

Metagenics' Comprehensive Weight Management Program for Individuals Affected by Obesity

OBESITY EPIDEMIC

The National Institutes of Health define obesity as a BMI of 30 or higher. The Centers for Disease Control and Prevention estimates that 35.7%—more than one out of every three—of U.S. adults are obese.¹ These individuals are at substantially increased risk for developing heart disease, stroke, high blood pressure, type 2 diabetes, certain types of cancer, and many other chronic diseases.² A nationally representative survey found that obese individuals spent an additional \$1,429 annually than did healthy-weight individuals on medical related spending (2006 data).³

What is BMI?

Body mass index (BMI) is an indicator of body fatness for most individuals. It is defined as the individual's body mass divided by the square of his or her height (kg/m^2). When calculating BMI with imperial units (pounds for weight and inches for height), use the same equation (lb/inch^2) and then multiply by a conversion factor of 703.

Although our life expectancy has consistently increased—and mortality decreased—since the 1960s, recent data suggest that widespread obesity (and illnesses associated with it) has begun to erode the steady gains in life expectancy.⁴ Moreover, individuals are becoming obese at a younger age, and they may experience an unprecedented long period of obesity over their lifetime.⁵ This translates to living with functional limitation and disability, poorer quality of life, and significant social and economic burden.

BMI categories

< 18.5	Underweight
18.5 – 24.9	Health weight
25 – 29.9	Overweight
30 – 34.9	Obesity class I
35 – 39.9	Obesity class II
≥ 40	Extreme obesity

NUMEROUS BENEFITS OF WEIGHT LOSS

Losing weight takes commitment. However, research has demonstrated that even modest weight loss—5 to 10% of total body weight—may yield several crucial health benefits:

- Reduce blood pressure
- Lower total cholesterol and LDL cholesterol
- Lower triglycerides
- Raise HDL cholesterol
- Decrease blood glucose levels
- Reduce waist size
- Improve survival rates in those who have diabetes, heart disease, or other obesity-related diseases
- Improve sleep patterns
- Improve quality of life

A HEALTHY, SCIENCE-BASED WEIGHT MANAGEMENT PROGRAM

The most successful weight loss strategy is lifestyle changes—a combination of food modification, physical activity, and behavior therapy—to achieve negative energy balance.² To be effective, the program needs to set goals that are specific, realistic, and forgiving.⁶

Following these clinically proven guidelines, the Functional Medicine Research Center® (FMRC)—the clinical research arm of Metagenics—diligently designed a comprehensive weight management program. Program components include:

- *High-protein, high-phytonutrient, low-glycemic food plan*
- *High-protein meal replacement and nutritional supplements*
- *Pedometer-monitored physical activity*
- *Cognitive behavioral therapy*

High-protein, high-phytonutrient, low-glycemic food plan.

No weight management program can be successful without a healthy food plan. A healthy diet emphasizes the balance and types of macronutrients (i.e., protein, carbohydrates, and fat)⁷ and content of micronutrients (e.g., vitamins, minerals).^{8,9} Research has shown that diets incorporating higher protein content reduce appetite, increase satiety, and promote more favorable body composition changes than diets with lower protein content.¹⁰⁻¹² Furthermore, a high-protein diet featuring a low glycemic load/index led to higher user compliance^{13,14}—a crucial factor for success in maintaining weight loss, glucose homeostasis, net nitrogen retention,^{15,16} and smaller fat cells.¹⁷ A food plan that includes high levels of vegetables provides high levels of phytonutrients, a variety of xenohormetic substances that confer stress resistance, fitness, and well-being to humans who consume them.¹⁸

High-protein meal replacement and nutritional supplements. Incorporating a meal replacement into a weight management program significantly helps patients lose weight and maintain weight loss.^{19,20} Metagenics provides high-protein options in three forms: shake, soup, and bar (**Table 1**). As part of the food plan, patients may choose to consume one of the three options each day.

Table 1. Nutritional content of Metagenics' high-protein products.

