

Clinic-Based Support to Help Overweight Patients With Type 2 Diabetes Increase Physical Activity and Lose Weight

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Background: Our objective was to test the effect of physicians providing brief health lifestyle counseling to patients with type 2 diabetes mellitus during usual care visits.

Methods: We conducted a randomized controlled trial of a 12-month intervention at 2 large community health centers, enrolling 310 patients with a body mass index (calculated as weight in kilograms divided by height in meters squared) of 25 or greater. In the intervention group, self-management goals for nutrition and physical activity were set using a tailored computer program. Goals were then reviewed at each clinic visit by physicians. The control group received only printed health education materials. The main

outcome measures included change in physical activity and body weight.

Results: In the intervention group, recommended levels of physical activity increased from 26% at baseline to 53% at 12 months ($P < .001$) compared with controls (30% to 37%; $P = .27$), and 32% of patients in the intervention group lost 6 or more pounds at 12 months compared with 18.9% of controls (odds ratio, 2.2; $P = .006$).

Conclusion: A brief intervention to increase the dialogue between patients and health care providers about behavioral goals can lead to increased physical activity and weight loss.

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OBESITY IS AN IMPORTANT modifiable risk factor for type 2 diabetes mellitus.^{1,2} The prevalence of obesity has increased substantially over the last decade,³⁻⁵ leading to increases in the incidence and prevalence of type 2 diabetes mellitus.⁶⁻⁸ Physical activity and weight control have been shown to be important in diabetes prevention⁹⁻¹¹ and diabetes management.¹⁻³ Among patients with type 2 diabetes, the beneficial effect of exercise on hemoglobin A_{1c} (HbA_{1c}) level is independent of any

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effect on body weight,⁹ and higher levels of physical activity are associated with significantly lower subsequent cardiovascular risk and overall mortality to a much greater extent than could be explained by glucose lowering alone.^{2,9,12} Weight loss of as little as 5 to 10 lb (2.25 to 4.5 kg) can improve metabolic control and associated risk factors.⁸ Thus, patients do not have to achieve ideal body weight to re-

alize the diabetes-related risk reduction benefits associated with increased physical activity and weight loss.^{1,2}



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To reduce diabetes-related morbidity and mortality, increased physical activity and adoption of a healthy diet are often additive to the benefits afforded by medications that lower lipid and glucose levels.¹²⁻¹⁶ Despite the potential to reduce complications of diabetes through lifestyle changes, overweight patients have difficulty losing significant amounts of weight through self-management.¹² Among patients with type 2 diabetes, weight loss attempts and efforts to increase physical activity may offer greater challenges than among patients without diabetes. For example, diabetes medications, including insulin, sulfonylureas, and thiazolidinediones, can cause weight gain. Increasing physical activity may be more challenging because of comorbid chronic illnesses such as heart disease, degenerative joint disease, and hypertension; patients'

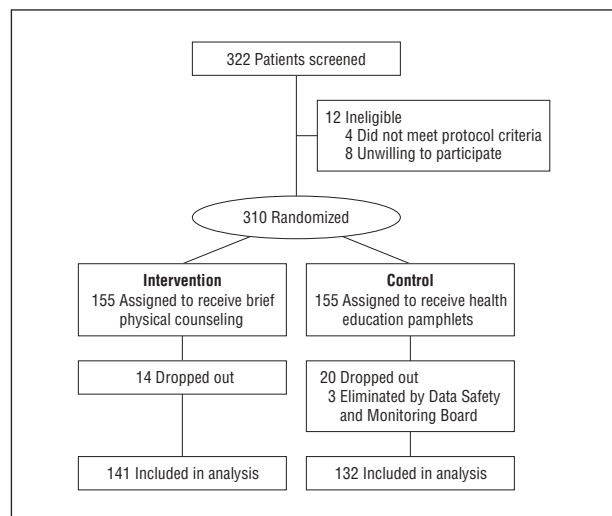


Figure 1. Flow of patients through the trial.

fears about injury and the effects of exercise on blood glucose levels; and the metabolic consequences of the diabetic state resulting in a reduction in exercise tolerance.¹⁷

Physicians are well aware of their potential to positively influence the lifestyle behaviors of patients with diabetes, but the many medical concerns and patient priorities during usual care visits often make it difficult to adequately address lifestyle modifications with each patient. Time constraints and lack of training on how to effectively counsel patients in nutrition, exercise, and/or weight management are barriers that can interfere with physician counseling about these positive lifestyle changes.¹⁸ To address these challenges, we investigated the efficacy of a simple physician counseling process to aid in delivery of brief but effective lifestyle counseling to sedentary overweight or obese patients with type 2 diabetes during usual care visits. The intervention process specifically addressed physician challenges related to time and counseling skills, as well as difficulties that patients with diabetes may encounter when trying to lose weight.

