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Abstract
Background*: Pharmacists are currently providing comprehensive medication management in the outpatient setting. However, there is little documented evidence demonstrating pharmacists are generating further improved health outcomes utilizing non-pharmacologic support, such as fitness and nutrition counseling. The objective of this study is to determine if a pharmacist-led wellness program with medication management and lifestyle modifications through fitness and nutrition coaching can lead to improved biometric markers.*
Methods*: The wellness program targeted corporate employees and was offered in a corporate headquarters' setting with an on-site workout facility. The program was expected to recruit approximately 15 patients into the wellness program consisting of two treatment arms. The standard group featured nutrition-based classes, medication therapy management and fitness education. The intervention group performed the standard group's activities plus direct, supervised fitness training once weekly. Measured biometric markers were assessed at baseline, 3.5 months, and 7 months and included body mass index (BMI), waist circumference (WC), fasting blood glucose (FBG), systolic and diastolic blood pressure (SBP and DBP), and full lipid panel (TC, TG, HDL, and LDL).*
Results*: Seventeen patients were enrolled in the study. The standard group (n = 11) and intervention group (n = 6) had relatively similar biometric markers at baseline. Seven total patients completed the study (4 from standard group, 3 from intervention group). The majority of biometric markers improved in both groups, and BP and LDL control was maintained for all who completed the study.*
Conclusion*: These data suggest that a licensed pharmacist with certified personal trainer credentials may be capable of maintaining biometric markers at healthy levels and improving where necessary in an employee wellness program through one-on-one medication, fitness and nutrition support. Additional, large-scale research is needed to verify the clinical outcomes and feasibility in a larger group setting.*

Background

Chronic medical conditions, such as cardiovascular disease, diabetes and obesity, represent some of the most common, most expensive and most preventable conditions in The United States.[1] According to the Centers for Disease Control and Prevention (CDC) in 2012, about one-half of US adults are burdened with one or more chronic conditions.[1] It is estimated that 47% of US adults have one or more risk factors for cardiovascular disease, such as uncontrolled high blood pressure, uncontrolled high LDL cholesterol or currently smoke. The American Diabetes Association in 2011 cited 8.3% of America, or 25.8 million American children and adults, have diabetes.[2] Additionally, 79 million Americans were found to have prediabetes, indicating a very large number of individuals are traveling down the path of diabetes and its associated complications.[2] In 2012, costs associated with diabetes reached astronomical amounts, totaling $245 billion. In 2009-2010, it was estimated that approximately one-third, or 78 million Americans, were classified as obese (BMI > 30 kg/m^2).[1] An even more concerning statistic reveals about one-fifth of our nation's youth are obese (BMI $\geq$ 95th percentile). This is resulting in earlier and more rapid onset of these aforementioned conditions, which significantly influences their health and well-being. The increased incidence of these conditions can be attributed to what the CDC terms "health risk behaviors," which encompasses a lack of physical activity, inadequate nutrition, tobacco use and excessive ethanol consumption.[1] Thus, it is evident from these statistics that additional interventions are warranted to manage and avert the development and progression of these conditions long-term.

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Former Surgeon General Dr. Richard H. Carmona indicated childhood weight gain is caused by an interplay of multiple variables, such as genetic, social, metabolic and environmental factors.[3] He further states that, "the fundamental reason that our children are overweight is this: Too many children are eating too much and moving too little." It is reasonable to deduce the increased incidence and prevalence of these chronic conditions in adults may be for similar reasons.

Physiologically, it has been shown that exercise causes an insulin-independent translocation of GLUT-4 receptors from the cytosol to the surface of skeletal myocytes.[4] Additionally, there is data to support there are two separate "pools" of GLUT-4 receptors; one is translocated when the insulin-signaling pathway is active, whereas the other is activated when skeletal muscle contracts. Furthermore, inhibiting the insulin-signaling pathway and contracting skeletal muscle still resulted in GLUT-4 translocation in rats. This contraction-induced pathway remains elevated for several hours after the cessation of exercise.[5] Thus, in patients with Type 2 Diabetes Mellitus (T2DM) who exhibit some dysfunction in the insulin-signaling pathway, exercise provides a viable physiologic strategy to increase glucose uptake into skeletal muscle via this separate pathway.

