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Clinical Research Article

Short-term Intensive Lifestyle Therapy in a Worksite Setting Improves Cardiometabolic Health in People With Obesity

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Abstract

Context: The Pritikin Program, which provides intensive lifestyle therapy, has been shown to improve cardiometabolic outcomes when provided as a residential program.

Objective: The purpose of the present study was to conduct a short-term, randomized, controlled trial to evaluate the feasibility and clinical efficacy of treatment with the Pritikin Program in an outpatient worksite setting.

Methods: Cardiometabolic outcomes were evaluated in people with overweight/obesity and ≥2 metabolic abnormalities (high triglycerides, low high-density lipoprotein (HDL) cholesterol, high blood pressure, HbA1c > 5.7%), before and after they were randomized to 6 weeks of standard care (n = 26) or intensive lifestyle therapy, based on the Pritikin Program (n = 28). Participants in the lifestyle intervention group were provided all food as packed-out meals and participated in group nutrition, behavioral education, cooking classes, and exercise sessions 3 times per week at a worksite location.

Results: Compared with standard care, intensive lifestyle therapy decreased body weight (−5.0% vs −0.5%), HbA1c (−15.5% vs +2.3%), plasma total cholesterol (−9.8% vs +7.7%), low-density lipoprotein cholesterol (−10.3% vs +9.3%) and triglyceride (−21.7% vs +3.0%) concentrations, and systolic blood pressure (−7.0% vs 0%) (all P values < .02), and increased exercise tolerance (time to exhaustion walking on a treadmill by +23.7% vs +4.5%; P < .001).

Conclusion: This study demonstrates the feasibility and clinical effectiveness of short-term, intensive outpatient lifestyle therapy in people with overweight/obesity and increased risk of coronary heart disease when all food is provided and the intervention is conducted at a convenient worksite setting.

Key Words: metabolic syndrome, low-fat diet, Pritikin diet, diabetes

Abbreviations: LDL, low-density lipoprotein; HDL, high-density lipoprotein.

Obesity is associated with a constellation of metabolic comorbidities, including hypertension, dyslipidemia, metabolic syndrome, and type 2 diabetes, which are major risk factors for coronary heart disease [1-3]. The cornerstone of therapy for people with obesity is lifestyle modification that involves decreasing energy intake and increasing physical activity to induce weight loss and improve metabolic health. The Pritikin Program is an intensive lifestyle intervention that combines diet therapy (comprising a diet that is low in fat, sodium, and refined carbohydrates, and high in whole grains, fruits, and vegetables) with multimodal exercise (comprising endurance, strength, and flexibility training) [4, 5]. An analysis of 4587 subjects who participated in the Pritikin Program for 3 weeks in a residential facility found this program decreased body weight and plasma total cholesterol, low-density lipoprotein (LDL) cholesterol, and triglyceride concentrations [6]. Providing this rigorous program in a residential setting enhances compliance because all meals are prepared and served on site and daily exercise is supervised, but decreases patient convenience and markedly increases program cost. We are not aware of any randomized controlled trials that evaluated the efficacy of the Pritikin Program provided in an outpatient setting on body weight and cardiometabolic outcomes.

The purpose of the present study was to conduct a short-term (6-week), randomized controlled trial to evaluate the feasibility and clinical efficacy of treatment with the Pritikin Program in an outpatient worksite setting in employees or their spouses who are overweight or obese with 2 or more components of the metabolic syndrome. To enhance compliance with the lifestyle intervention, group nutrition/behavioral educations sessions and supervised exercise sessions were provided 3 times per week and all food was provided as packed-out meals.

Materials and Methods

Study Subjects

A total of 57 men and women who were overweight or obese and who were either employees or spouses of employees of

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Ballad Health System (Johnson City, TN) participated in this study. Subjects were recruited through information sessions, email blasts, and flyers provided within the Ballad Health System. All subjects completed a comprehensive medical evaluation that included a history, physical examination, standard blood tests, and a 12-lead electrocardiogram. Subjects were required to have 2 or more of the following cardiometabolic abnormalities: (1) plasma triglycerides >150 mg/dL; (2) plasma high-density lipoprotein (HDL) cholesterol <50 mg/dL in women and <40 mg/dL in men; (3) high blood pressure (systolic blood pressure ≥130 mmHg or diastolic blood pressure ≥80 mmHg, or being treated with antihypertension medication); and (4) high HbA1c (≥5.7%) or type 2 diabetes. Potential subjects were excluded if they were unable to perform daily exercise, smoked cigarettes in the last year, or were not able to commit to attending all the exercise and behavioral modification sessions. All subjects provided written informed consent before participating in this study, which was approved by the Ballad Health Institutional Review Board.

