Physical Activity Levels in a Community Lifestyle Intervention: A Randomized Trial

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INTRODUCTION

The US Diabetes Prevention Program (DPP) (11) and other clinical trials (19,25,32) demonstrated that intensive lifestyle interventions with goals of increasing physical activity (PA) and losing weight was shown to be efficacious in preventing type 2 diabetes and decreasing risk of cardiovascular disease (CVD) in the US Diabetes Prevention Program (DPP). Modified versions of the DPP lifestyle intervention are being translated into diverse community settings and have been successful in decreasing weight and improving metabolic markers. However, comprehensive evaluations of PA levels within these community translation intervention efforts are rare. The purpose of this study is to evaluate the effectiveness of a DPP-based community lifestyle intervention for improving PA levels. Two hundred twenty-three overweight adults at risk for type 2 diabetes and/or CVD were randomized (immediate or 6-month delayed-start group) to a 12-month DPP-based lifestyle intervention. The past month’s PA level was assessed at baseline and postintervention with the Modifiable Activity Questionnaire. Simple and mixed-effects regression models were used to determine changes in the PA level between and within groups over time. The between-group mean difference for change in PA levels from baseline to 6 months indicated significantly greater improvement in the intervention compared with the delayed-start group (+6.72 MET·h·wk−1 (SE = 3.01), P = 0.03). Examining combined within-group change from baseline to postintervention, we found that mean PA levels significantly increased by +14.69 MET·h·wk−1 (SE = 1.43) and +9.50 MET·h·wk−1 (SE = 1.40) at 6 and 12 months postintervention, respectively. This PA change offset to approximately +10 MET·h·wk−1 at both 6 and 12 months after adjusting for the baseline PA level and season (all, P < 0.01). Other than the season, sex impacted on change in the PA level. In conclusion, this community-based lifestyle intervention significantly increased PA levels among overweight adults at risk for type 2 diabetes and CVD, even after adjusting for key variables.

ORIGINAL INVESTIGATION

A behavioral lifestyle intervention program with goals of increasing physical activity (PA) and losing weight was shown to be efficacious in preventing type 2 diabetes and metabolic syndrome. The DPP lifestyle intervention participants were shown to significantly increase self-reported leisure PA levels from baseline (8,11), with nearly 70% of participants meeting the 150 min-wk−1 PA goal after roughly 3 yr of follow-up (40). In addition, in post hoc analyses, for those not meeting the weight loss goal, achievement of the PA goal was associated with a 46% reduction in diabetes incidence over the same period (8).

Since the end of the original DPP trial, its lifestyle intervention has been translated for delivery in a variety of community settings (39). Modified versions of the DPP lifestyle intervention vary in structure and content, but encourage the DPP lifestyle goals of 150 min-wk−1 of moderate-intensity PA and 7% weight loss. In regard to the effectiveness of these studies, successful weight loss has been demonstrated in most of these community translation efforts (3,4,39). In contrast, much less is known about PA, the other primary intervention goal, because only a subset of published DPP translation efforts report results pertaining to PA change (5). In addition, even among translation studies that address PA and its change, there are inconsistencies in PA assessment and outcome reporting. As a result, the impact of DPP-based lifestyle intervention translation efforts on changing PA levels in the community setting is still not well documented.

This manuscript plans to address this hole in the translation literature regarding PA change in community efforts. Specifically, it will focus on examining the impact of an adapted DPP-based behavioral lifestyle intervention conducted in a worksite and three senior community centers on change in PA levels among adult participants at risk for diabetes and cardiovascular disease (CVD). It is hypothesized that leisure PA will significantly increase because of the lifestyle intervention. If the primary hypothesis is supported, a secondary
examination of participant, program, and environmental characteristics and each of their potential to impact on PA levels will be conducted. This knowledge will help guide future community DPP translation intervention programs in their efforts to evaluate program effectiveness in regard to the PA goal.

