

Weight Loss, Body Measurements, and Compliance

A 12-Week Total Lifestyle Intervention Pilot Study

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Although more than 1000 diet books are available today¹ and each year millions of Americans enroll in commercial and self-help weight-loss programs,² the prevalence of obesity continues to rise.³ Approximately 119 million Americans, or 64.5 percent of adult Americans, are either overweight or obese. Estimates of the number of obese American adults rose from 23.7 percent in 2003 to 24.5 percent in 2004. Sixteen (16) percent of active duty U.S. military personnel are obese, and it is currently the biggest reason for the discharge of soldiers.⁴ Being obese puts an individual at higher risk for disease than smoking and obesity has reached epidemic proportions. Obesity-related statistics include the following facts:⁵

- 80 percent of type II diabetes is related to obesity.
- 70 percent of cardiovascular disease is related to obesity.
- 42 percent of breast and colon cancer is diagnosed among obese individuals.
- 30 percent of gallbladder surgery is related to obesity.
- 26 percent of obese people have high blood pressure.

In addition, obesity-related costs already overwhelm our health care system, with type II diabetes being the most costly at \$63.14 billion per year. Obesity also occurs in the workplace, contributing to \$39.3 million of workdays lost per year. Physician office visits cost companies \$62.7 million per year and increase insurance premium substantially.⁵

Diets: What the Research Shows

In a comparison of the Atkins, Ornish, Weight Watchers, and Zone diets, all diets were comparable with respect to weight loss.¹ Of the 160 participants who participated in the study for 1

year, approximately 25 percent of those who remained in the study sustained a 1-year weight loss of more than 5 percent of initial body weight.

This loss would translate to a 300-pound obese individual sustaining a weight loss of slightly more than 15 pounds. While this may reduce cardiac risk factors, it would hardly be noticeable and could be a contributing factor to the high attrition rates for all these programs (35–50 percent). The restriction of following a diet and exercise plan may not be worth this small weight loss at the end of 1 year.

The expert panel of the National Heart, Lung and Blood Institute does not recommend the use of very-low-calorie diets such as Optifast or Medifast after reviewing randomized trials from academic institutions that showed no long-term advantage after 1 year follow-ups over more conventional diets because most participants gain back a substantial amount of weight at the end of 1 year.²

There are also metabolic consequences of weight cycling that contribute to obesity and can make it harder to lose substantial weight in a reasonable amount of time. Research has shown that refeeding after severe food restriction may result in 15 percent lower energy expenditure when more normal food intake is resumed.⁶

In addition, this adaptation results in greater fat deposition when calories are increased (even if a prudent diet is followed) rather than protein, which, in turn, contributes to a higher fat-to-muscle ratio, further slowing metabolism and making weight loss more difficult.

Many severely overweight and obese individuals have utilized medically and nonmedically supervised very-low-calorie diets (meal replacements)² that may have contributed to this adverse metabolic consequence. In addition, severe calorie restriction results in greater muscle loss rather than fat loss, further contributing to metabolic disruption.

Lifestyle Intervention Program: A New Study

This 12-week study was undertaken as a pilot-feasibility study to determine overall efficacy of a specific lifestyle intervention program and to assist with the design of a larger, double-blind, placebo-controlled trial.

Table 1. Initial Enrollment and Completion by Gender

Practitioner/ Investigator	Initial Male (n)	Initial Female (n)	Completed Male (n)	Completed Female (n)	% Completed Male	% Completed Female	% Completed Total
Dr. Spahr	7	17	4	15	57	88	79
Dr. Stanton	2	17	2	12	100	70	68
Martinez & Grindler	2	11	2	1	100	9	23
Totals	11	45	8	28	N/A	N/A	N/A

NA = not applicable.

Materials and Methods

Subjects

The investigators included 2 physicians, with active practices at two separate locations, and 3 certified exercise trainers who conducted the study at a church rather than at their exercise facilities. All participants signed informed consent forms.

Exclusion criteria included subjects weighing more than 300 pounds or having serious medical conditions, as deemed by their physicians, which would otherwise prohibit them from participating in the study. The physicians enrolled patients from their practices. The exercise trainers had an additional release form that specifically asked if each participant had an existing medical condition or was under the care of a physician and required a physicians' signature to participate in the study.

