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The Effects of a Supplemental, Theory-Based Physical Activity Counseling Intervention for Adults With Type 2 Diabetes

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Background: Physical activity (PA) is a cornerstone in the management of type 2 diabetes (T2DM). This pilot investigation explores the effects of a standard diabetes education program compared with a supplemental PA intervention on diabetes-related health outcomes. ***Methods:*** Using a prospective 2-armed design, 96 adults with T2DM were randomly assigned to either standard care (diabetes education program; n = 49) or standard care supplemented with an 8-week, individualized-counseling and community-based PA component (n = 47). Measurements were taken at baseline, 3, 6, and 12 months. Primary outcomes were changes in PA (self-report) and HbA1c. Between group changes were compared using analysis of covariance (ANCOVA) and changes over time using repeated-measures ANOVA. ***Results:*** In comparison with standard care, the supplemental group demonstrated an increase in PA (Ps < 0.01) and cardiorespiratory fitness (Ps < 0.05) from baseline to all follow-up time-points. HbA1c levels declined (P < .05) from baseline to all time points in the standard care group. Reduction in cholesterol-ratio (P < .01), increase in HDL (P < .05), and reductions in blood pressure, resting heart rate and BMI (approaching statistical significance Ps < 0.10) were also reported for both groups. ***Conclusions:*** PA counseling in addition to standard care is effective for promoting PA behavior change and positive health-related outcomes among individuals with T2DM.

Keywords: exercise, fitness, intervention, HbA1c

The prevention and management of type 2 diabetes mellitus (T2DM) is a major concern.[1] As part of lifestyle management, it is recommended that people with T2DM achieve a minimum of 150 minutes of moderate-to-vigorous aerobic physical activity over a 7-day period.[1] In achieving these guidelines, improvements in cardiovascular risk profile, increased cardiorespiratory fitness, and improved quality of life among individuals with T2DM can be expected.[2–4] Despite the known benefits of PA, reports have confirmed its under-utilization for the management of this disease. For example, a Canadian population-based study found that nearly 72% of adults with T2DM were not achieving recommended aerobic PA levels.[5] A lack of support or follow-up by health-care professionals may, in part, be a contributing factor for the low levels of PA.[5,6]

The self-management process for T2DM is primarily guided by interactions with health-care professionals and participation in diabetes education programs (DEP). Although evidence-based program planning and measuring, and comparing health outcomes has been recommended, there has been limited research examining the effectiveness of DEPs worldwide.[7,8] Furthermore, the effectiveness of self-management training for improving health-related outcomes in adults with T2DM has proven variable.[9–11]

Evidence strongly supports the promotion of both aerobic and resistance-based PA among individuals with T2DM.[4,12,13] The mode of PA program delivery (ie, individual or group, structured or unstructured) however, may have an effect on its success. A recent review highlights that structured PA programs for adults with T2DM.[12] (ie, supervised, facility-based) make up the majority of the existing evidence. Although findings generally confirm

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the efficacy of structured programs for improving glycemic control and cardiovascular risk,[10,14,15] these programs can be time-consuming and costly[16] and experience high attrition rates.[17]

Less intensive, individually-tailored PA initiatives may provide a viable alternative to the structured programs. There is limited empirical evidence to support the efficacy of individualized PA counseling in promoting PA behavior change in the short, intermediate, and long-term in adults with T2DM.[12,18–20] The evidence that does exist does however suggest individually-tailored PA initiatives can lead to improved glycemic control and reductions in cardiovascular risk.[14,19,20] As a consequence, PA consultations have been recommended as an important component of diabetes care.[18]

To expand on the existing knowledge-base surrounding diabetes and PA-related self-management best practices, we sought to compare potential differences in diabetes-related health outcomes and aerobic-based PA behavior between participants in a standard 4-week DEP, and participants in the same DEP supplemented with an 8-week, individualized, community-based, PA component (DEP*plus*PAS) after 3, 6, and 12 months. The independent effect of each of these programs on PA behavior and diabetes-related health outcomes was also investigated. It was hypothesized that the supplemental group (DEP*plus*PAS) would demonstrate significantly greater improvements in PA behavior and HbA1c (glycated hemoglobin) in comparison with the DEP group over the short (ie, 3 months), intermediate (ie, 6 months) and long-term (ie, 12 months) time points indicated above. This study was undertaken as a pilot project due to the lack of existing evidence regarding the most effective and feasible strategy for self-management behavioral intervention aimed at improving health outcomes and aerobic-based, PA behavior among adults with T2DM. The results of this preliminary investigation are intended to inform the merit of implementing and evaluating a community-based program on a larger scale.

Methods

Patients and Screening Procedures

One-hundred-and-fifteen adults with T2DM were recruited from voluntary-enrollment diabetes education programs, in Red Deer, Canada. The appropriate sample size (31 subjects/group) was calculated based on 80% power to detect a 0.9% change in HbA1c with an anticipated standard deviation of 0.13[21] ($\alpha = 0.05$, $\beta = 0.2$, 2-tailed *t* test). In addition to statistical power, estimated attrition rates (DEP = 10–15%; DEP*plus*PAS = 25–30%) were taken into consideration during recruitment (see Figure 1 for study flow). This number (ie, 31) per group is also adequate to detect a large effect size (f = .40; $\alpha = 0.05$; 80% power) for PA behavior.[22] Based on our retention rates, we were able to detect an effect size (f) of .30 ($\alpha = 0.05$; 80% power) for PA behavior which approximates Cohen's suggested medium effect size (f) of .25.[22]

Inclusion criteria were: physician confirmed diagnosis of T2DM based on recommended clinical screening protocols (eg, fasting plasma glucose, casual plasma glucose, 2-hour plasma glucose, in a 75-gram oral glucose tolerance test, glycosulated hemoglobin and glycosuria assessment), no diagnosis of either type 1 or gestational diabetes, and no physician identified contraindications associated with PA. This study was approved by the Alberta Community Research Ethics Board and all participants completed informed consent in writing before entering the study.