**METHODS**

This investigation is a secondary analysis of a National Institutes of Health-funded randomized intervention trial, the Healthy Lifestyle Project (PI: Dr. A. Kriska; clinicaltrials.gov identifier NCT01050205), evaluating the effectiveness of a DPP-based lifestyle intervention implemented in economically diverse community settings. The Consolidated Standards of Reporting Trials (CONSORT) checklist was used to guide reporting of this investigation (see Document, Supplemental Content 1, CONSORT checklist, http://links.lww.com/TJACSM/A6). The study intervention program, Group Lifestyle Balance™ (GLB), is a 12-month, 22-session adaptation of DPP that was developed by members of the original DPP Lifestyle Resource Core who are now faculty members of the University of Pittsburgh Diabetes Prevention Support Center. The study investigators partnered with a worksite and three community centers from a range of socioeconomic neighborhoods to implement the DPP-GLB Program. The study protocol was approved by the University of Pittsburgh Institutional Review Board.

The Healthy Lifestyle Project used a randomized 6-month delayed control design. This design mimics the real-life circumstances facing many community-based providers in that resources may limit the frequency and capacity of programming, requiring interested participants to wait before they can begin the intervention program. Researchers used a stratified randomization scheme to assign participants within each intervention site to begin the DPP-GLB Program immediately (immediate) or after a 6-month delay (delayed) in a 2/1 ratio. The randomization allocation was balanced for each site using a simple randomized sampling procedure and programmed in SAS 9.3 (SAS Institute, Inc., Cary, NC) by a single study researcher. The randomization assignment was distributed to each participant in a sealed envelope at the end of their baseline assessment visit. Participants and investigators were not blinded to the randomization assignment.

**Study Population**

Recruitment was conducted in the Pittsburgh, Pennsylvania, metropolitan area during September 2010 to November 2010 at a worksite (30) and September 2011 to December 2011 at three community centers. Site-specific strategies were used to generate interest, including program flyers, “lunch and learn” sessions, e-mail blasts, and mailing. On-site screening involved a finger stick for fasting plasma glucose, HbA1c, and lipid measurements as well as assessment of blood pressure, height and weight to determine body mass index (BMI), and waist circumference. Eligible adults (age \( \geq 18 \) yr) had a BMI \( \geq 24 \) kg·m\(^{-2}\) (\( \geq 22 \) kg·m\(^{-2}\) for Asians) and prediabetes (American Diabetes Association criteria [10]) and/or metabolic syndrome (National Cholesterol Education Program criteria [6]), or treatment for hyperlipidemia and at least one additional component of the metabolic syndrome. Eligible and interested individuals provided written informed consent before enrolling in the study. Before engaging in the intervention, enrolled participants were required to obtain physician approval for increasing PA levels.

**Intervention**

The DPP-GLB curriculum has been described elsewhere (14,17,37), and program materials are available online (www.diabetesprevention.pitt.edu). In brief, the 1-yr, 22-session program focuses on healthy eating behaviors, increasing PA to at least 150 min of moderate intensity per week, and losing 7% of the initial body weight. Participants were encouraged to self-monitor diet, PA, and weight information daily during the 12-month program.

At the time of randomization, participants were given the option of completing the first 12 weekly DPP-GLB sessions in face-to-face groups or participating via individually viewed DVD. One-hour group sessions were conducted by a Diabetes Prevention Center-trained lifestyle coach. DVD participants were contacted weekly by the lifestyle coach and had the option of attending monthly group sessions. The remaining 10 biweekly and monthly sessions were delivered as face-to-face groups.

General health information was mailed to delayed participants periodically during the 6-month wait-control period. This included handouts on wearing proper shoes during activity, staying hydrated, and reducing salt in the diet. At the end of the 6-month wait-control period, delayed participants received the DPP-GLB program in its entirety in the delivery mode of their choice.

**Assessment**

All measures were collected by trained research staff following a standard protocol. Because of the study design, participants in the delayed arm attended one additional assessment visit at the end of the 6-month wait-control period during which the same measures completed at baseline were repeated. For the purposes of this evaluation, baseline is in reference to randomization and postintervention time points (6, 12, and 18 months) are in reference to time from an individual’s start of intervention, regardless of randomization assignment. Participants received a $25 gift card for each clinical assessment visit completed, but did not receive compensation for attending intervention sessions.

