Increasing Physical Activity in People With Type 2 Diabetes

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OBJECTIVE — To evaluate effect of exercise consultation on physical activity and resultant physiological and biochemical variables at 6 months in people with type 2 diabetes.

RESEARCH DESIGN AND METHODS — A total of 70 inactive people with type 2 diabetes were given standard exercise information and were randomized to receive an exercise consultation (n = 35) or not (n = 35). Exercise consultation, based on the transtheoretical model, combines motivational theory and cognitive behavioral strategies into an individualized intervention to promote physical activity. Changes from baseline to 6 months were assessed in *1*) physical activity (7-day recall, accelerometer, cardiorespiratory fitness, stage, and processes of change), *2*) physiological variables (blood pressure and BMI), and *3*) biochemical variables (HbA_{1c}, lipid profile, and fibrinogen).

RESULTS — Between-group differences were recorded for the change in minutes of moderate activity ($P < 0.001$) and activity counts ($P < 0.001$) per week. Experimental participants recorded an increase in activity counts per week and minutes of moderate activity per week ($P < 0.001$). The control group recorded no significant changes. More experimental participants increased stage of change ($\chi^2 = 22.6$, $P < 0.001$). Between-group differences were recorded for the change in total exercise duration and peak gradient ($P < 0.005$), HbA_{1c} ($P = 0.02$), systolic BP ($P = 0.02$), and fibrinogen ($P = 0.03$).

CONCLUSIONS — Exercise consultation increased physical activity and improved glycemic control and cardiovascular risk factors in people with type 2 diabetes.

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Traditional exercise guidelines to improve cardiorespiratory fitness recommend a minimum of 20 min of moderate to vigorous exercise three times a week (1). Participation in moderate, accumulated physical activity, which does not necessarily improve cardiorespiratory fitness, has the potential to improve health. Additional physical activity guidelines to improve and maintain health have been developed, and they recommend a minimum of 30 accumulated min of moderate physical activity 5 days a week (2). Around 60–80% of people with type 2 diabetes do not meet these guidelines, and in comparison to the general population, they report more relapse from physical activity (3). People with type 2 diabetes report receiving less support, education, and encouragement for physical activity compared with any other aspect of diabetes management (4). Information is required to determine how to promote physical activity to this population.

In line with traditional exercise guidelines, the majority of research investigating the effects of physical activity on diabetes management have used structured exercise programs. These programs are effective at increasing physical activity and improving glycemic control and cardiovascular risk factors in people with type 2 diabetes over the short term (up to 3 months). These programs often target motivated, healthy people, are expensive to develop and maintain, and achieve poor long-term adherence. A large prospective study reported that only 25% of people with type 2 diabetes continued supervised exercise after 2 years (5).

Recently, physical activity counseling interventions have emerged as an alternative to structured programs. These interventions generally focus on the new physical activity recommendations and are a promising strategy for attracting sedentary people to increase physical activity (6). Studies in the general population with intermediate to long-term follow-up (6–24 months) have demonstrated effective physical activity promotion with counseling interventions (6–8). In a randomized controlled trial comparing fitness assessment, exercise consultation, and standard exercise information, Lowther et al. (6) showed that only participants receiving an exercise consultation maintained significantly more physical activity at 12 months.

Exercise consultation (9) is a minimal intervention that could realistically be incorporated into diabetes care. Two randomized controlled pilot studies demonstrate exercise consultation to be effective for increasing short-term (1 month) physical activity in people with type 1 (10) and type 2 (11) diabetes. This randomized controlled trial describes the 6-month effects of exercise consultation on physical activity and the resultant effects on glycemic control and cardiovascular risk factors in people with type 2 diabetes.