There were 56 participants (11 men and 45 women) enrolled. The age range of these participants was 25–60 (Table 1).

The exercise trainers put up flyers about the study at a local church and were unfamiliar with all but 3 of the participants prior to the study. None of their enrollees had existing medical conditions. None of the participants received monetary compensation for participating in this study.

Diet and Supplementation

All participants received a Transitions Lifestyle System Daily Journal in which they were able to chart their food intake, exercise, and dietary supplement compliance. The Daily Journal also included positive affirmations, stress-reduction exercises, suggested menu plans, and food lists that differentiated between low-, moderate-, and high-glycemic-index foods.

Participants were encouraged to choose low-glycemic-index foods, consume moderate-glycemic-index foods on occasion, and avoid high-glycemic-index foods altogether. The subjects were discouraged from calorie counting and were not provided with calorie contents for any foods.

The first page of the Daily Journal had a "commitment" page that the subjects were required sign prior to entering the program. This was a commitment they made to themselves. The Daily Journal served as an educational tool because it also had information about the benefits of a low-glycemic-index diet, exercise, and stress reduction as well as the impor-

tance of following all components of the program.

The Daily Journal also provided a tracking tool in which participants were encouraged to log their food intakes and exercise activity. Participants were encouraged to engage in at least 30 minutes of aerobic exercise at least 3 times each week as well as strength training at least 2 times per week.

The program included two dietary supplements: a Fat Conversion Inhibitor and a Carbohydrate Absorption Inhibitor.

Subjects were instructed to take two tablets before each meal of the Fat Conversion Inhibitor.

Two (2) tablets of this supplement provided:

- 67 mcg of elemental chromium (as chromium dinicotinate glycinate)
- 133 mg of *Gymnema sylvestre* leaf extract (25 percent gymnemic acids)
- 1500 mg of *Garcinia cambogia* (60 percent hydroxycitric acid)
- 2.6 mg of bioperine (from a black pepper [*Piper nigrum*] extract).

The subjects were also instructed to take 1 capsule of the Carbohydrate Absorption Inhibitor before each meal. This capsule provided:

- 50 mg of elemental magnesium (as magnesium citrate)
- 100 mcg of elemental chromium (as chromium dinicotinate glycinate)
- 10 mg of a wheat amylase inhibitor
- 16 mg of banaba (*Lagerstroemia speciosa*) leaf extract
- 50 mcg of elemental vanadium as bis(maltolato)oxavanadium IV)
- 100 mg of a bitter melon fruit extract.

If any of the doses were missed, subjects were instructed to take the supplements at any other time during the day to make sure that the dietary supplements were taken 3 times per day. The dietary supplements and the Daily Journal were supplied by Market America (Greensboro, North Carolina). Participants were allowed to take a multivitamin and mineral supplement if they had been taking these prior to entering the study but were otherwise prohibited from taking other supplements during the study.

