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Efficacy of a Lifestyle Program Designed to Help Indigent, Obese Adult Patients Lose Weight

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ABSTRACT

Introduction. Modest weight loss (5 to 7%) reduced the incidence of type II diabetes in the Diabetes Prevention Program (DDP) trial. A DPP-inspired lifestyle intervention requiring minimal patient self-data collection and tailored to low-SES patients through minimal cost was developed for our indigent, obese patients.

Methods. Obese (BMI ≥ 30 kg/m2), indigent (≤ 200% Federal Poverty Level) adults (age 18 - 70) were offered a no-cost weight loss intervention as an adjunct to their usual primary care in a residency outpatient clinic. The intervention provided options for diet plans and social support. The goal was to achieve a 5% loss of body weight over six months.

Results. The sample (n = 158) was 86% female and 62% white, with a median age of 45 and median BMI of 40.9. Two-thirds of subjects chose the 50% diet; YMCA membership was selected by all but one. The 5% weight loss goal was met by 12.8%; another 8.7% gained that amount. Subjects who either had pre-existing YMCA membership or used their provided membership were successful, relative to those who received but never used their membership (0.6% loss vs 0.9% gain; $p < 0.05$). Changes in weight over six months were observed in the youngest (gain of 3.9 lbs., $p < 0.05$) and the oldest (loss of 4.0 lbs., $p < 0.05$) age quartiles.

Conclusions. A DPP-inspired lifestyle intervention tailored to low-SES patients did not lead to overall weight loss, reinforcing that weight reduction programs must provide a significant amount of support for participants to see success. Older age and a behavioral commitment to physical activity improved the likelihood of success. ***KS J Med 2016;9(4):83-87.***

INTRODUCTION

Diabetes is a leading cause of morbidity and mortality worldwide.[1] In 2014, an estimated 422 million of the world's population lived with diabetes. The expectation is that by 2030, the number will increase to over 552 million. As of 2012, diabetes affected 29.1 million people in the US, with type II diabetes responsible for 90 - 95% of all cases.[2] Additionally, 86 million Americans have pre-diabetes with an increased risk for developing type II diabetes. The Diabetes Prevention Program (DDP) trial demonstrated that modest weight loss (5 to 7% of body weight) reduces the incidence of type II diabetes.[3] The United States Preventive Services Task Force (USPSTF) recommends screening all adults for obesity.[4] For patients with a body mass index (BMI) of 30 kg/m2 or higher, it is recommended that clinicians offer intensive, multicomponent behavioral interventions. Such interventions were used successfully by the DPP and were based on the three legs of nutrition, activity, and social support.

In our residency program outpatient clinic, many patients appropriate for referral to behavioral intervention are indigent, introducing an additional challenge. Financially and socially disadvantaged patients tend to suffer more from an inability to effect change because of social determinants of health.[5] Based on the principles of DPP, we developed and offered our indigent, obese patients a lifestyle intervention tailored to their economic circumstances through low cost, minimal record keeping options focused on a goal of restricting caloric intake and increasing caloric expenditure to reach weight loss of 5 to 7% over a six-month period.

METHODS

Participants. The program was designed by faculty of a large Family Medicine residency program to assist obese, indigent clinic patients with weight loss. Obese (BMI ≥ 30 kg/m2), indigent (≤ 200% Federal Poverty Level) adults (age 18 - 70) without contraindications to weight loss were included. Prospects were identified on daily reports of scheduled patients (based on age and most recent BMI); patients scheduled acutely were added occasionally to the list when identified by clinic staff. Patients were solicited at clinic visits by physicians or staff. Staff of the eight clinic teams referred interested patients to the study coordinator for additional screening and enrollment of eligible participants willing to provide informed consent. The protocol was approved by the Via Christi Institutional Review Board.

Lifestyle Program. Participants consented to a no-cost one year lifestyle intervention program, comprised of a six-month acute phase in which the goal was a 5% loss in body weight, followed by a six-month maintenance phase in which the goal was retention of weight loss. Physical activity was promoted by offering all participants a pedometer, a coupon for a pair of athletic shoes and socks, and their choice of either a membership to the YMCA or an exercise prescription. Nutrition was addressed by offering a choice of three simplified "diet plans". We believed choice was important to enhance participation or 'buy-in'. The first plan provided a specified calorie count, so participants did not need to count calories. The "meal plan" was centered on limiting calories to 900 to 1000 per day. The meal plan limited daily intake to two 11 oz. bottles of SlimFast©, one Healthy Choice© or Lean Cuisine© frozen meal, a piece of fruit, and another 100 calorie snack. The second option ("50% diet") reduced quantity without giving up favorite foods and was based on portion size and "simply eating half of whatever you have been eating".[6] A third plan displaced unhealthy eating with healthy habits. The final plan ("5210") is based on the 5210 plan used by Let's Go

