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Implementation in a Family Medicine Clinic of a Lifestyle Program Designed to Help Indigent, Obese Adult Patients Lose Weight

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ABSTRACT

Introduction. Efficacy of interventions in research settings may not translate to usual-care settings. The impact of interventions varies depending upon factors, such as the proportion and composition of the population reached and engaged, as well as participation and implementation characteristics of providers.

Methods. A lifestyle intervention meant to achieve a 5% loss of body weight in six months was offered to obese, indigent adult patients in a Family Medicine residency outpatient clinic. Implementation variables were assessed, including determination of individual patient penetration and participation rate, demographic representativeness, completion rate, outcomes, and differential impact, as well as setting participation rates and implementation fidelity.

Results. From a population of 743 potentially eligible patients, 356 were invited to participate (48% penetration) and 158 were enrolled (44% participation). Those enrolled were heavier (BMI of 42.6 vs 39.0), younger (43.5 vs 47.0 years) and more likely female (87% vs 69%) than those not enrolled. Individual completion rate was 81%; overall weight loss was negligible. Setting participation was broad, but fidelity to background standard of care was only 50%.

Conclusions. Providers were eager for a tool to help their obese, indigent patients lose weight, but the intervention proved ineffective and the usual care of enrolled patients was not strongly supportive of their weight loss efforts. ***KS J Med 2016;9(4):77-82.***

INTRODUCTION

In the United States, 26.9% of adults are obese (i.e., have a body mass index greater than 30.0) and, in Kansas, 28.8% of adults are obese, putting them at high risk for diabetes.[1] The United States Preventive Services Task Force (USPSTF) has recommended that "Clinicians should offer or refer patients with a body mass index of 30 kg/m2 or higher to intensive, multicomponent behavioral interventions (B recommendation)."[2]

Initiatives such as the Diabetes Prevention Program (DPP) based on the three tenets of increased physical activity, nutrition, and social support have been effective in promoting lifestyle change and weight loss, and ultimately preventing diabetes.[3,4] Extensions of the DPP into community settings, such as the YMCA, have shown efficacy can be transported into wider populations.[5] However, even the most promising intervention can be undermined by weak implementation. A review of implementation of 38 DPP-style programs concluded that program intensity plays a major role in weight loss outcomes.[6] Programs that have high uptake, both in terms of good coverage of invitees and their willingness to accept the invitation, can have considerable impact in lowering diabetes risk in a population, even with a low intensity intervention that only leads to low or moderate weight loss. This is an important finding for resource-constrained settings.

Primary care physicians in our residency outpatient clinic care for an economically disadvantaged clinical population with a high rate of obesity. In this time- and resource-constrained setting, physicians were eager to find simple and affordable options for patients to lose weight and prevent diabetes. Given that the effectiveness of primary care delivered weight loss programs has been demonstrated among adults with socioeconomic disadvantages,[7] we chose to provide a practical, simplified DPP-style program to our indigent clinic patients who were obese and at the highest risk for diabetes.[8,9] A separate report will detail the intervention and its efficacy. This report describes the clinical aspects of implementation of the program within a large Family Medicine residency outpatient clinic using metrics derived from the models RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance)[10] and PIPE (Penetration, Implementation, Participation, Effectiveness).[11]

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 (body mass index [BMI] ≥ 30 kg/m2), indigent (≤ 200% Federal Poverty Level, FPL) adults (age 18 - 70) without contraindications to weight loss were included. Potential participants were identified on daily reports of scheduled patients (based on age and most recent BMI); patients scheduled acutely were occasionally added to the list when identified by clinic staff. Patients were approached at clinic visits regarding study participation 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. Indigency was determined first from insurance coverage: Medicaid and forms of charity care indicate an income of < 200% FPL. For individuals who were insured privately or on Medicare, self-report of income was considered in the context of household size; for a family of four, 200% FPL is $47,100. 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.