Study Protocol

After subjects fasted for ~12 hours overnight at home, the following assessments were conducted at the Bill Gatton Center for Advanced Cardiac Rehabilitation and other Ballad Health System facilities: (1) body fat mass and fat-free mass determined by using dual-energy x-ray absorptiometry; (2) blood pressure; (3) plasma lipid profile (total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides); (3) HbA1c; (4) C-reactive protein; and (5) exercise tolerance determined by evaluating time to exhaustion while walking on a treadmill using the Bruce protocol. Because of technical issues, the C-reactive protein assay was not performed in 1 participant in the standard care group, and dual-energy x-ray absorptiometry scans were not performed in 2 participants (1 in the standard care and 1 in the lifestyle intervention group). In addition, LDL cholesterol concentrations were not calculated using the Friedewald equation for 4 participants (2 in the standard care and 2 in the lifestyle intervention group) as their plasma triglyceride concentrations were >400 mg/dL (>4.52 mmol/L).

After baseline testing was completed, subjects were randomized and stratified by sex and type 2 diabetes, by using a randomization table, to either the lifestyle intervention (30 subjects) or standard care group (27 subjects). Three subjects (2 in the lifestyle intervention group, and 1 in the standard care group) dropped out of the study after baseline testing was performed because of personal reasons or the need for a medical procedure (cholecystectomy), so 54 of the 57 enrolled subjects (95%) completed the study. Accordingly, 26 participants in the standard care group and 28 participants in the lifestyle intervention group completed the study and their data were included in the final data analysis.

Participants in the standard care group attended an inaugural group meeting at the start of the intervention, where they were advised to continue any medical treatment from their primary care providers and did not receive any additional dietary or exercise advice from the study team. The purpose of the meeting was to foster engagement in the study and enhance retention. The lifestyle intervention group participated in a 6-week outpatient Pritikin Lifestyle Therapy Program. The lifestyle intervention group was provided with all food as frozen Pritikin packed-out meals, which adhered to the Pritikin Eating Plan guidelines (3 meals/day with option to include whole fresh fruit and/or vegetables or to choose a Pritikin soup or an existing meal as a snack). The diet consisted of 10% to 15% of calories from fat, 15% to 20% from protein (primarily from plants but also from seafood, foul, or bison), and 65% to 75% from carbohydrate (comprising whole grains, vegetables, and fruits), and contained about 40 g/1000 kcal of fiber. Education guidelines and meals limited salt intake to <1500 mg/day, dietary cholesterol intake to <100 mg/day, caffeine intake to <400 mg/day, and the consumption of seafood, foul, and bison to 3.5 to 4.0 oz/day. Use of alcohol and tobacco products were not allowed. Food was shipped to each participant's home every week, and receipt was confirmed by mail tracking. All food and freezers for storing food at home were provided by the Pritikin ICR, LLC.

