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Original article

A novel endocrinology-based wellness program to reduce medication expenditures and improve glycemic outcomes

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ABSTRACT

Aims: The purpose of this study was to determine the difference in diabetes-related medication expenditures as a result of a 16-week lifestyle intervention program. Medical expenditures for patients with diabetes are twice as high compared to patients without this condition. Secondary objectives were changes in HbA1C, BMI, weight, body fat, and program satisfaction.

Methods: The Wellness Life! Program includes educational sessions focused on nutrition, fitness, and behavioral therapy. Medication costs were based on Average Wholesale Prices, tabulated from the 2010 Red Book.

Results: A total of 36 patients (49–80 years old) enrolled, of which 27 patients have diabetes mellitus (Type 2 = 26, Type 1 = 1). Mean 30-day anti-diabetic medication costs decreased by $142.92. Clinical mean parameters improved in both the overall group and the diabetic subgroup, respectively: HbA1C (%) −0.69, −0.82; weight (lbs) −16.94, −17.11; BMI −2.73, −2.88; and body fat (%) −1.71, −1.79. Participants were generally satisfied with the program.

Conclusions: Employing a multidisciplinary wellness program within an endocrinology practice can reduce anti-diabetic medication expenses; however, long term follow-up is needed to determine if medication reductions and improved clinical parameters persist.

1. Introduction

Obesity is a growing epidemic in the U.S. and is clearly linked to the dramatic rise in the incidence of Type 2 diabetes [1,2]. Statistics from 2008 report that 26.1% of the U.S. adult population is obese. Excess weight can result in a number of conditions or worsen existing conditions including diabetes, hypertension, dyslipidemia, and osteoarthritis. Obesity and diabetes are interrelated and associated with increased medical costs. In the U.S. the medical economic burden was $116 billion for diabetes in 2007, and $147 billion for obesity in 2008 [1,2]. Medical expenditures for patients with diabetes are 2 times higher than those without this medical condition. Health care costs are projected to reach at least $860 billion in 2030 related to overweight and obesity management [3].

The delivery of patient education, particularly on diet and exercise can be difficult to accomplish in the outpatient setting. Recognition and reimbursement for initial and follow-up support for nutritional, behavioral, and fitness counseling is inconsistent and often lacking. Lifestyle interventions have proven to be effective in diabetes prevention and management, and in overweight/obese patient populations [4–9]. The Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults recommends a combined intervention of behavior therapy, low calorie diet, and increased physical activity [10]. Lifestyle modification in diabetes mellitus is necessary in addition to pharmacologic therapy to improve insulin resistance and lower blood glucose. Weight loss can improve insulin sensitivity significantly; thereby allowing decreased anti-diabetic medication use which minimizes the potential for drug-related adverse events and cost of care [11].

The reduction in out-of-pocket costs associated with weight loss in patients with Type 2 diabetes and obesity has been studied previously [12–14]. When implementing a very low calorie diet (800 kcal), Collins et al. was able to reduce participants' weight on

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average by 33.7 pounds and reduce monthly out-of-pocket costs for anti-diabetes and anti-hypertensive medications and supplies by $42.90 [12]. Medication costs were calculated based on average out-of-pocket retail costs. However, an 800 kcal caloric restriction is unrealistic and not practical for most people and can be unsafe without frequent monitoring by a health care provider. The ICAN (Improving Control with Activity and Nutrition) investigators discovered that a dietitian-led lifestyle case management program can reduce pharmaceutical costs by $239.00 over 12 months ($P$ = NS) [5,13]. However, patients only lost 5.3 pounds and HbA1C was reduced by 0.2% on average with their protocol. Medication costs were based on pharmacy claims information. Their intervention focused on the use of a dietitian, and only implemented physician support as needed which does not allow for timely medication adjustments. Changes in medication use from the Look AHEAD trial were recently published [14]. Monthly anti-diabetic costs were reduced by $15.00. Participants in the 1-year intensive lifestyle intervention arm were able to reduce body weight by 19.2 pounds and HbA1C by 0.6% [7]. Actual medication dosages were not obtained, and cost was based on a dose of ~50% of the maximum or effective dose. Also, cost was based on a national online pharmacy and generic medication costs were substituted whenever available. Based on the evaluated trials, Wellness Life! intended to provide a program that was feasible, provided a realistic diet, improved clinical parameters significantly, and used a succinct method to evaluate medication use.