A joint position statement from the American College of Sports Medicine and The American Diabetes Association in 2010 cites numerous recommendations to circumvent the development of diabetes and how to optimally manage existing diabetes with exercise modalities.[5] For prevention of diabetes, it is recommended that individuals participate in at least 2.5 hours per week of moderate to vigorous physical activity. Individuals with existing diabetes are encouraged engage in aerobic exercise for 150 minutes per week, three days per week with no more than 2 consecutive days between bouts of aerobic activity. Additionally, it is recommended individuals with T2DM engage in resistance training at least 2 to 3 days per week. Also, there is data that support the combination of aerobic and resistance training with a qualified supervisor or personal trainer confers additional benefits than if each activity was performed on its own or in an unsupervised fashion.[5] Thus, the incorporation of a personal trainer into a T2DM patient's care plan may be an effective strategy for managing their condition by ensuring proper exercise technique as well as maintaining accountability and motivation.

The national guidelines for cardiovascular disease, diabetes and obesity recommend both pharmacologic as well as non-pharmacologic options for chronic management.[6,7,8,9] For the majority of guidelines, there are target goals for specific biometric markers that indicate whether a patient's condition is adequately managed, for example, fasting blood glucose (FBG) $\leq$ 130 mg/dL for individuals with diabetes.[8] This represents a feasible and simple method of monitoring patient progress in the outpatient setting. However, there is little documented evidence that pharmacists are generating further improved outcomes by utilizing a combination of pharmacologic and non-pharmacologic support.

This study was developed to test the hypothesis that a pharmacist with personal trainer credentials (PPT) may have a unique expertise in being an on-site wellness consultant, capable of managing both pharmacologic and non-pharmacologic options simultaneously at a single location while maintaining patient accountability. Therefore, the purpose of this study is to determine if a pharmacist-led wellness program with medication management and lifestyle modifications through fitness and nutrition can lead to improved biometric markers.

Methods

The PPT was a licensed pharmacist and a Certified Personal Trainer from the National Strength and Conditioning Association who practiced one day per week at a large grocery chain Division Office in Westerville, Ohio. Employees of the office were notified of the study via email and flyers, and were randomized into two treatment arms. The standard group had nutrition-based presentations given once monthly, a comprehensive medication review and fitness education. The intervention group had the standard group's activities plus once-weekly personal training. The measured biometric markers of the study were systolic blood pressure (SBP), diastolic blood pressure (DBP), body mass index (BMI), waist circumference (WC), total cholesterol (TC), triglycerides (TG), high-density lipoprotein (HDL), low-density lipoprotein (LDL), and fasting blood glucose (FBG). Inclusion criteria were based on an existing health coaching program within the employer group, which included patients with a BMI $\geq$ 29 or BMI $\geq$ 27 with one or more of the following documented: FBG > 100 mg/dL, BP > 120/80 mmHg, or LDL-C > 140 mg/dL. All participants were required to complete an exercise clearance form prior to participation to verify no current medical conditions would be exacerbated by physical activity. Patients were excluded if the patient's physician did not grant clearance to participate in the program. Formal feedback was not solicited, however, verbal/written feedback was accepted if offered during the study period. The authors planned for a study duration of approximately 7 months. A midpoint evaluation was scheduled to occur half-way through the study to assess progress.

Nutrition-based presentations included an initial visit/background, basics of nutrition, meal planning (given by a Registered Dietician), dining out/portion control/dieting, physical activity, importance of adequate protein intake, and physical activity. Each interactive class lasted 1-hour in length and was open to questions during and post-presentation. Intervention participants were instructed to engage in 150 minutes of aerobic activity per week in addition to resistance training 2 to 3 times per week on non-consecutive days, with one of those sessions being with the PPT. Prescribed workouts were full-body in nature, emphasizing major upper and lower body push/pull movements.

Cholesterol and glucose were measured with Alere Cholestech LDX analyzers. Descriptive statistics were used to denote changes over time and differences between groups and were analyzed with Microsoft Excel 2010. This study was approved by Ohio Northern University's Institutional Review Board and patient consents were obtained.