**Demographic Information**

Participant birth date (used to determine age), race, ethnicity, sex, and educational attainment were collected by interviewer-administered questionnaire at the on-site screening visit. PA

PA levels were assessed via two interviewer-administered questionnaires. At baseline, and 6 and 12 months, the past month’s version of the Modifiable Activity Questionnaire (MAQ) was used to capture leisure PA levels. Specifically, the MAQ determines the frequency and duration of recreational activities that are primarily moderate or greater in intensity and occur in bouts of 10 min or more. The MAQ is a reliable and valid instrument for use in adult populations (9,18,26,27,29) with strong correlations (\( \rho > 0.60 \)) to bouts of moderate–vigorous activity from the accelerometer output (27). The intensity of each activity on the MAQ is estimated in MET tasks, which are units that approximate energy cost (28). The MAQ uses standard MET values (1) to calculate the approximate energy cost in MET-hours per week of each reported activity (e.g., 150 min (2.5 h) of brisk walking (MET ~4) is approximately 10 MET-h). At baseline, and 6, 12, and 18 months, a simple lifestyle questionnaire (LSQ) developed by members of the research team for use in community translation studies also queried PA. The LSQ

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asked participants about the frequency (<1 d per month or never; 2–3 d per month; or 1, 2, 3, 4, 5, 6, and 7 d wk⁻¹) and duration (average minutes per day) of a typical PA. PA measured by the LSQ was expressed in minutes per week by multiplying frequency and duration, with the midpoint of the range divided by 4 to get days per week for reported frequencies of <1 d wk⁻¹. The LSQ has not been previously validated. The PA level recorded by the LSQ was compared with the validated MAQ to see if PA trends detected by both were similar.

**Season**

The winter season occurs in Pittsburgh, PA, during the months of January to March, when the average monthly temperatures are 39.3°F and the average snowfall is 10.3 inches (23). The summer season occurs during the months of July to September, when the average monthly temperatures are 81.4°F and the average rainfall is 3.48 inches (23). The calendar month of participant assessment visit determined which season was linked with participant data.

**Anthropometric and Blood Marker Measurements**

Weight, height (baseline only), waist circumference, and fasting (8–16 h) blood samples were collected at baseline, and 6 and 12 months. Weight was recorded from a digital physician scale with participants in light clothing and without shoes. Height was recorded from a stadiometer to the nearest quarter inch and used to calculate BMI. Waist circumference was measured at the midpoint between the bottom of the 12th rib and top of the iliac

![Figure 1: CONSORT flow diagram: participants enrolling in the community lifestyle intervention trial.](http://www.acsm-tj.org)
crest. Blood samples were collected by venipuncture into serum-separating tubes and transported to Quest Diagnostics Laboratories (Pittsburgh, PA) for analysis. Samples were analyzed for glucose, hemoglobin A1c, and lipids (total cholesterol, HDL-C, LDL-C, and triglycerides) using standard protocols. The results for these measures have been reported in other publications arising from this project (12,15).

Analysis
Linear regression models compared least squares mean changes in PA levels between the immediate and delayed intervention arms during the 6-month wait-control period. Postintervention change in the PA level was calculated as postintervention PA at 6, 12, and 18 months minus PA at randomization (baseline). Linear mixed-effects regression models were used to generate restricted maximum likelihood-based estimates for mean change in the PA level at postintervention time points using all available participant data (intention to treat). Models were fit with an unstructured covariance matrix to account for within-subject clustering of data from repeated measures over time (intraclass correlation coefficient = 0.32–0.83) and provide less biased fixed effect estimates and SE (20). Residuals were examined to verify that model assumptions were fulfilled.

Participant demographic characteristics, including age, sex, and educational attainment, were tested in univariate and multivariate mixed-effects regression models to examine modification in estimates of PA change by these factors. Univariate and multivariate mixed models were fit with binary indicators for the season of PA measurement (winter or summer), community setting (worksite or community centers), and primary intervention delivery mode (face-to-face group or DVD) to determine whether these factors had an independent effect on change in the PA level. Covariates were selected for multivariate models based on univariate effects (P < 0.25) and model fit evaluated by the Akaike Information Criterion and Bayesian Information Criterion. The intervention site was included as a random effect to account for within-site clustering of the data for the outcomes reported (intraclass correlation coefficient = 0.03–0.18). An α of 0.05 (two-sided) was used to determine significance for all statistical tests. SAS 9.4 (SAS Institute, Inc.) was used to conduct all analysis.

