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Improving Employee Health: Evaluation of a Worksite Lifestyle Change Program to Decrease Risk Factors for Diabetes and Cardiovascular Disease

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Abstract

Objective—To determine if an evidence-based, behavioral lifestyle intervention program delivered at a worksite setting is effective in improving type 2 diabetes and CVD risk factors.

Methods—A randomized six-month delayed control design was utilized, with two-thirds of the participants assigned to begin intervention immediately and one-third beginning six months later. The year-long program (weekly for 3 months transitioning to monthly) focused on weight loss and increasing physical activity.

Results—The immediate intervention group had greater mean weight loss (–10.4 lbs., 5.1%, vs. –2.3 lbs., 1%, $p=0.0001$) than the delayed control group at 6 months and relatively greater improvements in activity, HbA1c and other risk factors. The delayed group experienced similar improvements after completing the intervention program.

Conclusions—A worksite behavioral lifestyle intervention is feasible and effective in significantly improving risk factors for diabetes and CVD.

Introduction

Type 2 diabetes is a chronic and potentially disabling disease which can lead to devastating systemic complications and long-term infirmity (1). Approximately 29.1 million adults in the US have type 2 diabetes, and it is estimated that another 86 million have pre-diabetes, a condition that increases risk for type 2 diabetes (1). In addition, about one-third of the adult US population has the metabolic syndrome, a constellation of risk factors that also increases

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risk for type 2 diabetes as well as cardiovascular disease (CVD)(2-5). Health care expenditures associated with diabetes are spiraling with approximately 254 billion dollars spent on direct and indirect medical costs related to diabetes in the US in 2012 (6).

These dramatic increases in chronic disease rates coupled with ongoing increases in the cost of general health care have caused widespread concern, particularly for employers who worry about employee health and productivity. This concern is reflected in the national US Patient Protection and Affordable Care Act of 2010 (ACA), which includes a component that supports the development of worksite health promotion activities (7). Subsequently, the percentage of US employers that offer some type of worksite wellness program has increased from about 6.9% in 2004(8), to approximately half of employers who offer health care benefits with at least 50 employees in 2012 (9).

Potential benefits of such workplace programs include improved absenteeism, productivity and retention of employees, and reduced health care costs for employers (10-12). It has been noted that the benefits of worksite interventions may be further enhanced when intervention is targeted toward those at highest risk (13). One meta-analysis of the costs and savings associated with worksite wellness programs found that every dollar spent on such programs results in an estimated decrease in medical costs of about \$3 (14). A 2013 review of the effect of wellness programs on health care costs generally suggests cost savings with some exceptions. (9)

A limitation in understanding the full scope of possible benefits from worksite wellness programs is that they are generally not well-described, nor is it clear that they are evidence-based. For example, one study found lower costs to be related specifically to disease management but not lifestyle management intervention; however, the specific components of these were not clearly defined, i.e. number of sessions offered, session content and materials, evidence base for the intervention, intervention goals, etc. (15). Worksite wellness programs constitute a variety of services, from the provision of gym membership discounts, health risk assessments, wellness newsletters, smoking cessation, stress management and immunization programs, to vaguely defined drug/alcohol programs, behavioral/lifestyle coaching, and disease management interventions for diabetes, asthma, obesity, depression and lower back pain (9, 16). In addition, while some form of program evaluation is completed for the majority of wellness programs, according to the Kaiser Family Foundation 2013 Report, only about one-third of all large firms and 9% of small firms offering wellness programs evaluated their programs based on health outcomes (16).

Not surprisingly, risk factors associated with diabetes and/or CVD, such as high glucose, high blood pressure, obesity and physical inactivity, have been shown to be among the top ten risk factors most strongly associated with increased per capita annual medical spending (17). Multiple studies have demonstrated the effectiveness of structured, behavioral lifestyle intervention programs in improving these specific risk factors (18-20). Most notably, the US Diabetes Prevention Program (DPP), a large National Institutes of Health funded clinical research trial, demonstrated that a behavioral lifestyle intervention focusing on weight loss through increased physical activity and healthy eating resulted in a 58% reduction in the development of type 2 diabetes in a high risk population that was diverse in age, race/

ethnicity, gender and geographical location (21). The DPP lifestyle intervention was also shown to be effective in lowering risk for development of the metabolic syndrome (21, 22), and significantly reducing risk factors for CVD (23).

Since release of the findings of the DPP in 2002, adaptations of the DPP lifestyle intervention have been successfully implemented in multiple community settings including primary care practices and out-patient diabetes education clinics (24-30), senior and community centers (31-35), the YMCA (36, 37), and churches (38-40). Although the worksite holds promise for successful delivery of DPP-like behavioral lifestyle intervention, such programs have not been extensively examined in this setting (41-45).

