

Evaluation of Medicare's Intensive Behavioral Therapy for Obesity: the Bienestar Experience



Roberto P. Treviño, MD,¹ Christina Piña, BS,² Jesús Cuéllar Fuentes, PhD,³ Melissa Nuñez, MPH⁴

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Introduction: In 2011, the Centers for Medicare and Medicaid Services began to reimburse primary care providers for intensive behavior therapy for obesity. This study evaluated a Centers for Medicare and Medicaid Services intensive behavior therapy for obesity program as implemented in primary care clinics.

Methods: Data for this retrospective cohort study were obtained between May 2012 and February 2015 and statistical analysis was performed in 2017. The sample included 643 participants who attended at least one Bienestar intensive behavior therapy for obesity program session. The primary outcome was weight, and covariates were number of sessions, age, race/ethnicity, diagnosis of hypertension and diabetes, and type of health insurance.

Results: Of 643 participants that initiated the Bienestar program, 641 had complete data. The median reduction in weight of participants was as follows: those who attended fewer than four sessions, 0 kg (95% CI=0, 0.11 kg); between four and eight sessions, 1.1 kg (95% CI=0.86, 1.59 kg); and more than eight sessions 3.7 kg (95% CI=3.36, 4.55 kg). Medians of weight were significantly different between each classification of session numbers ($p < 0.01$). Participants lost on average 0.102 kg of weight per session attended.

Conclusions: The Bienestar program showed that the weight of participants decreased as they attended more sessions. Further studies are needed to determine if these results can be reproduced in other office-based primary care clinics and the program's impact on chronic disease.

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INTRODUCTION

The first and second most expensive medical diseases in the U.S. have a common denominator—obesity. The healthcare cost for diabetes and ischemic heart diseases in 2013 were estimated at \$101 billion and \$88 billion, respectively.¹ Obesity is not only associated with these two diseases, but also with stroke, hyperlipidemia, hypertension, asthma, several cancers, and musculoskeletal conditions.^{2–6} Therefore, it is no surprise that obesity is associated with significant higher all-cause mortalities.^{4,7}

In 2003, the U.S. Preventive Services Task Force recommended that clinicians screen adult patients for obesity and offer intensive behavioral therapy to promote sustained weight loss.⁸ The U.S. Preventive Services Task Force found fair evidence that the service improves

health outcomes and the benefits outweigh harms. Based on this recommendation and further analysis, in November 2011 the Centers for Medicare and Medicaid Services (CMS) began to reimburse primary care providers whose clinics offered intensive behavior therapy for obesity (IBT-O) to their patients.⁹

There are no studies that have evaluated programs based on the Medicare-reimbursement for IBT-O policy

From the ¹Department of Health and Human Performance, University of Texas Rio Grande Valley, Edinburg, Texas; ²Bienestar Healthy Lifestyle Advocacy Program, Social and Health Research Center, San Antonio, Texas; ³Cuéllar Associates Statistical Consultants, San Antonio, Texas; and ⁴Health Informatics, South Alamo Medical Group, San Antonio, Texas

Address correspondence to: Roberto P. Treviño, MD, Department of Health and Human Performance, University of Texas Rio Grande Valley, 1201 West University Drive, Edinburg TX 78539. E-mail: roberto.trevino@utrgv.edu. 0749-3797/\$36.00

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in the setting of office-based primary care physicians. Office-based physicians are in private practice and thus exclude physicians practicing in universities, hospitals, and occupational settings.¹⁰ The office-based primary care setting is important because it is where the majority (84%) of visits occur.¹¹ In May 2012, South Alamo Medical Group (SAMG) began implementing the Bienestar Healthy Lifestyle Advocacy program following the guidelines set by CMS. The objective of this study is to evaluate a program based on the Medicare-reimbursement for IBT-O policy. The outcomes were BMI and weight.

METHODS

This retrospective cohort study was conducted at SAMG clinics. SAMG is a group of 21 office-based primary care physicians, physician assistants, and nurse practitioners practicing in six clinics—one pediatric and five adult medicine. The project was reviewed by the University of Texas Health Science Center at San Antonio IRB (protocol number: HSC20150654N). Because the project did not meet the definition of human subject research, it was exempt from IRB oversight.