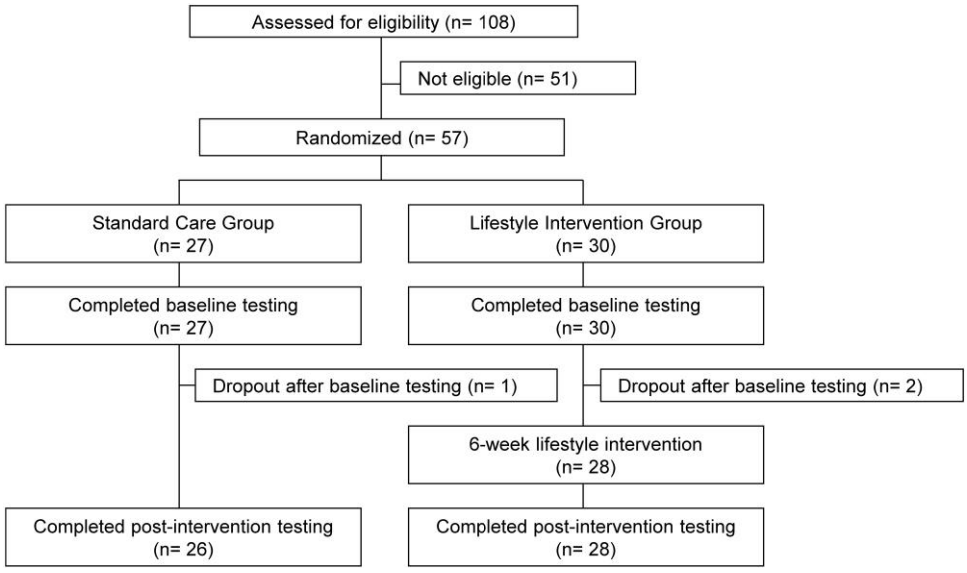

Figure 1. CONSORT flow diagram.

The lifestyle intervention group participated in small group nutrition and behavioral modification education sessions, cooking classes, and supervised physical activity. Subjects participated in 18 educational sessions (3 sessions/week) that were focused on how to incorporate low calorie-dense foods, regular physical activity, and stress management into their current lifestyle. These sessions involved group classes led by trained health professionals, printed materials and educational videos that provided nutrition education, behavior education, and information on obesity related chronic diseases. Subjects also participated in 18 supervised 1-hour exercise training sessions (3 sessions/week) that involved endurance, strength, and flexibility exercises. The exercise program was individualized for each subject, based on physical ability; the endurance exercise program was designed so that the subject achieved a heart rate of 70% to 85% of maximal heart rate during the session. All subjects were also encouraged to exercise on nonsupervised days.

All testing procedures conducted at baseline were repeated within 7 days after completing 6 weeks of lifestyle intervention or standard care. Participant satisfaction with the lifestyle intervention program was evaluated by using a 1 to 5 Likert-style questionnaire.

Statistical Analysis

Student's t test for independent samples t-tests was used to evaluate the statistical significance of differences in the characteristics of participants in the standard care and the lifestyle intervention groups at baseline with the exception of sex, which was analyzed by using a Pearson's chi-square test. Student's t test for paired samples was used to compare the absolute and percent change in body mass between groups after the 6-week intervention. Bonferroni-adjusted Student's t tests for paired samples were used to assess the statistical significance of differences in values before and after intervention

Table 1. Body composition and cardiometabolic variables before and after intervention

		Standard care group (n = 26)		Lifestyle intervention group (n = 28)		ANCOVA (*P* value)
		Before	After	Before	After	
Age(years)		55 ± 7	—	54 ± 9	—	—
Sex (M/F)		3/23	—	7/21	—	—
Weight (kg)		97.5 ± 14.0	97.1 ± 14.9	112.7 ± 24.0*	107.1 ± 23.5†	<.001
BMI (kg/m^2)		37.7 ± 5.4	37.5 ± 5.7	41.6 ± 8.3*	39.5 ± 8.2†	<.001
Fat-free mass[a](kg)		52.4 ± 8.9	52.4 ± 8.8	58.6 ± 11.5*	57.2 ± 10.9†	.020
Fat mass[a](kg)		43.4 ± 9.0	42.9 ± 9.2	49.8 ± 12.6*	45.8 ± 12.6†	<.001
Body fat[a](%)		45.2 ± 5.8	44.9 ± 5.9	45.7 ± 7.0	44.2 ± 7.4†	<.001
SBP (mmHg)		144 ± 16	144 ± 21	142 ± 14	132 ± 13†	.007
DBP (mmHg)		81 ± 11	78 ± 11	82 ± 13	75 ± 10†	.218
Total cholesterol						
mg/dL		174 ± 42	188 ± 41	182 ± 43	164 ± 40†	<.001
mmol/L		4.51 ± 1.09	4.85 ± 1.07	4.70 ± 1.12	4.24 ± 1.03†	<.001
HDL cholesterol						
mg/dL		41 ± 8	42 ± 9	40 ± 9	38 ± 9†	.005
mmol/L		1.06 ± 0.21	1.09 ± 0.22	1.04 ± 0.24	0.99 ± 0.23†	.005
LDL cholesterol[b]						
mg/dL		101 ± 33	111 ± 32	112 ± 34	100 ± 32†	.008
mmol/L		2.62 ± 0.86	2.86 ± 0.86	2.89 ± 0.88	2.59 ± 0.83†	.008
Triglyceride						
mg/dL		200 ± 88	206 ± 104	206 ± 97	161 ± 72†	.006
mmol/L		2.26 ± 0.99	2.33 ± 1.17	2.33 ± 1.09	1.82 ± 0.82†	.006
HbA1c						
%		6.9 ± 1.2	7.0 ± 1.3	7.4 ± 1.7	6.2 ± 0.9†	<.001
mmol/mol		51.5 ± 12.8	53.3 ± 14.5	57.2 ± 18.2	44.7 ± 9.5†	<.001
C-reactive protein[c]	(mg/L)	6.1 ± 8.3	5.4 ± 7.0	7.8 ± 6.7	6.1 ± 6.6*	.018
ETT duration	(seconds)	356 ± 97	372 ± 108	361 ± 157	447 ± 165*	<.001