Subjects were recruited on a rolling basis and randomized to 1 of the study groups over a 12-month period. Of eligible volunteers, 96 completed the baseline assessment and were enrolled in the study. Participants ranged in age from 25 to 78 years (mean = 60 years), 60% were female, 65% had some postsecondary education, and 28% were employed full time; 69% were married/common-law, and 64% resided in an urban environment. At the time of enrollment, the average time from diagnosis of T2DM was 6.0 ± 9.8 years. The proportion of the sample at baseline that respectively had experienced a myocardial infarction, angina, or stroke was 11.4%, 10.5%, and 6.1%. Based on current guidelines,[1] the proportion of the respective DEP and DEP*plus*PAS groups who were overweight/obese using both BMI (ie, 25–30 = overweight; >30 = obese), and waist-based BMI (ie, cut off >102 cm for males and >88 cm for females), hypertensive (ie, diastolic blood pressure >130/80 mmHG), and dyslipidemic (ie, LDL cholesterol >2.0 mmol/L; total cholesterol/HDL-C ratio >4.0 mmol/L) were as follows. The DEP's group profile consisted of 21.2% being overweight and 76.9% obese; 86.5% were overweight according to the waist-based assessment; 71.2% had high blood pressure; 61.7% had high LDL cholesterol; and 56% had a high total cholesterol/HDL-C ratio. The DEP*plus*PAS group characteristics revealed 27.7% and 60% were overweight and obese, respectively; 89.4% were overweight according to the waist-based assessment; 61.7% had high blood pressure; 72.7% had high LDL cholesterol; and 50% had a high total cholesterol/HDL-C ratio.

Experimental Design

Participants were randomly assigned, using a computer-generated random number table, to either the DEP or DEP*plus*PAS study arm. To prevent contamination across groups, diabetes education classes were composed of individuals in either DEP or DEP*plus*PAS conditions, but not both. See Figure 2 for the study design.

Primary and Secondary Outcomes

Primary outcome measures were changes in self-reported PA behavior (moderate plus vigorous weekly minutes) and HbA1c. Secondary outcomes were changes in aerobic fitness, blood specimens assessing fasting glucose

