

# Validation of a Counseling Strategy to Promote the Adoption and the Maintenance of Physical Activity by Type 2 Diabetic Subjects

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**OBJECTIVE** — There is enough evidence that physical activity is an effective therapeutic tool in the management of type 2 diabetes. The present study was designed to validate a counseling strategy that could be used by physicians in their daily outpatient practice to promote the adoption and maintenance of physical activity by type 2 diabetic subjects.

**RESEARCH DESIGN AND METHODS** — The long-term (2-year) efficacy of the behavioral approach ( $n = 182$ ) was compared with usual care treatment ( $n = 158$ ) in two matched, randomized groups of patients with type 2 diabetes who had been referred to our Outpatient Diabetes Center. The outcome of the intervention was consistent patient achievement of an energy expenditure of  $>10$  metabolic equivalents (METs)-h/week through voluntary physical activity.

**RESULTS** — After 2 years, 69% of the patients in the intervention group ( $27.1 \pm 2.0$  METs  $\times$  h/week) and 18% of the control group ( $4.1 \pm 0.8$  METs  $\times$  h/week) achieved the target ( $P < 0.001$ ) with significant ( $P < 0.001$ ) improvements in BMI (intervention group  $28.9 \pm 0.2$  versus control group  $30.4 \pm 0.3$  kg/m<sup>2</sup>) and HbA<sub>1c</sub> (intervention group  $7.0 \pm 0.1$  versus control group  $7.6 \pm 0.1\%$ ).

**CONCLUSIONS** — This randomized, controlled study shows that physicians can motivate most patients with type 2 diabetes to exercise long-term and emphasizes the value of individual behavioral approaches in daily practice.

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Many studies have shown that regular physical activity reduces the risk of coronary heart disease, stroke, colon cancer, and mortality from all causes (1,2). It is particularly advantageous in type 2 diabetes, and indeed, intervention trials have recently shown that diet plus exercise programs reduce the risk of developing diabetes by  $\sim 60\%$  in

subjects with impaired glucose tolerance (3,4). In subjects with overt type 2 diabetes, diet and exercise are associated with more weight loss and less use of hypoglycemic medications than diet alone (5).

Despite this, many physicians do not spend time making an effort to convince type 2 diabetic subjects to exercise, probably because older adults comply poorly

with their recommendations. In fact, adults with diabetes are less likely to engage in regular physical activity than the general adult population (6), and only 23% of older adults with type 2 diabetes reported  $>60$  min of weekly physical activity (7). The fact that people with diabetes have greater concerns with exercise than the general public might explain these negative figures, signifying the importance of proper education.

Regular physical exercise requires more time and effort than modifications to diet and taking medications, and patients often perceive it as a significant and difficult change in their lifestyle. For this reason, there is the need for reproducible interventions that can be used in daily ambulatory practice to motivate diabetic patients to regularly practice physical activity. In 1996, the U.S. Department of Health and Human Services reviewed all the interventions facilitating participation in physical activity (8), and consequently, we designed individualized counseling strategies based on the approaches that this panel of experts showed to be most effective.

To validate the long-term (2-year) efficacy of our intervention, we compared two groups of patients with type 2 diabetes who had been referred to our Outpatient Diabetes Center: a control group ( $n = 158$ ), treated with the usual care, and the intervention group ( $n = 182$ ). The intervention aimed at a consistent patient achievement of an energy expenditure of  $>10$  metabolic equivalents (METs)-h/week through voluntary physical activity. This target roughly corresponds to recommendations from the Centers for Disease Control and Prevention (CDC) and the American College of Sports Medicine (ACSM) (9), which both advise at least 30 min of moderately intense physical activity most days and preferably every day. The results of the study have been analyzed as intention-to-treat.

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**Abbreviations:** MET, metabolic equivalent.