RESEARCH DESIGN AND METHODS

Participants

A total of 70 people with type 2 diabetes participated in this study. The study group consisted of 35 male and 35 female subjects, with a mean age of 57.6 ± 7.9 years, BMI 34.6 ± 6.8 kg/m^2, and diabetes duration of 6.0 ± 4.5 years. A total of 50 participants were obese (BMI >30 kg/

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Abbreviations: ACSM, American College of Sports Medicine; BP, blood pressure; CDC, Centers for Disease Control and Prevention; HDL-C, HDL cholesterol; LDL-C, LDL cholesterol.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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m^2), 16 were overweight (BMI 25–30 kg/m^2), and 4 were of normal weight (BMI <25 kg/m^2). Diabetes was defined according to established criteria (12) and controlled by diet, oral hypoglycemic agents, or insulin. Participants were in either a contemplation or preparation stage of exercise behavior change, i.e., they were not meeting current physical activity guidelines but intended to become more active (13). Patients with concurrent medical conditions preventing exercise were excluded. The ethical committee of the Argyll and Clyde Health Board approved the study, and written informed consent was obtained from all participants.

Primary outcome measures

Physical activity levels. The CSA uniaxial accelerometer (Computer Science and Applications, Shalimar, FL) was used to provide an objective assessment of physical activity measured by bodily acceleration (14). Monitors were secured by a strap to the participant's right ankle and worn for 7 days during all waking hours except bathing. The CSA monitor records the magnitude of accelerations during body movement at a rate of 10 samples per second. These were summed to produce activity counts at 1-min intervals. On return, monitors were downloaded and a total weekly activity count was calculated.

The 7-day physical activity recall (15) was used as a subjective measure of physical activity and involved a structured interview following a standard set of questions. The time spent per week in sleep and light, moderate, hard, very hard, and strengthening and flexibility activities was recorded.

Behavior change. Stage of exercise behavior change (13) was assessed by asking participants to read a definition of regular physical activity, defined using American College of Sports Medicine (ACSM)/Centers for Disease Control and Prevention (CDC) guidelines (1,2). Participants indicated which of five statements, each representing a stage of change, best described their current physical activity. Precontemplation was defined as not being regularly physically active and having no intention to become active in the next 6 months, contemplation as not being regularly physically active but thinking about starting in the next 6 months, preparation as doing some physical activity but not enough to meet the description of regular physical activity, action as being regularly physically active but having only begun in the last 6 months, and maintenance as being regularly physically active for longer than 6 months.

The processes of exercise behavior change (16) are the techniques and strategies people use when changing behavior. A questionnaire developed and validated by Marcus et al. (16) was used to assess the frequency of using each process over the past month. Questionnaire results were not used to tailor exercise consultations but to assess if there was a change in process use as a result of the intervention.

Cardiopulmonary fitness. Peak exercise tests were performed on a motorized treadmill, using an individualized protocol. Participants walked at a normal-to-brisk speed for 3–5 min. The treadmill gradient was then increased between 1/2 and 2% each minute (depending on fitness) to the limit of tolerance, or evidence of inappropriate electrocardiogram or blood pressure (BP) changes. Heart rate and BP were monitored, and expired gases were sampled using a Cosmed K4b^2 metabolic system (Cosmed, Rome, Italy). Peak values for oxygen uptake were calculated by averaging the last 30 s of exercise. Total exercise duration, peak gradient, and reasons for termination were recorded.

Secondary outcome measures

BMI and BP. BMI was calculated as weight (kg)/height $(m)^2$. BP was measured from the left arm in a seated position with an Omron 705CP automatic BP monitor (Omron Healthcare, Tokyo, Japan).

Glycemic control, lipid profile, and fibrinogen. A blood sample was taken with minimal venous occlusion, after an overnight fast of 12 h, and analyzed for HbA_{1c}, total cholesterol, HDL cholesterol (HDL-C), LDL cholesterol (LDL-C), triglycerides, and fibrinogen. HbA_{1c} was measured by latex-enhanced turbidimetric immunoassay (17) (nondiabetic range 4.5–6.0%). Cholesterol, triglycerides, and HDL-C were measured directly using enzymatic methods, and LDL-C was calculated using the Friedewald formula (18). Fibrinogen was measured by the Clauss method (19).