The purpose of this investigation was to implement a clearly defined, evidence-based behavioral lifestyle intervention directed toward reducing risk factors for type 2 diabetes and CVD delivered in a worksite setting, and to formally evaluate the intervention for feasibility and long-term effectiveness based on measured health outcomes. The results of this study will provide valuable information to employers and health care planners in guiding future worksite wellness efforts.

Methods

The intervention utilized for this study, DPP Group Lifestyle Balance™ (DPP-GLB), is a comprehensive lifestyle behavior change program adapted directly from the successful lifestyle intervention used in the DPP which was originally developed at the University of Pittsburgh. Members from the original DPP lifestyle team who are now faculty of the University of Pittsburgh Diabetes Prevention Support Center (DPSC) adapted and updated the individual intervention to a group-based program with a recommended delivery schedule of 22 sessions during a one-year period of time (16 core sessions in the first 6 months transitioning to monthly post-core support sessions).

In order to provide a more flexible delivery mode, a DVD of the initial 12 core sessions was developed, and consists of a series of taped sessions of a staged group following a script that was developed to closely follow the program. The DPP-GLB program, delivered by DPSC trained prevention professionals in face to face groups and/or via DVD, has been shown to be effective in reducing weight and other risk factors for diabetes and CVD in several community settings (24, 25, 27-29, 32, 33, 35, 37), but has not been evaluated within a workplace setting.

Study Design

The study utilized a randomized six-month delayed control intervention design, where two-thirds of the participants were randomly assigned to begin intervention immediately after enrollment, and one-third were assigned to begin approximately six months later (Figure 1). After receiving their randomization assignment, participants were given the choice to attend a face-to-face group version of the intervention delivered at the worksite or to participate in an individually-viewed DVD version of the intervention program coupled with monthly group meetings. This study design allowed for comparison between those who received intervention and the control group at six-months, as well as pre/post evaluation of both

groups combined. Further, this study design ensured that all participants received the intervention in the delivery mode of their choice, with a delay period similar to what might be found in a “real-world” setting in which individuals could wait for a program to begin due to program availability, limited staffing, etc.

Recruitment and Study Population

The study was implemented at Bayer Corporation, a large international company with a worksite in the Pittsburgh metropolitan area at which approximately 1,800 individuals are employed. The makeup of individuals employed at Bayer Pittsburgh consists of professional/technical employees, with a mix of salaried and hourly workers. Bayer, and specifically the medical director and team, was a very active partner in this entire process, guiding all aspects of the implementation of the program at their worksite. Much of the planning phase focused on how the DPP-GLB program would interface with the company’s existing offerings and programs. Participant recruitment (September-November, 2010) involved the use of employee communication strategies typically used by the company such as mailing, e-mail blasts, “lunch and learn” meetings, etc. Employees were assured that their individual results from the study were confidential and would not be shared with their employer.

Subjects were screened initially by telephone, and those who met eligibility were invited to attend an onsite screening. Employees, contractors and adult family members were invited to participate. *Telephone screening* eligibility criteria included: 18 years of age, no previous history of diagnosis of diabetes, not planning to move away in the next 18 months, not pregnant, recently pregnant or planning to become pregnant and self-report of BMI $\geq 24\text{kg/m}^2$.

Those found to be eligible and interested via telephone screening were invited to participate in an onsite assessment to establish intervention eligibility. Each individual who attended an onsite screening received a \$5 gift certificate provided by Bayer for their onsite café. *Intervention eligibility* criteria included: documented BMI $\geq 24\text{kg/m}^2$ ($\geq 22\text{kg/m}^2$ for Asians) and evidence of pre-diabetes (46), the metabolic syndrome as defined by the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) criteria and/or hyperlipidemia and one component of the metabolic syndrome (47).

A total of 176 individuals were screened over the phone, with 171(98%) found to be eligible for and interested in the onsite screening assessment. Of those eligible for onsite screening, 160 (94%) completed the screening with 107 (67%) found to be eligible for the study. Of the 53 ineligible, 45 (84.9%) did not have pre-diabetes or the metabolic syndrome, six (11.3%) had fasting plasma glucose or HbA1c levels in the diabetes range and two (3.8%) had BMI $<24\text{kg/m}^2$. Eighty-nine individuals enrolled in the study, with 60 randomized to begin the intervention immediately after enrollment, and 29 assigned to begin the intervention in approximately six months. This study received University of Pittsburgh Institutional Review Board approval, and all subjects signed informed consent.

Intervention

As in the original DPP lifestyle intervention, the goals of the DPP-GLB program are to achieve and maintain a 7% weight loss, and to safely and progressively increase to 150 minutes per week of moderately intense physical activity similar to a brisk walk.

The two lifestyle coaches involved in this study completed a two-day training workshop provided by the DPSC (24). In addition, the Nurse Practitioner employed by the worksite attended the training workshop and observed each session. The lifestyle coaches were assessed initially by the investigators for competency and fidelity in session delivery, and participated in regular conference calls with the DPSC to address any issues that arose during program implementation.