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

**Table 1—Clinical features of type 2 diabetic patients at baseline**

	Intervention group (n = 182)	Control group (n = 158)	P*
Sex (men/women)	88/94	73/85	
Age (years)	62.0 ± 0.7	61.6 ± 0.8	0.71
BMI (kg/m <sup>2</sup> )	29.3 ± 0.2	29.8 ± 0.3	0.16
HbA <sub>1c</sub> (%)	7.6 ± 0.1	7.7 ± 0.1	0.48
Duration of diabetes (years)	7.6 ± 0.3	7.6 ± 0.4	0.90
Diet only	20 (11)	15 (10)	0.78
Oral antidiabetic drugs	139 (76)	118 (75)	0.81
Insulin	23 (13)	25 (16)	0.49
Insulin + metformin	40 (22)	32 (20)	0.79
Diet prescription (kcal/day)	1,535 ± 34	1,460 ± 31	0.11
Units/day of insulin	51 ± 4	47 ± 5	0.53
Energy expenditure through voluntary physical activity (METs × h/week)	1.0 ± 0.3	0.8 ± 0.2	0.59
Percent of patients >10 METs × h/week	2.8	3.8	0.53

Data are means ± SE or n (%). \*P = control group versus intervention group.

## RESEARCH DESIGN AND METHODS

— Eligibility criteria included type 2 diabetes diagnosed at least 2 years previously and age of 40 years or older. Patients who had illnesses that could seriously reduce their life expectancy and/or cardiac, liver, or renal failure were excluded from the study. All consecutive eligible patients attending our Outpatient Diabetes Clinic over a period of 2 months were randomized to the intervention group or the control group. Table 1 shows the clinical features of diabetic subjects and control subjects, which, at baseline, did not differ for age, sex, BMI, duration of diabetes, HbA<sub>1c</sub>, type of therapy, and energy expenditure through voluntary physical activity.

All patients were seen by a physician in our Outpatient Diabetes Clinic. In accordance with our usual care criteria, in a 30-min session, control subjects underwent a clinical examination and received counseling for diet and physical activity and the therapeutic prescription. The intervention group, in addition to the usual visit, received an additional 30 min of structured counseling recommending physical activity. During the first counseling session, the physician consecutively discussed with the patient the seven points listed below, which are summarized in the checklist (Table 2). The physician conducted the counseling using the checklist to strictly follow the protocol.

1. *Motivation.* The physician explained the benefits of exercise as reported by

scientific literature for the general population and, specifically, for diabetic subjects, stressing those appealing most to the individual patient. Our efforts were designed 1) to convince the patient that regular physical exercise is the preeminent cure for type 2 diabetes and is beneficial for people in general, including physicians, and 2) to understand what positive expectations the individual patients held from this change in behavior.

2. *Self-efficacy.* Self-efficacy was promoted by patient collaboration in designing an individualized program of physical activity, based on age and physical state, they were confident they could positively perform. The program started with simple tasks (e.g., a 20-min walk daily) that were increased at weekly intervals, setting realistic personal goals.

3. *Pleasure.* We asked about the patient's previous experience of exercise. Several interchangeable indoor and outdoor aerobic activities (at least two to three different types) were proposed to identify those that were more appealing and to rule out those the patients perceived as boring.

4. *Support.* Approximately 70% of patients were accompanied to the initial counseling session by a partner. Partners were invited to share the sessions of physical activity with the patients. When patients came alone, we suggested they exercise with family members or friends. Although we did not offer any structured indoor or outdoor activity, we favored group walking by suggesting, especially to urban patients, the meeting points of known groups of walkers.

5. *Comprehension.* The physician listened to the patients to be sure that they had really understood the valuable advantages of the behavioral change. After the exercise program had been established, the physician posed a few questions to determine whether the patients had a really positive attitude toward the behavioral change. Enough time was spent listening to patients to recognize their uncertainties and perceived impediments to physical activity.

6. *Lack of impediments.* The physician helped the patient overcome potential obstacles to regular exercise. Instead of simply suggesting a solution, we invited the patients to solve the problem and their proposal was supplemented with our advice on time management strategies.

7. *Diary.* The patient was asked to record daily the type and time of physical ac-

**Table 2—Checklist of the initial counseling session designed to promote an exercise program**

● Motivation	Explain the benefits of regular aerobic exercise
● Self-efficacy	Plan a step-by-step training program with the patient
● Pleasure	Suggest two to three different types of attractive aerobic physical activities
● Support	Invite family members to share the exercise sessions with the patient
● Comprehension	Understand whether the patient has a really positive attitude toward the behavioral change
● Lack of impediments	Help the patient overcome a solution for obstacles to physical activity
● Diary	Invite the patient to record the type and times of physical activity

tivity they performed. On the subsequent visits (every 3 months), the diary was used to record the amount of physical activity, to encourage patients' self-efficacy, to increase the time or frequency of the exercise sessions, to overcome the practical problems related to exercise, and when required, to modify the treatment.