Results

Seventeen patients were recruited at baseline. Six individuals were randomly selected to be in the intervention group for this pilot study. Randomization and recruitment results are noted in Figure 1. Both groups presented in a generally healthy state. Baseline characteristics can be found in Table 1. Average baseline, midpoint and final biometric markers for the standard and intervention groups can be found in Table 2. Blood pressures and LDL cholesterol in both groups were well-controlled at baseline. Average BMI and WC were higher than recommended values (BMI $\geq$ 30, WC $\geq$ 40 inches for men, $\geq$ 35 inches for women). Average lipid profiles in the standard group were generally healthy, but the intervention group had TG > 150mg/dL and HDL < 40mg/dL.

The standard group at the midpoint evaluation experienced a decrease in BMI, WC, TG, LDL, and FBG. An increase was seen in TC which may have been in part due to increased HDL. FBG remained in the normal fasting range. Out of the 11 patients in the standard group, four individuals chose not to continue participating in the program up to the midpoint evaluation. At the conclusion of the study, three more individuals were lost to follow-up, leaving a total of 4 individuals to be evaluated. Formal assessment of rationale for declined participation was not accomplished; however, several patients informed the PPT that discontinuation was related to time constraints. The results were generally similar to the midpoint evaluation, with some markers improving slightly. After formal medication review, no medication changes were deemed necessary, but counseling was provided as clinically appropriate.

The intervention group at the midpoint evaluation experienced a decrease in TG and LDL and slight increase in HDL. BP and FBG only slightly decreased. Weight measurements remained comparable to baseline. No dropouts occurred during the first half of the program. At the conclusion, three individuals dropped out; two were for non-study related medical reasons, and the PPT was notified of their discontinuation. BP was maintained at levels similar to baseline. BMI and WC decreased from midpoint. TG, LDL and FBG continued to decrease, while HDL increased slightly compared to the midpoint (see Table 2). Similar to the standard group, no medication changes were deemed necessary, but counseling was provided as clinically appropriate. The final data analysis included two individuals with T2DM. The three individuals who completed the study conveyed both written and verbally a high level of satisfaction.

Table 3 illustrates the difference between the baseline and final assessment, and average change of biometric markers for the individuals completing the study. For the intervention group, patients 1 and 3 have diabetes; patient 2 exhibited a lipid profile and FBG that were maintained within normal ranges. Two individuals in the standard group experienced, at face value, a substantial increase in SBP, however, these values were still within normal ranges. Similarly, patient 4 in the standard group experienced a substantial increase in TG, but this marker remained within normal limits through the duration of the study. BP and LDL remained controlled for all individuals who completed the study.

Discussion

Participant groups presented with generally controlled BP and lipids, but obesity was highly prevalent among this population. Lifestyle changes, specifically improved nutrition and increased exercise, would be anticipated to improve all of the studied biometric markers. Biometric markers improved in both groups within an expected margin given the study duration. One key difference between the two groups was the frequency of encounters with the PPT. The intervention group met approximately four days per month, whereas the standard group met once per month. Although statistical tests for analysis were not completed due to small sample size, trends for further improvement were shown in the intervention group as compared to the standard group.

The three individuals in the intervention group subjectively reported a very high degree of satisfaction, improved sense of well-being, higher energy and increased productivity. In contrast, very little feedback was given from the standard group. The intervention group also specifically cited the value of a weekly check-in. The partnership/relationship developed

with the PPT was exclusive to this group and may be a key reason why this group experienced more significant improvements in their health. Thus, the number of overall encounters with a PPT may impact several personal components of patient care, such as developing rapport, motivation and trust. This demonstrates that, albeit with a very small sample size, a PPT is capable of beginning and maintaining relationships while keeping individuals accountable and on-track to meet their health goals.

The individuals in both groups often cited general reasons as to why they no longer wanted to participate, with the majority citing time constraints as a limiting factor. Two individuals in the intervention group cited medical reasons for not being able to complete the protocol that were non-study related.