The primary aim of this study was to determine the change in diabetes-related medication expenditures before and after completing a 16-week lifestyle intervention program. The costs of all anti-diabetic medications were considered.

2. Research design and methods

2.1. Study design

This retrospective, non-randomized, study determined the program's impact on patient medication use and costs. This study was approved by a Central Institutional Review Board.

2.2. Wellness Life! program overview

In 2011, Northeast Florida Endocrine & Diabetes Associates launched Wellness Life!, a 16-week multidisciplinary lifestyle and weight management program set within a private endocrinology practice. Table 1 lists the weekly topics. Patients considered eligible for the program were overweight or obese. Each weekly class meets for 1 h. The total cost for the 16-week program is $794 per individual, which includes body composition and metabolic testing plus the weekly group meetings. The primary goal of this program is to make wellness a way of life.

Table 1
Course outline.

Diagnostics	
Registration – weigh in and diet plan	
Nutrition session #1	Understanding your meal plan/portion control
Nutrition session #2	Starting off on the right foot
Behavior change session #1	Reasonable expectations
Exercise session #1	Getting started with exercise
Exercise session #2	Refining your exercise technique
Nutrition session #3	Supermarket safari
Behavior change session #2	Motivation and support
Exercise session #3	Overcoming exercise obstacles
Nutrition session #4	Dining out the healthy way
Behavioral change session #3	Mindful eating – am I really hungry?
Exercise session #4	Why strength training is important for everyone
Nutrition session #5	Recipe modification
Behavior change session #4	Emotional eating
Exercise session #5	Maintaining exercise motivation
Behavior change #5	Behavior change wrap up
Nutrition session #6	Nutrition wrap up

The presentations are delivered by a registered dietitian, psychologist, and personal fitness trainer. However, endocrinologists, nurses, and certified diabetes educators are also involved to assist with program performance and improvement. Dietitians meet one-on-one with participants to determine their caloric goal at the beginning of the program. Nutritional targets were tailored to each individual patient based on age, height, sex and resting metabolic rate. Meal replacement options, including cookies and shakes, were made available to all participants. The cost of a meal replacement tool was $4 per meal. Exchange menus were provided for additional meal planning options for patients to prepare their own meals. Fitness instruction was personalized, based on any physical limitations for people within each group. Equipment included use of resistance bands and items that can be found within most households. Patients have access to meet with the behavioral specialist independent of group meetings.

2.3. Procedure

Patient data, including demographic information, medical conditions, medication regimens, and other clinic information were captured upon program enrollment. If participants did not have labwork completed within 4 weeks prior to program initiation, labs (hemoglobin A1c, thyroid-stimulating hormone, Chem 20, complete blood count, lipid panel) were ordered. All subjects were medically monitored weekly by the research nurses and medications were adjusted as necessary to reduce risks of hypoglycemia. During the program patients were seen by their endocrinologist at least once throughout the intervention period. To assess appropriateness of medication changes or need for medication adjustments, subjects were asked to continue to monitor blood glucose and report symptoms of hypoglycemia or low blood glucose values.

2.4. Outcome measures

The primary outcome measure was change in cost of anti-diabetic medications. All changes in medications during the course of the intervention were captured including additions, discontinuations, and dose adjustments. Our main aim was to reduce medications as appropriate for program effectiveness and to minimize hypoglycemia risk. We analyzed medication data at enrollment and again at completion of the program to determine change in total medication costs for individual patients. Medication costs were based on Average Wholesale Prices (AWP), tabulated from the 2010 Red Book [15]. Monthly expenditures were based on a 30-day month. Secondary measures included weight, body mass index, body fat %, HbA1C, and program satisfaction. Trained personnel recorded all measures at baseline and at the end of the program. Body fat composition was measured using the Hologic Discovery DXA system (Hologic, Inc., Bedford, MA). The voluntary program satisfaction survey used Likert-scale (range of 1–10) and short answer in 3 domains: nutrition, fitness, and behavioral health.

2.5. Statistical analyses

Descriptive statistics were calculated for age, gender, ethnicity, and employment, as well as for clinical variables and medication-associated costs. We used paired t-tests for the comparison of baseline to post-intervention change in normally distributed variables; for nonparametric data, we used the Wilcoxon signed

rank test. McNemar's test was used to compare the proportion of patients using each medication class pre- and post-intervention. A correlation analysis using Spearman's Correlation was performed for HbA1C, weight, BMI, and anti-diabetic medication expenses for the subgroup with diabetes. Since 4 patients were missing values for post-intervention body fat composition, we conducted a sensitivity analysis for this variable under the assumption that each of these patients maintained baseline body weight. The results of this sensitivity analysis did not differ from the primary analysis in which these patients were excluded, thus the results of the sensitivity analysis are not presented. For all analyses, a p-value of $\leq$0.05 was considered statistically significant. Statistical analyses were performed using SAS statistical software 9.3 (SAS Institute, Cary, NC).