In the intervention group, the initial counseling session was followed, 1 month later, by a telephone call at home and, every 3 months, by an appointment of ~15 min in the Outpatient Diabetes Clinic. The telephone call was made by the same physician who conducted the initial counseling to determine whether the patient was performing the physical activity as programmed. If the patient referred to problems or obstacles to physical activity, the phone call was prolonged to ~15 min to reinforce the points discussed in the initial counseling session.

Subjects in the control group were given appointments at 3-month intervals and were treated with our usual care at the Outpatient Diabetes Clinic. They were given general advice and brochures about the benefits of healthy nutrition and regular physical activity and a diary to report their voluntary physical activity. Patients in the control and intervention groups were treated for diabetes and other diseases according to accepted guidelines. Diet for all patients contained 55% calories from complex carbohydrates, 30% from fat, and 15% from protein. Normal weight patients received an isocaloric diet calculated by adding to the basal metabolism (estimated using the Harris and Benedict formula) the estimated energy expenditure from routine and voluntary physical activity. Overweight and obese patients were given a diet with a negative balance of ~300 kcal/day, which included the estimated energy expenditure from routine and voluntary physical activity.

In both groups, levels of voluntary physical activity, assessed every 3 months using the Modifiable Activity Questionnaire (10), were calculated as the product of the duration (hours  $\times$  week) of the different activities weighted by an estimate of the MET of each activity (3). The intervention was aimed at consistent patient achievement of an energy expenditure of  $>10$  METs  $\times$  h/week through voluntary physical activity.

## Methods

HbA<sub>1c</sub> was determined by high-performance liquid chromatography using a Hi-AUTO A1C, TM HA 8121 apparatus (DIC; Kyoto Daiichi, Kogaku, Japan) (values in nondiabetic subjects  $<6.1\%$ ).

## Statistical analysis

Data were expressed as means  $\pm$  SE and were analyzed as intention-to-treat using paired or unpaired Student's *t* test as appropriate. Data that failed normality using the Kolmogorov-Smirnov test and equal variance using the Levene Median test were analyzed using nonparametric procedures, i.e., Wilcoxon's signed-rank test or Mann-Whitney rank-sum test as appropriate. Differences between proportions were calculated using the  $\chi^2$  test with Yates correction for continuity. Linear regressions were performed according to the least-squares method. A *P* value  $<0.05$  indicated significant differences. Analysis was performed using Sigma Stat 2.0 (Jandel).

**RESULTS**— The results were collected at baseline and 2 years after the first counseling session. Physician adherence to the protocol was complete because all physicians (three authors) accurately followed the counseling strategy reported in RESEARCH DESIGN AND METHODS, as confirmed by three other authors who were present at the counseling sessions. Three of the 182 patients in the intervention group did not complete the study because one was lost at follow-up and two died (one was sedentary, one was physically active).

## Levels of physical activity

At baseline, the average energy expenditure (METs  $\times$  h/week) through voluntary exercise did not differ between the control group ( $1.0 \pm 0.3$ ) and the intervention group ( $0.8 \pm 0.2$ , *P* = 0.570), nor did the low percentage of subjects who had energy expenditure  $>10$  METs  $\times$  h/week through voluntary physical activity (control group 3.8%, intervention group 2.8%; *P* = 0.830).

After 2 years, the intervention group increased energy expenditure (METs  $\times$  h/week) through voluntary physical activity from  $0.8 \pm 0.2$  to  $27.1 \pm 2.0$  METs  $\times$  h/week (*P*  $<0.001$ ), a value that was sevenfold greater (*P*  $<0.001$ ) than in the control (usual care) group ( $4.1 \pm 0.8$  METs  $\times$  h/week). In the intervention

group, 125 of 182 patients (69%) in the intervention group and 28 of 158 patients (18%) in the control group had energy expenditure through voluntary physical activity  $>10$  METs  $\times$  h/week (*P*  $<0.001$ ). In the intervention group, 63% of patients had an energy expenditure  $>16$  METs  $\times$  h/week ( $\sim 1,000$  kcal/week).

## BMI and HbA<sub>1c</sub>

At baseline, BMI did not differ between the control group ( $29.8 \pm 0.3$ ) and the intervention group ( $29.3 \pm 0.2$ , *P* = 0.158). After 2 years, BMI in the intervention group ( $28.9 \pm 0.2$ ) was significantly lower than at baseline (*P*  $<0.01$ ) and than in the control group ( $30.4 \pm 0.3$ , *P*  $<0.001$ ). In the control group, BMI increased significantly (*P*  $<0.01$ ) after 2 years.