Participants who chose face to face group delivery attended 12 weekly sessions onsite at the Bayer campus, followed by bi-weekly and then monthly meetings for one year. The one-hour sessions were conducted by a DPSC trained lifestyle coach and were held during the employee lunch hour. Two groups were held for those who were assigned to immediate intervention and chose face to face delivery (n=30), and one group was initiated six months later for those in the delayed group who chose this delivery mode (n=12). To ensure the “dose” of the intervention, the DVD was provided in conjunction with the specific session material for participants who missed any of the initial 12 weekly group meetings.

Those who chose to take part in the program using the DVD watched one session each week for 12 weeks, and also received a brief weekly telephone call from a DPSC-trained lifestyle coach to assess weight, physical activity and to ascertain understanding of the program content. Two groups were held monthly for those who were assigned to immediate intervention and chose DVD delivery (n=30) and one group was held monthly for those in the delayed intervention (n=16).

All study participants were weighed at each in-person meeting, and participants in both groups received the session handouts, a Fat and Calorie Counter, self-monitoring logs, a pedometer, and exercise bands. Participants who were assigned to begin intervention in six months received periodic handouts to promote engagement and retention.

Outcome Measures/Assessments

The primary outcome was the change in weight between baseline and 6 months. Secondary outcomes assessed included BMI, physical activity (assessed via the Modified Activity Questionnaire-MAQ), HbA1c, fasting glucose, serum insulin, and lipids, blood pressure, and waist circumference. All measures were collected by trained research staff following a standard protocol at baseline, 6 and 12 month in-person assessment visits. In addition, participants completed a brief medical and medication history at each assessment. Participants were asked to attend a brief in-person visit at 18 months from baseline to obtain weight and general physical activity information, and received the results of all visits, with test results sent to their physician if they provided permission to do so. Participants received a \$25 gift card for completing the baseline, 6, 12 and 18 month research assessment visits, but received no compensation for attending intervention sessions as that would not be in line with the goals of community translation.

Data Analysis

To assess whether the lifestyle intervention program (DPP-GLB) leads to the reduction of risk factors, evaluation is provided in two ways: 1) the change in outcomes measures between the intervention group (face to face and DVD) is evaluated against the control delayed-intervention group at six months and 2) the change in outcomes measures from baseline is examined for all participants combined at 6, 12 and 18 months (pre/post). Since the focus is on delivering an effective “dose” of lifestyle intervention to as many employees as possible, the two DPP-GLB delivery modalities sometimes overlapped in order to allow participants the most flexibility in receiving the intervention. Thus, the current study was not designed to compare the two DPP-GLB delivery modes.

Primary evaluation compared the change in weight from baseline to 6 month post-intervention assessment in the intervention groups compared to the change in the control delayed-intervention group using a two sided, two-sample t test (or a nonparametric equivalent such as the Mann-Whitney U, when appropriate). These analyses were repeated for each of the various secondary outcomes measures.

Evaluation of data was conducted in two general ways: 1) for those who attended the assessment visits, and 2) by using last observation carried forward (LOCF) when data were missing. In addition, “CDC protocol” analysis was completed following the Centers for Disease Control and Prevention National Diabetes Prevention Program (CDC DPRP) recognition guidelines for evaluation at 6 months including those who attended at least 4 of the 16 core sessions, and at 12 months including those who meet the 6 month criteria and also attended at least one of six post-core support sessions (48). Attendance for DVD participants was defined as weekly phone or email contact completed for each session viewed.

Results

A total of 89 participants (mean age 52.3 years old at baseline; range 34-70 years) took part in the study. The majority were white (93.3%), with a fairly even distribution of gender (55% female).

Baseline characteristics for both immediate and delayed groups combined are shown in Table 1. Those assigned to the immediate group were older than those assigned to the delayed group (53.4 vs. 49.9, $p=0.03$). No significant differences were noted between the groups for any other measures at baseline.

Randomized immediate group versus 6 month delayed control group

During the first six months of the study, those assigned to immediate intervention completed an average of 12 out of 16 DPP-GLB sessions, with approximately 91% attending four or more of the core sessions. Results for comparison between those assigned to immediate intervention ($n=56$) and those assigned to the delayed intervention (control) ($n=28$) groups at 6 months are shown in Table 2. Those assigned to the immediate intervention had a significantly greater mean weight loss than those assigned to delayed control at 6 months (-10.4 lbs. or 5.1%, vs. -2.3 lbs. or 1%), as well as significantly greater improvements in

HbA1c, systolic blood pressure, BMI and waist circumference. A significant decrease was noted in triglycerides for the immediate group but not for the control group although the between group difference was not significant. When outcomes were analyzed using LOCF and CDC protocol methodology for both groups, similar significant results were noted (data not shown).

