# **Original** Article

## Obesity intervention in persons with spinal cord injury

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Study design: A single group uncontrolled trial.

**Objectives:** Despite widespread emphasis on the obesity-related health risks in persons with spinal cord injury (SCI), limited research has been carried out to intervene in this problem. This study was conducted to assess the initial effectiveness of a weight loss program on various health outcomes in persons with SCI.

Setting: A rehabilitation center in Birmingham, Alabama, United States.

**Methods:** A total of 16 individuals with chronic SCI who were overweight or obese participated in a weight management program that consisted of 12 weekly classes, covering nutrition, exercise, and behavior modification. Various outcomes were examined over a 6-month period (baseline, week 12, and week 24), including body composition measured by dual energy X-ray absorptiometry, physiologic measures, diet behavior, and psychosocial and physical functioning. Of these, 13 participants returned for the week 24 follow-up.

**Results:** Weight loss averaged  $3.5\pm3.1$  kg (3.8% of the initial weight) at week 12 and  $2.9\pm3.7$  kg (3.0% of the initial weight) at week 24. There was a significant reduction from baseline values at weeks 12 and 24 in body mass index, anthropometric measurements, and fat mass and improvement in diet behavior and psychosocial and physical functioning, while lean mass and blood albumin and hemoglobin levels were maintained. A correlation analysis showed that a greater weight loss was importantly (r > 0.4) associated with a greater reduction in total cholesterol at weeks 12 and 24 and in systolic and diastolic blood pressure at week 24. Several factors were important (r > 0.4 or r < -0.4) in determining the success in weight loss, including age, race, marital and employment status, family history of overweight/obesity, level and duration of injury, and cholesterol level at baseline.

**Conclusions:** This is the first demonstration that a carefully planned program with time–calorie displacement diet is effective for overweight/obese individuals with SCI to lose weight without compromising total lean mass and overall health. It provides foundation for a future large clinical trial for weight loss of persons with SCI or other spinal cord dysfunction.

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#### Introduction

Over the last few decades, there has been a dramatic increase in the prevalence of obesity in the United States, from approximately 15% in the years 1976-1980 to 31% in  $1999-2000.^1$  Body mass index (BMI), calculated by dividing weight in kilograms by the square

of height in meters, is widely used to define overweight  $(25 \text{ kg/m}^2 \leq \text{BMI} < 30 \text{ kg/m}^2)$  and obesity  $(\text{BMI} \geq 30 \text{ kg/m}^2)$ . The prevalence of overweight/obesity increased from 56% in 1988–1994 to 65% in 1999–2000.<sup>1</sup> Overweight and obesity are especially evident among persons with disabling conditions. It was about 2.5 times more common among individuals with lower extremity disability than those without any disability.<sup>2</sup>

During the initial phase of spinal cord injury (SCI), individuals tend to lose weight because of

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hypermetabolism and hypercatabolism following major trauma.<sup>3–5</sup> After the acute phase, with the loss of metabolically active muscle mass, the resting energy expenditure decreases.<sup>5–7</sup> As a result of a relatively sedentary lifestyle after injury, the energy needs for physical activity decreases as well.<sup>8</sup> Without an appropriate adjustment for the dietary intake after injury, the energy intake easily exceeds daily energy requirements, which predisposes the affected individuals to weight gain.<sup>5</sup> A recent survey of 348 persons with chronic SCI showed that approximately 40% were overweight or obese.<sup>9</sup> More importantly, given the same height and weight, individuals with SCI usually carry a larger amount of fat mass than able-bodied persons, particularly in the abdominal area.<sup>10</sup>

Obesity-related health risks are of great concern for the SCI population. Coronary heart disease, hypertension, diabetes, impaired glucose tolerance, and an abnormal lipid profile were reported to be more common in persons with SCI than in able-bodied control subjects.<sup>11–13</sup> More medical complications were observed among individuals with SCI who were overweight or obese than those in an underweight/ideal weight group.<sup>9</sup> Persons with SCI may suffer additional burdens related to excess weight, such as diminished physical functioning, independence, and community integration. Social stigmatization and discrimination are additional concerns.