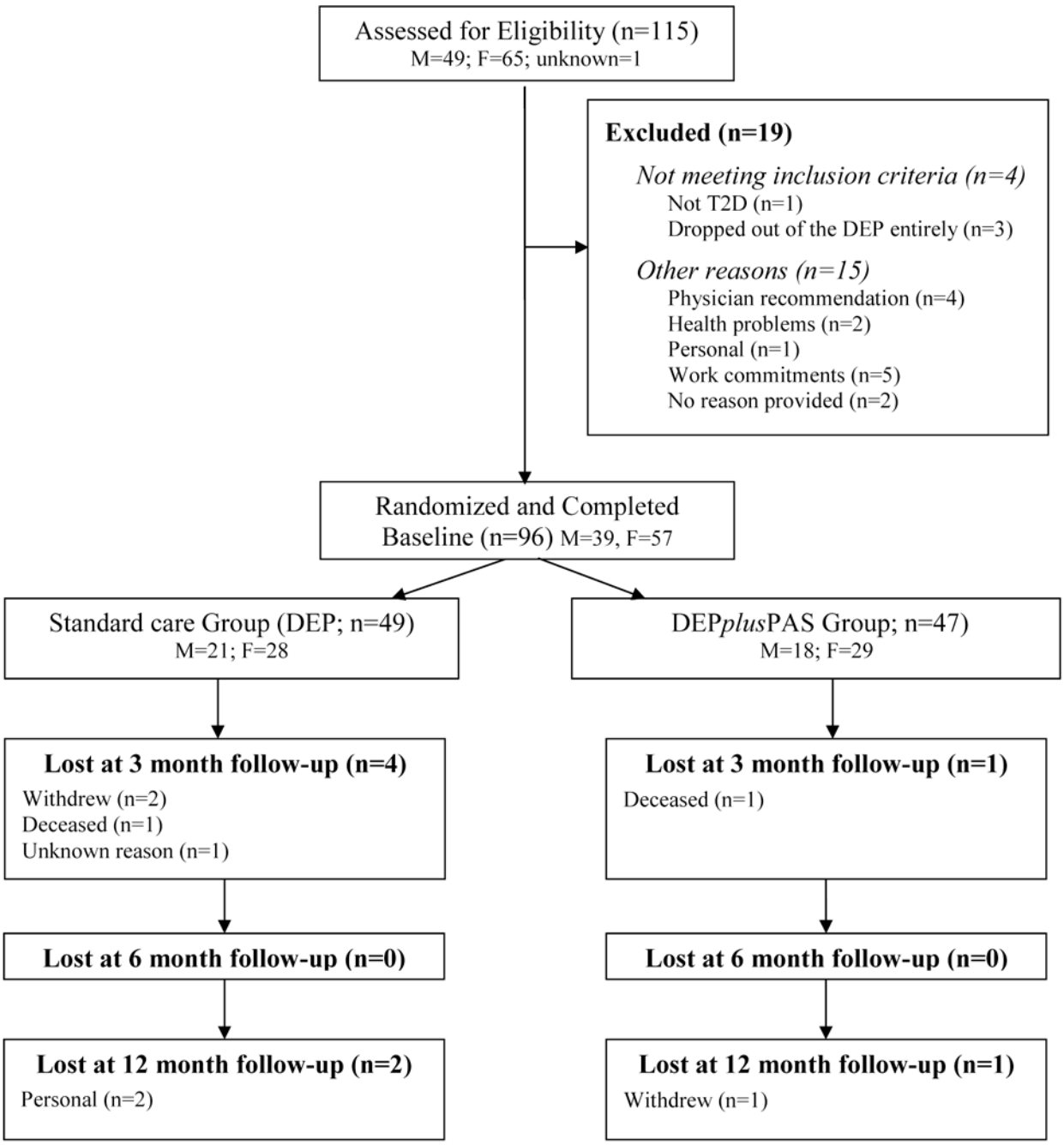

Figure 1 — Study flow diagram. *Note.* The randomization process included randomizing each DEP session, using a computer-generated random number table, in to either control or intervention to avoid cross-contamination of participants in the same DEP program. It worked out in such a way that there were 4 additional control participants at baseline.

and lipids, C-reactive protein, and urinary samples assessing microalbumin, and albumin-to-creatinine ratio. Other secondary outcomes included changes in anthropometric measures, clinical cardiovascular risk factors, levels of insulin (for those on insulin at baseline), and oral antidiabetic agents (ie, sulfonylurea, meglitinide, biguanide, thiazolidinedione, α-glucosidase inhibitor, and combination biguanide/thiazolidinedione). We also measured a host of social-cognitive measures aligned to Social Cognitive Theory and the Transtheoretical Model; these results are not presented in this paper.

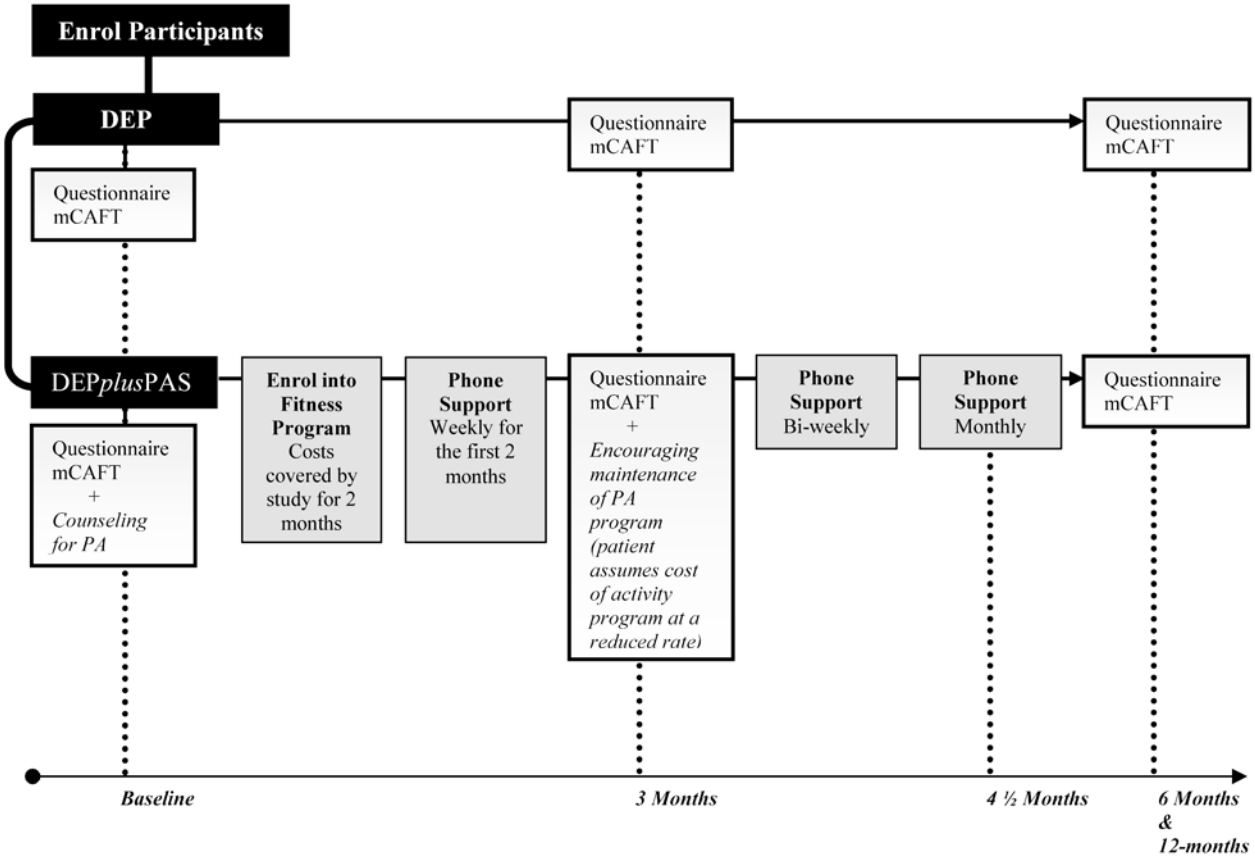

Figure 2 — The study timeline for DEP and DEP*plus*PAS groups. Diabetes Education Program = DEP; Physical Activity Supplement = PAS; Modified Canadian Aerobic Fitness Test = mCAFT; Physical Activity = PA.