Participants were offered a pedometer, a coupon good 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". The first ("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-cal snack. A second option ("50% diet") was based on portion size and "simply eating half of whatever you have been eating". 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 5 fruits and vegetables per day, limiting "screen time" to 2 hours, engaging in 1 hour of physical activity, and having 0 sugared drinks and 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. The primary outcome was six-month change in body weight; secondary outcomes were blood glucose or HgbA1c levels at six months and maintenance of weight loss in the following six months.

Standard of Care. The lifestyle program was approved as research intended to operate in the context of 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 includes 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 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. The concept of Reach[10] was used to describe what proportion of the target population was enrolled in the study (individual participation rate) and how well they represented the eligible clinic population (demographic representativeness). Reach was described as the proportion of eligible clinic patients invited (penetration) and the proportion of invited patients enrolled (participation).[11] Effectiveness was described in terms of individual completion rate, categorical outcomes, and differential impact of sex and age for participants and subgroups of participants who completed each phase (six-month acute; six-month maintenance). Adoption was evaluated in terms of setting participation rates of clinic providers and implementation in terms of fidelity to Standard of Care protocols by clinic providers. Descriptive statistics were used to characterize the population, inferential statistics (analysis of variance, chi-square) to compare groups statistically, and effect sizes (ES; Cohen's d, partial eta squared, Pearson correlation coefficient, or phi) to estimate clinical significance. Analyses were conducted in SPSS 19; $p < .05$ was used to define statistical significance.

RESULTS

Reach. The pool of potential participants was formed from a total of 832 patients: 784 pre-scheduled patients whose weight history and age met inclusion criteria and 48 patients scheduled acutely and deemed evaluable by clinic staff. 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 (for a penetration of 48%) and enrolled 158 (for participation of 44%); the resultant individual participation rate was 21% (158/743; Figure 1). Demographic representativeness was evaluated by comparing potentially eligible patients subsequently enrolled with those not enrolled (Table 1).

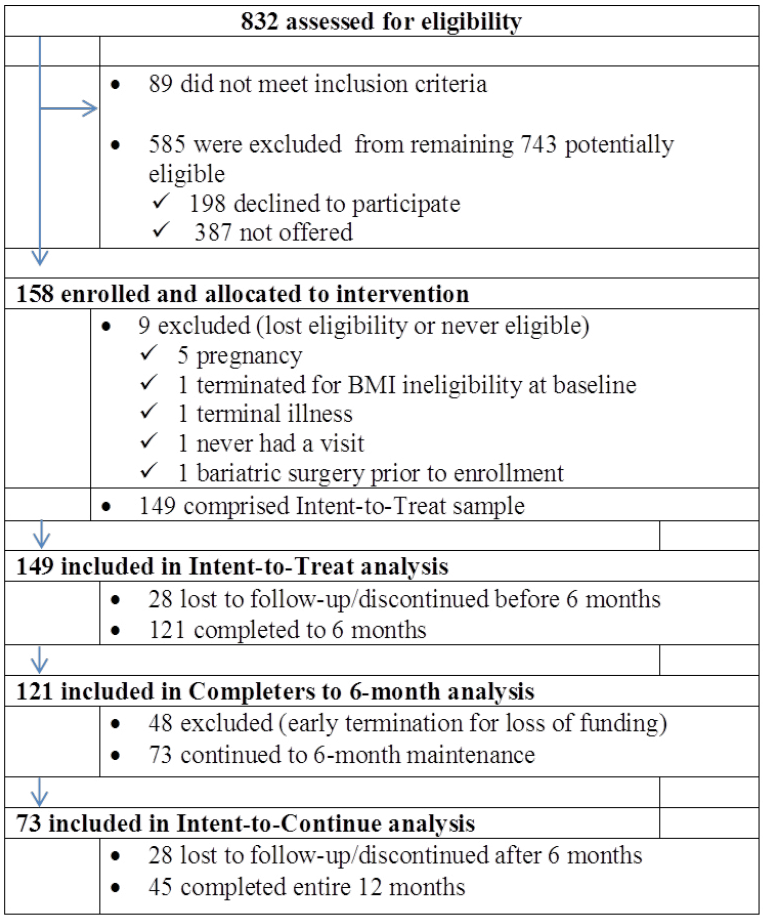

Figure 1. Participant flow.