RESULTS
Enrollment and Baseline Characteristics
The study enrolled 223 participants at a worksite and three community centers (Fig. 1). Participant enrollment and program implementation within each setting has been previously reported (12,15). Because changes in PA were similar across settings, participants from the worksite and all three community centers were combined for this current evaluation. No harms or unintended effects occurred during the study.

Baseline characteristics for the entire study population and by randomization assignment are presented in Table 1. Demographic and behavioral characteristics were similar between the immediate and delayed intervention arms. The 6-month delayed control design created the opportunity to investigate the impact of the season on attempts to increase PA because some of the participants began the lifestyle intervention in the winter season (with a 6-month assessment in the summer), whereas the rest began intervention during the summer season (with a 6-month assessment in the winter).

Six-Month Wait-Control Behavioral Changes
Participants in the immediate arm reported significantly greater improvements in the PA level at the end of the 6-month wait-control

### TABLE 1. Baseline Characteristics for Participants Enrolled in the DPP-Based Community Lifestyle Intervention Program.

<table>
<thead>
<tr>
<th>Randomization Assignment</th>
<th>Total (N = 223)</th>
<th>Immediate (n = 148)</th>
<th>Delayed (n = 75)</th>
<th>Between-Group P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD) (yr)</td>
<td>58.4 (11.5)</td>
<td>59.0 (11.4)</td>
<td>57.2 (11.6)</td>
<td>0.28</td>
</tr>
<tr>
<td>Sex: female, n (%)</td>
<td>139 (62.3)</td>
<td>92 (62.6)</td>
<td>47 (62.7)</td>
<td>0.94</td>
</tr>
<tr>
<td>Ethnicity: non-Caucasian, n (%)</td>
<td>14 (6.3)</td>
<td>10 (6.8)</td>
<td>4 (5.3)</td>
<td>0.78</td>
</tr>
<tr>
<td>Education: n (%)</td>
<td>82 (36.8)</td>
<td>57 (38.5)</td>
<td>25 (33.3)</td>
<td>0.73</td>
</tr>
<tr>
<td>HS/some college</td>
<td>68 (30.5)</td>
<td>45 (30.4)</td>
<td>23 (30.7)</td>
<td></td>
</tr>
<tr>
<td>BS degree</td>
<td>73 (32.8)</td>
<td>46 (31.1)</td>
<td>27 (36.0)</td>
<td></td>
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<tr>
<td>Employment status: full time/part time, n (%)</td>
<td>147 (65.9)</td>
<td>98 (66.2)</td>
<td>49 (65.3)</td>
<td>0.90</td>
</tr>
<tr>
<td>Weight, mean (SD) (lb)</td>
<td>208.8 (41.8)</td>
<td>209.2 (43.9)</td>
<td>208.1 (37.6)</td>
<td>0.85</td>
</tr>
<tr>
<td>BMI, mean (SD) (kg·m⁻²)</td>
<td>33.8 (6.0)</td>
<td>34.0 (6.5)</td>
<td>33.5 (5.0)</td>
<td>0.50</td>
</tr>
<tr>
<td>MET-hours per week of LPA (median, IQR; MAQ)</td>
<td>7.88 (2.19–16.69)</td>
<td>8.69 (2.19–19.57)</td>
<td>6.31 (2.38–12.66)</td>
<td>0.20</td>
</tr>
<tr>
<td>Minutes per week of the usual PA (median, IQR; LSQ)</td>
<td>120 (30–210)</td>
<td>120 (30–240)</td>
<td>120 (20–180)</td>
<td>0.13</td>
</tr>
</tbody>
</table>

BS, bachelor of science; HS, high school; IQR, interquartile range; LPA, leisure PA.
period than those in the delayed participants (Table 2). Model estimated mean leisure PA, as determined by the MAQ, increased in the immediate and delayed arms by +18.75 and +12.23 MET·h·wk⁻¹, respectively, with a significant intervention effect of +6.72 (SE = 3.01, P = 0.03). Similar trends in PA were observed on the basis of the LSQ, in which immediate participants reported a nonsignificant greater mean increase in minutes of the usual PA per week compared with the delayed participants.