Study Population

SAMG has 23,203 active patients enrolled in its six clinics, of which 89% are minority, 60% have government assistance insurance (Medicare, Medicaid, Children's Health Insurance Programs, or county coverage), and 5.4% are uninsured. The electronic health records (EHR) of participants from the five SAMG adult medicine clinics who were referred to the IBT-O program between May 2012 and February 2015 were reviewed to extract the measures of interest. To get reimbursed by the health insurance plan for IBT-O services, the Healthcare Common Procedure Coding System code G0447 must be billed along with one of the ICD-9 codes for BMI ≥ 30.0 (V85.30–V85.45).

The inclusion criterion that was specified by CMS, is that participants had to have a BMI ≥ 30 . In addition, patients needed to be cleared by their primary care provider to participate in moderate physical activity. To be included in the analysis, all patients had to have at least one IBT-O session. There were no exclusion criteria. Patients were referred by their provider to the health educator using task messaging. Task messaging is an intramural secure e-mail via the EHR that connects all SAMG clinics regardless of location.

Measures

The Bienestar follows the guidelines set by CMS.^{9,12} The CMS guideline is that participants be screened for obesity, nutritional assessments be performed, and that the behavioral intervention be consistent with the U.S. Preventive Services Task Force's 5-A framework (Assess, Advise, Agree, Assist, and Arrange). Specifically, the nutrition and physical activity instruction is from the Bienestar coordinated school health program.^{13–16} The Bienestar is recognized as proven effective by the National Cancer Institute,¹⁷ Agency for Healthcare Research and Quality,¹⁸ and Healthy Communities Institute.¹⁹

The schedule recommended by CMS is the following: one session every week during the first month, two sessions a month for months 2 to 6, and one session a month for the next 6 months. According to the CMS IBT-O policy, at the 6-month visit, a re-assessment of obesity should be performed. To be eligible for additional face-to-face visits beneficiaries must have achieved a reduction in weight of > 3 kg (6.6 lb) over the first 6 months of intensive therapy. For beneficiaries who do not achieve a weight loss of > 3 kg during the first 6 months of intensive therapy, their readiness to change was assessed. If they showed readiness to follow the IBT-O recommendations, they were asked to repeat the more-intense sessions for another 6 months.

All sessions were performed individually, at the clinics, by a health educator. The health educator has 8 years of experience implementing lifestyle interventions. She was also responsible for reminding patients about their appointment and if the patient was a "no-show," she would call the patient within the same business day to reschedule their appointment.

To maintain objective data collection, height and weight were taken at the beginning of each session by a clinic vital sign staff member, not the health educator conducting the sessions. All measures were collected using a Detecto scale. And a clinic health analyst not involved with the intervention extracted the measures from the EHR. SAMG uses eMDs Solution Series, version 8.0. BMI and weight were extracted from each of the IBT-O sessions. Covariates extracted were the following: date and number of sessions, date of birth, race/ethnicity, diagnosis of hypertension and diabetes, and type of health insurance coverage divided into: government-assistance health insurance (Medicare, Medicaid, county) and nongovernment-assistance health insurance (private plans).

Statistical Analysis

The statistical analysis was performed in 2017. The analysis considered two approaches to assess the impact of the Bienestar IBT-O program on the change of BMI and weight: (1) compare their first with last session and (2) longitudinal over time. The effect of the program on the change in BMI and weight between the first and last session was first evaluated by classifying the number of sessions in less than four, between four and eight, and more than eight, and comparing the changes among the three categories. The differences in BMI and weight were calculated for each participant by subtracting the measure in the last from the measure in the first session. The distributions of these differences of the three categories were not symmetric, hence, the medians of differences of these three distributions were compared using nonparametric relative effects based on pseudo-ranks.^{20,21} Next, a regression analysis was used to evaluate the relation of weight measured at the final session with the number of sessions, age, race/ethnicity, diagnosis of hypertension and diabetes, health insurance type, and initial weight as predictors.^{22,23} A stepwise method was used to identify explanatory variables with a statistically significant effect on the final weight. The results of the regression analysis were practically the same for the BMI measured at the last session with the initial BMI included as a predictor in the model.