At baseline, HbA<sub>1c</sub> was similar (*P* = 0.482) in the control group ( $7.7 \pm 0.1\%$ ) and the intervention group ( $7.6 \pm 0.1\%$ ). After 2 years, HbA<sub>1c</sub> decreased to  $7.0 \pm 0.1\%$  in the intervention group (*P*  $<0.001$ ), which was significantly lower (*P*  $<0.001$ ) than in the control group ( $7.6 \pm 0.1\%$ ).

In the intervention group, the reduction of either BMI or HbA<sub>1c</sub> was positively and significantly (*P*  $<0.001$ ) related to the increase of energy expenditure through voluntary physical activity (BMI *r* = 0.55, HbA<sub>1c</sub> *r* = 0.63).

## CONCLUSIONS

— The results of this study validate a simple, reproducible counseling strategy that effectively motivated ~70% of type 2 diabetic patients to perform a regular aerobic exercise program. These results are relevant in clinical practice for several reasons: an unselected population of type 2 diabetic patients was successfully motivated, the 2-year follow-up confirmed that the behavioral change was established, and patients in the intervention group achieved a substantial increase of energy expenditure (mean 27 METs  $\times$  h/week). The intervention, analyzed as intention-to-treat, reduced both BMI and HbA<sub>1c</sub>, with a significant correlation emerging between the reductions and the amount of voluntary physical activity and the reductions of either BMI or HbA<sub>1c</sub>. In contrast, only 18% of the subjects in the control group, who received routine advice about benefits of physical activity, reached the minimum goal of 10 METs  $\times$  h/week. The

**Table 3—Effects of the 2-year intervention on levels of physical activity (energy expenditure through voluntary physical activity, METs × h/week), caloric intake, BMI, and HbA<sub>1c</sub> compared with the usual care (control group)**

	Intervention group		Control group		P*
	2 years	Δ versus basal	2 years	Δ versus basal	
Percent of patients > 10 METs × h/week	69	+66.2	18	+14.2	<0.001
METs × h/week	27.1 ± 2.0	+26 ± 2.0	4.1 ± 0.8	+3.2 ± 0.7	<0.001
Diet prescription (kcal/day)	1,677 ± 36	+142 ± 10	1,485 ± 31	−25 ± 4	<0.01
BMI (kg/m <sup>2</sup> )	28.9 ± 0.2	−0.4 ± 0.1	30.4 ± 0.3	+0.6 ± 0.1	<0.01
HbA <sub>1c</sub> (%)	7.0 ± 0.1	−0.6 ± 0.05	7.6 ± 0.1	−0.1 ± 0.04	<0.001

Data are means ± SE. \*P = control group versus intervention group.

BMI of this group tended, as expected (11), to increase over the years.

Our counseling strategy was designed based on the conclusions of the report released in 1996 by the U.S. Department of Health and Human Services (8), regarding the efficacy of the interventions to promote physical activity in adults. The report states: "Having confidence in one's ability to be active (self-efficacy); enjoying physical activity; receiving support from family, friends, or peers; and perceiving that the benefits of physical activity outweigh its barriers or costs appear to be central determining factors influencing activity levels across the life span" (8). According to Bandura's social cognitive theory (12), for a person to change behavior, he must believe that he is able to perform the behavior (self-efficacy) and must perceive that the positive expectations from the new behavior will outweigh the negative (motivation). Our counseling strategy focused on these two central aspects of motivation and self-efficacy and was supplemented by other approaches (pleasure, support, comprehension, lack of impediments, and diary) that have been demonstrated to play a positive role in promoting physical activity (8).

Motivation was the first issue. Our experience shows that understanding the expectations of the patient allowed us to focus the conversation on individual outcomes. To change his/her behavior, a person must perceive an incentive to do so (12); therefore, the counseling was individualized to convince the patient that regular physical activity was the proper strategy to realize his/her personal goals. The fact that the people who explained the benefits of exercise for diabetes were physically active physicians played a positive role. The Latin philosopher Lucius Annaeus Seneca (5–65 DC) wrote in one of his letters to Lucilio: "People believe

more from their eyes than from their ears." Contemporary research has confirmed that counseling about health habits by physicians with good health habits is more successful than counseling by those with poor health habits (13). Because physicians conducted the counseling in our study, we cannot establish from it whether other health care professionals might achieve similar positive results. However, the experience with the Lifestyle Coaches (case managers) of the Diabetes Prevention Program (3) demonstrates that well-trained health care professionals are capable of effectively promoting healthy behavioral changes.