Procedures

The flow of participants through the trial is illustrated in Fig. 1. Participants completed a maximum of five visits for study assessment. During visit 1, demographic details and current medication were recorded. BMI was calculated, and a peak exercise test was performed to screen participants for significant silent ischemic heart disease before randomization and to assess cardiopulmonary fitness. Participants were fitted with an accelerometer.

Visit 2 occurred ~7 days after visit 1. BP was measured, and a fasting blood sample was taken to measure full lipid profile, glycemic control, and fibrinogen. The stage and processes of exercise behavior change and 7-day physical activity recall questionnaires were completed. All participants then received standard exercise information and were randomly assigned to the experimental or control (standard care) group.

Participants were randomly assigned on an individual basis in blocks of 20 using consecutively numbered, sealed envelopes. Four people were excluded from randomization. One patient reported being in a maintenance stage of change. One patient had uncontrolled hypertension, and two patients had a positive exercise test (>2 mm ST depression, indicating myocardial ischemia) with no documented evidence of coronary heart disease. Only experimental participants returned for visit 3. During this visit, participants received an exercise consultation. At 6 months, all outcome measures and procedures carried out at baseline were repeated.

Exercise intervention

The exercise consultation involved a ~30-min one-on-one discussion with a trained research assistant and was carried out following published guidelines (9). Exercise consultation is based on the transtheoretical model (20). The transtheoretical model proposes that individuals move through stages when changing behavior (precontemplation, contemplation, preparation, action, and maintenance). The model includes three mediators of change (self-efficacy, decisional balance, and processes of change). During the exercise consultation, a person's stage of change was confirmed, and stage-tailored strategies and techniques known to influence the mediators of change were used to encourage physical activity behavior

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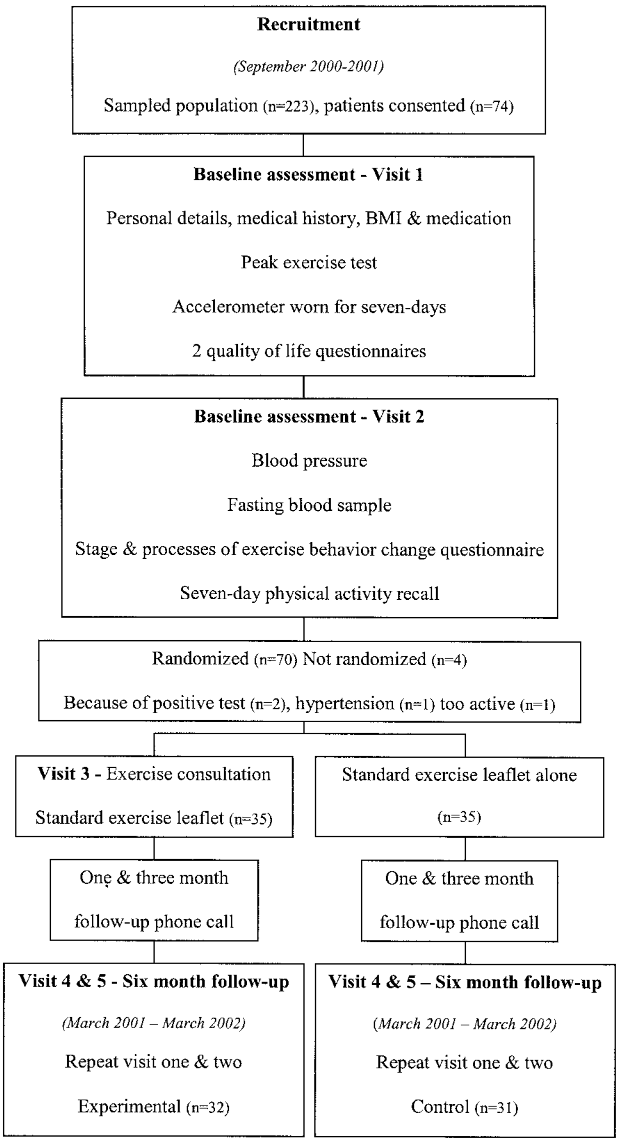

Figure 1—*Flow of participants through trial.*

change. Because all participants were in either a contemplation or preparation stage, the strategies and techniques used were similar for all participants. These included: investigating current physical activity; benefits, barriers, and costs of becoming more active; suitable activities; social support; goal setting; and relapse prevention.