Enrolled subjects, relative to non-enrolled, were heavier (BMI = 42.6 vs 39.0; ES = 0.43, $p < .01$), younger (43.5 vs 47.0; ES = 0.27, $p < .01$), and more likely to be female (87% vs 69%; ES = 0.16, $p < .01$). Enrolled subjects also were more likely to be solicited through active agency of the clinic rather than the daily report of pre-scheduled patients (18% vs 2%; ES = 0.28, $p < .01$). Enrolled and non-enrolled patients did not differ in racial distribution (ES = 0.07, $p > .10$) or in diagnosis of diabetes or other relevant diagnosis (ES = 0.05, $p > .10$).

There was a tendency for insurance indicating indigency (Medicaid or no insurance) to be found more often among enrollees (68.4% vs 61.0%; ES = 0.06, p < .10). Disability (defined as Medicare insurance prior to age 65) did not differ between patients who were enrolled and those not enrolled.

Table 1. Demographic characteristics of potentially eligible patients subsequently enrolled or not enrolled (n = 743).

		Enrolled n = 158		Not Enrolled n = 585		Effect Size	p
		Mean	S.D.	Mean	S.D.		
Age		43.5	11.9	47.0	13.8	0.27	< **.01**
BMI		42.6	8.9	39.0	7.7	0.43	< **.01**
		n	%	n	%		
Sex	Female	137	86.7	403	68.9	0.16	< **.01**
	Male	21	13.3	182	31.1		
Race	White	97	61.4	394	67.4	0.07	> .10[a]
	Black	52	32.9	174	29.7		
	Other	9	5.7	17	2.9		
Diagnosis	Diabetes Mellitus	44	27.8	208	35.6	0.05	> .10[b]
	Other Relevant Diagnosis[c]	4	2.5	0	0		
	No Relevant Diagnosis	110	69.6	377	64.4		
Source	Daily Report	129	81.6	571	97.6	0.28	< **.01**
	Added Patients	29	18.4	14	2.4		
Insurance	Medicaid Only	64	40.5	218	37.3		
	Medicaid + Medicare	30	19	115	19.7		
	Uninsured	14	8.9	24	4.1		
	Commercial	20	12.7	111	19.0		
	Medicare Only	12	7.6	85	14.5		
	Unknown	18	11.4	32	5.5		
Indicating Indigence[d]							
	Yes	108	68.4	357	61.0	0.06	< .10
	No	50	31.6	228	39.0		
Indicating Permanent Disability[e]							
	Yes	40	25.3	154	26.3	0.01	> .10
	No	118	74.7	431	73.7		

[a]white vs. non-white
[b]diabetes mellitus or other relevant diagnosis vs. no diagnosis
[c]other relevant diagnosis: antepartum diabetes, dysmetabolic syndrome X (2), abnormal glucose
[d]insurance indicating indigency (Medicaid, uninsured) vs. not (commercial, Medicare only, unknown)
[e]insurance indicating disability (Medicare received before 65 years) vs. not

Effectiveness. Of 158 participants enrolled, eight were excluded from analysis because they were or became ineligible and one was excluded because of no visits, thus no data. Among the 149 participants who could have completed through six months, 28 were lost to follow-up or discontinued prior to six months for an individual completion rate of 121/149 or 81%.

Average weight loss over six months was small among the 121 completers (0.28 lb, ES = 0.18). Average loss was 0.5% of body weight at one month, 0.5% body weight at three months, and 0.1% at six months. When outcomes were classified against the goal of achieving 5% loss of body weight at six months, 18 (14.9%) were successful, 12 (9.9%) gained 5% of body weight, and 91 (75.2%) changed by less than 5% (Table 2).