Substantial evidence documents the improvement in health outcomes even after modest weight loss in the general population.<sup>14</sup> There is, however, a lack of information regarding the health outcomes of weight loss in individuals with SCI. The use of dietary extremes to achieve weight loss may compromise the lean body mass, bone mineral content, and nutritional status of the affected individuals and consequently increase their already-high risk of various medical complications.

Limited educational resources are available on nutritional issues and weight control for this high-risk population. Weight loss programs designed for ablebodied persons may not have appropriately addressed the special health,<sup>9,11–13,15–19</sup> nutrition,<sup>20–29</sup> and management needs<sup>30</sup> of individuals with SCI. We therefore conducted a pilot study to assess the effectiveness of a modified weight management program in various health outcomes over a 6-month period. We demonstrated that among overweight/obese individuals with SCI, weight loss is achievable without compromising the muscle mass and overall health with the time–calorie displacement dietary approach. The study protocol and instruments for data collection were approved by the University of Alabama at Birmingham Institutional Review Board.

## Methods

## Weight management program

Dietary approach Time-calorie displacement diet, developed at the University of Alabama at Birmingham,

Birmingham, Alabama, United States in 1976, emphasizes the ingestion of large quantities of high-bulk low-energy-density foods (primarily vegetables, fruits, high-fiber grains, and cereals) and moderation in highenergy-density foods (meats, cheeses, sugars, and fats).<sup>31</sup> This dietary pattern has been shown to prolong eating time, displace intake of more energy-dense foods, and produce equal satiety at significantly lower energy intake as compared to a high-energy-density diet.<sup>32,33</sup>

Starting at 1200 kilocalories for women and 1400 for men, participants are prescribed the number of daily servings for five food groups (fat, meat/dairy, starch, fruit, and vegetable) in order from high energy density to low energy density.<sup>31,34,35</sup> Each food group contains a list of the preferred foods that provide more fiber and less energy and the occasional foods that have high sodium and few nutrients. Participants are encouraged to choose from the preferred foods for most of the meals.

In adapting the time-calorie displacement diet for persons with SCI, we specifically looked at the special nutritional needs, metabolic characteristics and convenience factors that might impact the affected individuals. We emphasized the importance of appropriate protein and nutrients in promoting or maintaining skin integrity, bowel function, bone health, and urinary tract health. Many tips were also provided for easier and healthier meal preparation.

Intervention protocol Once a week for 12 weeks, participants and their spouses or attendants attended a 90-min group class, primarily led by a registered dietitian. These classes were intended to increase the knowledge of nutrition and exercise on weight control, address setting realistic goals on weight reduction, provide skill training necessary to change health behaviors, and enhance social support among participants (Table 1).

Beginning in week 6, a 30-min exercise session of specifically designed home-based activities for persons with SCI was incorporated into each weekly class and was intended to encourage participation in physical activity for fun, strength, and endurance. The importance of injury prevention, body temperature regulation, and monitoring exercise intensity was also emphasized.

Psychologists were consulted in areas related to stress management, relaxation techniques, problem-solving, and behavior change strategies. The intervention protocol was initially tested, mainly for the feasibility, on four individuals with SCI who were overweight or obese. Based on their evaluations, additional changes were made to this program prior to finalization.

## Subjects

Study subjects were recruited at the community level. The inclusion criteria were: (1) age 19 years or older, (2) traumatic or nontraumatic SCI for more than 1 year, (3)  $BMI \ge 25 \text{ kg/m}^2$ , and (4) not currently enrolled in a