Childhood Obesity Program (http://www.letsgo.org) and involves eating five fruits and vegetables per day, limiting "screen time" to two hours, engaging in one hour of physical activity, and having no sugared drinks or desserts in the house. Social support was in the form of a weekly call from a study coordinator, whose function was to provide a means of accountability, assistance in identifying barriers and solutions, and communication with the study investigators and clinic team. Weekly telephone support has been shown to be as successful as in-person support of intensive primary care weight loss interventions.[7] Availability to take the call, but no other structured information, was collected. Some funds were available to support subject transportation and child care needs as requested by the primary care physician or coordinator. The primary outcome was a six-month change in body weight; secondary outcomes included blood glucose/HgbA1c and maintenance of weight loss in the following six months.

Standard of Care. The lifestyle program was approved as research intended to operate against the clinic's self-defined Standard of Care "for patients with or at risk of diabetes who have made a commitment to lose weight and require focused visits to achieve that end". This Standard included visits to evaluate and counsel on the patient's progress scheduled at one month, three months, six months, nine months, and one year following initial evaluation, and measurement of HbA1c and lipid levels at baseline and one year. Weight, vital signs, and laboratory data were extracted from the patient's medical record, as were any visit notes pertinent to counseling on physical activity or nutrition.

Data Analysis. Descriptive statistics were used to characterize the population. Inferential statistics (analysis of variance, chi-square) compared groups statistically. Effect sizes (ES; Cohen's d, partial eta squared, Pearson correlation coefficient, or phi) estimated clinical significance. Analyses were conducted in SPSS and $p < 0.05$ (2-tail) was deemed statistically significant.

RESULTS

Participants. From a pool of 832 potential participants, study criteria excluded 89, leaving 743 patients potentially eligible (unless qualified by virtue of Medicaid insurance, indigency could not be assessed except through screening). We invited 356 and enrolled 158, thus capturing approximately 21% (158/743) of our population of interest. Of 158 participants enrolled, eight were excluded from analysis because they were or became ineligible and one was excluded because they had no visits and no data, leaving 149 participants in the Intent-to-Treat (ITT) sample.

Characteristics of the ITT subjects are shown in Table 1. The sample was largely female (85.9%) with a median age of 45.0 (IQR: 34.5 - 53.5) and median BMI of 40.9 (IQR: 35.9 - 46.1). About two-thirds were Caucasian and one-third were African-American. A minority (28%) had a diagnosis code of 250.xx (diabetes). Reflecting the indigent state of our patient population, Medicaid was the most common form of insurance (59%) and Medicare received prior to age 65 indicating disability was noted in over one-quarter of subjects.

Table 1. Characteristics of patients included in Intent-to-Treat sample (n = 149).[a]

		Median	IQR
Age		45.0	34.5 - 53.5
BMI		40.9	35.9 - 46.1
		n	%
Sex	Female	128	85.9
	Male	21	14.1
Race	White	92	61.7
	Black or African American	49	32.9
	Other	8	5.4
Diagnosis Code	250.xx	42	28.2
	No 250.xx	103	69.1
	Other	4	2.7
Insurance	Commercial	20	13.4
	Medicare only	12	8.1
	Unknown	16	10.7
	Medicaid	88	59.0
	Uninsured	13	8.7
Evidence of Disability[b]	Yes	40	26.8
	No	109	73.2
Source	Daily report	125	83.9
	Staff referral	24	16.1

[a]Numbers may not equal 100% due to rounding.
[b]Evidence of disability is Medicare insurance received before 65 years old.

Physical Activity. A single adult membership to the YMCA was selected as the physical activity option by 148 of 149 analysis subjects; only one subject, who was blind, chose "Exercise Prescription". Nine already had a membership (usually a family membership or employer-sponsored), and two others subsequently were unable to attend (one was prohibited by parole restrictions; one had an unpaid bill at the YMCA).