Data are means ± SD.
Abbreviations: ANCOVA, analysis of cobariance; BMI, body mass index; DBP, diastolic blood pressure; ETT, exercise tolerance test; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SBP, systolic blood pressure.
[a]Standard care, n = 25; lifestyle therapy, n = 27.
[b]Standard care, n = 24; lifestyle therapy, n = 26.
[c]Standard care, n = 25; lifestyle therapy, n = 28.
*$P < .05$ vs corresponding before value in the standard care group.
†$P < .05$ vs corresponding after value.

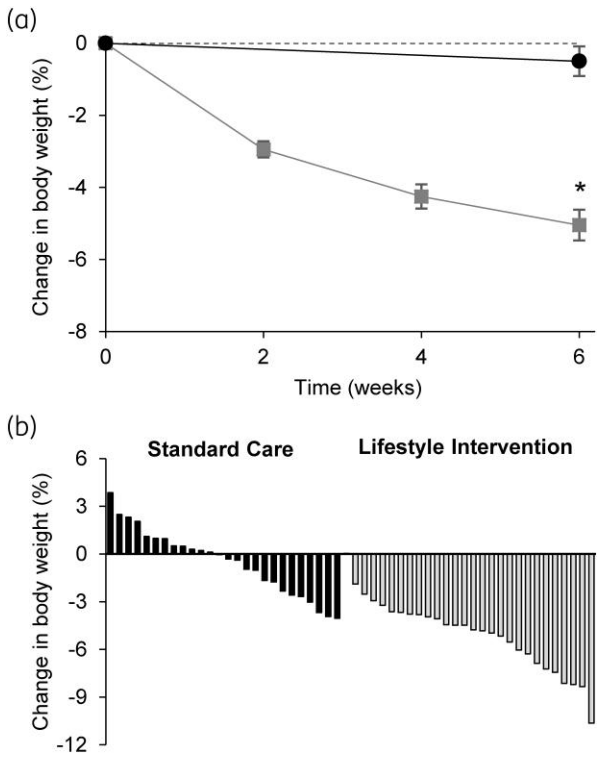

Figure 2. Percent change in body weight. Mean ± SEM change in percent body weight from baseline over time (A), and change in percent body weight from baseline at the end of the study in each participant (B) in the standard care (black bars; n = 26) and lifestyle intervention (gray bars; n = 28) groups. *Value significantly different from corresponding standard care group value, $P < .001$.

within each group. Analysis of covariance, with the postintervention value as the dependent variable and the baseline value as the covariate, was used to evaluate the significance of the effects of lifestyle intervention compared with standard care on all study outcomes assessed before and after the intervention. Relationships between change in body weight and fat mass and change in metabolic outcomes were assessed by using Pearson correlation coefficients. Data are presented as mean ± SD unless otherwise noted. Statistical significance was defined as $P < .05$. Data were analyzed by using SPSS (version 28; IBM, Amonk, NY).