Although comparing BMI and weight between the first and last Bienestar session of all participants provide useful insight, the analysis ignores the measurements of BMI and weight in the

intervening sessions. The last part of the analysis considered longitudinal observations of BMI and weight. For this analysis, the longitudinal measurements were indexed using the times of the Bienestar sessions from the first session in weeks, this time variable was designated as time index. This was necessary because of the irregularity of the visits of the participants. For example, some participants had their second visit 4, 5, 6, or 7 days after the first visit. A mixed linear model was used to assess the relationship between the longitudinal measurements of BMI and weight with the fixed explanatory variables age, sex, race/ethnicity, health insurance type, and diagnosis of hypertension and diabetes; and with time index and participant's identification number as random explanatory variables.²⁴ The Akaike and Bayesian information criteria and likelihood ratio tests were used to identify explanatory variables with a statistically significant effect on the longitudinal measurements of weight. All analyses were performed using R, version 3.4.1. Because the analysis of the repeated measures of BMI and weight produced the same results, only the results of weight are presented in the Results section.

RESULTS

Of 643 participants who initiated the Bienestar, 641 had complete data (Table 1). The median age was 54 years (interquartile range [IQR], 45–64 years), and most were female (456 [71.1%]) and Hispanic (449 [70.1%]). The median weight was 101.7 kg (IQR, 89.6–116.6 kg) and the majority of participants had either a diagnosis of diabetes (47 [7.4%]), hypertension (209 [32.6%]), or both (264 [41.2%]). Only 121 (18.9%) had no history of either diabetes or hypertension. The baseline median weight of participants with either one of these diseases or both was 102.8 kg (IQR, 55.6–263.2 kg, $p=0.007$) and those with

none of these diseases were 96.4 kg (IQR, 55.9–159.1 kg, $p=0.0004$).

The distribution of the number of Bienestar sessions was positively skewed where 208 participants attended between one and three sessions (i.e., fewer than four sessions), 209 attended between four and eight sessions, and 224 attended between nine and 32 sessions (i.e., more than eight sessions). Clinic staff interviewed 62 patients that missed appointments and the patients' responses were: forgot/lack of reminder (34%), personal emergencies (19%), clinic scheduling error (13%), dissatisfied with clinic service (9%), lack of transportation (8%), family emergencies (5%), and other (19%). The number of sessions ranged from one to 32. Those that attended more than 22 sessions were self-pay. The average time for the first session was 47 minutes and for follow-up sessions it was 32 minutes. The time duration was taken from the eMD EHR. The eMD keeps track of the time when the patient's chart is opened and closed during clinic visits.

The IBT-O was covered by Medicare and 19 other private health plans at SAMG clinics. Medicare reimbursement was \$24.21, but because private insurance paid a higher amount, the average reimbursement per session was \$27.55. The average cost (health educator salary, benefits, mobile phone) per session was \$39.81. This cost was based on seeing an average of 118 patients per month.

The median reduction of participants' weight who attended fewer than four sessions was 0 kg (95% CI=0, 0.11 kg), four to eight sessions was 1.1 kg (95% CI=0.86, 1.59 kg), and more than eight sessions was 3.7 kg (95% CI=3.36, 4.55 kg) (Figure 1). Medians of weight were significantly different between each classification of session numbers ($p<0.01$).

Table 2 presents the estimates of the coefficients of the explanatory variables included in the regression model fitted to weight measured at the final session of each participant. The p -values indicate that the number of Bienestar sessions attended, age, and the category of males diagnosed with diabetes had a significant effect. The negative coefficients for the number of Bienestar sessions attended and age indicate that the final weight decreased as the number of sessions and age increased. The positive coefficient for the category of males diagnosed with diabetes only indicates that, on average, their weight was higher at the beginning of the study as compared with males with hypertension, hypertension and diabetes, and with no diabetes and no hypertension; and to females with any diagnosis.

The mixed model for the longitudinal observations for weight showed that the time index in weeks and the interactions of age with diagnosis category were significant

Table 1. Baseline Characteristics of Participants ($n=641$)

Characteristic	Data
Number of sessions, median (IQR)	6 (3–12)
Age (years), median (IQR)	54 (45–64)
Sex (%)	
Female	71.1
Male	28.9
Race/ethnicity (%)	
Hispanic	70.1
Non-Hispanic white	8.1
African American	3.7
Other	13.0
BMI, median (IQR)	38.1 (34.0–43.3)
Weight, kg, median (IQR)	101.7 (89.6–116.6)
Medical history (%)	
Diabetes	7.4
Hypertension	32.6
Both diabetes and hypertension	41.2
No diabetes or hypertension	18.9

IQR, interquartile range (first quartile–third quartile).