Table 2. Weight outcomes overall, by sex, by age quartile completers to 6 months (n = 121).

		n	%		
Overall					
6 month status	5% loss	18	14.9		
	< 5% change	91	75.2		
	5% gain	12	9.9		
		Mean	S.D.	Effect Size	p
Pounds lost at 6 months		0.3	12.0	0.18	> .10
Subgroup Analyses					
Pounds lost	women, n = 102	0.3	10.1		> .10
	men, n = 19	3.4	19.2		> .10
Pounds lost	18-36 years	-5.2	14.2	0.11	.07
	36-46 years	1.0	10.1		> .10
	46-53 years	0.1	8.8		> .10
	53-65 years	4.5	13.0	0.11	.07

Differential impact of sex and age was assessed in six-month completers. Weight did not change over time in subgroups defined by sex (ES < 0.04, p > .10). Trends (ES = 0.11, p = .07) toward weight gain in the youngest age quartile and weight loss in the oldest were noted. Subsequent correlation analysis indicated that increasing age was related positively to weight loss (ES = .23, p < .05), and more so in men (ES = .47, p < .05) than in women (ES = .16, p > .10).

Maintenance. Loss of funding led to early termination of 48 of 121 completers to six months. 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 and 0.1% at one year. Nevertheless, when outcomes were classified as the proportion achieving 5% loss of body weight, 5 (11.1%) were successful at six months and 10 (22.2%) were successful at one year. There were no differences within sex or within age quartiles in weight across maintenance visits (Table 3).

Table 3. Weight outcomes overall, by sex, by age quartile completers to 12 months (n = 45).

		n	%		
Overall					
1 year status	5% loss	10	22.2		
	< 5% change	28	62.2		
	5% gain	7	15.6		
		Mean	S.D.	Effect Size	p
Pounds lost	6 months	-1.2	11.7		
	12 months	0.0	15.5	0.02	> .10
Subgroup Analyses					
Pounds lost	women, n = 38	-0.7	10.1		> .10
	men, n = 7	1.0	19.9		> .10
Pounds lost	18-36 years	-4.2	18.3		> .10
	36-46 years	-2.2	13.4		> .10
	46-53 years	-0.5	13.7		> .10
	53-65 years	6.7	15.0		> .10

Adoption. Setting participation was distributed broadly across residents and teams. The majority of residents on each team were active in enrolling patients; all residents but one or two per team enrolled at least one patient. Study information was offered to 52 - 63% of potentially eligible patients at Clinic 1; at Clinic 2 the range was 21 - 44%. Ultimately, Clinic 1 enrolled 16 - 24% of their potentially eligible patients; at Clinic 2 the range was 13 - 28% (Table 4).

Table 4. Outcomes by team and clinic: Adoption of program.

Clinic 1			Clinic 2	
# residents enrolling/# residents				
team 1	5/6	83%	6/7	86%
2	5/6	83%	5/7	71%
3	6/8	75%	6/7	86%
4	5/7	71%	5/7	71%
# solicited/# opportunities				
team 1	63/111	57%	22/68	32%
2	54/103	52%	13/63	21%
3	79/126	63%	38/87	44%
4	64/102	63%	23/83	28%
# enrolled/# opportunities				
team 1	27/111	24%	9/68	13%
2	25/103	24%	9/63	14%
3	30/126	24%	24/87	28%
4	16/102	16%	18/83	22%

Implementation. Usual care visits during the first six months were evaluated for implementation of Standard of Care procedures (Table 5).

Table 5. Outcomes by team and clinic: Implementation of Standard of Care components.

