% reported using diet alone, and 1% reported using exercise only. Diet strategies included restricting food type (87.6%), portion control (44%) and calorie counting (43%). There were major similarities in how patients maintained their reduced weight. Four maintenance habits were consistently reported: (1) consuming a low calorie and low fat diet; (2) high levels of physical activity (over 1 h per day of moderate activity); (3) frequent weight measurements; and (4) consuming breakfast on a daily basis. Wing et al. said their findings suggest that successful weight loss maintainers continue to act like recently successful weight losers for many years after their weight loss. The strongest factor associated with weight regain in this group was how long weight maintenance had occurred. Those patients who maintained weight for 2 or more years had the least likelihood of a relapse; they reduced their risk of subsequent regain by nearly 50%. This might suggest that weight loss maintenance may become easier over time. Other factors associated with long-term success included having low levels of depression and infrequent 'loss of control' as well as responding to a significant medical trigger to enhancing further weight loss such as a physician warning of high cholesterol, having a heart attack or other medical events uncovered during treatment.

Preventing small regain (even 2–4 lb) from turning into larger relapses appears critical to recovery among successful weight losers. The present author in the book, *The Thinderella Syndrome* [29] claims that patients must be able to take action if they have a weight regain of 3–5%. Those patients who 'sound a red alert' and take action are more successful at preventing weight regain.

All the research indicates that the most important attribute for preventing weight regain for an individual is having a continuous third-party support system. Wing *et al.* looked at 345 participants from the Weight Registry in a study called 'A self-regulation program for maintenance of weight loss'. In this study, patients who were successful weight losers were randomized into three groups: a face-to-face programme, an internet-based programme and a newsletter control group. The primary outcome was weight regain over an 18-month period [30]. In the control group, greater than 70% of patients regained 5 lb or more in 18 months. The internet group regained 54.8% of their weight, while the face-to-face group did the best, regaining only 45.7% of the weight originally lost. Clearly, the study suggests that successful maintenance of weight requires persistent and periodic follow-up and interaction. Although face-to-face follow-up did best, internet contact with patients also demonstrated meaningful improvement for prevention of weight regain.

Conclusions from the Study to Prevent Regain were as follows: (1) weight regain occurs frequently and is the biggest concern affecting long-term success; (2) weight regain must be tackled early and quickly before an individual regains greater than 5 lb (red alert/red zone weight); and (3) regain of greater than 5 lb is associated with complete relapse in 89% of cases. Wing significantly suggested that future studies should examine ways to refine types of intervention to improve their efficacy.

The Weight Management System presented here takes on these challenges. We present preliminary data that support a methodology that enhances weight maintenance success. Weight loss techniques recommended by us for permanent lifestyle changes are similar and resemble techniques used by most of the previous studies mentioned as follows:

- · food records;
- high quality meal replacements;
- exercise goals;
- occasional 'one-on-one' counselling sessions by a nutritionist;
- · social support groups; and
- pharmacotherapy (managed by physicians).

Importantly, long-term successful permanent weight loss benefits from the following: (1) a continuation of the behaviour modification techniques that were initially implemented to lose weight; (2) continued health care and professional follow-up; and (3) an internet-powered weight management system.

The solution in practice includes the following:

- The management programme resides in a central server.
- Clients are interviewed by the clinical practitioner to collect data including personal metrics, history and preferred style of communication.
- The data are entered into the central server creating a permanent client file.
- Patients weigh in daily or at reasonable intervals of their choice.
- The weight data are captured via computer/personal digital assistants or other defined device and automatically sent to the central server for analysis. The analysis is based on proprietary algorithms that consider metrics, history, weight behaviour (short-term and long-term), social patterns (i.e. seasons, holidays, etc.) and health.

- The server then 'reports back to client and health professional observer'.
- The system tracks weight behaviour (and trends) by applying proprietary algorithms that are able to report a given subject's weight state in real time. This provides the means for detecting a weight regression event before it would normally be noticed, thereby initiating a preventative action in a timely and effective way.