The primary outcome of the study was the change in body weight. Based on the interindividual variability of weight loss in participants with obesity we previously studied (SD = 3.7%) [7], we estimated that 24 participants per group would be needed to detect a difference of 3.6% change in body weight between groups with a 2-tailed test, an α-value of .05, and a power of 0.9. Therefore, we planned to randomize 60 participants (30 per group) based on the conservative assumption that 80% of all participants would complete the study. The computation was performed by using G*Power 3.1.9.7.

Results

Study Flow and Compliance

Twenty-six participants in the standard care group and 28 participants in the lifestyle intervention group completed the study (Fig. 1). There was 99% attendance at the nutrition and behavioral educational sessions and cooking classes and 98% attendance at the supervised exercise sessions in subjects randomized to the lifestyle intervention group (25 of the 28 participants attended all sessions, 1 participant attended all nutrition and behavioral educational sessions, and 15 of the 18 total exercise sessions; the remaining 2 participants attended 15 of the 18 nutrition and behavioral educational sessions and 15 of the 18 exercise sessions). Most subjects (>90%) in the lifestyle intervention group reported satisfaction with the nutrition and behavioral education program (97%) and the exercise program (99%).

Body Mass and Composition

Baseline body weight, fat mass, and fat-free mass were higher in the lifestyle intervention than in the standard care group (all $P < .05$). At 6 weeks, mean body weight decreased by 5.0 ± 2.3% (5.6 ± 2.7 kg) in the lifestyle intervention group, but did not change in the standard care group (−0.5 ± 2.1% and −0.4 ± 2.0 kg; both $P < .001$ lifestyle intervention group vs standard care group) (Table 1 and Fig. 2A). We estimated that the mean daily energy deficit in the lifestyle intervention group needed to achieve the weight loss observed during the 6-week intervention, estimated by using National Institute of Diabetes and Digestive and Kidney Diseases body weight planner (https://www.niddk.nih.gov/bwp), was ~800 kcal/day. However, there was considerable individual heterogeneity in the change in body weight in both the lifestyle intervention and standard care groups; percent weight change ranged from (+0.04% to −10.6% in the lifestyle intervention group and from +3.9% to −4.0% in the standard care group (Fig. 2B). Body fat mass decreased by 8.4 ± 3.8% and fat-free mass by 2.3 ± 3.0% in the lifestyle intervention group; the decrease in fat and fat-free masses accounted for 78 ± 20% and 22 ± 20% to the decrease in total body mass, respectively. Body composition did not change in the standard care group (Table 1).

Cardiometabolic Outcomes

There was no differences in cardiometabolic variables between groups at baseline (Table 1). Compared with baseline values, systolic blood pressure, plasma total cholesterol, LDL cholesterol, triglyceride, C-reactive protein, and HbA1c decreased and exercise tolerance increased in the lifestyle intervention group, but did not change in the standard care group (Table 1). There was a significant decrease in plasma HDL cholesterol in the lifestyle intervention group, without a change in the standard care group. Including baseline body or fat mass as a covariate in our statistical analysis did not affect the statistically significant differences between groups. Percent weight loss at 6 weeks in the entire cohort was positively associated with change in systolic blood pressure, total, and LDL cholesterol, triglycerides, and HbA1c and negatively associated with exercise tolerance (Fig. 3A). In addition, change in fat mass was positively associated with change in total, and LDL cholesterol, and HbA1c and negatively associated with exercise tolerance (Fig. 3B).

Discussion

This randomized, controlled trial evaluated the effectiveness of a short-term (6 weeks), intensive lifestyle intervention program, provided at a worksite setting, on body composition and cardiometabolic outcomes in metabolically unhealthy