Table 2. Initial and Final Measurements for Subjects Who Completed the Study

Subject		Weight ^a	% Body fat	Waist	Hips	Chest
PB	Initial	243.2	34.1	46.5	N/A	49.0
	Final	202.6	25.4	40.5	N/A	44.0
	Change	-40.6	-8.7	-6.0	N/A	-5.0
SB	Initial	186.6	44.6	47.0	48.0	N/A
	Final	170.0	38.7	43.0	44.0	N/A
	Change	-16.2	-5.9	-4.0	-4.0	N/A
AB	Initial	240.8	46.9	49.0	50.5	N/A
	Final	234.4	44.5	44.0	50.0	N/A
	Change	-6.4	-2.4	-5.0	-0.5	N/A
JA	Initial	204.6	46.4	46.5	48.5	N/A
	Final	199.8	45.5	45.0	48.0	N/A
	Change	-4.8	-0.9	-1.5	-0.5	N/A
JL	Initial	189.2	30.3	42.5	N/A	44.0
	Final	190.0	26.9	41.0	N/A	42.0
	Change	+0.8	-3.4	-1.5	N/A	-2.0
SF	Initial	182.8	41.5	37.0	46.0	N/A
	Final	166.8	37.8	36.0	41.5	N/A
	Change	-16.0	-3.7	-1.0	-4.5	N/A
KG	Initial	180.2	43.2	38.5	44.5	N/A
	Final	174.0	40.5	36.0	43.0	N/A
	Change	-6.2	-2.7	-2.5	-1.5	N/A
RH	Initial	300.0	51.5	58.0	58.0	N/A
	Final	269.0	50.1	51.5	55.5	N/A
	Change	-31.0	-1.4	-6.5	-2.5	N/A
BK	Initial	136.0	b	33.5	40.5	N/A
	Final	131.6	b	33.0	39.0	N/A
	Change	-4.4	b	-0.5	-1.5	N/A
CK	Initial	161.8	37.4	33.5	42.0	N/A
	Final	150.2	35.4	31.0	42.0	N/A
	Change	-11.6	-2.0	-2.5	0.0	N/A
SK	Initial	284.0	49.8	57.5	56.0	N/A
	Final	266.2	49.0	52.0	54.5	N/A
	Change	-17.8	-0.8	-5.5	-1.5	N/A
SM	Initial	176.6	39.4	38.0	45.5	N/A
	Final	171.8	38.6	35.0	44.0	N/A
	Change	-4.8	-0.8	-3.0	-1.5	NA
KM	Initial	246.2	29.1	49.0	N/A	49.0
	Final	226.2	27.8	44.5	N/A	46.0
	Change	-20.0	-1.3	-4.5	N/A	-3.0
KO	Initial	236.8	48.1	53.5	50.5	N/A
	Final	213.8	44.9	46.5	48.5	N/A
	Change	-23.0	-3.2	-7.0	-2.0	N/A
EP	Initial	213.2	42.5	48.0	49.5	N/A
	Final	183.0	36.2	42.0	45.5	N/A
	Change	-30.2	-6.3	-6.0	-4.0	N/A
NQ	Initial	203.6	45.2	48.0	48.0	N/A
	Final	190.4	44.0	39.0	46.0	N/A
	Change	-13.2	-1.2	-9.0	-2.0	N/A
SS	Initial	329.8	44.8	58.5	N/A	54.5
	Final	312.8	38.7	54.5	N/A	52.0
	Change	-17.0	-6.1	-4.0	N/A	-2.5

Table 2. (Continued)

Subject	Weight ^a	% Body fat	Waist	Hips	Chest	
DS	Initial	155.2	37.5	36.0	45.5	N/A
	Final	145.0	33.5	32.5	42.0	N/A
	Change	-10.2	-4.0	-3.5	-3.5	N/A
EW	Initial	272.6	48.6	46.5	55.0	N/A
	Final	266.4	47.2	43.0	54.0	N/A
	Change	-6.2	-1.4	-3.5	-1.0	N/A
BB	Initial	146.2	34.7	33.0	37.7	N/A
	Final	136.8	31.0	30.0	36.0	N/A
	Change	-9.4	-3.7	-3.0	-1.7	N/A
MB	Initial	217.6	28.1	39.5	N/A	42.0
	Final	209.0	22.9	38.0	N/A	42.0
	Change	-8.6	-5.2	-1.5	N/A	No change
DC	Initial	216.4	44.3	44.5	46.5	N/A
	Final	201.8	42.2	39.0	47.0	N/A
	Change	-14.6	-2.1	-5.5	+0.5	N/A
JN	Initial	279.2	49.8	46.0	53.0	N/A
	Final	277.0	48.8	46.0	53.0	N/A
	Change	-2.2	-1.0	No change	No change	N/A
BP	Initial	289.4	51.7	51.5	58.0	N/A
	Final	250.0	49.0	47.0	57.0	N/A
	Change	-39.4	-2.7	-4.5	-1.0	N/A
BR	Initial	142.2	33.6	28.5	41.0	N/A
	Final	134.8	31.1	27.0	37.0	N/A
	Change	-7.4	-2.5	-1.5	-4.0	N/A
SR	Initial	310.1	52.9	54.0	52.0	N/A
	Final	290.8	48.9	50.5	50.0	N/A
	Change	-19.3	-4.0	-3.5	-2.0	N/A
JS	Initial	147.8	34.0	41.0	39.0	N/A
	Final	135.4	29.6	30.0	39.0	N/A
	Change	-12.4	-4.4	-11.0	No change	N/A
ES	Initial	178.6	42.9	35.5	45.0	N/A
	Final	167.2	38.0	32.0	42.0	N/A
	Change	-11.4	-4.9	-3.5	-3.0	NA
NT	Initial	156.0	37.5	36.0	42.0	N/A
	Final	151.4	34.0	33.5	38.0	N/A
	Change	-4.6	-3.5	-2.5	-4.0	N/A
PT	Initial	261.8	46.0	49.0	N/A	48.0
	Final	235.6	43.0	43.0	N/A	45.0
	Change	-26.2	-3.0	-6.0	N/A	-3.0
GW	Initial	159.6	41.4	38.0	41.0	N/A
	Final	160.2	40.4	35.0	40.5	N/A
	Change	+0.6	-1.0	-3.0	-0.5	N/A
SW	Initial	187.0	43.4	36.5	45.0	N/A
	Final	177.4	40.8	34.0	44.5	N/A
	Change	-9.6	-2.6	-2.5	-0.5	N/A
JJ	Initial	131.0	28.0	31.5	38.7	N/A
	Final	124.0	26.5	28.5	36.7	N/A
	Change	-7.0	-1.5	-3.0	-2.0	N/A
TB	Initial	180.0	26.7	42.6	N/A	39.7
	Final	155.0	18.2	38.5	N/A	34.5
	Change	-25.0	-8.5	-4.1	N/A	-5.2