Diabetes Education Program

The DEP is offered as part of standard care from the local health authority in Red Deer, Canada for adults with T2DM and enrollment in the program was voluntary. The 4-week program was comprised of 8 group sessions (totaling 12 hours) as well as follow-up sessions at 3, 6, and 12 months. All study participants were enrolled in the DEP program (approximately 8 participants/group/session). Participants received access to telephone support from a Diabetes Educator throughout their enrollment period as well as telephone and mail reminders for attendance at the follow-up sessions. The educational objectives of the DEP focused on self-management with a teaching method grounded in social-cognitive approaches encouraging patient participation and empowerment. The program was comprised of 8 different modules covering self-care topics including diet and PA. With regards to PA, emphasis was placed on the role of PA for the management of diabetes and participants were encouraged to increase their PA to meet the CDA guidelines.[1]

Supplemental PA Intervention

Participants in the DEP*plus*PAS received concurrently, an 8-week supplemental program (ie, in addition to the standard DEP) consisting of: individualized PA counseling and prescription, a 2-month membership to a community recreational facility or an "at-home" PA program and continued personal telephone support. The goal of the supplemental PA intervention was to achieve and maintain PA levels according to Canadian Diabetes Association[1] (that are congruent to the US Diabetes guidelines[23]). The PA counseling and prescription was provided by a certified personal trainer. At the commencement of the study, participants in the DEP*plus*PAS attended an individual counseling session with the personal trainer, which was grounded in Social Cognitive Theory[24] and tailored to their current stage of change according to the Transtheoretical Model.[25] Current fitness level, PA preferences and perceived barriers to PA were discussed and a plan for type, frequency and location of future PA was initiated. The PA prescription was created with the

participant and tailored to the participant's fitness level, interests and stage of change to increase feelings of empowerment and therefore the likelihood of success. The personal trainer facilitated relationships between the participants and their preferred community PA program (ie, aerobics classes, walking programs, strength training programs, or recreational sports). All PA program costs were provided with study participation.

Telephone support (provided by the personal trainer) was provided to the DEP*plus*PAS group participants on a weekly basis for the first 2 months, then biweekly for the next 2-and-a-half months, and finally on a monthly basis for the remainder of the study.

Testing Protocols and Measurements

All measurements were completed at baseline, 3, 6, and 12 months with the following exceptions: albumin-to-creatinine ratio, microalbumin, C-reactive protein, plasma insulin levels, and oral antidiabetic agents, which were measured at baseline and 12 months follow-up only. All clinical and anthropometric measurements were taken by a nurse trained in the study protocol, at the Regional Health Authority in Red Deer, Canada.

Energy Expenditure and Fitness

PA was assessed using the Godin Leisure-Time Exercise Questionnaire (GLTEQ)[26] to calculate metabolic equivalent minute (METmin) values for total and leisure energy expenditure (kcal/kilogram/day).[5] The reliability of the GLTEQ compares favorably to nine other measures of self-reported PA, objective activity monitors, and fitness indices[27] and has been used extensively in adults with T2DM.[5] For analysis, 2 distinct outcomes for aerobic PA were used: (i) moderate plus vigorous weekly minutes of PA; and (ii) total weekly minutes of PA (ie, mild, moderate and vigorous), which included mild intensity activities. Responses for vigorous, moderate, and mild activity were converted into a MET score by multiplying the weekly frequency of activities by 2.5, 4.0, and 7.0 METs, respectively.[5]

Aerobic fitness was assessed using the Modified Canadian Aerobic Fitness Test (mCAFT).[28] The mCAFT is a valid and reliable method for estimating relative maximal oxygen consumption during progressive increases in workload or energy demand.[29] When completing the mCAFT, individuals are asked to complete a prespecified stepping cadence up and down a set of 3 stairs (set at 20.3 cm). While completing each 3-minute stage, the stepping cadences (foot plants) is monitored and recorded. At the end of each 3-minute interval, heart rate is monitored and recorded while at rest (no stepping). To increase workloads, the cadence is increased in 3-minute blocks and this protocol is followed in sequence until the participant's heart rate reaches 85% of their age and sex specific estimate of aerobic power. To estimate maximal oxygen consumption (ml/kg/min) a reference chart based on stepping cadence in foot plants/min is used. As an example, a 60 year-old female who weighed 80kg and completed stage 4 of the test by reaching her ceiling heart rate would have a stepping cadence of 114 foot plants/min with an oxygen consumption of 24.5ml/kg/min. The Aerobic Fitness Score would be $10[17.2 + (1.29 \times 24.5) - (0.09 \times 80) - (0.18 \times 60)] = 308$. Health-benefit zones based on mCAFT scores for 60 to 69 year-old males are: excellent, 384+; very good, 328 to 383; good, 287 to 327; fair, 235 to 286; and, needs improvement, <235. Health-benefit zones for 60 to 69 year-old females are: excellent, 358+; very good, 328 to 357; good, 296 to 327; fair, 235 to 295; and, needs improvement, <235. (Given our study target population is generally in the "needs improvement category," one might argue that any increase in the fitness estimate is clinically relevant.)