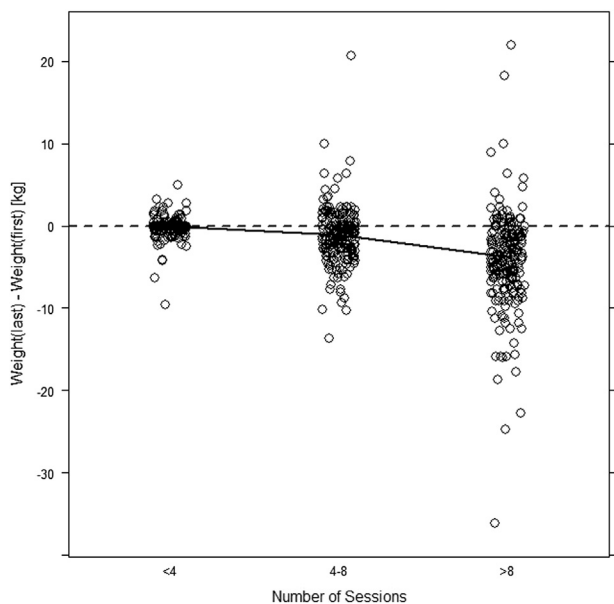


Figure 1. Differences in weight for fewer than four sessions, four to eight sessions, and for more than eight sessions. Note: The solid lines connect the medians of each group. BMI (last) is the BMI value obtained at the last session and BMI (first) is the BMI value obtained at the first session. Weight (last) is the weights measured at the last session and weight (first) is the weight measured at the first session.

(Table 3). These findings assumed that the trend over time is linear. The plot of the population residuals versus the fitted values did not show a departure from linearity, hence validating this assumption. Furthermore, the plots of the within-subject residuals also validated the assumptions of equal variance and normality.

Table 2. Coefficient Estimates of the Covariates in the Regression Models for the Weight at the Final Session

Variables in the model	Coefficient estimate	Pr(> t)
(Intercept)	9.3495	0.0002**
lweight	0.9726	<2e-16**
No sessions	-0.5909	<2e-16**
DM	1.6950	0.3315
HTN	-0.7430	0.5203
DM and HTN	0.8436	0.4727
Age	-0.0615	0.0458*
Males	-1.0006	0.6123
DM X males	8.3492	0.0134*
HTN X males	1.5510	0.5132
DM and HTN X males	2.3034	0.3067

Note: Pr(>|t|) is the two-sided p-value (*p<0.05; **p<0.01). DM, diabetes mellitus; DM and HTN, diagnosis of both diabetes and hypertension; HTN, hypertension; lweight, weight measured at the initial session.

Table 3. Coefficient Estimates of the Covariates in the Linear Mixed Model for the Longitudinal Observations

Variables in the model	Coefficient estimate	95% CI
Intercept	88.3487	73.9573, 102.7401
Tindex ^a	-0.1022	-0.1194, -0.0850
Age	0.2305	-0.0743, 0.5353
DM ^a	54.0707	28.1074, 80.0340
HTN ^a	38.7433	19.7278, 57.7588
DM and HTN ^a	45.9129	27.8820, 63.9438
Age X DM ^a	-0.8584	-1.3845, -0.3323
Age X HTN ^a	-0.6487	-1.0261, -0.2713
Age X DM and HTN ^a	-0.6966	-1.0534, -0.3398

^aSignificant factors. DM, diabetes mellitus; DM and HTN, diagnosis of both diabetes and hypertension; HTN, hypertension; Tindex, time index in weeks.

The estimated coefficients of time index showed that weight, on average, decreased 0.102 kg per session attended. The negative coefficients of the interactions of age with diagnosis category indicate that at baseline participants with diabetes, hypertension, or both weighed less the older they were. The average weight of participants at baseline with no diabetes and hypertension, on the other hand, did not change with age.

DISCUSSION

To the authors' knowledge, this is the first study to evaluate the effectiveness of a program based on the Medicare reimbursement for IBT-O policy in the setting of office-based primary care clinics. This study found that the more sessions participants attended the more their median BMI and weight decreased, regardless of age, sex, race/ethnicity, health insurance plan, or whether they had a diagnosis of diabetes, hypertension, both, or neither. Another significant finding was that at baseline patients with diabetes, hypertension, or both weighed significantly more than patients without either disease.