Week	Topic		
1	Choose Right • Understand the basics of time-calorie displacement theory • Provide Food Plans and sample menus to follow		
2	<ul> <li>Record Right</li> <li>Understand basic facts that help in weight management</li> <li>Learn to record diet and physical activity</li> </ul>		
3	<ul> <li>Goal Setting</li> <li>Understand steps to setting realistic goals</li> <li>Set personal goals and complete Action Plan for weight loss</li> </ul>		
4	<ul> <li>Plan Right</li> <li>Know important factors to consider in planning meals</li> <li>Practice planning menus for an entire week</li> </ul>		
5	<ul> <li>Shop Right</li> <li>Know ways to avoid temptations when grocery shopping</li> <li>Learn how to read the information on a food label</li> </ul>		
6	<ul> <li>Move Right</li> <li>Introduce physical activities for fun, strength, and endurance</li> <li>Learn tips for measuring exercise intensity and injury prevention</li> </ul>		
7	<ul> <li>Dine Right</li> <li>Learn tips for eating out and still following the Food Plan</li> <li>Enjoy eating a meal out at a restaurant by planning ahead</li> </ul>		
8	<ul> <li>Heart Smart</li> <li>Understand the potential for health within the context of spinal cord injury</li> <li>Recognize diet and lifestyle adjustment to maximize health</li> </ul>		
9	<ul> <li>Cook Right</li> <li>Learn ways to prepare healthier meals by adding grains, fruits and vegetables, and to revise recipes for fewer calorie</li> <li>Know how to take shortcuts for easier meal preparation</li> </ul>		
10	<ul> <li>Think Right</li> <li>Understand the relationship between food and feelings</li> <li>Develop strategies to alter personal environmental clues to control eating behavior</li> </ul>		
11	<ul> <li>Stress Management</li> <li>Know signs and symptoms associated with stress</li> <li>Identify sources of stress and strategies for stress management</li> </ul>		
12	<ul> <li>Start Right</li> <li>Know important factors for weight regain</li> <li>Develop strategies for keeping weight off</li> </ul>		

weight loss program, receiving weight loss medication, or taking medication that would influence weight change. They were excluded from the study if they were pregnant or had concurrent medical conditions for which changes in exercise or diet would be contraindicated.

To maintain smaller individual group sizes for the intervention, four cohort groups (including the pilot test group) were established between 2001 and 2003. One woman dropped out of the study during program intervention because of transportation problems and

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was not included in the analysis. A total of 16 participants completed the intervention program (Table 2). In all, 15 individuals had traumatic SCI (one woman was injured during the birth delivery), whereas one woman had spina bifida.

#### Data collection

A face-to-face interview was conducted at initial visit to obtain information on sociodemographic characteristics and weight history. Medical history and medication use

Characteristics	n (%)
Gender	
Male	9 (56)
Female	7 (44)
Race	
White	13 (81)
African American	3 (19)
Marital status	
Married or living as married	6 (37.5)
Divorced	6 (37.5)
Never married	4 (25)
<i>Education</i> High school graduate or less	5 (31)
Some college or technical school	6 (38)
College graduate or higher	5 (31)
Employment status Employed full- or part-time	6 (38)
Retired	5 (31)
Student	2(12)
Unemployed	3 (12)
Chemployed	5 (17)
Family history of overweight/obesity	
Yes	11 (69)
No	5 (31)
Level of injury	
Tetraplegia	4 (25)
Paraplegia	12 (75)
ASIA Impairment Scale	
A	9 (56)
С	3 (19)
D	4 (25)
	Mean (Range)
Age (years)	43.8 (21.0-66.0)
Years since injury	17.5 (1.7-60.3)

**Table 2** Characteristics of study participants (N = 16)

ASIA = American Spinal Injury Association

were also reviewed to ensure qualification. Data on health outcomes were collected over a 6-month period: at baseline, week 12 (immediately after intervention), and week 24 (12 weeks after intervention). The information obtained previously was blind to data collectors at each assessment visit.

*Physiologic measures* Participants were asked to wear light clothing and no shoes for these measures. Body weight was measured to the nearest 0.1 kg on a scale adapted for use with wheelchairs. Height was measured to the nearest 0.1 cm in a supine position with legs outstretched and feet in dorsiflexion.

Measurements of waist and neck were taken to the nearest 1 mm in the sitting position using a nonstretch-

able tape measure. Skinfold thickness was examined over chest, biceps, triceps, subscapula, and suprailiac. Measurements were made on the right side of the body by the same research personnel throughout the 6-month period according to standardized procedures.<sup>36</sup> Dual energy X-ray absorptiometry (DXA) scan was used to estimate fat mass, lean mass, and bone mineral content for the whole body or for any defined anatomical region. DXA scan was not performed for the pilot test group.