Laboratory Values and Analysis

After an overnight fast, HbA1c, glucose, microalbumin, creatinine, total cholesterol, LDL, HDL, and triglyceride levels were measured using standard laboratory procedures at the Regional Health Authority in Red Deer, Canada. To ensure consistency in analysis techniques, all measures were analyzed at the same laboratory using the Roche Integra 400 Chemistry Analyzer, with the exception of plasma insulin and C-reactive protein, which were analyzed elsewhere using the Synchron LX20 analyzer (Beckman Coulter, Inc., Fullerton, CA) and Roche Diagnostics Elecsys 2010 system (Roche Diagnostics, Indianapolis, IN), respectively.

Anthropometric Measurements

To calculate BMI, weight was measured to the nearest 0.1kg using a balance beam scale and height was assessed to the nearest cm using a wall-mounted stadiometer. Waist circumference was measured to the nearest 0.5 cm. All measurements were performed in accordance to standard practices[28] and were taken twice at each time point by the same practitioner and the average value was used.

Clinical Cardiovascular Measurements

Blood pressure and heart rate were measured using standard physician-based guidelines[1,30] and were completed by the same practitioner using the same stationary blood pressure cuff at each time point.

Statistical Analysis

All analyses were intention-to-treat. The last observation carried forward was employed for the limited missing values and lost-to-follow-up (see Figure 1). To limit the effect of outliers on distributional properties of the outcome variables, extreme cases for any given outcome were reassigned values equal to 3.29 standard deviations from the original mean insert.[31] Outliers for the study variables were limited, ranging between 0% to 5% of the cases across all study variables.

To meet the study objectives, separate planned contrasts examining short-term (ie, 3 months), intermediate (ie, 6 months), and long-term (ie, 12 months) change in the outcome variables were performed. Interaction contrasts were carried out to examine potential differences in mean change from baseline between the DEP and DEP*plus*PAS groups at each time point using analysis of covariance (ANCOVA). The independent variable for the ANCOVA was the intervention group (DEP or DEP*plus*PAS), and the dependent variables were the clinical and behavioral outcomes as presented in Table 1. For each ANCOVA, the value observed at baseline for each dependent variable was used as the covariate.[32] Within group analyses for 3, 6, and 12 months in comparison with baseline were completed using analysis of variance with repeated measures (RM-ANOVA). As suggested by others[33] and aligned with our comprehensive approach of this pilot study, all contrasts at the $P < .10$ level are also denoted to identify significant trends for this pilot/exploratory investigations. Chi-square analyses were employed to examine changes in diabetes medication. Data were analyzed with SPSS v.15.0 (SPSS Inc., Chicago, Illinois, USA).

Results

Participant flow through the study is depicted in Figure 1. Behavioral and clinical characteristics of study participants at baseline and all follow-up time points are reported in Table 1; no significant differences were observed between the groups at baseline for any of the demographic or cardiovascular history study variables.

Adjusted mean change scores and confidence intervals (95%) for the entire set of outcome variables, are provided in Table 1. Due to the large number of contrasts represented, individual test statistic values and specific p-values for each comparison are not displayed

Primary Outcome Measures

Physical Activity. When compared with baseline values, participants in the DEP group reported nonsignificant increases in mean weekly METmins of 125.9 and 95.0 at 3 and 6 months, respectively, and a nonsignificant decrease of 33.9 METmins, at 12 months. The DEP*plus*PAS group reported significant increases of 601.6, 549.1, and 654.2 METmins ($P < .01$) across the 3 respective time points. The differences in PA behavior change scores between groups were significantly larger for the DEP*plus*PAS group at all 3 time points ($P < .01$). Results based on the second set of metabolic intensity weights, which included mild intensity PA, were similar to the moderate and vigorous PA results. Approximately 19% and 12% of participants in the intervention and control groups, respectively, were meeting guidelines (ie, minimum of 150 minutes of moderate and vigorous activity) at baseline, while 38% and 14% of participants in the intervention and control groups, respectively, met these guidelines at the 12 month assessment. During this 12 month period the intervention group significantly ($P < .001$) increased their mean weekly moderate and vigorous activity by 121.6 minutes, while the controls decreased by 37.8 minutes ($P = .24$). Further, there were no recorded adverse effects from engaging in PA during the course of the study for either group.

HbA1C. Mean HbA1c levels changed differently for participants in the 2 programs, however no interaction was found. Specifically, 3 months after program completion, mean HbA1c declined by 0.4% ($P < .05$) for the DEP group, but did not change for the DEP*plus*PAS group. After 12 months, HbA1c significantly declined by 0.5% ($P < .01$) for the DEP group and a nonsignificant mean reduction of 0.4% for the DEP*plus*PAS group.

Secondary Outcome Measures

Cardiorespiratory fitness as measured by the mCAFT score improved in the DEP*plus*PAS group from baseline to 3 months ($P < .01$) and 6 months ($P < .05$) as well as at the 12-month follow-up visit ($P < .01$). Fitness did not improve in the DEP group at any time point. In addition, both the DEP and DEP*plus*PAS groups showed increases in HDL at all 3 follow-up assessments ($P < .05$). At the 6-month follow-up, the mean change in HDL from baseline was greater for the DEP*plus*PAS group ($P < .1$). The cholesterol ratio was lower at the 12-month assessment for both groups ($P < .01$). As indicated in Table 1, for both groups, waist circumference, BMI, systolic and diastolic blood pressure and resting heart rate decreased between baseline and the 12-month follow-up ($P < .1$). Insulin use and levels of insulin and oral agents (ie, sulfonylurea, meglitinide, biguanides, thiazolidinedione, α-glucosidase inhibitor, and combination biguanides/ thiazolidinedione) were similar within and between groups at baseline and at all time points with the exception of biguanides, where a lower proportion of the DEP*plus*PAS was taking biguanides at the 12-month follow-up compared with the DEP group ($\chi^2 = 3.994$; $P < .05$).