A green zone safe weight may automatically congratulate and positively support the client without the need for professional intervention. If a cautionary yellow and red alert are generated, a message is sent to both client and professional observer. Yellow alerts may produce a response or suggestion directly from the professional or possibly an automated suggestion. 'Red alerts' require immediate intervention by the professional.

Our preliminary pilot study using such a rudimentary system revealed successful weight loss maintenance over a 2.5-year period. Those clients who utilized our system for greater than 5 months persistently lost approximately 7.8% of their weight. A group of clients who used the system less than 5 months on an intermittent basis lost approximately 0.3% (Figure 2). A third group of clients who got the system but never utilized it at all actually gained approximately 3.6% in weight [15]. The data indicate the sooner a regain trend can be detected and an intersession initiated, the better chances are for a successful weight management outcome. The data indicate that successful weight maintenance is improved through continuous monitoring and continuous contact using both personal and multiple means of electronic communications now available. We can now approach our patients in a very different manner. Patients up to now had to come to a clinician to get advice, counselling and treatment. Patient accountability could be forestalled and amended. The patient simply needs to just cancel an appointment, and this would 'free' the patient from being responsible. The new system brings accountability to the patient at home, work or, for that matter, anywhere in the world. The very fact that patients are aware that we are aware of their progress brings a new dimension to patient support. We can truly say your health provider is 'in' while you weigh in at home.



Figure 2. Remote daily weight management

Conclusion

Although many people lose weight, few keep weight off for a period of greater than 2 years. Preventing weight regain takes great effort and vigilance [31]. Most of the people who are successful in the weight registry accepted a very intensive lifestyle change to continue to maintain the reduced weight, with long-term success more likely after being successful for 2 years. Patients have proven that with continued support and vigilance especially using an accountability system for weight maintenance and weight regain, prevention is possible. If we are to decrease the type 2 diabetes epidemic, save healthcare dollars and ultimately save lives, a system that successfully sustains weight maintenance is an important goal.

Conflicts of interest

Dr Gage received a \$10.00 fee per month per participant for server use on this study. His family owns patents and

proprietary formulas on a software system designed for weight loss and maintenance. He shares no financial interest or support from Dr Rena Wing and has no other conflicts of interest to report.

Editors' comment

Losing weight is a challenge. Numerous scientific articles and popular diet fads deal with this issue. Maintaining the weight loss is the ultimate extreme true challenge that most of us avoid dealing with, primarily because of the absence of tools with which to do it. Dr Dennis Gage's article tackles the problem and provides potential solutions that have been tested and shown to be of value. It is in this light that we consider his article important. We hope it will also stimulate others to come up with additional methods.

> Martin M. Grajower, MD, FACP, FACE Jesse Roth, MD, FACP

References

- National Center for Health Statistics. Prevalence of overweight and obesity among adults: United States. 1999. National Center for Health Statistics. http://epsl.asu. edu/ceru/Documents/NCHS_obesity.pdf
- Flegal KM, Carroll MD, Kuczmarski RJ, Johnson CL. Overweight and obesity in the United States prevalence and trends, 1960–1994. Int J Obes 1998; 22: 39–47.
- Flegal KM *et al.* Prevalence and trends in obesity among US adults, 1999–2000. *JAMA* 2002; 288: 1723–1727.
- Hedley AA *et al.* Prevalence of overweight and obesity among US children, adolescents, and adults, 1999–2002. *JAMA* 2004; **291**(23): 2847–2850.
- Ogden CL *et al.* Prevalence of overweight and obesity in the United States, 1999–2004. *JAMA* 2006; **295**(13): 1549–1555.
- Hill JO, Peters JC. Environmental contributions to the obesity epidemic. *Science* 1998; 280: 1371–1374.
- Hill JO, Melanson EL. Overview of the determinants of overweight and obesity: current evidence and research issues. *Med Sci Sports Exerc* 1999; 31: S515–S521.
- National Heart, Lung, and Blood Institute Obesity Education Initiative. The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults. NIH Publication Number 00–4084, October 2000. http:// www.nhlbi.nih.gov/guidelines/obesity/ prctgd_c.pdf
- Rolls BJ, Morris EL, Roe LS. Portion size of food affects intake in normal weight and overweight men and women. *Am J Clin Nutr* 2002; **76**(6): 1207–1213.
- Uwaifo GI, et al. Obesity-eMedicine. http://emedicine.medscape.com/article/ 123702- overview [28 May 2010].
- Willet WC et al. Guidelines for healthy weight. NEngl J Med 1999; 341: 427–434.