Clinic 1			Clinic 2	
# visits in first 6 months (median, range)				
team 1	3	(1 - 4)	4	(3 - 4)
2	3	(2 - 4)	4	(3 - 4)
3	4	(2 - 4)	4	(2 - 4)
4	4	(2 - 4)	4	(3 - 4)
% completed visits with dietary counsel documented (median, range)				
team 1	0	(0 - 100)	50	(0 - 50)
2	0	(0 - 75)	25	(0 - 50)
3	0	(0 - 75)	25	(0 - 100)
4	0	(0 - 33)	33	(0 - 75)
% subjects with HbA1c or glucose within first month				
team 1	41		83	
2	65		43	
3	67		70	
4	54		58	
Standard of Care scores and ranks[a]				
team 1	1.75	51.9	2.39	82.8
2	1.74	46.8	1.90	56.6
3	1.97	60.3	2.35	78.8
4	1.65	48.3	2.26	75.1

[a]Standard of Care Score: Sum of proportion fidelity to 4 standards of care [% expected visits; % visits with documentation on nutrition, % visits with documentation on activity; HbA1c or glucose obtained by 1 month; Maximum score = 4, average rank = 61]

Most subjects (70/121) completed the expected four visits in six months. About half (61/121) had no documentation of dietary counseling at any visit, and most (74/121) had documentation of exercise counseling at no more than one visit. Laboratory values were examined, showing that most subjects (72/121) had either HbA1c or glucose drawn by the one-month visit.

For each subject completing six months, a Standard of Care Score (maximum value = 4) was derived by summing (1) proportion of four visits completed; (2) whether (= 1) or not (= 0) HbA1c or glucose was obtained by one month; (3) proportion of visits with documentation of dietary counseling; and (4) proportion of visits with documentation of exercise counseling. The median Standard of Care score was 2.0 (IQR: 1.5 to 2.5), thus the component implementation rate was 2.0/4 = 0.5. Post-hoc analysis of ranked scores revealed a substantial effect of clinic on Standard of Care score (means of 52.8 vs 74.9; $p < .01$; ES = 0.66).

DISCUSSION

The clinical goal of helping indigent, obese patients lose 5% of body weight in six months was not realized. Average weight loss in completers to six months was only 0.1%. Aspects of program implementation that may have affected the odds of success were identified, including an individual participation rate of 22% and enrollment of younger, heavier, and more often female subjects when it was older men who tended to be more successful.

Implementation rate for the Standard of Care procedures that had been expected to support the intervention was 50%. Although there was no correlation evident between Standard of Care and weight outcomes, it suggested a lower Standard of Care than was intended for the lifestyle program to be successful. More hopeful for future planning efforts was the retention of subjects once enrolled: individual completion rate to six months was 81%, and 62% to one year. Participation of clinic teams and physicians was broad.

Reach. Fewer than half of our potentially eligible patients were solicited. Because lack of continuity is common in a teaching clinic, inconsistency in visit providers could have decreased the number of patients approached. Though its determination was a strength of the study, our penetration rate of 48% was lower than other real-world diabetes prevention programs. In a review of 38 such programs, only seven had reported their penetration, with five of the seven reported as "high" (> 66%).[6]

Even when offered the enrollment benefits of a free pair of athletic shoes and a free YMCA membership, more eligible patients declined than agreed to participate, suggesting that the simple elimination of certain cost barriers was not sufficient to achieve weight loss. This was consistent with a large survey of health and lifestyle practices of people at high risk of developing type 2 diabetes, where only 57% of those surveyed were even "considering" a plan to lose weight.[12] The higher rate of enrollment in acutely scheduled patients suggests a bias to offer the program preferentially to those thought most likely to enroll (though it says nothing about actual weight loss). Participation rates of other DPP-style studies must be interpreted carefully because denominators are not defined in the same way. In the Aziz review,[6] 92% of the 38 DPP-style studies reported participation rate and 71% had "low" (< 26%) participation. In this context, our participation rate of 44% was "moderate", higher than most of the studies reviewed.

Those who agree to the intervention are not necessarily reflective of the clinic population or typical of those who would benefit. Enrollment favored younger, heavier, and more often female patients. Women report attempting to lose weight 50% more often than men.[13] From prior experience with a childhood obesity study, our clinicians shared the common finding that they lack sensitivity to obesity at the lower end of the range.[14] This can be an issue because bariatric surgery is an alternative that may be more appropriate for heavier patients.