Conclusions

The results of this pilot study illustrate an 8-week PA program, in addition to a standard DEP, proved more effective at increasing self-reported PA levels than a standard DEP program alone among individuals with T2DM. The PA changes were supported by an increase in cardiorespiratory fitness and a reduced resting heart rate. Despite the increase in PA, completing the DEP*plus*PAS program did not result in any significant change in HbA1c in contrast to that seen in the DEP program.

Individual PA counseling strategies have proven effective for improving PA behavior among adults with T2DM.[12,18–20] However, much of this research has focused on PA behavior change over the short-term (ie, ≤3 months).[12,20] The current findings suggest the supplemental program can facilitate sustained increases in PA

Table 1 Baseline Means (and Standard Deviations) and Adjusted Mean Change Scores (95% CI) at 3, 6, and 12 Month Follow-Up; Unadjusted Mean Scores and Standard Deviations Are Additionally Provided for the Primary Outcomes (ie, METmin/week, HbA1c) for Each of the Study Time Points

Variable*	Baseline	3 months	6 months	12 months
PA behavior & fitness				
METminMV (METmin/week)				
DEP				
Adjusted		125.9 (-73.9–325.7)	95.0 (-98.5–288.5)	-33.9 (-213.6–145.8)
Unadjusted	233.6 ± 387.1	424 .0 ± 773.8	393.1 ± 739.8	245.4 ± 438.7
DEP*plus*PAS				
Adjusted		601.6 (393.3–809.9)[a§]	549.1 (347.4–750.9)[a§]	654.2 (466.9–841.6)[a§]
Unadjusted	276.7 ± 461.8	824.8 ± 886.5	769.4 ± 772.2	897.6 ± 955.8
METminLMV (METmin/week)				
DEP	456.4 ± 518.2	163.5 (-80.2–407.2)	117.6 (-88.9–324.2)	-50.8 (-348.6–247.0)
DEP*plus*PAS	530.4 ± 637.3	656.5 (402.4–910.6)[a§]	555.2 (339.9–770.6)[a§]	1039.6 (729.2–1350.1) [a§]
mCAFT score				
DEP	226.72 ± 62.76	4.4 (-7.3–16.0)	4.7 (-6.4–15.9)	-1.9 (-16.3–12.5)
DEP*plus*PAS	231.21± 51.80	17.5 (5.0–30.0)[§]	18.5 (3.7–33.3) [†]	28.2 (14.2–42.2) [b§]
Glycemic control				
HbA_{1c} (%)				
DEP				
Adjusted		-0.4 (-0.8–0.0)[†]	-0.4 (-0.7 to -0.1)[§]	-0.5 (-0.9 to -0.2)[§]
Unadjusted	7.8 ± 2.0	7.3± 1.6	7.3± 1.7	7.2± 1.6
DEP*plus*PAS				
Adjusted		-0.2 (-0.6–0.2)	-0.4 (-0.7–0.1)	-0.4 (-0.7–0.0)
Unadjusted	7.3 ± 1.3	7.3 ± 1.6	7.1± 1.4	7.2± 1.4
Fasting blood glucose (mmol/L)				
DEP	8.3 ± 3.2	-0.2 (-0.6–0.9)	0.3 (-0.5–1.1)	-0.2 (-0.8–0.4)
DEP*plus*PAS	7.8 ± 2.5	-0.1 (-0.9–0.6)	-0.2 (-1.1–0.6)	-0.8 (-1.4 to -0.2)[‡]
Cardiovascular				
HDL (mmol/L)				
DEP	1.2 ± 0.3	0.1 (0.0–0.2)[†]	0.1 (0.0–0.2)[†]	0.1 (0.0–0.2)[†]
DEP*plus*PAS	1.1 ± 0.3	0.1 (0.0–0.2)[†]	0.2 (0.1–0.3) [c§]	0.1 (0.1–0.2)[§]
LDL (mmol/L)				
DEP	2.9 ± 1.7	-0.3 (-0.6 to -0.1)[‡]	-0.5 (-0.7 to -0.2)[§]	-0.4 (-0.7 to -0.2)[†]
DEP*plus*PAS	2.7 ± 1.2	-0.3 (-0.6 to -0.1)	-0.3 (-0.6 to -0.1)	-0.4 (-0.7 to -0.2)[‡]
Total cholesterol (mmol/L)				
DEP	4.7 ± 1.2	-0.1 (-0.4–0.2)	-0.3 (-0.5–0.0)[†]	-0.3 (-0.5 to -0.1)[†]
DEP*plus*PAS	4.5 ± 1.0	-0.2 (-0.5–0.1)	-0.1 (-0.3–0.2)	-0.3 (-0.6 to -0.1)[‡]
Cholesterol ratio				
DEP	4.2 ± 1.3	-0.2 (-0.5–0.2)	-0.5 (-0.7 to -0.2)[§]	-0.5 (-0.8 to -0.3)[§]
DEP*plus*PAS	4.4 ± 1.6	-0.2 (-0.5–0.2)	-0.3 (-0.5–0.0)	-0.4 (-0.7 to -0.2)[§]
Triglycerides				
DEP	2.1 ± 1.3	-0.1 (-0.4–0.1)	-0.2 (-0.4–0.1)[‡]	-0.1 (-0.4–0.2)
DEP*plus*PAS	2.0 ± 1.2	-0.2 (-0.4–0.1)	0.0 (-0.3–0.3)	-0.2 (-0.5–0.1)