Product (1 serving)	Shake	Soup	Bar
Energy	101 kcal	109 kcal	217 kcal
Total carbohydrate	4.0 g	5.0 g	20.0 g
Sugar	3.0 g	2.0 g	6.0 g
Protein	20.0 g	20.0 g	18.0 g
Total fat	< 0.2 g	0.9 g	6.0 g
Saturated	< 1.0 g	< 1.0 g	4.0 g
Monounsaturated	< 1.0 g	< 1.0 g	2.0 g
Polyunsaturated	< 1.0 g	< 1.0 g	< 1.0 g
Trans	< 0.01 g	< 0.01 g	0.02 g
Dietary fiber	2.0 g	< 1.0 g	5.5 g
Unavailable carbs			
Polydextrose			7.0 g
Glycerine			7.0 g

To offset the potential nutrition imbalance due to reduced caloric intake during weight loss, the program offers additional nutritional supplements that provide the following:

- Powdered fiber drink to add satiety-enhancing fiber
- Broad-spectrum, phytonutrient-rich multiple vitamin/mineral formula
- Concentrated and stabilized omega-3 formula that provides natural marine lipid concentrate
- Bioactive vitamin D₃ supplement
- Probiotics

Did you know?

- The largest weight loss study to date, Action for Health in Diabetes (Look AHEAD study), found that the top 3 factors contributing to weight loss are physical activity, session attendance, and meal replacements.

Pedometer-monitored physical activity. As an essential component of a healthy weight loss program, exercise helps reduce cardiovascular and diabetes risks and is critical in preventing weight regain. Walking is one of the best ways to begin increasing physical activity; it's safe, easy, and can be done every day. The use of a pedometer, thanks to its instant feedback capability, has shown to successfully motivate individuals to increase their physical activities.²¹ However, it is necessary to have a measurable step goal. A comprehensive review reported that 10,000 steps per day has the greatest beneficial impact and is a reasonable goal for adults.²²

Interesting fact:

The National Weight Control Registry found that a key to successful weight loss maintenance in the long term is simply to weigh oneself every day.

Cognitive behavioral therapy. A person's emotions closely links to his/her behaviors. Because weight loss is an emotional journey, what a person thinks and believes will likely contribute to the success or failure of his/her daily weight loss plan. Cognitive behavioral therapy—delivered to weight loss participants during scheduled group educational sessions—can help patients develop a variety of skills leading to successful weight loss. Cognitive behavioral therapy helps patients:

- Become aware of the risk of being overweight and obese, and the tremendous benefit of returning to healthier weight levels.
- Enhance motivation.
- Commit to and set goals for lifestyle changes.
- Adhere to a food plan and physical activity.
- Monitor progress over time.
- Build social support.
- Perceive and overcome barriers that impede sustained weight loss.
- Solve problems that emerge over time such as motivational plateaus, treatment fatigue, and mental stress.

WEIGHT MANAGEMENT STUDY FROM FMRC

The FMRC conducted a clinical study to evaluate the efficacy of this 12-week comprehensive weight management program in volunteers who were obese. Results were very encouraging:

- 100 of 130 participants completed the study; 92 of them lost $\geq 7.5\%$ of their total body weight
- The group lost 11.2% (23.9 pounds) of their total body weight
- 62 participants lost $> 10\%$ of their total body weight
- 13 participants lost $> 15\%$ of their total body weight
- Significant reductions (clinically and statistically) in body fat percent
- Significant improvement in biomarkers of dyslipidemia: total cholesterol, triglycerides, cholesterol/HDL, and triglyceride/HDL
- Significant improvement in biomarkers of dysglycemia: glucose, hemoglobin A1c, insulin, and HOMA score
- 77% retention rate

INDIVIDUAL CASE MANAGEMENT

The following section describes the results of 2 individuals who completed the 12-week weight management program at the FMRC. (Disclosure: These cases are not representative of experiences of all individuals.)

CASE 1 is a 47-year-old Caucasian male who weighed 235.4 pounds before starting the program. His BMI of 36.3 put him in the “obesity class II” category. He believed his sedentary lifestyle had contributed to his weight gain during the past several years. Noticing problems associated with obesity, he was ready to make lifestyle changes when he learned about FMRC’s weight management study. After a screening visit, he began the program aiming at reducing 7.5% of his total body weight by the end of 12 weeks.

Results:

Body weight: The patient’s weight was monitored every 2 weeks. At the end of the program, he lost 16.3%, or 38.4 lbs, of his total body weight (**Figure 1**), surpassing the original 7.5% goal.