When examining achievement of weight goals, a significantly higher proportion of those assigned to the immediate group achieved at least 5% and 7% weight loss than those assigned to the delayed group (45% versus 7%, $p=0.0005$ and 29% versus 4%, $p=0.007$, respectively). In addition, a significantly lower proportion in the immediate versus the delayed group experienced any weight gain during the six month period (9% vs. 46%, $p<0.0001$) (Figure 2).

Both immediate and delayed groups demonstrated a significant increase in median MET-hours leisure activity between baseline and 6 months (+16.23, IQR 10.23-35.18 vs. +11.95 IQR 4.16-19.34). The difference in increase of median self-reported minutes of physical activity per week between those assigned to the immediate intervention compared to those in the delayed group was not significant (+75 minutes, IQR 30-126 vs. +40 minutes IQR 0-112.5, $p=0.17$).

All participants combined regardless of randomization assignment at 6, 12 and 18 months

When combining all participants from immediate and delayed groups together, participants attended a median of 12.5 (IQR 9-15) of the 16 core sessions and a median of 2 (IQR 0-5) of 6 post-core support sessions. Results for all participants at baseline and following 6 and 12 months of intervention are shown in Table 3. At the six month point, average weight loss for the combined groups was 11.2 lbs, (-5.4%, $p<0.001$) with significant increases found in physical activity levels (median MET-hours leisure activity of +11.7 IQR +1.1–+24.6, $p<0.0001$). Significant decreases were noted in triglycerides, HbA1c, systolic and diastolic blood pressure, BMI and waist circumference.

At 12 months, a significant decrease in mean weight of 10.3 pounds from baseline (-5%, $p<0.001$) along with significant improvements in physical activity, HbA1c, systolic and diastolic blood pressure, waist circumference and BMI were observed (Table 3). Analysis completed following LOCF and CDC protocol methodology demonstrated similarly significant improvements in results.

When stratified by gender, results at 6 and 12 months appeared relatively similar with the exception of an increase in HDL in men and a slight decrease in HDL in women at 6 months ($p=0.02$). When stratifying by age greater than or equal to 50 years old versus less than age 50, HbA1c decreased significantly more in those age 50 and older than those <50 (-0.1% vs. -0.02%, $p=0.03$), and serum insulin decreased in those aged 50 and older and increased slightly for those <50 (-1.1mg/dl vs. 0.5mg/dl, $p<0.001$).

At 18 months from baseline, only weight, waist circumference and self-reported physical activity minutes per week were assessed. For those who attended the 18 month assessment ($n=62$), significant decreases in mean weight (-8.6 lbs., 4.2%, $p<0.0001$) and waist

circumference (-1.6 inches, 3.9%, $p < 0.0001$) were observed, as well as a significant increase from baseline in median self-reported physical activity minutes per week ($+25.0$ minutes, IQR -47.5 - $+115$, $p = 0.04$) (data not shown).

Face to Face and DVD Delivery Modalities

Although the current study was not designed to statistically compare the effectiveness of the two DPP-GLB delivery modalities (face to face and DVD), an evaluation of changes in outcomes between baseline and 6 and 12 months was completed for both groups. At baseline, a significantly higher proportion of women chose face to face delivery versus DVD (73.3% vs. 40%, $p = 0.009$); however no other significant differences were noted between the two groups. For those who attended the assessment visits, at 6 months significant decreases in mean weight loss were noted for participants who chose face to face group delivery ($n = 38$, -9.3 lbs, 4.6%, $p < 0.0001$), as well as for those who chose DVD delivery ($n = 44$, -12.9 lbs., 6.1%, $p < 0.0001$). In addition, similar results for improvements in physical activity and other risk factors for diabetes and CVD were noted regardless of whether participants chose face to face or DVD delivery. At 18 months, similar improvements in weight and self-reported physical activity were observed for both groups.

Participant Satisfaction

Of those participants who responded to a satisfaction survey administered after completing 12 months of intervention ($n = 73$), 70 (96%) reported that they felt it was beneficial to offer the program at the worksite, and 72 (99%) indicated they would recommend the DPP-GLB worksite program to their co-workers. Within this group, 35 (100%) of those who took part in the program via face to face group, and 33 (87%) of those who took part via DVD responded that they found the DPP-GLB group and DVD programs respectfully, to be useful and informative.

Discussion

Findings from this worksite effort clearly demonstrate that a worksite behavioral lifestyle intervention is not only feasible and convenient for employees, but effective in significantly improving key behavioral risk factors along with several important physiological risk factors for diabetes and CVD. Specifically, participants who were randomly assigned to the DPP-GLB immediate intervention had significantly greater improvements in weight, physical activity and other risk factors for diabetes and CVD at 6 months than those assigned to the control delayed group. Most importantly, regardless of when they started the intervention, both groups demonstrated significant weight loss and improvements in diabetes and CVD risk factors at 6 and 12 months, as well as significant increases in physical activity levels. These improvements in weight and physical activity were observed irrespective of gender or age, and were also noted at 18 months.