METHODS

We conducted a prospective randomized controlled trial in outpatient clinic settings among patients with type 2 diabetes mellitus at 2 large urban community-based health centers—the Denver Health and Hospital Authority’s Sandoz Westside Neighborhood Health Center in Denver, Colorado (DH), and the Pueblo Community Health Center, Pueblo, Colorado (PCHC). Of the patient participants, 41% came from DH and 59% came from PCHC. More than 60% of patient populations who served at both study test sites were Hispanic/Latino, and approximately 65% of patients at both sites had family incomes at or below 100% of the US poverty level (\$20 650 annually for a family of 4). The patients participating in the study were selected from the general clinic population of patients with type 2 diabetes. The study protocol was approved by the appropriate institutional review boards in Pueblo and Denver and conformed to all applicable standards for human subjects research.

Subjects met the following eligibility requirements: Latino/Hispanic in ethnicity with a language preference of either

English or Spanish, aged 18 to 75 years, with a diagnosis of type 2 diabetes; a body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) of 25 or higher; and uninsured, Medicaid eligible, or Medicare beneficiaries. We excluded patients with substance use or abuse, severe arthritis or other medical conditions limiting physical activity, recent myocardial infarction or stroke, or peripheral vascular disease or who had undergone or been scheduled for gastric bypass surgery.

Clinic staff at the study sites used diabetes registries to identify potential study subjects and invited eligible patients to consider volunteering for the study during their next usual care visit. There were 1200 adults with type 2 diabetes in the DH diabetes registry and 1419 in the PCHC registry. Clinic staff reported that more than 97% of the approximately 335 eligible patients who were contacted expressed an interest in the study. Potential subjects were contacted, screened, and enrolled sequentially without consideration for their interest in losing weight. Enrollment stopped when predetermined enrollment targets were reached. A total of 322 patients were screened for inclusion in the study, and 310 patients were enrolled from October 2003 to April 2004 (**Figure 1**).

Patients were requested to arrive at the clinic 30 minutes prior to their physician visit. The receptionist informed the research associate (RA) who, after administering informed consent to participate in the study, randomly assigned patients to either the intervention or control group (155 intervention and 155 control). Assignments to 1 of these 2 groups were based on a computer-generated random number sequence. Assignment was concealed to the RA by a padded envelope that also contained a kit of baseline enrollment materials.

At the baseline visit, the RA measured the patients’ height and weight with a standard office scale/stadiometer and measured waist circumference with a tape measure at the level of the superior iliac crest, with the tape measure parallel to the floor at the end of a relaxed expiration.¹⁹ Energy expended in physical activity was estimated by the validated 7-day physical activity recall instrument.^{20,21} Energy intake (kilocalories) was assessed using a validated food frequency instrument that was adapted for the study.^{22,23}

INTERVENTION GROUP

Participants assigned to the intervention group completed a computer-based assessment of their motivational readiness to increase physical activity and make dietary changes. This assessment took less than 10 minutes to complete, and more than 90% of patients were able to complete the program with only approximately 30 seconds of instruction from the RA. The program solicited information on usual dietary habits and awareness of the role of diet and exercise in the management of diabetes. All materials were prepared in both English and Spanish languages. On completion of the assessment, the computer expert system generated a 4- to 5-page individualized, tailored report, which provided feedback addressing participant-identified barriers to improving their physical activity and diet. The purposes of this feedback were (1) to enhance participants’ motivation to increase physical activity and reduce caloric intake, (2) to identify potential barriers to making lifestyle changes, and (3) to provide tailored counseling suggestions to enhance readiness, decision making, and self-efficacy to make lifestyle changes. Prior to the baseline clinic visit, intervention patients read their report and listed 2 or 3 dietary and/or physical activity self-management goals they wanted to achieve. In addition, intervention group patients were given a 30-page planning guide that provided supplemental information on diabetes and achieving a healthy lifestyle.