Table 2. (Continued)

Subject	Weight ^a	% Body fat	Waist	Hips	Chest
TC Initial	306.0	44.0	52.5	N/A	52.
Final	296.2	35.2	50.7	N/A	50.
Change	-9.8	-8.8	-1.8	N/A	-2.0

N/A = not applicable.

^aWeight is expressed in pounds and anthropometric measurements are expressed in inches.

^bBK's body fat analysis was unavailable because her feet were too small for the bioimpedance calculation.

Group Meetings

Subjects who completed the study met at least once per week. Each co-investigator led the group and covered reading food labels, health benefits of the program, exercise suggestions (both aerobic and strength training), how to order food in restaurants, how stress may affect weight management, and other topics that were of interest to the participants. The subjects also were encouraged to talk about their successes, share tips with each other about staying on the program as well as "falling off the wagon," and discuss other issues that could potentially interfere with compliance.

Experimental Design

There were a total of 12 sessions and the subjects participated in the actual program for a total of 11 weeks. During the first, fourth, eighth, and twelfth meetings, the following measurements were taken and recorded for each subject: weight; percent body fat; hip and waist circumference (women); and chest and waist circumference (men).

Weight and body fat were analyzed using the Tanita digital scale and bioelectrical impedance body-fat analyzer model number BF682 (Tanita, Tokyo, Japan). Waist circumference was measured at the minimum circumference between the umbilicus and iliac crest. Hip circumference was measured at the widest circumference around the buttocks. Chest circumference was measured around the shoulder blades and across the chest over the nipple area.

Statistical Analysis

The primary endpoint was mean absolute changes from baseline weight; percent body fat; and waist, hip, and chest circumference at 12 weeks. The following data analysis was performed: *t*-Test Paired Two Sample for Means and one sample *t*-test. Significance was set at $p < 0.05$.

Results

The percentages of subjects who completed the study in the two physician groups (68 percent, 79 percent) were higher than those reported in other studies.^{1,2} The percentage of subjects who completed the study was lower in the exercise-trainer group compared to the average reported in other studies (23 percent).^{1,2} Other studies have shown completion rates that range from 50 percent to 65 percent with corresponding attrition

rates of 35–50 percent. The mean percentage of completion for all investigators combined was 56.6 percent (35 of 49 participants), which is within the results reported for other studies. See Table 1 for the breakdown on the participants by gender and enrollment.

Table 2 shows the initial and final measurements by patient for subjects who completed the study. Weight, percent body fat, waist circumference, hip circumference, and chest circumference were all significantly decreased ($p < 0.05$) compared to initial measurements by the end of the 12-week pilot study. Table 3 shows the results of the *t*-Test: Paired Two Sample for Means.