The aim of the consultation was to encourage patients to accumulate 30 min of moderate physical activity most days of the week (2). Follow-up support phone calls were given at 1 and 3 months after the exercise consultation. During these, participants were not classified by stage of change, and a general discussion was conducted of previously set activity goals, experienced benefits, barriers and cost of becoming more active, and relapse prevention. To maintain equal between-group contact time, phone calls were also given to control participants. For the control group, these phone calls involved discussions about topics unrelated to exercise.

A leaflet titled *Exercise and Your Diabetes*, approved by Diabetes U.K., was used as standard exercise information to provide a minimal service to the control group. The leaflet covered the following topics: Why should I exercise?; How much exercise should I do?; How to get started?; and Will exercise affect my diabetes? The leaflet was given to both experimental and control participants. The content of the leaflet was not explained to participants.

Statistical analysis

Estimation of sample size. Statistical power was calculated using the difference in mean change in physical activity counts per week between the experimental and control group at 30 days, obtained from a pilot study (11). There was a 90% power of detecting a true 23% difference in counts per week (baseline mean = 1,813,893; mean difference = 409,780; SD = 444,779), with a minimum of 25 patients in each group given a significance level of 5%. A total of 35 patients were recruited in each group to allow for drop-out. Because of time constraints, statistical power was not adequate to analyze gender effects.

Analysis. Data were analyzed using Minitab (version 13.30). Two-sample *t* tests were conducted to assess whether baseline measured variables were similar between the experimental and control groups. The effect of the intervention was analyzed using paired (within group) and two-sample *t* tests (between group). Nonparametric equivalent tests were used when the data did not follow a normal distribution. Categorical data are reported as a proportion and were analyzed using χ^2 or Fisher's exact tests. $P < 0.05$ was considered to be statistically significant. A Bonferroni correction was applied when a large number of comparisons were conducted to control for type 1 errors.

RESULTS

No between-group differences were found at baseline, confirming successful randomization.

Primary outcome measures

Physical activity levels. The changes by group in total activity counts per week recorded from the CSA accelerometer are illustrated in Fig. 2. There was a significant between-group difference for the change in activity counts per week (95% CI 594,501 to 1,723,539) and for the activity counts per week recorded at 6 months (−1,786,768 to −491,490).

A significant between-group difference was recorded for the median change in self-reported moderate and total activity (moderate + hard + very hard + strength and flexibility) per week from the 7-day recall (95% CI moderate 100.0 to 220.0, total 120.0 to 245.0). The experimental group reported a significant median increase of 128 min of moderate

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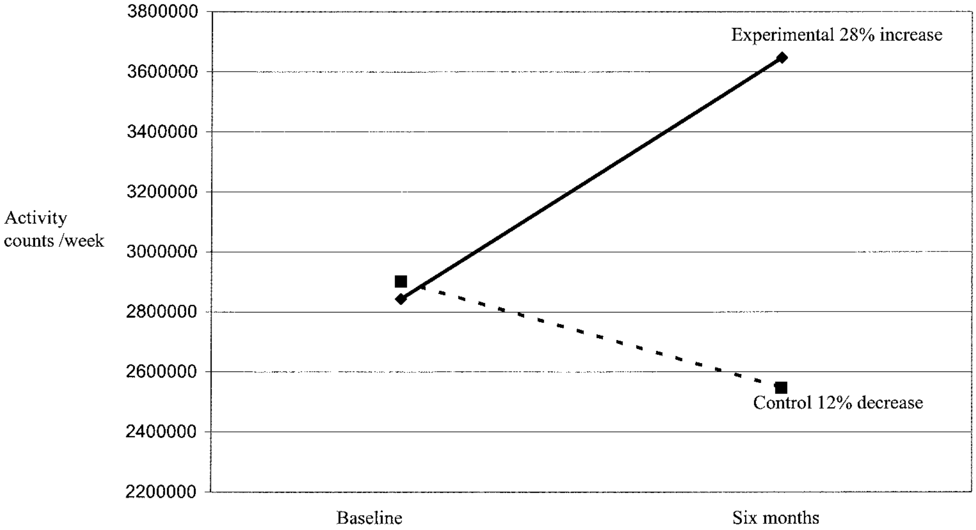