Table 1. Baseline Characteristics of the Study Participants

Characteristic	Control Group (n=155)	Intervention Group (n=155)	P Value ^a
Sex, No. (%)			
Male	50 (32)	55 (35)	
Female	105 (68)	100 (65)	
Race or ethnic group, No. (%)			
Hispanic/Latino	155 (50)	155 (50)	
Age, mean [SD], y	53.4 [10.70]	53.0 [11.25]	.75
Weight, mean [SD], lb ^b	200.2 [44.7]	207.0 [47.3]	.19
BMI, mean [SD]	34.8 [7.11]	35.4 [6.62]	.44
Waist circumference, mean [SD], cm	116.6 [15.23]	118.1 [14.95]	.38
Hemoglobin A _{1c} , mean [SD], %	8.29 [1.93]	8.08 [2.02]	.50
Serum lipids, mean [SD], mg/dL			
Total cholesterol	189.61 [54.72]	191.16 [46.33]	.79
LDL-C	105.82 [38.81]	100.18 [32.10]	.16
HDL-C	44.29 [18.44]	42.04 [12.67]	.21
Triglycerides	185.72 [112.25]	178.67 [103.71]	.57
Blood pressure, mean [SD], mm Hg			
Systolic	132.26 [17.43]	131.80 [17.02]	.81
Diastolic	77.83 [9.58]	76.56 [10.53]	.27
Physical activity, mean [SD], MET-min ^c	442.0 [709.9]	478.2 [1098.1]	.73
Participant total caloric intake per week, mean [SD] ^d	12 211.5 [3495.1]	12 787.3 [3187.2]	.13

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; MET-min, metabolic equivalent task minutes.

SI conversion factor: To convert to millimoles per liter, multiply by 0.0249 for cholesterol and by 0.0113 for triglycerides.

^aP values were determined by a 2-tailed *t* test for the difference between the groups.

^bTo convert to kilograms, multiply by 0.45.

^cMET-min is the ratio of the work metabolic rate to the resting metabolic rate. One MET-min is defined as 1 kcal/kg/min and is roughly equivalent to the energy cost of sitting quietly.

^dWeekly total caloric intake was collected via interview with research associates.

The computer expert system also generated a companion report for the patient's physician, which included a brief, bulleted summary of the findings from the patient's assessment (ie, priority change areas and perceived barriers to change) and provided the physician with patient-specific counseling recommendations. Prior to baseline patient visits, 19 physicians completed a 3-hour training session on how they should use these patient lifestyle change goal sheets to provide brief motivational interviewing counseling to help patients make changes in dietary and physical activity behaviors.

During a regularly scheduled study-related visit, intervention patients met with their physician who discussed the patient's tailored lifestyle change goals and provided encouragement in attaining these goals. Neither physicians nor patients could be blinded to the intervention assignment.

CONTROL GROUP

Control group patients were given a packet of health education materials at the baseline visit addressing diabetes, diet, and exercise.^{24,25} Thereafter, they completed their regular clinic visit with their usual physician but had no additional prompts or motivational interviewing from their physicians regarding their specific goals for weight or physical activity other than what they might receive during usual care.

FOLLOW-UP VISITS AT 3, 6, AND 9 MONTHS

Participants completed study-related usual care visits every 3 months, consistent with recommended guidelines for patients with diabetes. At each 3-month visit, control patients received usual care, while patients assigned to the intervention group reviewed their goal sheet with their physician, who was trained

to provide motivational interviewing counseling to reinforce patients' lifestyle change goals.

DATA ANALYSIS

The primary end point of this study was weight loss, expressed as mean weight lost and the fraction of subjects in each group achieving a clinically meaningful weight loss defined as a 5% reduction in body weight. Secondary analyses included the change in physical activity, estimated in metabolic equivalent task minutes (MET-min), change in energy intake, and changes in lipid and HbA_{1c} levels. Sensitivity analyses were conducted to more specifically examine levels of weight change in each group. Analyses were tied to a priori hypotheses. We conducted intention-to-treat analyses using a "last-record-carried-forward" method in which the last available data from dropouts were used when analyzing 12-month data. Using this analysis, we found no substantial change in the various study end points reported herein. Post hoc analyses of subject records were conducted to examine the role of medication changes, intercurrent illnesses, readiness to change, and other patient factors that might have been involved in observed changes.

RESULTS

A total of 310 patients were recruited and randomly assigned to the intervention (n=155) or control (n=155) group; 273 patients completed the study and are included in the analyses (141 intervention and 132 control) (Figure 1). Baseline characteristics of the study participants are summarized in **Table 1**.