Research has shown that overweight/obese employees are a significant health care burden for employers and suggests that those who are overweight with type 2 diabetes may represent the highest burden (49). Despite these concerns for employers, there have only been a few investigations of DPP translation efforts offered in the worksite setting. One of

the first involved an evaluation of a DPP lifestyle intervention in which 44 employees (36 with prediabetes and 8 with diabetes) participated and were asked to attend weekly sessions for the first 24 weeks, followed by monthly sessions (41). Results were provided for 35 participants who had complete data sets for attendance at baseline, 6 and 12 month assessments. Attendance at the intervention sessions averaged 67%. This small study demonstrated significant weight losses of 3.2% and 5.5% at 6 and 12 months respectively, as well as a significant improvement in aerobic fitness and other risk factors for diabetes (41).

Another small worksite study involved a 12 week DPP intervention followed by monthly sessions for one year delivered in a county government worksite setting for individuals at risk for, or already diagnosed with type 2 diabetes. This pilot study also utilized a randomized delayed study design and found a significant difference in change in weight at 3 months between the intervention group (n=21) and the wait control group (n=24) of -2.23 kg (-2.1%) [-3.5 to -0.97] versus $+0.73$ kg ($+0.7\%$) [$+0.17$ to $+1.28$], $p < 0.001$ and significant improvements in physical activity and waist circumference; however no significant changes in blood pressure, fasting glucose and lipids or HbA1c were noted (42). Over 12 months, 9 out of 40 (22.5%) lost more than 5% body weight and 5 out of 40 (12.5%) lost more than 7% body weight. Weight regain was noted after three months, but reduction in waist circumference was maintained (42).

More recently, a comparative effectiveness study was done in several diverse worksites (43) comparing an individual one-on-one DPP based intervention provided by a lifestyle counselor in which members were held accountable for the program goals, a group delivered program provided by a health educator in which accountability for the program was not individualized or formalized, and a “passive” intervention where members received lifestyle information via e-mails, flyers, and periodic educational presentations. A total of 264 participants began the study and chose their delivery mode, with 151 (57.2%) completing the 26 week program. Overall mean weight loss was 2.58 pounds (-1.4%) with those who chose the individually delivered intervention demonstrating a mean weight loss of 5.27 pounds (-2.8%), significantly higher than the group or passive interventions (-1.52 pounds $< 1\%$, and -0.96 pounds, $< 1\%$ respectively) (43). The whole group also had significant increases in self-reported physical activity levels, a reduction in arterial blood pressure, and a reduction in diabetes risk score (43).

A pilot study evaluated a 6 month self-directed DPP program augmented by peer health coaches and the onsite nurse in a locomotive maintenance facility. Participants (n= 67) met initially with a nutritionist or health educator, and completed the program through self-study following the same schedule as the original DPP (16 lessons over 24 weeks). A total of 59 (88%) participants completed the 6 month assessment and demonstrated significant mean weight losses of 1.34kg (-1.3%) at 6 months and 2.83kg (-2.8%) at 12 months (44). Significant improvements in self-reported healthy eating and exercise were also noted at 6 months.

Finally, another small study evaluated the 16-session DPP intervention in 35 overweight/obese individuals in a manufacturing worksite using a pre-post non randomized study design. This study demonstrated a significant decrease in median weight of -2.5% at the end

of the intervention; however, PA data was not reported, and other clinical outcomes were not assessed (45).

Thus, a few studies of DPP translation efforts in the worksite setting have been conducted to date, and, despite limitations of small sample size, short term follow-up and/or poor adherence, all demonstrated some success. The current study, using a year-long structured program in which employees chose their preferred delivery mode i.e. group or DVD, demonstrated excellent program adherence and provides long term follow-up (18 month) results which are consistent with if not better than DPP translation efforts in other community settings (50).

Implementation of the DPP-GLB program was feasible in this worksite setting and focused on utilizing the organizational structure that was already in place. For example, recruitment was conducted via existing communication tools such as employee mailing, e-mail blasts, and provision of “lunch and learn” and other standard meetings to spread the word about the program. Because this was a research study, the investigators provided onsite screening to allow for consistency in results reporting, but in many companies, HRA and/biometric screenings are frequently part of standard operating procedures (9). These screenings could easily be utilized to simultaneously identify those at risk for diabetes and CVD and enroll such individuals in a worksite DPP lifestyle intervention program.

For the current project, a lifestyle coach was provided. However, the worksite health professional also completed training and observed program implementation so was able to continue to offer follow up meetings to study participants at the conclusion of the study, and is now poised to offer the program to other employees and family members at this worksite. This model could certainly be replicated in other worksites by training onsite health professionals to provide the DPP-GLB program, or alternatively a trained health professional from the community could be contracted to provide the program onsite.