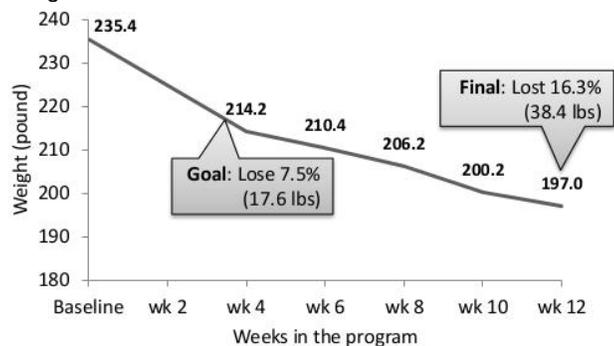


Figure 1. Weight change over the 12-week period for Case 1.

BMI and waist circumference: The patient reduced his BMI from 36.3 at baseline to 30.4 at end of 12 weeks. He reduced his waist circumference by 7.7 inches (**Figure 2**).

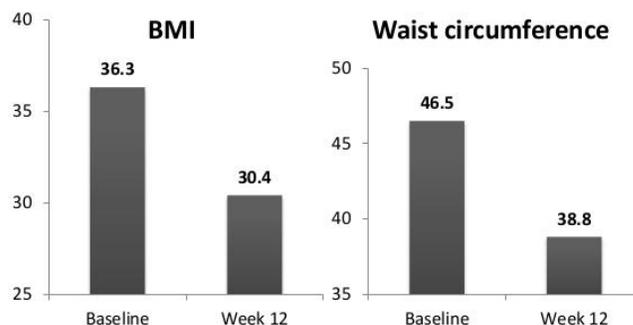


Figure 2. BMI and waist circumference measurements at baseline and week 12.

Body composition: The patient’s body composition was assessed using bioelectrical impedance analysis (BIA, a convenient and noninvasive technique that measures body fat) before and after the program. His fat mass was reduced from 70.4 lbs at baseline to 46.1 lb at Week 12; his lean body mass from 165.0 lb to 150.9 lb. Proportionally, his body composition was improved: the program helped him reduce fat mass percentage but maintain his lean body mass percentage (**Figure 3**).

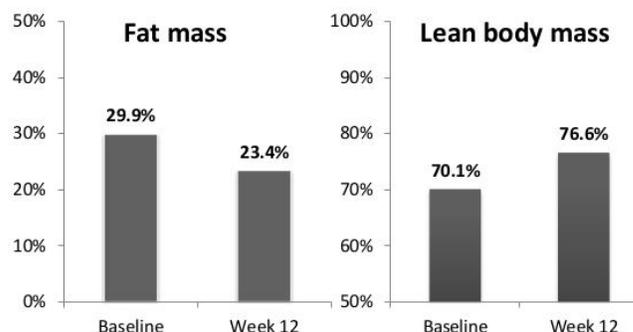


Figure 3. Body composition analysis by BIA at baseline and week 12.

Blood biomarkers of dyslipidemia and dysglycemia: The patient provided fasting blood samples before and after the weight management program for the analysis of various cardiometabolic biomarkers (**Table 2**). The program led to improvements in his triglycerides (TG), TG-to-HDL ratio, hemoglobin A1c (HbA1c), and insulin levels. His cholesterol, HDL, glucose, and C-reactive protein (CRP) were maintained within the reference range.

Table 2. Various cardiometabolic biomarkers at baseline and Week 12.

	Baseline	Week 12	Desirable range
Triglycerides (mg/dL)	115	68	< 100
Cholesterol (mg/dL)	194	193	< 200
HDL (mg/dL)	47	43	> 40
LDL (mg/dL)	124	136	< 130
TG/HDL	2.45	1.58	< 3*
Cholesterol/HDL	4.13	4.49	
Glucose (mg/dL)	86	82	< 100
HbA1c (%)	5.5	5.1	< 5.7
Insulin (μU/mL)	19	5.0	< 12
CRP (mg/L)	1.9	2.3	< 1.0

*American units

Adherence to lifestyle changes: Every 2 weeks, the patient rated the level of difficulty to follow the food plan and exercise regimen (0 indicated very easy and 10 very hard). The patient expressed that Metagenics' high-protein, high-phytonutrient, low-glycemic food plan and pedometer-monitored physical activity were quite easy to follow (**Figure 4**). By Week 12, he found no difficulty following these lifestyle changes.