Blood pressure was taken on the left arm with a mercury manometer after the subject had been sitting quietly for 10 min. Serum lipids (total cholesterol, highdensity-lipoprotein (HDL) and low-density-lipoprotein (LDL)-cholesterol) were determined in venous blood samples using standardized laboratory techniques. Blood hemoglobin and albumin concentrations were monitored to assess the nutritional safety of the intervention.

Diet behavior The usual food intake was measured by the Health Habits and History Questionnaire. This food frequency questionnaire, developed at the National Cancer Institute, asks the respondent to indicate the average frequency of consumption for approximately 100 foods and their portion size (small, medium, or large) over the past year.37 The time frame for the dietary recall was modified as over the past month for follow-up assessments at weeks 12 and 24. Nutrient calculations were performed using a standard computer program (DietSys). Participants were also asked to rate their eating habits, their knowledge of nutrition, and nutritional quality of their diets using a 4-point scale (1 = poor, 2 = fair, 3 = good, and 4 = excellent) and also the confidence of their ability to control weight using a 5-point scale (1 = not at all, 2 = a little confident,3 = moderately confident, 4 = very confident, and 5 = extremely confident) at initial and week 12 visits.

*Psychosocial well-being* Subjective feelings of wellness and distress during the last month were assessed by the General Well-Being Schedule.<sup>38</sup> It is an 18-item selfadministered questionnaire to assess six dimensions (anxiety, depression, general health, positive well-being, self-control, and vitality) with a total possible scores ranging from 0 to 110. The proposed cutoff points to represent three levels of distress are 0–60 (severe distress), 61–72 (moderate distress), and 73–110 (positive well-being). This instrument appears to be highly reliable with good test–retest reliability (r = 0.68-0.85) and internal consistency ( $\alpha$  coefficient = 0.93) and is significantly correlated with similar measures of emotional distress.<sup>38</sup>

To assess the impact of weight on psychosocial and physical functioning, participants were asked to rate statements that best describe them during the past month on a 5-point scale (1 = never true, 2 = rarely true, 3 = sometimes true, 4 = usually true, and 5 = always true), 'I am troubled by heartburn,' 'Because of my weight, I have trouble with transferring,' 'Because of my

weight, I have difficulty putting on or taking off my clothing,' 'Because of my weight, I do not feel sexually attractive,' and 'Because of my weight, my self esteem is not what it should be.' These items have been shown to be sensitive to weight change.39 In addition, bowel function was assessed by self-reported time required for the bowel program from the time the individual tried to start a bowel movement or began stimulation to the time when the last stool came out.

## Statistical analysis

Significance of the change in each of these health outcomes between initial and follow-up assessments was determined by a paired *t*-test or equivalent nonparametric method (Wilcoxon's signed rank sum test). The association of weight change with participants' characteristics and other health outcomes was examined by the Pearson's correlation analysis. To explore potentially clinically important factors that were associated with weight loss in this small-scale pilot study, we considered a correlation coefficient greater than 0.40 or less than -0.40 as important association regardless of the statistical significance level. Also, to avoid unjustified dismissal of potentially meaningful findings in this pilot study, no adjustment for multiple comparisons was made in the analysis. A probability of less than 5% was considered to be statistically significant.

## Results

The present study was conducted to assess the initial effectiveness of a weight management program on weight reduction and health improvement over a 6-month period. The initial weight of the 16 participants averaged 97.4 kg with BMI of  $34.3 \text{ kg/m}^2$  (range: 26.6–  $42.5 \text{ kg/m}^2$ ). The average weight gain of the 13 participants after injury who had appropriate information on preinjury weight was 20.7 kg (standard deviation: 20.2), approximately gaining 2.0 kg per year.

## During intervention

Over the 12-week program intervention, 14 participants lost weight  $(4.2\pm2.7 \text{ kg})$ , whereas one participant maintained his initial weight and one participant gained 2.3 kg. Overall weight loss of this group was 3.5 kg, representing an average loss of 3.8% of the initial weight. There was a significant decrease in BMI, waist circumference, neck circumference, and skinfold thickness over the intervention period (Table 3). Among the 12 participants with information on DXA scan, the total body fat significantly declined, whereas the lean mass and bone mineral content did not change significantly.