While the employee time required to participate in the DPP-GLB program is minimal, the offering of different program delivery modalities (face to face group or DVD) allowed for even greater flexibility in encouraging employee participation and further minimizing time away from work. For the current project, the worksite team determined that holding group meetings at the lunch time hour was the most logical for that group; although the optimal timing of the group sessions would likely vary as one takes this program into other worksites. Inclusion of a DVD option enhanced participation for those individuals who did not wish to or were not able to attend group meetings. For face to face group participants, use of the DVD as a replacement for missed sessions provided a mechanism to ensure that individuals received the full “dose” of intervention. Participants in both face to face group and DVD demonstrated similarly improved outcomes. In addition the high proportion of those who found the group and DVD program to be useful and informative indicates wide spread participant satisfaction with both delivery modes. In fact, the medical director indicated that employee feedback which was unsolicited regarding this initiative was among the most positive he had ever received during his time at Bayer (D. Molenaar, former Bayer Medical Director, personal communication 4/8/2014). While it could be speculated that individuals completing a lifestyle program via a DVD delivery mode might feel isolated, the

individual weekly telephone support from the lifestyle coaches and the monthly group meetings may have mitigated that problem as suggested by the high level of satisfaction noted by those in the DVD group.

There are several strengths to the current study. First, a randomized control delayed design was utilized to provide a temporary control group as it also allowed for all study participants to eventually take part in the program. The current study design also included follow up of participants for 18 months. Finally, almost 50% of the study population was male which is unique as men are usually underrepresented in these types of lifestyle intervention studies. It is possible that the inclusion of the DVD, rather than attending a group, as an option for program delivery contributed to the study's success in recruiting males.

There are also several limitations that should be mentioned. There may have been self-selection bias in which only employees/family members motivated to improve their health took part. In addition, physical activity was self-reported, and there were likely other confounding factors which influenced changes in physical activity such as those related to changes in season and exercise activities offered at the worksite. Another limitation is that the population of the current worksite may not be representative of all worksites, thus the results may not be generalizable to other groups. Further study in other worksite settings is needed. Finally, the current manuscript focuses on program implementation and health outcome results; however, cost analysis is in progress and will be reported in the future.

Conclusion

The DPP-GLB program delivered in this worksite setting in groups or via DVD was feasible to implement and effective in reducing weight, increasing physical activity, and improving several other risk factors for diabetes and CVD for employees and their family members, regardless of age or gender. These improvements were sustained at 12 months from the start of intervention, with significant improvements in weight and physical activity continuing to be observed at 18 months.

As we move forward with DPP translation efforts in the community, offering a structured, evidence-based lifestyle intervention program such as the DPP-GLB as part of a worksite wellness plan in conjunction with onsite screenings to identify individuals at risk for type 2 diabetes and CVD should be considered by employers as an effective and potentially cost saving option for improving the health of employees and their family members.

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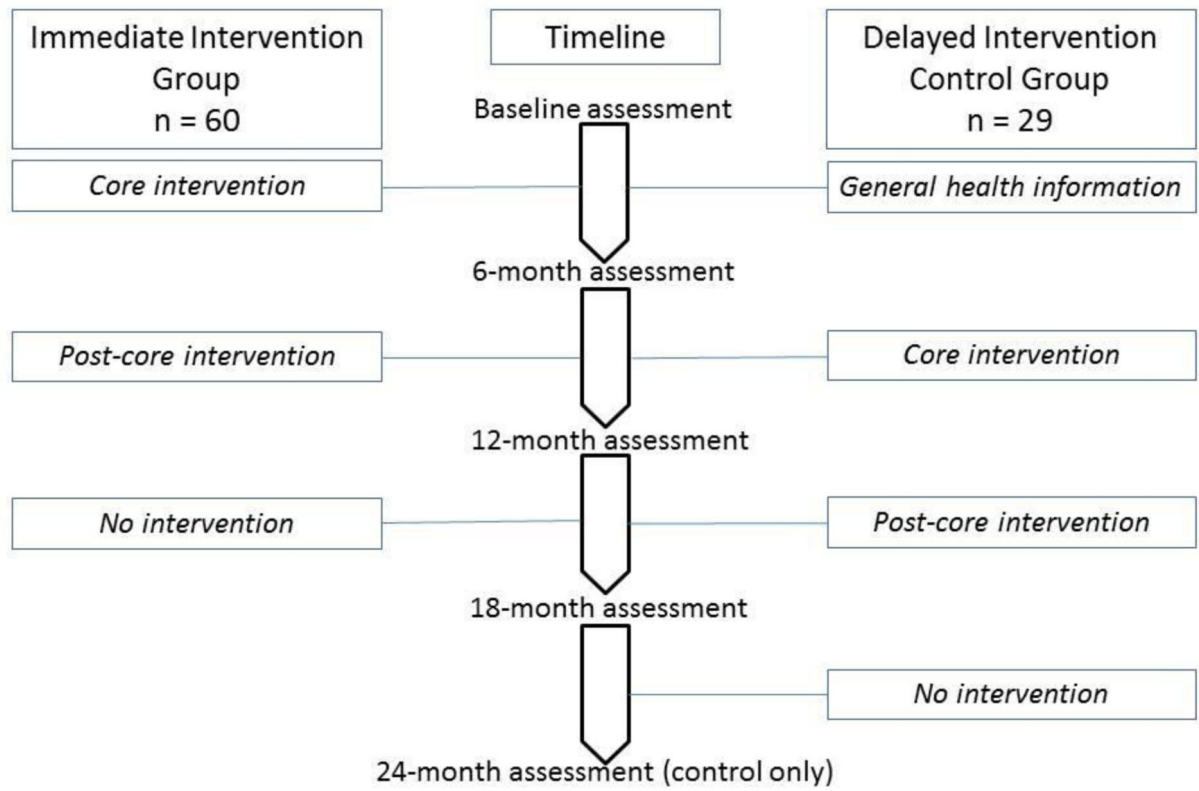