The patients who were on medications in the physician-treated group were all able to discontinue or substantially reduce their medications by the end of the study: Patient PB stopped taking trandolapril and verapamil; SB stopped taking amlodipine besylate and continued only on lisinapril; AB stopped taking atenolol; JA stopped insulin and continued on glucophage; RH reduced diovan from 160 mg to 80 mg; EP stopped atenolol, reduced verapamil from 240 mg to 120 mg, and reduced diovan from 160 mg to 80 mg; and ES had total serum cholesterol lowered by 25 points. No other laboratory data were available for this study.

The study coordinators reported very good compliance for participants who completed the study with respect to making entries in the Daily Journal, taking the supplements, following a low-glycemic-index diet, and exercising. Some participants did not regularly crosstrain by adding strength training to their programs apparently because of time constraints. All participants reported that they walked at least 30–60 minutes, 3 times each week. Compliance was similar to that reported in other studies.^{1,2,7}

Discussion

All measurements significantly decreased from baseline for participants who remained in the study. In a comparison study of the Atkins, Ornish, Weight Watchers, and Zone diets.¹ Overall weight loss at 2 months in kg was as follows: -3.6 (+3.3) for Atkins; -3.8 (+3.6) for Zone; -3.5 (+3.8) for Weight Watchers; and -3.6 (+3.4) for Ornish. Overall weight loss at 12 months for all diets was: -2.1 (+4.8) for Atkins; -3.2(+6.0) for Zone; -3.0 (+4.9); and -3.3(+7.3) for Ornish. Waist circumference change as centimeters at 2 months was: -3.3 (+3.1) for Atkins; -3.0 (+3.5) for Zone; -3.5 (+4.2) for

Table 3. t-Test: Paired Two Sample for Means

Parameter	Measure	Significance
Weight: t_{35}	7.91	$p < 0.05$
Mean weight change	-6.29 kg (+4.72)	$p < 0.05$
Body fat: t_{34}	8.68	$p < 0.05$
Mean % body fat change	-3.72 kg (+3.07)	$p < 0.05$
Waist: t_{35}	9.64	$p < 0.05$
Mean waist change	-9.73 cm (+5.96)	$p < 0.05$
Hips: t_{27}	6.44	$p < 0.05$
Mean hip change	-4.57 cm (+3.70)	$p < 0.05$
Chest: t_8	4.76 cm	$p < 0.05$
Mean chest change	-7.21 cm (+4.28)	$p < 0.05$

For mean changes, data are displayed as kg and cm.

Weight Watchers; and -2.7 (+3.2) for Ornish. Waist circumference change at 12 months was -2.5 (+4.5) for Atkins; -2.9 (+5.3) for Zone; -3.3 (+5.4) for Weight Watchers; and -2.2 (+5.5) for Ornish. None of the waist circumference losses were significant.

Our data for the Transitions Lifestyle System at 12 weeks suggest a greater weight loss of -6.29 kg (+4.72), which appears to be almost twice that for all diets in the comparison study at 2 months and 12 months; and a waist circumference loss of 9.73 cm (+5.96), which appears to be almost triple of what was achieved at 2 months or at 12 months in the comparison study.

Furthermore, all the mean differences in this study were significant, including waist circumference and, in the comparison study, this change was insignificant. While a direct statistical evaluation cannot be made since the Transitions Lifestyle System was not evaluated in the comparison study, the results are nonetheless compelling.

The Atkins diet is extremely low-glycemic-index with severe restriction of carbohydrate intake and the Zone diet is also low-glycemic index. All of the diets in the comparison study encouraged at least 60 minutes of exercise per week. However, there were no weekly meetings as provided in the Transitions Lifestyle System.

In another comparison study evaluating major commercial weight-loss programs in the United States,² Weight Watchers was rated as one of the diets with the best outcome with weekly support groups that resulted in a mean weight loss was approximately 5 percent of initial weight with a mean weight loss at 26 weeks (6.5 months) of -5.3 kg, which is lower than the mean weight loss reported in this study (-6.29 kg) at 12 weeks. There was no measurement of waist circumference or percent body fat loss.