The HDL-cholesterol fell 3.2 mg/dl from a baseline of 43.1 mg/dl, whereas the LDL-cholesterol did not change significantly. There was no significant change in blood pressure, hemoglobin, or albumin level. Average energy intake of this group, estimated by the food frequency

questionnaire, decreased 219.5 kcal/day with a significant reduction in the intake of saturated fat and cholesterol and an increase in fiber intake. Subjective feelings of the ability to control weight, eating habits, knowledge of nutrition, nutritional quality of diet, and psychosocial and physical functioning significantly improved. The time required for bowel movement also seemed to improve, although not statistically significantly.

There was a moderate-to-strong correlation of the amount of weight loss with the decrease in waist circumference (r = 0.41) and cholesterol level (r = 0.43); LDL, r = 0.36; HDL, r = -0.18) and increase in nutritional quality of diet (r = -0.45). The increase in fiber intake was also somewhat importantly (r = -0.39)associated with weight reduction. However, none of these correlations reached statistical significance (P > 0.05) perhaps because of the small sample size.

## Postintervention follow-up

Three individuals did not return for the week 24 assessment visit because of health reasons. One man and one woman had a grade II-III pressure ulcer over the sacral/coccygeal area, while one man had severe dehydration and anemia requiring hospitalization for fluid replacement and blood transfusion. Of the 13 individuals with follow-up information, six continued to lose weight  $(2.1\pm1.8 \text{ kg})$  over the 12 weeks after completing the intervention program, four kept off the lost weight, and three gained weight (3.0+2.2 kg). A total of 10 individuals had weights that were below their baseline. Overall weight loss of the 13 individuals was 2.9 kg from initial weight of 98.2 kg (Table 4).

There was a significant reduction from baseline values in BMI, total fat mass, waist circumference, and dietary intake of saturated fat over the 12 weeks after intervention. Participants reported improvement in performing activities of daily living (transferring and dressing) and in body image (sexual attractiveness).

The amount of weight loss at week 24 was importantly associated with a decrease in cholesterol level (r = 0.52; LDL, r = 0.34; HDL, r = -0.02), systolic blood pressure (r=0.51), diastolic pressure (r=0.49), heartburn sensation (r = 0.65), and subjective feelings of sexual unattractiveness (r = 0.46). None of these measures except heartburn sensation (P=0.02), however, reached statistical significance (P > 0.05).

#### Associated factors

Many baseline factors were important, with correlation coefficients >0.4 or <-0.4, in determining the amount of weight reduction during program intervention (week 12). These included being white (r = -0.44), tetraplegic (r = -0.43), married or living as married (r = -0.67), and having greater confidence in weight control (r = -0.42). Being older age (r = -0.39) and of longer duration postinjury (r = -0.36) were also somewhat