A limitation of the study is the ability to generalize these conclusions to a larger population. The location was a single workplace that employed fewer than 150 individuals, not all of which would have met the inclusion criteria. Additionally, facilities limited the number of individuals that could exercise simultaneously. Patients were notified of the study via email and flyers, thus voluntarily decided to participate in the study. The inability to impact a large number of individuals over a state-wide division or a nation-wide corporation is not feasible with a single practitioner at a single site. Thus, implementation into a massive, nation-wide corporation would require additional sites and providers to allow for the greatest possible impact. It is uncommon for an individual to be licensed as both a pharmacist and personal trainer, therefore reproducibility may be more difficult than a model where the pharmacist did not require additional certification.

Future research could investigate a similar model with a larger sample size and/or in related practice settings. Additionally, it would be beneficial to determine a method or technique to motivate individuals who may not possess a high degree of intrinsic motivation. Also, it may be worthwhile to investigate if the magnitude of improvement could be greater in a population with worse baseline health and need for increased pharmacologic support. In this study, patients often had higher levels of motivation because of the voluntary nature of recruitment. Therefore, finding a viable strategy to recruit patients who lack motivation could be a worthwhile endeavor to improve employee health.

Conclusion

This was a small, exploratory study by design to determine the viability of a wellness model and its potential implementation in a workplace setting. This specific model required a facility with direct patient access and fitness room with a combination of aerobic and resistance training options; however, very similar models could be developed with synergy for other worksites. When facilities are available and a sufficient quantity of interested participants are available, not only is a PPT able to help improve biometric markers, but participants who received weekly intervention felt an improved sense of well-being, more energy and increased productivity. Additional, large-scale research is warranted to verify the potential success of implementation within other workplace environments.

References

1. Chronic Diseases and Health Promotion. Centers for Disease Control and Prevention. Updated 9 May 2014. Accessed 14 May 2014. Available from: http://www.cdc.gov/chronicdisease/overview/index.htm?s_cid =ostltsdyk_govd_203#ref1.
2. Statistics about Diabetes; Data from the National Diabetes Statistics Report. American Diabetes Association. 2014. Accessed 14 May 2014. Available from: http://www.diabetes.org/diabetes-basics/statistics/.
3. Carmona RH. The Obesity Crisis in America. Testimony Before the Subcommittee on Education Reform Committee of Education and the Workforce United States House of Representatives; 2003. Accessed 14 May 2014. Available from: http://www.surgeongeneral.gov/news/testimony/obesity07162003.html.
4. Goodwin ML. Blood Glucose Regulation during Prolonged, Submaximal, Continuous Exercise: A Guide for Clinicians. J Diabetes Sci Technol. May 2010; 4(3): 694–705.
5. Colberg SR, Sigal RJ, Fernhall B, et al. Exercise and type 2 diabetes: the American College of Sports Medicine and the American Diabetes Association: joint position statement. Diabetes Care 2010; 33: e147–167.
6. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults: Executive summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). *JAMA* 285:2486–2497, 2001.
7. James PA, Oparil S, Carter BL, et al. 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults: Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8). *JAMA.* 2014;311(5):507-520.

8. American Diabetes Association: Standards of medical care in diabetes—2014 (Position Statement). Diabetes Care 37 (Suppl. 1):S14–S80, 2014.
9. Jensen MD, Ryan DH, Donato KA, Apovian CM, Ard JD, Comuzzie AG, Hu FB, Hubbard VS, Jakicic JM, Kushner RF, Loria CM, McMurry KY, Millen BE, Nonas CA, Pi-Sunyer FX, Stevens J, Stevens VJ, Wadden TA, Wolfe BM, Yanovski SZ. 2013 AHA/ACC/TOS guideline for the manage ment of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. *Circulation.* 2013.