Figure 2—*Mean change in accelerometer (counts/week).*

(95% CI 85.0 to 182.5) and 153 min of total (112.5 to 207.5) activity, respectively. These changes represent a 7.2- and 7.6-fold increase from baseline. The control group reported no significant changes. At follow-up, the experimental group reported participating in more self-reported moderate (95%CI −148.4 to −20.5) and total (−161.7 to −38.6) activity per week. No other significant differences were reported on any 7-day recall variable. At baseline, 20% (7 of 35) of the experimental group and 29% (10 of 35) of the control group reported meeting current ACSM/CDC physical activity guidelines (2) ($\chi^2 = 0.7$, df = 1, $P = 0.4$). At follow-up, a significantly greater number of the experimental group (73%, 22 of 30) compared with control group (13%, 4 of 31) group were meeting these guidelines (2) ($\chi^2 = 22.0$, df = 1, $P < 0.001$)

Behavior change. Change from baseline to follow-up in stage of change was categorized into progression, no change, or regression in stage. Of the experimental participants, 83% (25 of 30) progressed one or more stages and 17% (5 of 30) reported no change. Of the control participants, 23% (7 of 31) progressed one or more stages, 71% (22 of 31) reported no change, and 6% (2 of 31) regressed. These changes in stage of exercise behavior were significantly different between the experimental and control group ($\chi^2 = 22.6$, df = 1, $P < 0.01$).

There was a significant between-group difference for the change in frequency of using three processes of change (98% CI self-liberation 0.84 to 5.60, counter-conditioning 1.3 to 5.6, and self-reevaluation 0.2 to 4.6). From baseline to follow-up, the experimental group significantly increased their frequency of using three processes of behavior change (self-liberation 0.64–4.59, counter-conditioning 1.15–4.47, and reinforcement management 1.0–4.08). The control group recorded no significant changes. At 6 months, there was a significant between-group difference in the frequency of using the processes self-liberation, counter-conditioning, and self-reevaluation (self-liberation −4.26 to −0.28, counter-conditioning −5.28 to −0.91, and reinforcement management −3.71 to −0.59).

Cardiopulmonary exercise test. Table 1 reports the changes from baseline to follow-up in cardiopulmonary exercise test variables. A significant between-group difference was recorded for the change from baseline to follow-up in total exercise duration and peak gradient. The experimental group recorded significant increases in total exercise duration and peak gradient. The control group recorded a significant decrease in peak oxygen uptake. At 6 months, significant between-group differences were recorded for peak gradient (95% CI −3.8 to −0.1) and $V\text{O}_2$ ml · kg^{-1} · min^{-1} (−3.3 to −0.04).

Secondary outcome measures

Table 1 describes the changes in secondary outcome measures from baseline to follow-up.

BMI and BP. No significant between- or within-group differences were recorded in BMI. There was a significant between-group difference for the change in systolic BP but not diastolic BP.