3. Results

3.1. Participants

From March 2011 to December 2011, 4 separate groups totaling 36 patients were enrolled into the Wellness Life! program. Demographic and clinical data for all participants and diabetes enrollees ($N = 27$) are provided in Table 2. All subjects in the diabetic cohort were taking anti-diabetic medications. Results below are provided for the diabetic subgroup solely.

3.2. Anti-diabetic medication use

Within the diabetic study group at baseline, 6 (22%) were taking 1 anti-diabetic agent, 12 (45%) were on 2 agents, 9 (33%) were on $\geq$3 agents, with a mean of 2.2 anti-diabetic agents. Also, 19 patients were using insulin therapy, 2 were using a glucagon-like peptide agonist, and 15 subjects were on an oral anti-diabetic agent. Mean 30-day prescriptions costs using AWP were $412.54.

By the end of the program, 8 (30%) of enrollees required only 1 anti-diabetic agent, 13 (48%) were now on 2 agents, and only 6 (22%) were still on $\geq$3 medications. Mean 30-day prescription costs were reduced to $269.62 following the interventional period, yielding an average reduction of $142.92 per patient per month. Insulin medication doses were decreased on average by 46% (basal insulin −37%, bolus insulin −55%) and oral medication doses were decreased on average by 12% (biguanide −2.5%, DPPIV inhibitor −16.7%, TZD 0%, and sulfonylurea −29%). There was no change in GLP-1 agonist dose. Two subjects were able to discontinue insulin use due to their improvement in insulin resistance. Table 3 summarizes the changes in medication use and cost.

Table 2
Baseline characteristics of Wellness Life! participants.

	Overall	Diabetes enrollees
N	36	27
Age	62 ± 7.2	64 ± 6.7
Sex (%)		
Male	17 (47%)	15 (56%)
Female	19 (53%)	12 (44%)
Ethnicity (%)		
African American	1 (2.8%)	1 (3.7%)
Non-Hispanic white	35 (97.2%)	26 (96.3%)
Employment status		
Employed	15	12
Unemployed	6	3
Retired	15	12
BMI (kg/m^2)	38.9 ± 8.4	40.1 ± 8.8
Overweight	2 (6%)	1 (4%)
Obese	34 (94%)	26 (96%)
Weight (lb)	245.7 ± 58.0	257.4 ± 60.0
HbA1C (%)	7.5 ± 1.7	8.1 ± 1.7
Body composition (%)	43.7 ± 6.1	43.7 ± 6.5

BMI, body mass index; HbA1C, hemoglobin A1C.

Table 3
Change in anti-diabetic medication use and cost.

	Pre-intervention	Post-intervention	*P*-value
Number of anti-diabetic medications/day	2.2 ± 0.9	2.0 ± 0.9	0.25
Insulin (%)	70.4	63.0	0.5
Biguanides (%)	48.1	44.4	1.0
Sulfonylurea (%)	22.2	25.9	1.0
Thiazolidinedione (%)	7.4	7.4	1.0
GLP-1 agonist (%)	7.4	7.4	1.0
DPP-4 inhibitor	22.2	18.5	1.0
Mean prescription costs ($)	412.54	269.62	$P < 0.0001$
Median prescription costs ($)	318.25	250.89	Not calculated

GLP-1, glucagon-like peptide 1; DPP-4, dipeptidyl peptidase IV inhibitor.

3.3. Clinical response

Mean weight loss among subjects was 17 pounds ($P < 0.0001$), from an average initial weight of 257 lbs to an average ending weight of 240 lbs. Mean reduction in BMI was 2.9 kg/m^2 and four participants classified as obese at enrollment according to BMI were reclassified as overweight by study end. The number of participants reaching the American Diabetes Association's glycemic goals doubled from baseline to post-intervention, 7–14 subjects. Average HbA1C reductions were 0.8% ($P < 0.0001$) and average body fat composition reductions were 1.8% ($P < 0.0003$). Patients with a baseline HbA1C greater than 8.0% ($N = 12$) experienced an average decrease of 1.3%.