Figure 1. Study design

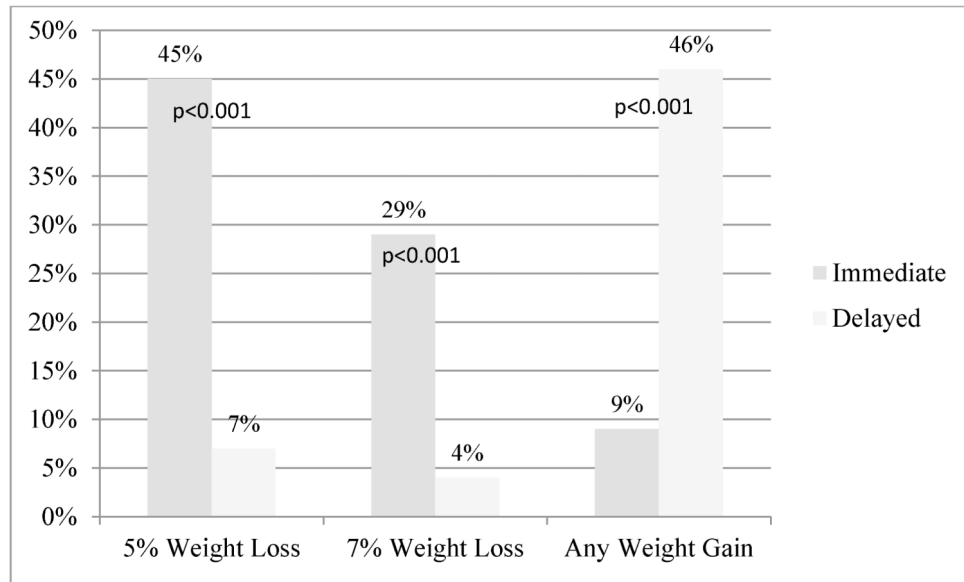


Figure 2. Change in Weight for Randomized Immediate Group versus Delayed Control Group at 6 months

Table 1
Baseline Characteristics of Study Population

Baseline Variable	n	Mean (sd), Median (IQR)
Gender (% female, n)	89	55.0%
Age (years)	89	52.3 years (7.2) (34-70)
Race/Ethnicity	89	6.7% Non-Caucasian
Weight (lbs)	89	209.2 (39.3) 205.2 (179.4-232.6)
BMI (kg/m ²)	89	33.0 (5.8) 31.5 (29.2-35.9)
Waist (inches)	89	41.1 (5.0) 41.0 (38-44)
Physical Activity MET/h (median, IQR)	89	4.67 (0.94-13.0)
Total Cholesterol (mg/dl)	88	195.2 (37.6) 195.5 (166.5-217)
HDL Cholesterol (mg/dl)	88	51.5 (14.3) 50.0 (41-59)
LDL Cholesterol (mg/dl) *	87	114.3 (31.3) 111.0 (92-136)
Triglycerides (mg/dl) (median, IQR)	88	134.0 (101-171)
Glucose (mg/dl)	88	92.0 (10.5) 90.0 (86-98)
HbA1c (%)	88	5.66 (0.28) 5.70 (5.5-5.8)
Insulin	87	6.77 (8.04) 4.0 (1.0-9.0)
SBP (mmHg)	89	120.7 (12.0) 119.0 (114-126)
DBP (mmHg)	89	80.9 (8.3) 81.0 (77-86)

* LDL-c could not be calculated for one subject

Table 2

Results for randomized immediate group versus 6 month delayed control group at 6 months