We paid for a single membership for 137 of the 149 subjects in the analysis population. Of the 137 subjects who accepted the YMCA membership and were presumed able to attend, 98 (72%) attended at least once. Subjects logged their attendance at the YMCA up to 21 times prior to the one-month visit, up to 44 times between one and three months, and up to 66 times between four and six months. Usage was generally not available for subjects who had their own membership.

Nutrition. Nutritional choice was missing from one participant, and one participant who began with the 5210 diet and immediately switched to the 50% diet was excluded from analysis. Most of the remainder (66%) initially chose the 50% diet plan; 23% chose meal replacement and 10% chose the 5210 plan. Subsequently, some subjects reported in their weekly support call that they had

changed their nutritional choice because of dissatisfaction with their initial choice, but this change was not tracked.

Social Support. Three coordinators were used during the study; two were physicians awaiting residency placement and the third was a research coordinator who conducted intervention programs in the community. Logs of support calls made by the coordinator were evaluated for the 138 subjects who attended more than the baseline visit. Seven (5%) were available for no more than a single call; 73 (49%) were available for fewer than half; and 58 (39%) were available for at least half.

Among the barriers to progress, participants most frequently noted medical problems (e.g., arthritis, recent surgery, back pain), transportation problems (e.g., no gas and car needing repairs), and family problems (e.g., death or illness in family). Five participants noted at some point during the study that they were homeless. Assistance with transportation (bus passes) was given to four subjects and child care (provided at the YMCA) was paid for three subjects.

Effectiveness. Average weight loss over six months was small (0.37 lb, ES = 0.0). Average loss was 0.5% of body weight at one month, 0.5% body weight at three months, and 0.2% at six months. When outcomes were classified against the goal of achieving 5% loss of body weight at six months, 19 (12.8%) were successful; 13 (8.7%) gained 5% of body weight, and 117 (78.5%) changed by less than 5% (Table 2).

Table 2. Weight outcomes overall, by sex, by age quartile (Intent-to-Treat sample, n = 149).

		n	%		
Overall Weight Loss					
6 month status	5% loss	19	12.8		
	< 5% change	117	78.5		
	5% gain	13	8.7		
		Mean	S.D.	Effect Size	p
Pounds lost at 6 months		0.4	11.1		
Subgroup Analyses[a]					
Pounds lost at 6 months by sex	Women, n = 127	-0.1	9.4		> .10
	Men, n = 21	2.7	18.4		> .10
Pounds lost at 6 months by age	18 - 34	-3.9	12.4	0.09	< .05
	35 - 45	0.7	10		> .10
	46 - 53	0.5	8.6		> .10
	54 - 65	4.0	11.9	0.10	< .05

[a]Repeated measures ANOVA.

The sexes did not differ in weight change. When examined within age quartiles, statistically significant changes in weight over six months were observed in the youngest (who gained 3.9 pounds, ES = 0.09, $p < 0.05$) and the oldest (who lost 4.0 pounds, ES = 0.10, $p < 0.05$) quartiles. Because attendance at the YMCA was unavailable for nine subjects who had a pre-existing membership, and zero for 39 subjects whose valid membership was paid by the investigators, we dichotomized attendance into those who had never used a study-provided membership and the remainder. Subjects who either had pre-existing YMCA membership or used a membership provided were successful, relative to those who received but never used their membership (0.6% loss vs 0.9% gain; $p < 0.05$; Table 3).

For the 107 who used or purchased a YMCA membership, about 20% were successful with weight loss, with no successes among the 39 who did not use their membership. There were no differences in percent weight loss at six months among the diet plans ($p = 0.44$). YMCA attendance increased with transportation or child care assistance, but weight loss did not necessarily increase.

Table 3. Weight outcomes overall, by sex, by age quartile (Intent-to-Treat sample, n = 149).

Source of membership	Subject	Study	Study
Use of membership	Unknown	Used	Not Used
n =	9	98	39
Weight loss (average %)	1.4	0.5	-0.9
Weight loss category			
Lost 5%	2 (22%)	17 (17%)	0 (0%)
Changed less than 5%	6 (67%)	72 (73%)	36 (92%)
Gained 5%	1 (11%)	9 (9%)	3 (8%)

Maintenance. The 121 completers at six months had consented to an additional six-month maintenance phase, but loss of funding led to early termination of 48. Only eight had a visit in the maintenance phase and their data were excluded. The remaining 73 subjects were included in the Intent-to-Continue analysis. The Individual Completion rate to one year in the maintenance phase was 62% (45 of 73).