## **Table 3** Changes in health profile during program intervention (week 12, n = 16)

Harlth muffle	Initial More (a.d.)	Change Mean (s.d.)	P <sup>a</sup>
Health profile	Mean (s.d.)		
Body weight (kg)	97.4 (17.8)	-3.5 (3.1)	0.0004
Body mass index (kg/m <sup>2</sup> )	34.3 (4.5)	-1.3 (1.2)	0.0005
Body composition $(kg)^{b}$			
Total fat mass	41.4 (11.2)	-2.9 (4.6)	0.05
Total lean mass	51.8 (10.2)	-0.8 (5.1)	0.58
Bone mineral content	2.31 (0.55)	0.02 (0.16)	0.68
Anthropometrics			
Waist circumference (cm)	117.4 (17.0)	-4.1 (5.0)	0.005
Neck circumference (cm)	42.7 (5.7)	-0.9 (1.4)	0.02
Skinfold thickness (mm) <sup>c</sup>	111.4 (34.5)	-10.7 (9.7)	0.0005
Blood pressure (mmHg) <sup>d</sup>			
Systolic	125.7 (19.3)	-2.1 (16.0)	0.63
Diastolic	71.2 (11.2)	0.6 (12.1)	0.85
Lipid profile (mg/dl)			
Total cholesterol	201.7 (30.2)	-5.8 (20.9)	0.28
HDL-cholesterol	43.1 (14.9)	-3.2 (5.4)	0.03
LDL-cholesterol	136.2 (20.5)	-1.8 (22.1)	0.76
Safety profile			
Hemoglobin (gm/dl)	13.4 (1.5)	0.08 (0.7)	0.63
Albumin (mg/dl)	3.8 (0.4)	-0.02 (0.3)	0.73
Diet behavior			
Total calories (kcal/day)	1605.6 (672.4)	-219.5 (664.1)	0.21
Saturated fat (gm/day)	23.2 (10)	-8.7(10.9)	0.006
Cholesterol (gm/day)	228.3 (99.0)	-77.2 (78.3)	0.001
Fiber (gm/day)	10.9(4.8)	7.6 (7.2)	0.0007
Confidence of weight control Self-rated knowledge of nutrition	2.5 (1.1) 2.1 (0.7)	$ \begin{array}{c} 1.1 (1.1) \\ 0.6 (0.7) \end{array} $	0.002 0.01
Self-rated nutritional quality of diet	2.3 (0.8)	0.0(0.7) 0.9(0.9)	0.01
Self-rated eating habit	2.3 (0.8)	0.6 (0.6)	0.002
Psychosocial and physical functioning			
General well-being schedule	68.4 (9.7)	5.3 (13.0)	0.12
Troubled by heartburn	2.3 (1.3)	-0.9(1.2)	0.008
Difficulty transferring	3.7 (1.4)	-1.1 (1.3)	0.004
Difficulty putting on/taking off clothing	3.1 (1.3)	-0.9(1.2)	0.02
Don't feel sexually attractive	3.3 (1.4)	-0.8(1.1)	0.02
Self-esteem not what it should be	3.3 (1.2)	-1.0 (1.0)	0.004
Duration of bowel program (min) <sup>e</sup>	74.6 (77.5)	-27.5 (86.1)	0.27

s.d. = standard deviation

<sup>a</sup>Paired *t*-test or equivalent nonparametric method

<sup>b</sup>Data based on persons with appropriate information (n = 12)

<sup>c</sup>Sum of four skinfolds: chest, biceps, triceps, and suprailiac <sup>d</sup>Data based on persons with appropriate information (n = 15)

<sup>e</sup>Data based on persons with appropriate information (n = 13), measured by self-reported time from starting a bowel movement or stimulation to the end of stool flow

importantly associated with a larger amount of weight loss. However, none of these associations was statistically significant except marital status (P = 0.005).

Success in maintaining weight below the initial level at week 24 was importantly associated with being older (r = -0.45), of longer duration postinjury (r = -0.49), tetraplegic (r = -0.42), employed full- or part-time (r = -0.45), without family history of overweight/ obesity (r = -0.46), and with lower total or LDLcholesterol level at baseline (r = -0.53 and -0.58,respectively). However, only LDL-cholesterol reached statistical significance (P = 0.04).

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#### **Table 4** Changes in health profile during postintervention follow-up (week 24, n = 13)