Glycemic control, lipid profile, and fibrinogen. Significant between-group differences for the change in HbA_{1c} were recorded. At 6 months, the mean HbA_{1c} recorded was significantly different between the experimental and control groups (95% CI 0.49 to 1.9). The between-group difference for the change in fibrinogen from baseline to follow-up was also significant. The control group recorded a significant increase in fibrinogen. The experimental group recorded no significant changes. At 6 months, the mean levels of fibrinogen were significantly different between the groups (95% CI 5.09 to 48.50).

CONCLUSIONS — The changes in primary outcomes for this study demonstrate that exercise consultation was more effective in promoting physical activity in people with type 2 diabetes than a standard exercise leaflet. The exercise consultation (9) is based on the transtheoretical model of change. During a consultation, a person's stage of change is identified, and strategies and techniques to promote and maintain behavior change that are tailored to the stage of change are incorporated and developed. In this study, the group receiving the exercise consultation increased their frequency of using four processes of change, and the majority reported an increase in stage of change. Positive changes were also recorded in cardiorespiratory fitness and objective and subjective measures of physical activ-

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Table 1—*Changes in physiological and biochemical variables*

Variable	*n*	Baseline mean	Mean change, baseline to follow-up	Between-group difference in change
Exercise time (min)				
Experimental	30	9.42 ± 3.28	1.56 (0.24 to 3.20)*	
Control	31	10.36 ± 4.39	−0.28 (−1.30 to 0.37)	56.6 to 231.5*
Peak gradient (%)				
Experimental	30	8.38 ± 4.6	2.4 (1.06 to 3.70)*	
Control	31	9.2 ± 5.7	−0.14 (−1.07 to 0.78)	0.94 to 4.1*
Peak $V\text{O}_2$ (ml/min)				
Experimental	28	1,925 ± 684	−30.8 (−139.1 to 77.6)	
Control	30	1,956 ± 600	−185.8 (−304.1 to −67.5)*	−1.8 to 311.9
Peak $V\text{O}_2$ ($\text{ml} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$)				
Experimental	28	20.1 ± 5.9	−0.04 (−1.06 to 0.99)	
Control	30	20.6 ± 5.5	−1.6 (−3.0 to −0.28)†	−1.06 to 0.99
BMI (kg/m^2)				
Experimental	32	35.4 ± 7.8	0.18 (−1.22 to 1.58)	
Control	31	33.7 ± 5.7	0.82 (−0.54 to 2.20)	−1.7 to 0.3
Systolic BP (mmHg)				
Experimental	32	149.4 ± 20.2	−3.67 (−15.53 to 8.20)	
Control	31	143.0 ± 19.5	7.14 (−4.51 to 18.80)	−24.7 to −2.0†
Diastolic BP (mmHg)				
Experimental	32	85.6 ± 9.7	−3.97 (−9.9 to 1.96)	
Control	31	82.0 ± 12.5	−1.34 (−7.27 to 4.59)	−9.8 to 1.7
HbA_{1c} (%)				
Experimental	26	8.3 ± 1.3	−0.31 (−1.02 to 0.40)	
Control	24	8.8 ± 1.5	0.37 (−0.35 to 1.10)	−1.23 to −0.07†
Cholesterol (mmol/l)				
Experimental	23	4.8 ± 1.1	−0.07 (−0.38 to 0.23)	
Control	24	4.72 ± 1.2	0.10 (−0.22 to 0.41)	−0.55 to 0.03
HDL-C (mmol/l)				
Experimental	22	1.14 ± 0.29	0.05 (−0.07 to 0.17)	
Control	21	1.12 ± 0.35	0.03 (−0.09 to 0.15)	−0.09 to 0.13
LDL-C (mmol/l)				
Experimental	21	2.73 ± 0.99	−0.10 (−0.31 to 0.10)	
Control	19	2.52 ± 0.64	0.01 (−0.21 to 0.23)	−0.32 to 0.02
Triglycerides (mmol/l)				
Experimental	23	2.1 ± 0.99	0.20 (−0.44 to 0.84)	
Control	23	2.7 ± 3.08	0.07 (−0.57 to 0.72)	−0.42 to 0.56
Fibrinogen (mg/dl)				
Experimental	22	310 ± 73.0	−3.59 (−25.48 to 18.30)	
Control	21	315 ± 54.7	21.53 (0.01 to 43.06)†	−57.2 to −4.3†

Data are means ± SD, mean (95% CI), and 95% CI. $^*P < 0.01$; $^†P < 0.05$.

ity. In comparison, the control group recorded no significant changes.