(continued)

Table 1 *(continued)*

Variable*	Baseline	3 months	6 months	12 months
Resting heart rate (bpm)				
DEP	79 ± 10	-1 (-4–3)	-2 (-5–2)	-3 (-6–0)‡
DEP*plus*PAS	81 ± 11	1 (-3–4)	0 (-4–4)	-4 (-6 to -1)†
Systolic blood pressure (mmHg)				
DEP	134.0 ± 16.1	-3.3 (-8.9–2.4)	-4.1 (-8.8–0.7)	-9.3 (-12.9 to -5.6)§
DEP*plus*PAS	134.0 ± 17.6	-1.5 (-7.4–4.4)	-7.5 (-12.4 to -2.5)§	-10.9 (-14.7 to -7.1)§
Diastolic blood pressure (mmHg)				
DEP	76.4 ± 9.3	-2.4 (-5.8–1.1)	-2.2 (-5.7–1.3)	-4.4 (-7.2 to -1.6)§
DEP*plus*PAS	76.5 ± 9.5	-0.5 (-4.0–3.1)	-5.0 (-8.6 to -1.3)†	-5.6 (-8.6 to -2.7)§
Anthropometrics				
BMI (kg/m^2)				
DEP	34.3 ± 5.7	-1.1 (-2.3–0.1)§	-0.8 (-1.9–0.4)	-1.2 (-2.0 to -0.4)§
DEP*plus*PAS	34.8 ± 9.0	0.5 (-0.8–1.8)	-0.3 (-1.5–0.8)	-0.8 (-1.6–0.1)‡
Waist circumference (cm)				
DEP	110.4 ± 12.7	-0.7 (-4.3–2.9)	-1.6 (-5.4–2.2)	-3.2 (-5.8 to -0.6)§
DEP*plus*PAS	111.8 ± 16.7	-1.1 (-4.9–2.7)	-2.9 (-6.8–1.1)	-5.2 (-7.9 to -2.5)§
Other clinical measures				
Microalbumin (mg/L)				
DEP	60.2 ± 102.3			-16.6 (-37.1–3.8)†
DEP*plus*PAS	37.9 ± 77.5			-3.6 (-24.7–17.6)
C-reactive protein (mg/L)				
DEP	7.6 ± 8.2			-1.9 (-4.6–0.8) [c]
DEP*plus*PAS	7.3 ± 7.6			1.6 (-1.2–4.4)
Albumin-to-Creatinine-ratio				
DEP	5.1 ± 9.2			-1.4 (-3.3–0.5)
DEP*plus*PAS	4.7 ± 9.1			-0.7 (-2.6–1.3)
Insulin (mU/L)				
DEP	17.7 ± 7.9			1.8 (-3.8–0.3)
DEP*plus*PAS	16.2 ± 11.6			0.1 (-5.3–5.5)

Note. Baseline values represent means ± standard deviation; Δ_{T2} = (adjusted 3 month—baseline); Δ_{T3} = (adjusted 6 month—baseline); Δ_{T4} = (adjusted 12 month—baseline); All analysis were completed by intention-to-treat with the last value carried forward.

§ $P < .01$; † $P < .05$; and ‡ $P < .1$; represent within group change from baseline using RM-ANOVA.

[a] $P < .05$; [b] $P < .01$; [c] $P < .1$; represent between group differences using ANCOVA.

* HOMA (ie, fasting insulin (mU/L) × fasting glucose (mM) / 22.5) revealed no group differences.

behavior for at least 12 months. In a similar study, Di Loreto and colleagues investigated the effects of a physician-lead, theory-based PA counseling strategy on long-term PA behavior change among adults with T2DM and found substantial increases in self-reported PA behavior at 2 years follow-up.[19] However, contrary to the findings from the Di Loreto group[19] and those of this study, Kirk et al recently reported no benefit for a physician-lead, individual PA counseling intervention, on PA behavior at 12 months follow-up.[34] The current investigation as well as that from Di Loreto et al[19] accessed diabetes clinics for recruitment which may, in part, help to account for the differing results since those who respond to public advertising (eg, media) may be more physically active. Future studies should consider targeting those who are not meeting PA guidelines.

Other studies, such as the LookAHEAD trial and Mediterranean Lifestyle Program (MLP) have included PA counseling as part of a large-scale, intensive lifestyle intervention aimed at behavior change and improving health outcomes among adults with T2DM.[35,36] Both of these trials have reported long-term (ie, 12 month and 12 and 24 months in the LookAHEAD and MLP, respectively) improvements in PA behavior.[35,36] However,

the feasibility of implementing such resource- and time-intensive programs on a large, community-based scale remains to be evaluated. The LookAHEAD trial and MLP are, however, very useful in providing information regarding mediators (ie, social-cognitive or environmental facilitators) of positive behavior change which should be considered when designing more targeted, less resource intensive community-based programs similar to this pilot study. Evidence suggests that improved long-term glycemic control can be achieved through increases in PA (duration and/or intensity).[2,4,37]