### Baseline to Postintervention Behavioral Changes

The intervention was successful for increasing PA in both randomized arms at 6 and 12 months postintervention relative to the study baseline (data not shown). Therefore, immediate and delayed arms were combined to describe and evaluate changes in PA as a result of the intervention. Examining baseline to postintervention PA levels, the unadjusted mean estimate of change in the past month’s leisure PA determined from the MAQ was +14.69 MET·h·wk⁻¹ (SE = 1.43) and +9.50 MET·h·wk⁻¹ (SE = 1.40) at 6 and 12 months, respectively (both P < 0.0001, Table 3). This unadjusted mean change in PA was significantly greater at 6 months compared with 12 months (P = 0.002). Adjusting for the baseline PA level alone resulted in similar trends (Table 3). However, further adjusting for the season significantly attenuated the change in PA from baseline to approximately +10 to +11 MET·h·wk⁻¹ at both 6 and 12 months (Fig. 2 and Table 3).

Adjusting for demographic characteristics, we found that the effect of sex was significant (P < 0.05) and contributed to the improved fit of the model. Specifically, men reported greater increases in the PA level than women. The effects of age and education were not significant. Program characteristics, including setting and delivery mode, did not significantly modify the effect of intervention on change in the PA level. The estimates of mean change in the PA level from the final model, which includes baseline PA, season, and sex, are presented in Table 3.

The improvement in PA levels demonstrated by the past month’s MAQ was reflected in the level of typical weekly PA captured by the simple LSQ. The model-based mean estimate of change in the usual PA was +52.2 min·wk⁻¹ (SE = 12.6, P < 0.0001) at 6 months postintervention, with sustained increases of +45.0 min·wk⁻¹ (SE = 14.9) and +51.5 min·wk⁻¹ (SE = 17.9) at 12 and 18 months postintervention, respectively (both P = 0.004). Adjusting for the season attenuated the estimated change to +41.5 min (SE = 14.8) at 6 months, +40.7 min (SE = 12.9) at 12 months, and +40.4 min (SE = 19.2) at 18 months (all, P < 0.05). Finally, the estimates of PA levels in minutes per week from the LSQ corresponded to 62.0%, 57.1%, and 52.2% of participants at the goal (150 min·wk⁻¹ or more of the usual PA) at 6, 12, and 18 months, respectively.

### DISCUSSION

These findings document the effectiveness of a DPP-based community program at increasing PA levels across several community settings. This is one of the few DPP-based translation efforts to report on PA-related outcomes in a large sample and the only known diabetes prevention translation effort to examine the impact of participant, program, and environmental factors on changes in the PA level. The results from this study can help guide future assessment and evaluation of the PA component of lifestyle change programs offered in community settings.

### Table 3

Linear Mixed-Effects Model Estimated Mean Change in MET-hours of Leisure PA per Week (MAQ) at 6 and 12 Months.

| Model | 6-Month Mean (SE) | 12-Month Mean (SE) | P Value for Time Effect*
<table>
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</thead>
<tbody>
<tr>
<td></td>
<td>Estimate of Change (MET·h·wk⁻¹)</td>
<td>Estimate of Change (MET·h·wk⁻¹)</td>
<td></td>
</tr>
<tr>
<td>Model 1: unadjusted</td>
<td>14.69 (1.43)*</td>
<td>9.50 (1.40)*</td>
<td>0.002</td>
</tr>
<tr>
<td>Model 2: adjusted for baseline PA level</td>
<td>18.45 (1.69)*</td>
<td>13.33 (1.62)*</td>
<td>0.002</td>
</tr>
<tr>
<td>Model 3: adjusted for baseline PA level, season</td>
<td>10.83 (1.94)*</td>
<td>10.04 (1.66)*</td>
<td>0.62</td>
</tr>
<tr>
<td>Model 4: adjusted for baseline PA level, season, and sex</td>
<td>12.41 (2.71)*</td>
<td>11.67 (2.56)*</td>
<td>0.64</td>
</tr>
</tbody>
</table>

*Intervention site included as random effect.

bTime effect is the difference in estimated mean change between 6 and 12 months.