Self-efficacy was implemented by designing, with the patient, a program starting with simple tasks (e.g., a 20-min walk daily) that were increased weekly to set realistic personal goals. This approach is based on the concept that learning a complex new pattern of behavior normally requires modifying the small habits that constitute an overall complex behavior pattern (14). This step-by-step approach intentionally avoided goals that the patient was unable to imagine attaining (12), and progressive achievement of the goals sustained long-term adherence by reinforcing the patient's willingness to perform physical activity (15,16), that is her/his self-efficacy (17).

Enjoyment, the major reason young people engage in physical activity (18), ensures long-term maintenance of physical activity by adults (8). Therefore, pleasure was the third issue in our counseling session, which identified at least two to three interchangeable indoor and outdoor aerobic activities that appealed most to the patient.

Many studies (19–21) have shown a positive relationship between social support from family or friends and adult physical activity. If the patients attended

the session with their partners or family members, we invited them to find physical activities that could be practiced together. In our study, 70% of patients were accompanied by partners or family members, even though they were not instructed to do so. This result is hardly surprising in Italy, which is known for deep family ties. In other settings, because social support is an important predictor of adoption and maintenance of exercise (19–21), we suggest inviting significant others to join in the session and become part of the counseling structure.

After the program of physical activity had been established, the physician asked a few questions to determine whether the patients had a really positive attitude toward the behavioral change. Listening to the patients was useful, because their uncertainties about exercise could be addressed, any perceived impediments could be discussed, and the patient could be coached to be the center of the diabetes care team.

Lack of time and negative attitudes were the most common obstacles reported by our patients. Instead of simply suggesting a solution, we invited the patient to solve the problem and his/her proposal was supplemented with our advice on time management strategies. Concerns about crime, an important barrier to outdoor physical activity (22), were not reported by our patients.

Before ending the first counseling session, we instructed the patients to record in a diary the type and time of exercise and, eventually, the reasons for not doing it. There is evidence that self-monitoring of physical activity is effective, at least in the short term (23). The diary was used in the follow-up sessions (every 3 months): 1) to reward the patients for their improvements with positive comments; 2) to analyze impediments to physical activ-

ity with the patients; and 3) to estimate the amount of their energy expenditure, in their presence. Accordingly, in overweight or obese subjects, the caloric intake often had to be increased to maintain a negative energy balance of no more than 300 kcal/day. At the end of the 2-year follow-up, the calories in the prescribed diet in the intervention group were significantly more than in the control group (Table 3). The increase in calories was particularly appreciated and proved to be an effective reinforcement for long-term maintenance of regular physical activity. Despite the greater caloric intake, BMI and HBA<sub>1c</sub> significantly improved in the intervention group, emphasizing the effectiveness of regular exercise in the management of type 2 diabetes.

Regular sessions were also used to solve problems related to physical activity and to encourage less active patients to increase the duration and/or the number of exercise sessions. After 2 years, the average energy expenditure by voluntary physical activity of the intervention group was 27 ± 2 METs-hour/week. Although routine advice about the benefits of exercise could have contributed to the increased amount of energy expenditure in the control group (Table 3), the average energy expenditure in the intervention group was approximately sevenfold greater. Clear evidence indicates an inverse linear dose response between amount of physical activity and all-cause mortality, total cardiovascular disease, and coronary artery disease incidence and mortality (24). In a recent review, Haenel and Lemire (24) estimated that the minimal effective dose of exercise associated with substantial benefits is ~1,000 kcal/week. This goal was reached by nearly two thirds of the patients in the intervention group, signifying the validity of the counseling strategy.

The use of intensive counseling to promote a healthy lifestyle has been proven to reduce the risk of developing diabetes by ~60% (3). Recent studies (25) show that modest increments in physical fitness in diabetic subjects reduce the risk of overall mortality twofold, thus demonstrating that physical activity programs need to become an essential part of the cure of type 2 diabetes. The results of the present study indicate that physicians can motivate most type 2 dia-

betic patients to long-term practice of exercise and emphasize the value of individual behavioral approaches in daily practice.

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