Because Medicare recognized IBT-O as a billable service, only one small study evaluated a program based on this policy.²⁵ The IBT-O was implemented by a nurse practitioner in accordance with the CMS schedule. The pilot study consisted of 36 participants who had attended four sessions or more. At 12 weeks, mean weight loss of the participants was 4.9 kg (p<0.05).

In light of the Medicare-reimbursed IBT-O, Carvajal et al.²⁶ reviewed eight randomized trials in which four were delivered by physicians and four by auxiliary health professionals. The mean weight loss ranged from 0.1 kg to 2.3 kg in studies that were delivered by physicians alone and from 1.6 kg to 4.5 kg in those delivered by

physicians and auxiliary health professionals. This review also showed that 30 minutes, instead of the 15-minute sessions provisioned by CMS, was needed to make an impact on weight loss.

To study the potential of the Medicare-reimbursement for IBT-O policy, Wadden and colleagues²⁷ conducted a systematic review of behavioral therapies for obesity that were implemented in primary care settings. The review included 12 trials. The mean weight loss ranged from 0.6 kg to 1.7 kg in studies that were delivered by physicians alone and from 3.5 kg to 4.5 kg in those that were delivered by trained interventionist in collaboration with physicians. Similar to the present findings, both review papers of behavioral therapies for obesity found that the duration of each session should be at least 30 minutes, the frequency of sessions was associated with greater weight loss, and the importance of auxiliary health professionals in the delivery of the service. The two review papers and the Bienestar experience suggest that the optimal length of an IBT-O session is 30 minutes.

The benefit of the IBT-O is not just the improvement of health outcomes, but also the potential for cost savings. Three studies of behavior therapy for obesity showed cost savings as measured by decreased use of prescribed medications.^{28–30} A third study did conduct a cost-effectiveness analysis using a Markov simulation model to estimate the cost and benefits of the Medicare-reimbursed IBT-O. This study estimated that the IBT-O would provide an incremental cost-effectiveness ratio of \$20,912 per quality-adjusted life year. A procedure or intervention is considered to be highly cost effective if it costs less than \$25,000 per quality-adjusted life year.³¹

Limitations

This study had several limitations. The first was program attendance. No-shows and cancellations are a common occurrence in office-based primary care practices. The no-show rate in the present study was 9%. According to the Medical Group Management Association, the no-show rate for most practices is 5–7%.³² An explanation for the higher no-shows at SAMG is that these clinics are located in mostly low-income neighborhoods (89% minority and 60% government-assistance insurance) and low-income populations have greater challenges in keeping their doctor's appointments.³³ Because the most frequent reason for no-shows in the present study was forgot/lack of reminder, methods to motivate patients and using technology, such as automated phone call reminders, might improve attendance. A second limitation was that this evaluation did not measure the impact of the Bienestar on hypertension and diabetes control. This evaluation was designed to evaluate the primary endpoint of the Bienestar, which is its effect on

BMI and weight. The impact of the policy on chronic diseases would have needed detailed tracking of medication changes and dosages to control for drug effects. The baseline finding, however, that healthier participants had lower weight than those diagnosed with hypertension, diabetes, or both, points to the benefits of weight-reduction programs.

Third, this evaluation was performed by one health educator and the clinics were located in mostly low-income neighborhoods with a high percentage of Hispanics. The authors are unsure if the same results would have been obtained if several health educators were involved and the clinics were located in more affluent neighborhoods with a more diverse patient population. Lastly, the cost per session exceeded the reimbursement. Profitability would have improved by increasing the number of patients seen per month. To break even in the present setting, the health educator would need to see 170 patients a month. The Bienestar would have been more costly and less effective if a healthcare provider rather than an auxiliary professional was conducting the sessions. The two review studies discussed showed that auxiliary professionals saw greater weight loss in patients in the program than physicians.

CONCLUSIONS

This study evaluated a program based on the Medicare-reimbursement for IBT-O policy to determine its effectiveness in reducing weight. Participants decreased weight as they attended more sessions. Specifically, participants lost on average 0.102 kg of weight per session attended. Future studies are needed to determine if the IBT-O results can be generalized to other office-based primary care practices, and if a favorable impact on biomarkers of chronic disease control can be achieved.

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