The 45 completers to one year had average gains (vs baseline) of 0.4% body weight at six months, 1.0% body weight at nine months, and 0.1% at one year. When outcomes were classified as the proportion achieving 5% loss of body weight, five (11.1%) were successful at six months and 10 (22.2%) were successful at 12 months. Repeated measures analysis by sex did not reveal differences in weight across maintenance visits (Females: $p > .10$, ES = 0.01; Males: $p > 0.10$, ES = 0.11). Repeated measures analysis within age quartiles did not reveal differences in weight across maintenance visits (all p values > 0.10, ES < 0.06).

Secondary Outcomes. Laboratory values were examined to determine whether an initial (within the first month) value had been obtained for HbA1c, glucose, or lipids. Most subjects (93/149) had either HbA1c or glucose drawn by the one-month visit, but the quantity of missing data precluded inferential statistics.

DISCUSSION

The clinical goal of helping indigent, obese patients lose 5% of body weight in six months was not realized: 13% of the Intent-to-Treat population achieved this categorical goal, but 9% gained as much and average weight loss was only 0.2%. In those eligible for the maintenance segment, the additional six months doubled the odds of success. Success was associated with two additional factors. First, behavioral engagement (e.g., having a YMCA membership at study entry or using a study-provided membership at least once during the study) was evident in all who achieved the goal of 5% weight loss. Second, age quartile was associated positively with weight loss.

As in the DPP[3], we used a goal-based behavioral intervention, where all participants were given the same weight loss goal, but individualization was permitted in tailoring of intervention activities to the diverse population and those with low literacy. Our goal of 5% weight loss over six months was modestly lower than the 6% achieved in the DPP and associated with a 58% reduction in the incidence of diabetes. The intervention used by DPP[3] was simplified for application in our clinic. For physical activity, DPP offered supervised sessions and a goal of at least 150 min of moderate physical activities similar in intensity to brisk walking. In the current study, physical activity sessions were translated into YMCA membership. The YMCA is established as a user friendly and income considerate place for physical activity. They also provide trainers and other support staff within the basic membership fee. Monthly reports of sign-ins from the YMCA were a proxy for supervision of exercise. We added provision of athletic shoes to reduce barriers to physical activity further.

To address nutrition, DPP[3] participants were taught behavioral strategies to realize and maintain long-term changes in their fat and calorie intake. Our program relied on diet plans that required no calorie-counting and would be simple to understand for our population. We chose not to have intensive educational sessions based on our prior office experiences that these sessions would be attended poorly.[8] Alternatively, we opted for nutritional handouts and anticipated that physicians' instructions would fill in other educational deficiencies. Educational nutrition handouts were available from the research coordinator and/or the physician.

For social support in the DPP[3], each participant was assigned a "lifestyle coach" who made frequent contact with and motivated the participant. They also delivered a 16-session core curriculum that ensured all participants were taught the same basic information about nutrition, physical activity, and behavioral self-management. In our program, support personnel called the patients on a weekly basis, both on the assumption that accountability is a major factor for success and a reduction in overall patient expense that would be required for similarly frequent office encounters. This meant limiting participants to only those who were English-speaking. The primary goal was to make contact with the patient, provide accountability, and resolve potential obstructions to success. Based on resources, we designated the frequency of patient contact to be weekly, documenting actual contacts and attempts to contact each patient. Contact was difficult in a population that was not able consistently to afford phone access. DPP provided funds for implementing strategies to overcome barriers in individual patients. Our program also had funds to pay for transportation, child care, or other amenities. The anticipated solution of providing bus passes was impeded when some subjects needed car repairs or gas instead, which were not covered.

Limitations included those associated with effectiveness studies, such as lack of blinding, lack of a control group, and flexibility in intervention choice. There was no measure of adherence to the diet choices or uptake of the nutritional intervention. This limitation was felt more keenly given the link between success in weight loss and adherence to the activity intervention. Verifying baseline intake for the patient would have given more objective and comparative data to support weight loss efforts. The intervention was not as intensive as the DPP. A more rigorous program might have resulted in more weight loss.

CONCLUSION

A DPP-based lifestyle intervention tailored to low-SES patients through low cost, minimal record keeping options did not lead to the hypothesized loss of 5% body weight in this sample of patients. Factors associated with weight loss success included age quartile and a behavioral commitment to physical activity. Together, these factors suggested that patient commitment must be high and that the support provided by the program must be intensive and individual. Future research should consider evaluation of patient readiness combined with simplicity and individual, intensive accountability and support.

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