In terms of benefit, it was older men who tended to be more successful with weight loss efforts. Age increased success at meeting weight loss goals in the DPP study.[15] Likewise, Williamson[16] reported that, in the normal course of events, adults 55 and over tend to lose weight; among younger adults (and consistent with our study) women were more likely than men to gain weight.

Efficacy. Individual completion rates were good. The success of our subjects can be placed in the context of a population-based cohort study of adult family practice patients in the UK, which reported that the annual probability of an obese patient losing 5% of body weight was 1 in 5 to 1 in 12.[17] Weighted calculations based on sex and initial BMI category indicated that over the six-month interval of our study, the proportion of participants losing 5% of body weight was no more than experienced by the British patients in usual care.

Adoption. Referral to formal fitness programs outside the clinic can be costly for a low-income population and primary care physicians of challenged patients were eager for a no-cost program. The demand led to broad adoption of the program across residents and teams. Physician interest was consistent with a primary care survey in which 67% of providers indicated interest in being more involved in helping patients manage their weight. Notably, when providers' patients were surveyed, only 44% wanted their primary care physician to be more involved in helping them manage their weight.[18]

Implementation. Only 50% of Standard of Care procedures were completed, suggesting a weak base on which to build a lifestyle intervention. Lack of a relationship between Standard of Care score and successful weight loss suggests the possibility that a higher general adherence to standards of care is a prerequisite for weight loss. Differences across clinical campuses were observed and can inform nursing and process changes.

One barrier to completion of visits was the lack of funding for physician visits or laboratory assessments because uninsured patients who could not pay for these services may have declined them. Also, the scheduling system did not allow for the primary care physician to schedule follow-up visits more than one month out. The need for patients to make their own follow-up appointments in usual care introduced a selection bias. Many visits were for acute problems or involved multiple chronic conditions. Though all participants were at high risk of diabetes by virtue of their obesity, only a minority of visit notes mentioned weight loss, and many of these were generic comments and did not mention the lifestyle program. A survey of providers to assess barriers to weight management counseling suggested perceived futility based on how providers view their patients' ability to lose weight, as well as environmental factors beyond their control.[18]

Annual HbA1c had been deemed 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. Most participants had no diagnosis that would drive obtaining routine lab values, and for those already diagnosed, the lack of a registry in the electronic medical record made population tracking problematic.

Evaluation of the implementation of this lifestyle intervention was limited by lack of feedback regarding why it was not offered to potentially eligible patients attending the clinic. When feedback was provided, it was often in the form of "patient not appropriate" without further description. One concern is that the reduction of obesity in this population

is impeded by their serious medical problems: about one quarter of our population is considered "permanently disabled". A related issue is that the reason for "permanent disability" is often not evident in the patient's medical chart, making its import hard to assess. Lack of consistency in providers can be a source of variability, and there was no assessment of how often a patient saw their regular provider at a usual care visit. Finally, the lack of efficacy of the intervention may have reduced provider and participant engagement and weakened measures of implementation.

In spite of the disappointing lack of efficacy of the intervention used in this study, valuable information was collected that can assist in planning future interventions in this setting. Physicians were eager to use a tool to help their obese, indigent patients. The rates of participant solicitation, enrollment, and retention were typical of other DPP-type studies. An electronic system supportive of scheduling and registry development was lacking during the intervention but has since been implemented. The most pressing need in the clinical setting may be to back-up provision of a simplified lifestyle intervention with greater engagement of providers at clinic visits. Alternatively, practitioners who wish to follow USPSTF recommendations to refer to intensive, multicomponent behavioral interventions may choose to consider evidence-based DPP adaptations such as the Group Organized – YMCA DPP,[5] which incorporates the DPP principles across a 16-lesson core curriculum phase, a 4-week training and refinement phase, and a long-term maintenance phase.

CONCLUSION

For an indigent population, overcoming cost barriers to gym membership, providing simple diet plans and a weekly support call was not sufficient to treat obesity effectively. For DPP adaptations to be tailored effectively for patients who experience a high burden of obesity and diabetes, researchers should provide detailed evaluation of program implementation.[19]

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