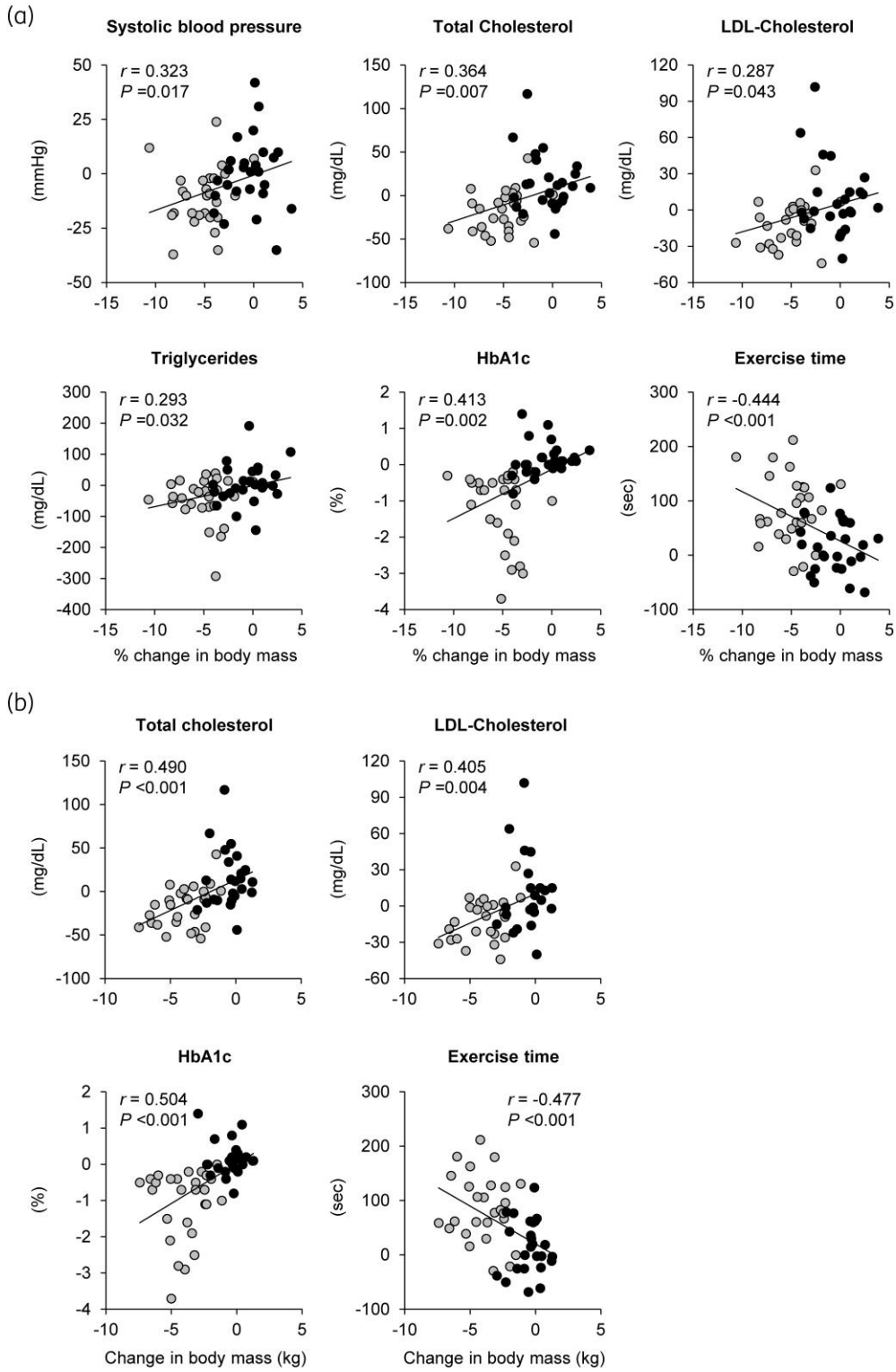

Figure 3. Relationships among changes in body weight and fat mass and cardiometabolic outcomes. Relationship between cardiometabolic outcomes and percent change in body weight (A), and absolute change in fat mass (B). Individual data points represent participants in the standard care (black circles) and lifestyle intervention (gray circles) groups.

people with obesity. The results demonstrate that providing nutrition/behavioral education and supervised exercise training at a convenient worksite location, in conjunction with the delivery of all meals and snacks to the subjects' homes, markedly improved multiple risk factors for cardiovascular disease. Despite the short duration of therapy, body weight and body fat mass, blood pressure, plasma triglycerides, total cholesterol, LDL cholesterol, plasma C-reactive protein, HbA1c, and exercise tolerance improved in the lifestyle intervention group but did not change in the standard care group. It is likely the therapeutic effects observed at 6 weeks of the intervention would have been even greater with a longer

duration of therapy. For example, although reductions in HbA1c can occur within 2 to 6 weeks after large dietary and pharmaceutical-induced changes in plasma glucose concentrations [8-10], improvements in HbA1c continue to occur when assessed over a longer duration that allows for complete red blood cell turnover (ie, 12 weeks or longer). Despite the intensity of the intervention, which involved face to face interactions 3 times per week, the attendance and overall satisfaction with the intense lifestyle program were very high. These data demonstrate the feasibility of providing effective and acceptable intensive lifestyle intervention in people with obesity at a high-risk of developing cardiovascular disease when convenience is enhanced by conducting the intervention at an easily accessible location and delivering all food to participants' homes.