Variable	Immediate			Delayed			p-value for Difference Between Groups
	n	Mean Change (sd), Median (IQR)	p	n	Mean Change (sd), Median (IQR)	p	
Weight (lbs)	56	-10.4 (8.7), -9.6(-15.1- -5.2)	<.0001	28	-2.3 (9.1), 0.3 (-4.7- +3.1)	0.34	0.0001
Total Cholesterol** (mg/dl)	51	-3.1 (24.3), 0 (-19-+15)	0.50	26	-0.5 (18.3), -1.5 (-9-+8)	0.77	0.63
HDL Cholesterol** (mg/dl)	51	+2.4 (8.7), 0 (-2-+5)	0.14	26	+0.8 (5.7), 0 (-3-+5)	0.74	0.41
LDL Cholesterol** (mg/dl)	50	-3.1 (20.7), 0 (-15-+11)	0.38	25	-4.5 (19.3), -6 (-15-+3)	0.06	0.74
Triglycerides** (mg/dl) (median, IQR)	51	-11 (-44-+18)	0.04	26	+6.5 (-28- +55)	0.49	0.74
Glucose (mg/dl)	56	-0.2 (8.8), 0 (-6-+2.5)	0.40	28	-1.2 (8.6), -1 (-5.5-+5.5)	0.46	0.62
HbA1c (%)	56	-0.1 (0.2), -0.1 (-0.2-0)	<.0001	28	-0.004 (0.16), 0 (-0.1-+0.1)	0.75	0.009
Insulin	56	-0.33 (4.8), 0 (-2-+2)	0.90	28	-1.1 (6.8), 0 (-2.5-+3.0)	0.95	0.59
SBP** (mmHg)	53	-1.8 (12.4), -1 (-10-+5)	0.24	26	+1.9 (7.3), +2 (-3-+6)	0.20	0.005
DBP** (mmHg)	53	-2.2 (9.2), -1 (-8-+3)	0.05	26	-0.7 (5.0), -0.5 (-6-+3)	0.51	0.35
Waist (inches)	56	-1.6 (2.2), -1 (-2.5-+0.25)	<.0001	28	-0.11 (1.5), -0.13 (-1-+1)	0.79	0.0006
BMI (kg/m ²)	56	-1.7 (1.4), -1.5 (-2.5--0.8)	<.0001	28	-0.36 (1.5), 0.04(-0.7-+0.5)	0.37	0.0003
Physical Activity (MET-hours Leisure; MAQ) (median, IRQ)	56	+16.23 (+10.35- +35.18)	<.0001	28	+11.95 (+4.16- +19.34)	<.0001	0.17

** Participants with medication changes related to the variable examined were excluded from analysis

Table 3

Results for all participants combined regardless of randomization assignment at 6 and 12 months

Variable	6 Month Results			12 Month Results		
	n	Mean Change (sd), Median (IQR)	p	n	Mean Change (sd), Median (IQR)	p
Weight (lbs)	82	-11.2 (10.7) -10 (-15.8--5.4)	<0.0001	72	-10.3 (13.6) -8.2 (-17--1.6)	<0.0001
Total Cholesterol** (mg/dl)	73	-4.6 (23.5) -2.0 (-19+14)	0.16	61	-1.8 (19.2) -2 (-11+9)	0.42
HDL Cholesterol** (mg/dl)	73	+1.0 (8.3) 0(-4+4)	0.64	61	+1.5 (7.2) +1.0 (-3+4)	0.20
LDL Cholesterol** (mg/dl)	72	-2.1 (20.1) 0 (-13.5+11)	0.42	61	-0.5 (19.5) -2 (-11+9)	0.71
Triglycerides** (mg/dl) (median, IQR)	73	-14.0 (-50+14)	0.002	61	-8.0 (-38+16)	0.09
Glucose (mg/dl)	82	0 (8.6) 0 (-6+5)	0.68	71	-0.04 (8.1) -1.0 (-6+6)	0.99
HbA1c (%)	82	-0.07 (0.16) -0.1 (-0.2-0)	0.0003	71	-0.06 (0.17) -0.1 (-0.2-0)	0.003
Insulin (mg/dl)	81	-0.5 (5.9) 0.0 (-3+2)	0.42	70	+0.09 (12.1) 0 (-3+1)	0.05
SBP** (mmHg)	77	-4.2 (11.6) -4.0 (-11+3)	0.0006	63	-5.1 (11.4) -5.0 (-13+1)	0.001
DBP** (mmHg)	77	-3.9 (8.9) -4.0 (-9+2)	<0.0001	63	-3.6 (7.5) -3.0 (-10+2)	0.0004
Waist (inches)	82	-1.7 (2.3) -1.4 (-2.9- 0)	<0.0001	72	-1.9 (2.5) -1.5 (-3.4--0.1)	<0.0001
BMI (kg/m ²)	82	-1.8 (1.6) -1.6 (-2.6--0.9)	<0.0001	72	-1.6 (2.1) -1.3 (-2.7--0.25)	<0.0001
Physical Activity (MET-hours Leisure; MAQ) (median, IRQ)	82	+11.7 (+1.1-+24.6)	<0.0001	71	+1.8 (-1.6-+9.5)	0.003

** Participants with medication changes related to the variable examined were excluded from analysis