A significant change in HbA1c did not accompany the improvements in both PA behavior and aerobic fitness levels among the DEP*plus*PAS in the current study. The lack of response in glycemic status may be partially explained by insufficient changes in muscular strength and or endurance as these are known to influence glycemic status.[38] It is more probable however, that because those in the DEP*plus*PAS group were in "better" glycemic control than the DEP group, there was less room for improvement due to a "floor effect."[15,39] For example, the DEP*plus*PAS group had a mean baseline value only marginally above the current guidelines (7.3%) whereas the DEP group were at 7.8%.[1] We might have found more favorable results among subjects with poorer control of their diabetes. In spite of being in relatively good glycemic control, both groups displayed similar absolute reductions in mean HbA1c after 12 months (0.4 and 0.5%, respectively). Findings from a recent Cochrane Collaboration review investigating the effects of individual patient education on metabolic control suggests individual education was more beneficial than usual care at reducing HbA1c only in a subgroup of patients with a baseline HbA1c greater than 8%.[11] It is also more than plausible that because the DEP group reported an increase in oral antidiabetic agents (ie, biguanides) and no increase in PA, the true effect of the increase in PA seen in the DEP*plus*PAS group may have been suppressed. Similar findings (ie, no significant between group differences in HbA1c levels and an increase in PA behavior) were also recently reported in response to an educational intervention among adults with T2DM (DESMOND trial).[40] Moreover, in a larger trial, neither resistance training alone nor aerobic training alone reduced HbA1c in subjects with baseline HbA1c below 7.5%.[41] Although there was limited improvement in HbA1c, the important issue here is that this indicator was "managed" and reflects a positive result in T2DM status/glucose metabolism as improvements in aerobic fitness is protective aside from any body composition changes in persons at risk for cardiovascular disease.[42]

Although good glycemic control is an important consideration for individuals with T2DM, they are also at great risk for cardiovascular disease.[1,28,43,44] Research among adults with T2DM has repeatedly demonstrated that fitness is inversely related to cardiovascular disease and associated mortality/morbidity, independent of other clinical measures.[38,45,46] Considering the strong link between fitness and cardiovascular-related morbidity and mortality, surprisingly few intervention studies involving adults with T2DM have included an estimate of cardiorespiratory fitness.[2,4,32,47] The estimate of fitness used in this study exhibited a marked improvement in the DEP*plus*PAS group at all follow-up time points thus suggesting the possibility of a positive impact of the program on cardiovascular disease risk. Furthermore, for the DEP*plus*PAS group the reduction in BMI, waist circumference, blood pressure, resting heart rate, and LDL in combination with the increase in fitness and HDL suggests a strong cardiovascular disease risk reduction.

Congruent with the current literature,[48,49] many of the secondary clinical outcomes improved in both groups. Most notably was the improvement in weight status. Although increased energy expenditure is associated with reduction in weight and waist circumference, there is evidence to suggest diet may have greater impact in adults with T2DM[2] for this salient diabetes-related health outcome. As a component of the DEP, both groups received the same dietary advice and therefore presumably adjusted their diets similarly thus leading to similar changes in body weight. Because information regarding dietary intake was not collected in this study, determination of the independent contributions for energy restriction or energy expenditure cannot be established. The provision of diet related curriculum would be worth examining in future studies along with a resistance training component.

DEPs are not standardized, and historically have been poorly evaluated with regards to their effectiveness.[8] However, theoretically grounded, evidence-based DEPs have demonstrated their effectiveness at reducing anthropometric measures (ie, weight, waist circumference and BMI) and HbA1c.[10,50,51] The DEP implemented in this study would be considered "well developed" as it is grounded in evidence-based guidelines as well as behavior change theory and it exhibited effectiveness for promoting long-term reductions in many clinical measures and thus, presenting a drawback when using it as a comparison condition. The lack of a "true control group" does present a limitation of this study; however, this is difficult to overcome as theoretically grounded, evidence-based DEPs have generally become "standard care" practice in Canada. The positive effect of the DEP on many of the clinical outcomes offers a potential explanation for the lack of between group differences documented in this study. Improvements in clinical measures promoted by the DEP in all study participants may have resulted in limited capacity for an additive effect of the PA intervention. The lack of an objective measure of PA is a limitation of the current study and future studies may want to consider using pedometers or accelerometers to evaluate PA behavior(s). Finally, as alluded to above, a significant limitation was this study did not include a dietary assessment nor a diet modification component which should be considered in the interpretation of the study findings.

This study has several strengths. First, the supplemental program was designed to complement the existing

DEP which, in Canada, is considered "standard care." This increases the potential for translation of these research findings into practice as the existing DEP would not be replaced but added to. Second, the potential for contamination between groups was low in this study due to the random assignment design as well as the inclusion of only individuals in either the supplemental or the standard care group in each DEP session. Finally, the application of few exclusion criteria in this investigation increased the potential for representation of all adults with T2DM voluntary enrolling in a DEP in Red Deer, Canada, and thus the generalizability of these results to this population.

In summary, this pilot work offers support for the effectiveness for improving behavioral PA, and some clinical (ie, cardiovascular disease risk), and physiological measures in the short and long-term among adults with T2DM. Further, we provide support for the addition of a supplemental PA program for improving PA behavior, fitness and cardiovascular disease risk profile among this population. In conclusion, our results suggest an effective, and potentially feasible, program for promoting long-term PA behavior change can improve fitness among individuals with T2DM. Future investigations may want to consider performing a cost analysis of the intervention to evaluate the system-level feasibility of community interventions.

Notes

I. The Canadian Diabetes Association 2008 Clinical Practice Guidelines recommend "Glycemic targets must be individualized; however, therapy in most individuals with type 1 or 2 diabetes should be targeted to achieve an A1C ≤ 7.0%" (p. S31).[1]

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