	Initial	Change Mean (s.d.) -2.9 (3.7)	<i>P</i> <sup>a</sup> 0.01
Health profile	Mean (s.d.)		
Body weight (kg)	98.2 (19.7)		
Body mass index (kg/m <sup>2</sup> )	34.5 (4.7)	-1.1 (1.4)	0.01
Body composition $(kg)^{b}$			
Total fat mass	42.1 (12.5)	-2.2(1.8)	0.007
Total lean mass	51.40 (10.85)	-0.08 (4.97)	0.96
Bone mineral content	2.24 (0.60)	0.02 (0.12)	0.69
Anthropometrics			
Waist circumference (cm)	117.1 (18.1)	-3.3 (5.2)	0.04
Neck circumference (cm)	42.6 (6.2)	-1.1(2.1)	0.08
Skinfold thickness (mm) <sup>c</sup>	114.1 (35.7)	-13.2 (10.6)	0.0007
Blood pressure $(mmHg)^d$			
Systolic	120.3 (12.5)	4.5 (23.1)	0.54
Diastolic	68.6 (10.9)	-1.6 (9.9)	0.59
Lipid profile (mg/dl)			
Total cholesterol	201.2 (32.7)	0.3 (24.1)	0.96
HDL-cholesterol	44.1 (16.1)	-0.9(5.4)	0.59
LDL-cholesterol	133.7 (19.9)	-4.2 (18.1)	0.42
Safety profile			
Hemoglobin (gm/dl)	13.6 (1.2)	-0.04(0.6)	0.83
Albumin (mg/dl)	3.8 (0.5)	-0.04 (0.2)	0.57
Diet behavior			
Total calories (kcal/day)	1657.4 (702.0)	-315.8 (567.2)	0.07
Saturated fat (gm/day)	23.5 (10.9)	-5.6 (8.1)	0.03
Cholesterol (gm/day)	234.1 (105.9)	-39.7 (86.0)	0.12
Fiber (gm/day)	11.1 (4.3)	3.1 (6.8)	0.13
Psychosocial and physical functioning			
General well-being schedule	69.1 (10.5)	0.7 (13.0)	0.85
Troubled by heartburn	2.2 (1.1)	-0.3 (0.5)	0.13
Difficulty transferring	3.6 (1.5)	-1.1(1.3)	0.02
Difficulty putting on/taking off clothing	2.9 (1.3)	-0.9(1.0)	0.02
Don't feel sexually attractive	3.1 (1.4)	-0.8(1.2)	0.03
Self-esteem not what it should be	3.0(1.2)	-0.6(1.2)	0.13 0.48
Duration of bowel program (min) <sup>e</sup>	68.8 (89.3)	-22.5 (96.0)	0.48

s.d. = standard deviation

<sup>a</sup>Paired *t*-test or equivalent non-parametric method

<sup>b</sup>Data based on persons with appropriate information (n=9)

<sup>c</sup>Sum of 4 skinfolds: chest, biceps, triceps, and suprailiac

<sup>d</sup>Data based on persons with appropriate information (n = 11)

<sup>e</sup>Data based on persons with appropriate information (n = 10), measured by self-reported time from starting a bowel movement or stimulation to the end of stool flow

## Discussion

Results from this study demonstrate that weight loss could be achieved with this 12-week program even among persons with tetraplegia and long duration of injury. Various measures of physical health and psychosocial functioning were improved or maintained after program intervention, while participants gradually developed favorable eating patterns. Moreover, the amount of weight loss was importantly associated with a reduction in the abdominal fat, blood cholesterol level, and blood pressure.

Previous randomized controlled trials in the ablebodied population reported that over 6 months of lifestyle intervention, an average weight loss of 8% of initial body weight could be achieved,<sup>14</sup> which is somewhat similar to the observed 3.8% in 12 weeks in the present study of persons with SCI. However, approximately a half of our study participants did not continue to lose weight during the postintervention follow-up, which resulted in an average weight loss of 3.0% in 24 weeks.

Difficulty in adhering to the weight loss strategies without the continuous support of a formal program intervention is a concern; among those seven participants, who failed to continue to lose weight, the calorie deficit in the diet from baseline was  $378.9 \pm 652.9$  kcal/day during program intervention and  $265.5 \pm 529.8$  kcal/day during postintervention follow-up. Extended intervention in clinical or community settings may be needed to help some individuals with SCI cope with the complexities of long-term weight management. Physical activity also plays an important role in creating an energy deficit to achieve additional weight loss,<sup>40</sup> because energy needs usually decrease after weight reduction.<sup>41</sup>

The potential for losing lean mass and compromising nutritional status during weight loss is a serious concern for individuals with SCI because they are susceptible to various medical complications.<sup>9,11–13,15,19</sup> Anthropometric and body composition measurements showed that the weight loss observed in this study was largely accounted for by reduction in abdominal fat (waist circumference), subcutaneous fat (skinfold thickness), and total fat mass (measured by DXA scan). The preservation of lean mass, bone mineral content, and nutritional status (as reflected by maintenance of the blood hemoglobin and albumin) may have resulted from the modest degree of caloric restriction, modest rate of weight loss, emphasis on an appropriate intake of protein, and weekly exercise sessions.<sup>31</sup>