Study participants were in a contemplation or preparation stage of change. Targeting people in these stages has been criticized, with arguments that this is an easy target group that has more chance of successful change (21). Because of restrictions of time and limited sample size, it was important to target a homogenous group in terms of intentions to change physical activity. If people in all stages of change had been included, a larger sample would have been required for subgroup analyses of change in outcomes related to stage because change in physical activity may differ by stage. The application of exercise consultation to people in other stages of change requires further investigation.

There is a limited amount of research that has evaluated the longer-term effects of physical activity interventions in people with type 2 diabetes. Vanninen et al. (22) reported no significant change in physical activity at 12 months after giving written and oral instructions for exercise. Uusitupa (23) reported similar results using a comparable intervention. The interventions used in these studies were not tailored to motivational or personal characteristics and did not include cognitive behavioral strategies or have a theoretical basis. In the general population, a number of physical activity interventions have been evaluated over the long term (up to 24 months). Project Prime (8), a randomized controlled trial comparing physical activity counseling delivered by person or

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by mail and telephone, reported significant increases in self-reported moderate physical activity of 187 and 164 min, respectively, at 6 months. Project Prime (8) used the same 7-day recall that was used in the present study. The changes recorded in Project Prime are slightly higher than those recorded in the present study and could be explained by a different study population or a more complex and intensive intervention. The intervention used in Project Prime involved 26 group meetings over 6 months during which cognitive behavioral strategies were discussed. Participants also received monthly stage-tailored manuals and activity calendars. In contrast, the exercise consultation that was used in the present study is a relatively minimal intervention involving one individual consultation and two supporting phone calls.

A number of physical activity intervention studies have recorded positive changes in control groups (6,8,24). Lowther et al. (6) reported a significant increase in physical activity from baseline to 6 months in the control group, which received a physical activity leaflet and exercise vouchers. It has been suggested that giving physical activity information in a supportive environment can be effective for promoting behavior change in the general population. In the present study, no significant changes in physical activity were recorded in the control group. Similar findings were recorded during a study evaluating the effectiveness of exercise consultation over 5 weeks in people with type 2 diabetes (11). This highlights the observation that giving people with type 2 diabetes physical activity information in a supportive environment is not effective by itself.

Experimental participants also demonstrated improvements in glycemic control and cardiovascular risk factors. From baseline to 6 months, the experimental group recorded a mean decrease in HbA_{1c} of 0.31% and the control group recorded a mean increase of 0.37%. These changes are consistent with the findings of a meta-analysis (25) that reviewed the effect of exercise on glycemic control in people with type 2 diabetes and that demonstrated an overall mean difference in HbA_{1c} of 0.66% between exercise and control conditions. Improvements in glycemic control and cardiovascular risk factors are important for this group of people. Cardiovascular disease is the leading cause of death in people with type 2 diabetes (26), and tight glycemic and BP control have been shown to reduce the development and progression of diabetic complications and risk of death related to diabetes (27,28).

Exercise consultation, a fairly minimal intervention, was effective for promoting physical activity and also resulted in positive clinical effects. Exercise consultation (9) holds many advantages for promoting physical activity in people with type 2 diabetes. This intervention offers an individualized physical activity prescription, tailored to motivational and personal characteristics. It develops cognitive behavioral skills and techniques, such as self-efficacy and social support, outlined in previous research as important for physical activity adherence (29). Exercise consultation also requires little expense, and with training it could be conducted by any member of the multidisciplinary diabetes care team. This study provides the evidence base for incorporating exercise consultation into current diabetes care.

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