Yet another study showed that 50 percent of participants stopped attending Weight Watchers meetings within the first 6 weeks and 70 percent stopped attending within the first 12 weeks.⁷ The mean attrition rate for the Transitions Lifestyle System at 12 weeks was 44 percent, which is lower than that reported for Weight Watchers at 6 and 12 weeks. The individuals who completed the pilot study in the two physician groups were familiar with the physicians' and the individuals who completed the study in the church group were familiar with the study coordinators from their gyms.

One paper⁸ examined data from The National Weight Loss Registry which is a self-selected population of more than 4000 individuals who are 18 and older and have lost at least 13.6 kg (30 lbs) and kept it off for at least 1 year. Eighty-three (83) percent of registry participants reported a trigger for their weight loss. Medical triggers were the most commonly reported at 23 percent. Therefore it is conceivable that physicians recruiting participants from their practices may experience less attrition and greater compliance than other populations of recruitment. In addition, it appears from this present study that prior acquaintance with a study coordinator may also improve attrition rate.

All of the researchers in the Transitions Lifestyle study have had substantial experience with weight management. They have all led group-support sessions with their patients/clients that encouraged exercise, stress reduction, and dietary adherence to a low-glycemic-index eating plan. The losses achieved with the Transitions Lifestyle System are greater than what any of the researchers have previously observed with their groups.

Our study was not double-blinded, placebo-controlled but the other studies reviewed were not either. It appears that similar components of low-glycemic index diets, exercise, stress reduction, and even weekly meetings were used in the other weight-management programs. It also appears in other studies^{1,2,7,9} that many of the participants were recruited from physician offices and clinics where patients were most probably familiar with the physician research coordinators.

The only major difference between this pilot study and the other studies reviewed was the use of nutritional supplements that were specifically developed to enhance weight loss when used in conjunction with a low-glycemic-index ad libitum diet and exercise program. The dietary supplements were added to the 12-week program in an attempt to accelerate weight loss as body fat as was evidenced by the statistically significant lowering of total body weight, waist circumference, and percent body fat.

None of the other studies reviewed^{1,2,7,9} added the component of a dietary supplement that was formulated to accelerate weight-loss efforts. Only multivitamin-mineral formulations were occasionally added to studies to ensure adequate Recommended Daily Intakes of essential vitamins and minerals. The mean weight change appears greater in this pilot study compared other studies reviewed at 2 months and 12 months. Mean waist circumference change was significant in this pilot study only.

Mean chest and hip circumference was significant in this pilot study (they were not measured in the other studies reviewed) and the mean percent body fat change was significant in this pilot study (it was not measured in other studies reviewed).

Waist circumference decrease appears to have a significant correlation with percent body fat decrease. The mean change of this measurement was insignificant in the comparison study, suggesting that the mean decrease in percent body fat, although not measured, may have been insignificant as well. Even an insignificant change of mean waist circumference and percent body fat in addition to overall weight loss appears to significantly reduce

metabolic syndrome, type II diabetes, hyperlipidemia, hypertension, and other cardiovascular risk factors.^{1,9,10} While adherence to a low-glycemic-index diet appears to reduce these factors also,^{9,10} it was remarkable that medication use for these types of disorders was either discontinued or substantially reduced in as little as 12 weeks in our study.

It will be important to include lipid profiles, c-reactive protein, fasting insulin, and other potential measurements of metabolic syndrome and cardiovascular disease risk factors in a larger-scale study to elucidate the significance of the Transitions Lifestyle System program further in reducing various risk factors for disease associated with being overweight or obese.

Conclusions

The Transitions Lifestyle System 12-Week Program significantly reduced mean total body weight, percent body fat, and all anthropometric measurements. While no direct statistical comparison can be made, it appears that this 12-week program resulted in approximately twice the amount of weight loss and triple the amount of waist-circumference loss compared to the Atkins, Ornish, Weight Watchers, and Zone diets¹ and was more effective than other diets reviewed.^{2,7,9,10}

Furthermore, mean waist circumference change has a direct correlation to mean percent body fat loss and was significant in this pilot study at 12 weeks and was insignificant in the comparison study¹ at 2 months and 12 months. Further studies are needed to elucidate the differences better between the groups taking the active supplements versus placebo with all other aspects of the program kept constant and to evaluate if weight loss is continued and/or maintained after 1 year. It is imperative that the best possible outcome is achieved to have a long-lasting impact on the ever-growing epidemic of overweight and obesity.

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