- 12. Chan J *et al*. Obesity, fat distribution, and weight gain as risk factors for clinical diabetes in men. *Diabetes Care* 1994; **17**: 961–969.
- Colditz G et al. Weight gain as a risk factor for clinical diabetes mellitus in women. Ann Intern Med 1995; 122: 481–486.
- Wing RR, Hill JO. Successful weight loss maintenance. Annu Rev Nutr 2001; 21: 323–341.
- Weigle DS. Human obesity. Exploding the myths. West J Med 1990; 153: 421–428.
- Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *NEJM* 2002; 346: 393–403.
- American Diabetes Ass. Inc. Within-trial cost-effectiveness of lifestyle intervention or metformin for the primary prevention of type 2 diabetes. *Diabetes Care* 2003; 26(9): 2518–2523.
- Nichols GA et al. Preventing diabetes with lifestyle interventions and medication. Diabetes Prevention Program Research Group. Lancet 2009; 374: 1677–1686.
- The Look AHEAD Research Group. The Look AHEAD Study: a description of the lifestyle intervention and the evidence supporting it. *Obesity* 2006; 14: 737–752. doi:10.1038/ OBY.2006.84.
- The Look AHEAD Research Group. Reduction in weight and cardiovascular disease risk factors in individuals with type 2 diabetes. *Diabetes Care* 2007; 30: 1374–1383.
- 21. Wing RR et al. Long-term effects of a lifestyle intervention on weight and cardiovascular risk factors in individuals with type 2 diabetes mellitus. The Look AHEAD Research

Group. Arch Intern Med 2010; 170(17): 1566–1575.

- Brink S. The Diabetes prevention program: how the participants did it. *Health Aff* 2009; **28**(1): 57–62.
- Fletchtner-Mors M et al. Metabolic and weight loss effects of long-term dietary intervention in obese patients: four-year results. Obes Res 2000; 8: 399.
- Wadden *et al.* Additive effects of behavior and meal replacement therapy with pharmacotherapy for obesity. *Arch Intern Med* 2001; 161: 218.
- 25. Perri MG *et al.* Structured weight-loss programs: meta-analysis of weight loss at 24 weeks and assessment of effects of intervention intensity. *J Consult Clin Psychol* 1988; **56**: 529–534.
- 26. Wing RR, Blair E, Marcus M, Epstein LH, Harvey J. Year-long weight loss treatment for obese patients with type 2 diabetes: does inclusion of an intermittent very low calorie diet improve outcome? *Am J Med* 1994; **97**: 354–362.
- National Heart, Lung, and Blood Institute. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults. The evidence report. *Obes Res* 1998; 6(Suppl): 51S–210S.
- Wing RR, Phelan S. Science-based solutions to obesity: what are the roles of academia, government, industry, and health care? Long-term weight loss maintenance. *Am J Clin Nutr* 2005; 82 (1): 222S–225S.
- 29. Gage D. The Thinderella Syndrome. Vantage Press: New York, 2004.
- Wing RR et al. A self-regulation program for maintenance of weight loss. N Engl J Med 2006; 355: 1563–1571.
- Gage D. Psychiatric complications of weight loss. *Prim Psychiatr* 2007; 14(5): 51–56.