Many randomized controlled trials in able-bodied individuals who were overweight/obese have demonstrated that weight loss through diet modification with or without physical activity intervention reduced blood pressure in both hypertensive and nonhypertensive individuals.<sup>14</sup> Serum total cholesterol and LDL-cholesterol were decreased by weight loss, whereas HDLcholesterol was somewhat increased.14 Although we did not observe a significant improvement in blood pressure or lipid profile, a correlation analysis showed that a greater weight loss was importantly (r > 0.4) associated with a greater reduction in total cholesterol level (mainly LDL-cholesterol) at weeks 12 and 24 and a greater decrease in systolic and diastolic blood pressure at week 24. The observed reduction in HDL-cholesterol at week 12, but not week 24, may be secondary to the effect of acute calorie deficit.

The improvement in psychosocial well-being and physical functioning was consistent with previous investigations in the able-bodied population.<sup>42</sup> These improvements, nevertheless, did not seem to relate to the amount of weight loss except the feeling of sexual unattractiveness and heartburn sensation at week 24. These findings suggest that a small change in weight among persons with SCI who are overweight or obese could make a significant difference in their psychosocial and physical functioning. However, since we did not

have an attention-controlled group, we cannot rule out the possibility that participating in a group wellness program could improve psychologic well-being, regardless of the amount of weight loss.

Several factors were found to be important to determine the success in weight loss. Persons who were married or living as married appeared to be more successful in weight loss during program intervention, which suggests the importance of psychologic and physical support provided by the spouse or partner. The impact of a family history of overweight/obesity on weight loss may suggest the influence of genetic predisposition, obesity-promoting environment in the family, or both. The other identified predictors including age, race, employment status, level and duration of injury, and preintervention cholesterol level may be associated with food intake and physical activity behaviors, motivation for avoiding obesity, and confidence for controlling weight that influence their success in weight loss.

There was no adverse effect on overall health reported during program intervention. The occurrence of pressure ulcers in two participants during postintervention follow-up was not likely secondary to poor nutritional status with this program since their albumin (3.9 and 3.7 mg/dl at baseline and week 12, respectively) and hemoglobin levels (11.5 and 11.6 gm/dl at baseline and week 12, respectively) were maintained during program intervention. Given that pressure ulcers are a common secondary condition with the prevalence up to 30%,<sup>15</sup> this observation (two out of 16 participants) seems not to be surprising. Severe anemia and dehydration were reported by one participant during postintervention follow-up, which was not anticipated with this program given his albumin level 3.4 mg/dl and hemoglobin level 15.4 gm/dl at week 12.

There are several limitations of the present study, the most important of which is the lack of a control or comparison group. We are not sure whether participants would have responded in the same manner if there had been no intervention or an intervention just on nonspecific factors such as group support and attention from professionals. Another issue concerns the selective sample of individuals with SCI. The education level of this group was relatively high. This clinic-based program also precluded persons from participation who could not travel to our institution once a week for 12 weeks. This program therefore may not be the ideal approach for those individuals excluded from this study and may need further modification for socio-culturally diverse groups. A relatively large variation in measurements was observed in this study of a small sample size and consequently, the precision for the estimate of the effect sizes was decreased.

Despite these limitations, the present findings establish a baseline for further large-scale randomized controlled trials, with respect to the dietary and behavioral approaches, for weight loss in persons with SCI or other disabling conditions. This class-based program also provides the foundation for future study to develop an obesity intervention in other alternative format.

#### Conclusion

This is the first study to demonstrate that a carefully planned program with time-calorie displacement dietary approach is effective for overweight/obese individuals with SCI to lose weight at an acceptable rate without compromising total lean mass and overall health. This program provides a new resource that could be used to educate persons with SCI and their caregivers about weight control.

The variation in the amount of weight loss by participants' characteristics suggests the importance of the flexibility of an intervention program and competence of practitioners in working with diverse sociocultural and injury severity groups. Although intervention protocol involving weekly meetings is effective, such setting sometimes is not possible for many persons with SCI because of a lack of transportation and time constraints. The cost-effectiveness of alternative methods requiring less face-to-face contact for administering intervention for weight loss deserves further investigations, particularly in persons with disabling conditions.

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