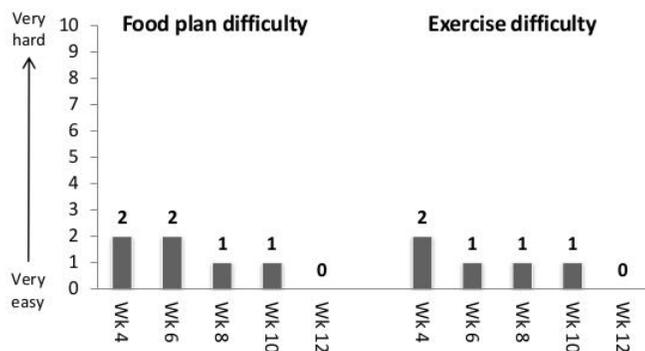


Figure 4. Level of difficulty to follow the food plan and exercise regimen over the course of 12 weeks.

Quality of life: The FMRC staff instructed the patient to assess his quality of life before and after the program using the Medical Symptoms Questionnaire (MSQ) and Medical Outcomes Study 36-Item Short Form Survey (MOS SF-36). MSQ scores were reduced from 21 at baseline to 6 at Week 12, indicating fewer medical related complaints. MOS SF-36 taps 8 health concepts; each ranges from 0 (unfavorable state) to 100 (favorable state). Comparing with baseline, the weight management program helped the patient improve his quality of life in several aspects, as indicated by the upward shift from the dotted line to the solid line (**Figure 5**).

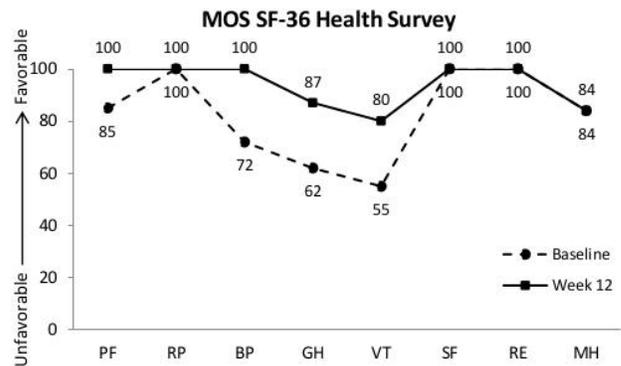


Figure 5. Assessment of quality of life using MOS SF-36 Health Survey. PF: physical functioning; RP: role limitations due to physical health problems; BP: bodily pain; GH: general medical health; VT: vitality; SF: social functioning; RE: role limitations due to emotional problems; MH: mental health.

CASE 2 is a 38-year-old Caucasian female who weighed 181.8 pounds prior to her visit to FMRC. Her BMI was 33.3, indicating she was in “obesity class I” category. She contacted the FMRC expressing her interest in participating in the weight management program. After a screening visit, she started the program aiming at reducing 7.5% of her total body weight by the end of 12 weeks.

Results:

Body weight: The patient lost weight steadily. At Week 12, she had lost 19.8%, or 36.0 lbs, of her total weight (**Figure 6**), surpassing the original 7.5% goal half-way through the program.

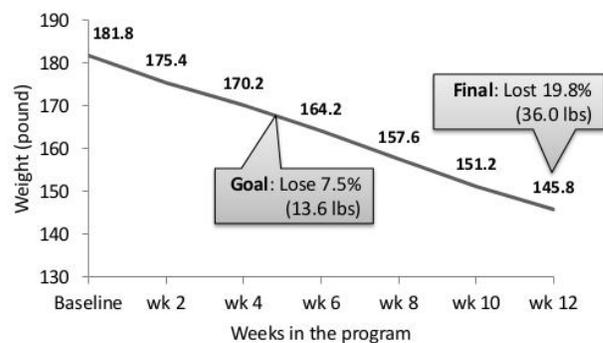


Figure 6. Weight change over the 12-week period for Case 2.

BMI and waist circumference: The patient's BMI was reduced from 33.3 to 26.7; she was no longer categorized as obese. She also reduced her waist circumference by 6.5 inches (Figure 7).