The Pritikin Program, which involved a very–low-fat (10-15% calories as fat), high-carbohydrate (65-75% calories as carbohydrate, primarily from unrefined complex carbohydrates) diet, limited amounts of red meat, alcohol, caffeine, and sodium, and 3 supervised exercise sessions per week, was used to provide an intensive outpatient lifestyle intervention in this study. We are aware of only 1 previous study that evaluated the clinical effects of an outpatient Pritikin Program intervention [11]. In that study, myocardial blood flow, systolic blood pressure, and exercise capacity improved in 13 men and women with a history of coronary artery disease, hypertension, and hypercholesterolemia who were treated for 6 weeks. A series of studies have evaluated the effect of 1 to 3 weeks of intensive residential Pritikin Program therapy on cardiometabolic health outcomes in thousands of men and women with cardiometabolic abnormalities and diseases [4, 6, 12, 13]. The residential program involves daily lifestyle, stress management, nutrition, cooking classes, and obesity-related disease education classes. In addition, all meals are provided and supervised group exercise training sessions are conducted 1 hour/day, 6 days/week. The data from these studies demonstrate short-term intensive residential therapy decreases blood glucose and insulin concentrations, improves plasma lipid profile, and decreases both systolic and diastolic blood pressures.

Although the present study demonstrated excellent attendance at all educational and physical activity sessions, there was considerable heterogeneity in percent weight loss among those randomized to the lifestyle intervention group, ranging from minimal weight gain to 12% weight loss. This variability in body weight change has been observed in previous weight loss studies involving diet therapy [14], pharmacotherapy [15-17], and bariatric surgery [18], and demonstrates that individual variability persists despite enhanced compliance with the lifestyle intervention and supervision of exercise training sessions, regular monitoring of dietary records, and provision of all food. It is likely that individual variability in dietary adherence in the lifestyle intervention group was an important contributor to the variability in weight loss [19]. In addition, we cannot determine the efficacy and acceptability of a longer duration of therapy. However, the results from 2 long-term observational studies suggest that the beneficial effects of a short-term residential Pritikin Program intervention can have durable effects. The data from these studies show moderate (6-7%) weight loss achieved after 26 days of a residential Pritikin Program conducted in people with type 2 diabetes [20] or coronary heart disease [21] was maintained 2 to 5 years later.

The Pritikin Lifestyle Therapy Program in this study was delivered in a hospital setting that had the necessary facilities and personnel to deliver the program. In addition, all food was provided to participants to help ensure dietary compliance. The cost of personnel needed to provide group diet, activity and stress management education, and supervised exercise training and the cost of providing the Pritikin foods was ~$100/week. However, it is likely that the cost of delivering this program will vary based on the resources available at a given worksite.

This study demonstrates the feasibility, compliance, and clinical effectiveness of an intensive diet and physical activity intervention in people with obesity, when the intervention is conducted at a convenient worksite setting, group physical activity sessions are supervised, and all food is provided to the participants. Additional studies of longer duration are needed to determine whether the efficacy and acceptability observed in this study can be extended to long-term outpatient therapy.

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Author Contributions

D.C.B., G.G.S., and S.K. designed the study. G.G.S., G.I.S., and S.K. analyzed the data. D.C.B. conducted the clinical studies. G.G.S., D.C.B., G.I.S., and S.K. interpreted the data and wrote the manuscript. All authors critically reviewed and edited the manuscript.

Disclosures

S.K. serves on scientific advisory boards for Altimmune and Merck and as a consultant for B2M Medical. The other authors have nothing to disclose.

Data Availability

Some or all datasets generated during and/or analyzed during the current study are not publicly available but are available from the corresponding author on request

Clinical Trial Information

ClinicalTrials.gov identifier NCT03929198 (registered on April 26, 2019).

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