Interaction term for sex and baseline PA level included.

°P < 0.0001 change from baseline.
This current large-scale community translation effort showed that PA levels increased approximately twofold as a result of the behavioral lifestyle intervention. In conjunction with increased PA, 62% of the participants reported achieving the PA goal at 6 months based on general lifestyle questions about the usual PA. This is comparable with results showing 41%–78% of participants reporting to have met the PA goal in other translation programs of similar length that presented PA data (2,7,13,16,34,33,38). The PA level increases in this study likely contributed to the significant weight loss and improvements in diabetes and CVD risk factors observed at 6, 12, and 18 months, which have been previously described (12,15). The finding that men increased PA more than women during intervention replicates earlier observations from the DPP and, more recently, a community DPP translation effort in which men were more likely to meet the PA goal than women (2,40).

The influence of the season on PA levels had been previously demonstrated in observational studies (21,22,24,31) but has not previously been considered in community-based translation efforts. The results of this investigation suggested that, after adjusting for the season, the mean increase in the past month’s leisure PA at 6 and 12 months postintervention was attenuated relative to the unadjusted values. The magnitude of the PA change due to the community DPP-based intervention after adjustment for the season was similar to that observed in the DPP at 1 yr (11). This adds credibility to our finding because PA levels in the DPP were assessed with the past year’s version of the MAQ, which is not as susceptible to season influence.

This current translation finding identifies the importance of accounting for the season when determining intervention impact on PA levels, because weather shifts related to seasonal change often occur during the course of intervention in temperate zones. These results also have important implications for implementation of these community programs such that participants who engage in an intervention during the winter months may need extra encouragement and strategies to increase or maintain PA levels.

This evaluation has a few limitations that should be noted. PA data were self-reported via a questionnaire and thus subject to recall and reporting bias. The addition of objective measures such as accelerometers can provide less biased estimates of the total time spent at different intensities of PA. However, accelerometers are not always feasible in community translation efforts, and these do not provide complete information regarding the context of movement that can be valuable to interventionists to provide participant feedback. In addition, although our communities varied by socioeconomic status, the racial and ethnic composition of the sample was representative of the communities surrounding the intervention sites (33), which unfortunately is low in racial and ethnic diversity. This restricted the ability to investigate the potential differences by race/ethnicity for observed changes in PA levels and limited the generalizability of these findings.

Finally, because of the study timeline, the season of PA measurement at any given postintervention time point (i.e., 6 or 12 months) was predetermined by randomization assignment. Although it cannot be certain that randomization assignment did not impact estimates of PA change, the evidence from observational (21,22,31) and experimental (24) studies supports the idea that the season may impact changes in PA levels during an intervention. Furthermore, as reported in other evaluations of this current effectiveness study (12,15,36), baseline to post-intervention changes in weight and risk factors for type 2 diabetes and CVD were similar in each randomization arm, contributing to the notion that an intervention delay does not impact on the success of the program. Future investigations using study designs that enable a more discriminate investigation of season effects on measured PA changes during a behavioral lifestyle intervention are needed.

**CONCLUSIONS**

This investigation provides evidence that a behavioral lifestyle intervention, modified from the successful DPP for delivery in multiple community settings, significantly improves PA levels in addition to the successful weight loss result among individuals at risk for diabetes and CVD. This evaluation allowed for the impact of the intervention on increasing PA levels to be considered independently from the changes in the PA level possibly due to the season. Future evaluations should include not only a thorough assessment of PA levels but also a careful consideration of the calendar season in which PA is measured, especially in temperate areas, to fully understand the impact of the intervention on improving PA behaviors and related health outcomes.

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The authors would like to thank the DPP-GLB participants, community and worksite partners, and staff for their time and continued commitment to this project.

**Figure 2:** Linear mixed model estimated baseline to postintervention mean change in MET-hours per week of leisure PA from the MAQ. (A) Adjusted for baseline physical activity level. (B) Adjusted for baseline physical activity level and season. *P* < 0.0001 for change relative to baseline. *P*-value in brackets is for time effect (difference in estimated mean change between 6 and 12 months).