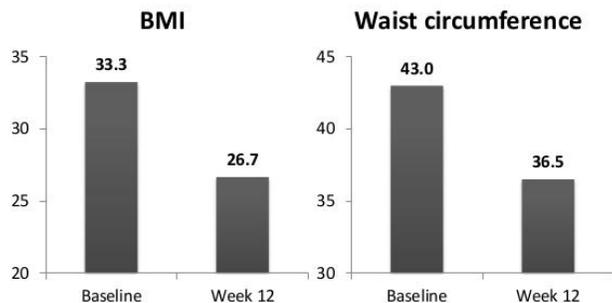


Figure 7. BMI and waist circumference measurements at baseline and Week 12.

Body composition: The patient's fat mass was reduced from 68.9 lbs at baseline to 39.4 lb at Week 12; her lean body mass from 112.9 lb to 106.4 lb. Proportionally, her body composition was improved: the program helped her reduce percent fat mass but maintain her percent lean body mass (Figure 8).

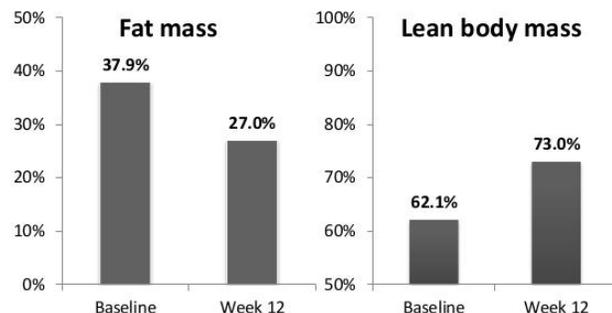


Figure 8. Body composition analysis by BIA at baseline and Week 12.

Blood biomarkers of dyslipidemia and dysglycemia: The patient's fasting blood samples were analyzed for various cardiometabolic biomarkers (Table 3). Compared with baseline, her triglycerides, HDL, TG-to-HDL ratio, HbA1c, and insulin were improved. Her cholesterol, LDL, glucose, and CRP were maintained within the reference range.

Table 3. Various cardiometabolic biomarkers.

	Baseline	Week 12	Desirable range
Triglycerides (mg/dL)	103	75	< 100
Cholesterol (mg/dL)	108	146	< 200
HDL (mg/dL)	41	45	> 60
LDL (mg/dL)	46	86	< 130
TG/HDL	2.51	1.67	< 3*
Cholesterol/HDL	2.63	3.24	
Glucose (mg/dL)	90	76	< 100
HbA1c (%)	5.4	4.8	< 5.7
Insulin (μIU/mL)	5.0	< 2	< 12
CRP (mg/L)	1.0	0.7	< 1.0

Adherence to lifestyle changes: Every 2 weeks, the patient rated the level of difficulty to follow the food plan and exercise regimen. At the first 6 weeks, she felt that the food plan was somewhat easy to follow. By the last 4 weeks, the food plan had become quite easy. She had little difficulty following the exercise regimen (Figure 9).

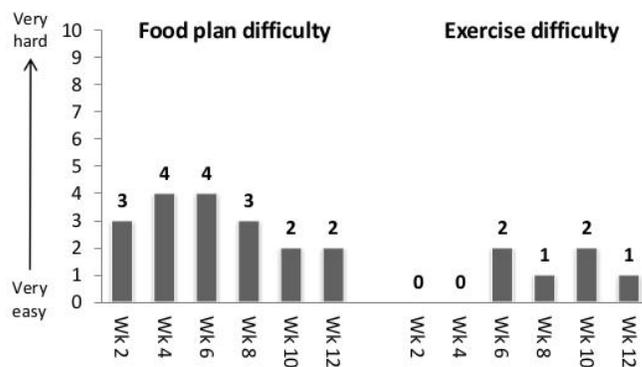


Figure 9. Level of difficulty to follow the food plan and exercise regimen over the course of 12 weeks.

Quality of life: The patient's MSQ scores were reduced from 5 at baseline to 2 at Week 12, indicating fewer medical related complaints. The MOS SF-36 data showed that the weight management program helped her improve quality of life in several aspects, as indicated by the upward shift from the dotted line to the solid line (Figure 10).