3.4. Program satisfaction

Twenty subjects completed the satisfaction survey after completing the lifestyle intervention, and 18 of these survey responders had diabetes. A copy of the survey and participant responses is available in Table 4. Overall, participants considered the nutrition education to be excellent. Exercise instruction was considered helpful and participants rated incorporation of the exercise program into their routine as slightly easy. The behavioral health component was considered helpful. Ten program attendees said they were following their meal plan daily, and 9 patients said they were adhering most days of the week. Only one survey completer said they were only following their meal plan occasionally. Fourteen of the 18 responders with diabetes stated they were consistently monitoring their blood glucose as recommended by their physician. Most of the patients said they only exercised a few days weekly.

4. Discussion

Lifestyle interventions and weight management can improve healthcare for diabetic patients. Our results illustrate the impact a wellness program can have on medication expenditures in obese/overweight patients with diabetes. If insurance companies were willing to financially support these programs, the cost savings would be significant. Extrapolating the results from this study, $142.92 saved monthly would result in a yearly savings of $1715.04, which far exceeds the cost of the program ($794).

Our study has several limitations. We enrolled a relatively small sample size in a predominantly Caucasian population with health insurance, which limits the generalizability to other populations. Patients were highly motivated since they paid out of pocket for the program. No comparator group was used to evaluate whether the standard of care could have had similar results. Average wholesale price was used to calculate medication expenditures instead of out-of-pocket expenses. However, this would be difficult to attain due to the different types of prescription coverage. The cost of diabetic supplies was not included in the cost analysis. A

Table 4
Patient Satisfaction Survey Responses ($N = 20$).

Questions	Responses		
	Mean	Min	Max
Nutrition	9.55	8	10
Please rate the *nutrition education* you have received through the Wellness Life! program (scale options: poor = 1, to excellent = 10)			
Exercise	7.4	1	10
Please tell us how helpful you have found the *exercise instruction* received through the Wellness Life! program (scale options: not helpful = 1, to very helpful = 10)			
Exercise	6.8	1	10
How easy was it to incorporate this *exercise program* into your routine (scale options: not easy at all = 1, to very easy = 10)			
Behavioral health/behavior change	8.1	1	10
Please tell us how helpful you have found the *behavioral health* portion of the Wellness Life! program (scale options: not helpful = 1, to very helpful = 10)			
Please rate the extent to which you are following your meal plan (scale: consistently = 1 to not = 4)	1.55	1	3
Please rate the extent to which you are monitoring your blood glucose (N = 18) (scale: consistently = 1 to not = 4)	1.28	1	3
Please rate the extent to which you are exercising (scale: consistently = 1 to not = 4)	2.37	1	4

longitudinal analysis at 1 year would be ideal to determine if reduction in medication expenditures and improvement in clinical outcomes persisted.

5. Conclusions

Implementing a wellness program which emphasizes the essential ingredients of nutrition, fitness, and behavior can reduce medication expenditures and improve care in overweight, Type 2 diabetics. This multidisciplinary format creates a timeframe that gives patients time to absorb the information, revisit strategies for management and engrave the behaviors into their minds. Covering these key elements is essential for patients to grasp and embrace the strategies to be successful and improve their condition.

Weight loss improves insulin sensitivity in overweight/obese diabetics; therefore, proactive reductions in anti-diabetic medications are often required for patients to achieve safe weight management goals and minimize risks of hypoglycemia. Of all the anti-diabetic medications used, insulin and sulfonylureas generally have the greatest risk of hypoglycemia and were targeted for initial and ongoing dose reductions. It is encouraging to note that clinical markers for diabetes care improved dramatically despite the fact that diabetes medications were reduced concomitantly.

Although other models have had similar results, this program is unique in that it is housed within an outpatient endocrinology practice with close patient supervision and oversight by their referring endocrinologist.

Recently, the Centers for Medicare and Medicaid Services (CMS) had announced the availability of reimbursement to primary care physicians who provide intensive behavioral therapy for patients with a BMI $\geq 30\ kg/m^2$ [16]. This reimbursement encompasses screening for obesity, nutritional assessment, and intensive behavioral counseling and behavioral therapy. This recognition of services should be extended to specialists. Endocrinologists specialize in diabetes and metabolism and are uniquely qualified in this arena and should be recognized by CMS and other payer sources as providers for obesity management and wellness.

Conflict of interest

The authors do not have anything to disclose.

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