Figure 1: Randomization and Recruitment

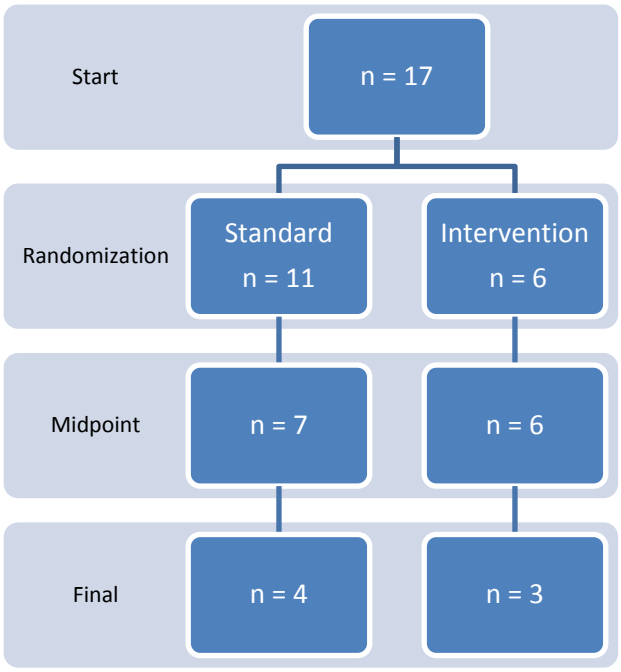

Table 1: Baseline Data

Characteristic	All participants (n=17)	Standard (n=11)	Intervention (n=6)
Average age	48 (range: 29-63)	48.1	48.5
Gender	M: 2 (12%) F: 15 (88%)	M: 1 (6%) F: 10 (94%)	M: 1 (17%) F: 5 (83%)
Hypertension	9 (53%)	5	4
Diabetes	3 (18%)	0	3
Hyperlipidemia	4 (24%)	1	3
BMI > 30	13 (76%)	7	6

Table 2: Average biometric markers collected during three collection points – Standard and Intervention groups

Biometric markers (units)	Standard group			Intervention group		
	Baseline (n=11)	Midpoint (n=7)	End (n=4)	Baseline (n=6)	Midpoint (n=6)	End (n=3)
SBP (*mmHg*)	123.7	126.0	132	126.0	122.7	122.3
DBP (*mmHg*)	82.1	79.1	86.5	82.8	77.7	77.0
BMI (kg/m^2)	32.6	31.0	30.9	38.1	38.2	35.5
WC (*inches*)	41.6	39.2	39.5	46.2	45.6	45.2
TC (*mg/dL*)	190.3	196.0	206.0	179.5	161.8	154.0
TG (*mg/dL*)	130.2	113.1	77.0	162.5	132.7	121.3
HDL (*mg/dL*)	50.9	59.6	65.0	34.7	36.0	38.0
LDL (*mg/dL*)	118.5	113.7	125.3	112.5	99.0	91.7
FBG (*mg/dL*)	95.5	94.4	100.5	113.7	112.2	106.0
Number of dropouts	N/A	4	7	N/A	0	3

Table 3: Standard and intervention group net changes from beginning to end.
"+" indicates an increase in value from baseline, "-" indicates a decrease from baseline

Biometric Marker (*units*)	Standard					Intervention			
	Net Δ Patient 1	Net Δ Patient 2	Net Δ Patient 3	Net Δ Patient 4	Avg Δ	Net Δ Patient 1	Net Δ Patient 2	Net Δ Patient 3	Avg Δ
SBP (*mmHg*)	-8	+4	+26	+16	+9.5	+2	-10	-7	-5
DBP (*mmHg*)	-14	+6	+10	+10	+3	-4	-1	-1	-2
BMI (kg/m^2)	-2	+0.5	-0.5	+1.2	-0.2	-1.2	-0.9	-1.8	-1.3
WC (*inches*)	+1.5	-4	+1	-2.5	-1	-5	0	-1.5	-2.2
TC (*mg/dL*)	+11	-15	-27	+10	-5.3	-27	-14	+17	-8
TG (*mg/dL*)	-14	-48	+2	+47	-3.3	-68	+17	-89	-47
HDL (*mg/dL*)	-8	-3	+13	+0	+0.5	0	+1	+18	+6.3
LDL (*mg/dL*)	+22	-2	-40	+0	-5	-13	-19	+16	-5.3
FBG (*mg/dL*)	+1	-3	+12	-7	+0.8	-6	+3	-8	-3.7