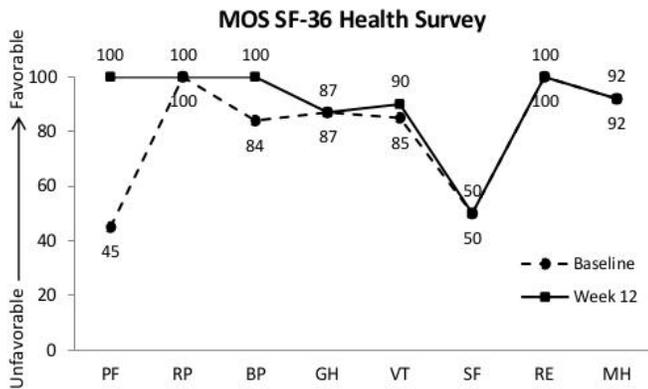


Figure 10. Assessment of quality of life using the MOS SF-36 Health Survey. PF: physical functioning; RP: role limitations due to physical health problems; BP: bodily pain; GH: general medical health; VT: vitality; SF: social functioning; RE: role limitations due to emotional problems; MH: mental health.

LONG-TERM WEIGHT MAINTENANCE STRATEGY

For health professionals and their patients, achieving or exceeding the initial weight loss goal is the beginning of weight loss maintenance (or further weight loss if appropriate), not the conclusion of the treatment. New physiological and psychological challenges may arise during this phase, requiring strategies to ensure long-term success.

We recommend the less restrictive, Mediterranean-style, low-glycemic-load food plan as the long-term dietary choice. Clinical trials have demonstrated its numerous benefits, including reductions in body weight, improvements in glycemic control, resolution of metabolic syndrome, and decreases in cardiovascular and diabetic risks.²³⁻²⁶ The use of high-protein meal replacements provides convenience and can enhance the benefit of the food plan. As the patients continue to achieve negative energy balance, nutritional supplements will help offset potential nutrition deficiencies.

Regular exercise predicts long-term weight maintenance. We recommend the continuation of the 10,000-step-daily, pedometer-monitored exercise regimen. Depending on the progress made during the initial 12 weeks, the patients may engage in more strenuous activities during weight maintenance.

Health professionals can significantly help patients sustain behavior changes during the weight maintenance phase, as evidence has shown that frequent contacts between providers and patients promote weight maintenance. Cognitive behavior therapy during this phase will help motivate patients to self-monitor (diet and exercise) progress, manage stress, control outside stimuli, solve problems, set realistic goals, build

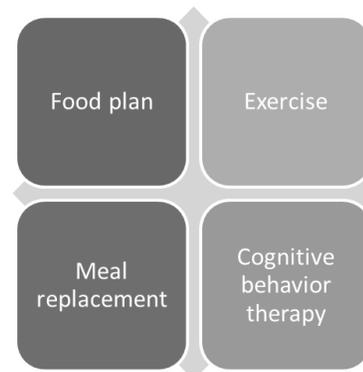
internal strengths, and successfully acquire a long-term, new set of eating and exercise habits.

Based on current research, the FMRC recommends an optimal cyclic program for long-term success:

- Phase 1: 3 to 6 months of the weight management program (high-protein, high-phytonutrient, low-glycemic food plan, meal replacements, and supplements, 10,000 steps daily exercise, and regular cognitive behavioral therapy sessions)
- Phase 2: 6 months of the weight maintenance program (Mediterranean-style, low-glycemic-load food plan, meal replacements, and supplements, 10,000 steps daily exercise, and regular cognitive/behavioral therapy sessions)
- After completion of the 9 to 12 month cycle, repeat the weight management program as needed until target weight is achieved and maintained.

SUMMARY

Metagenics' weight management program is a comprehensive, structured, evidence-based lifestyle program. It is designed for overweight and obese adults to obtain healthy weight level to reduce associated risks such as high triglycerides, high cholesterol, metabolic syndrome, type 2 diabetes, coronary heart disease, and others.



The summary from FMRC's weight management study and the detailing of two individual cases demonstrated that Metagenics' weight management program is effective in improving body weight, body composition, cardiometabolic risk factors, and the quality of life of individuals affected by overweight and obesity.

Individuals who believe it is important to stay healthy will appreciate the program's balanced approach in addressing their lifestyle (diet and exercise) needs, as well as psychological challenges. Those who are ready to take responsibility for their own health will find the program logical, supportive, and efficacious.

Designed to help people live happier, healthier lives, Metagenics' weight management program provides comprehensive tools that health professionals can rely on—educational materials, food plan details, exercise instructions, cognitive/behavior therapy techniques, seminars, and science-based products—to address the increasing obesity epidemic.

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Genetic Potential Through Nutrition

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