Table 2. Summary of Results by Patient Outcome^a

Outcome	Intervention Group (n=141)		Control Group (n=132)		P Value ^b
	Result	95% CI	Result	95% CI	
Change in weight, mean [SD], lb ^c	-0.18 [10.92]	-2.00 to 1.65	1.39 [10.60]	-0.43 to 3.22	.23
Lost ≥5% body weight, No. (%)	30 (21)	NA	14 (11)	NA	.02
Change in hemoglobin A _{1c} , mean [SD], % ^d	-0.141 [1.76]	-0.44 to 0.15	-0.46 [1.63]	-0.74 to -0.18	.12
Change in physical activity, mean [SD], MET-min/wk	354 [574]	257.5 to 451.4	51 [443]	-25.72 to 127.72	<.001
Change in physical activity, %	78.1	NA	12.5	NA	NA
Change in caloric intake, mean [SD], total kcal/wk	-947 [1936]	-1271.0 to -623.4	-507 [1963]	-847.7 to -166.3	.07
Change in caloric intake, %	-8.3	NA	-4.4	NA	NA
Change in serum lipids, mean [SD], mg/dL ^e					
Total cholesterol	-15.84 [44.76]	-23.29 to -8.39	-3.93 [45.15]	-11.70 to 3.84	.03
HDL-C	-0.43 [17.10]	-3.28 to 2.42	1.56 [11.60]	-0.33 to 3.45	.26
Triglycerides	-13.60 [97.06]	-29.76 to 2.56	-9.48 [95.67]	-25.95 to 6.99	.72
LDL-C	-14.62 [38.52]	-21.03 to -8.21	-3.81 [38.51]	-10.44 to 2.82	.01
Change in blood pressure, mean [SD], mm Hg					
Systolic	-2.55 [20.37]	-5.942 to 0.841	-4.66 [20.81]	-8.243 to -1.077	.40
Diastolic	-2.60 [13.79]	-4.896 to 0.304	-2.54 [11.63]	-4.640 to -0.637	.97
Change in waist circumference, mean [SD], cm	-1.764 [7.045]	-2.941 to 0.586	-0.543 [6.498]	-1.670 to 0.589	.14

Abbreviations: CI, confidence interval; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; NA, not applicable. SI conversion factor: To convert to millimoles per liter, multiply by 0.0249 for cholesterol and by 0.0113 for triglycerides.

^aThirty-seven enrolled patients withdrew from the study. Their characteristics were similar to the baseline population and are covered in Table 1.

^bP values were determined by a 2-tailed *t* test for the difference between the groups.

^cTo convert to kilograms, multiply by 0.45.

^dDiabetes drugs were being taken by 98% of the participants in the intervention group and 95% in the control group.

^eCholesterol-lowering drugs were being taken by 67% of the participants in the intervention group and 69% in the control group.

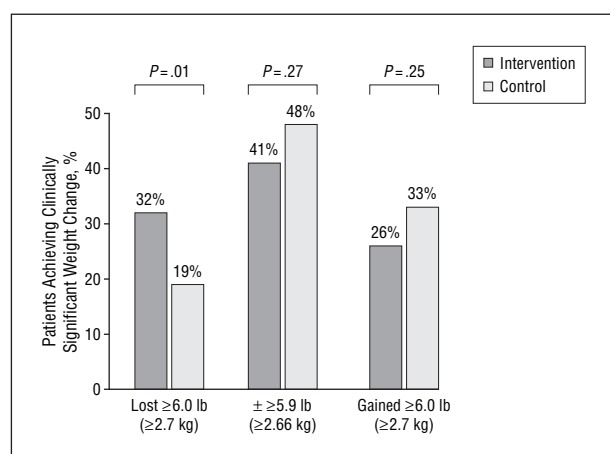


Figure 2. Percentage of patients sustaining a clinically significant weight change for 12 months. ± Indicates gained or lost.

CHANGES IN PHYSICAL ACTIVITY

The percentage of intervention patients who achieved a MET-min equivalent of 150 or more minutes of physical activity or exercise per week at a moderate level of intensity increased from 26% at baseline to 53% at 12 months ($P<.001$) compared with controls (30% to 37%; $P=.27$). The intervention patients increased self-reported levels of physical activity by a mean of 354 MET-min/wk vs a 51 MET-min/wk for controls ($P<.001$).

WEIGHT CHANGE

When mean changes in body weight were compared between intervention and control groups, no significant dif-

ferences were found (**Table 2**). However, 21% of intervention patients sustained a weight loss of 5% of total body weight or greater at 12 months compared with 10.6% of controls ($P<.01$). We found that 28% of intervention patients sustained a weight loss of 6 lb (2.7 kg) or more at 6 months and 32% at 12 months compared with 24% of controls at 6 months and 19% at 12 months (odds ratio, 2.2; $P=.01$) (**Figure 2**). An analysis of characteristics of patients who succeeded in weight loss indicated that BMI, sex, and age did not predict success (data not shown).

CHANGES IN LIPID AND HbA_{1c} LEVELS

Compared with patients in the control group, patients in the intervention group achieved significant reductions in total cholesterol and low-density lipoprotein cholesterol levels (Table 2). Many of the changes in lipid levels were likely related to differences in the use of lipid-lowering medications. Although 59% of the intervention patients experienced reductions in HbA_{1c} level, this was not significantly different from the controls. Ninety-eight percent of patients were taking antihyperglycemic medications, and 51% of patients had changes in their medication regimen during the study. We were not able to determine the independent effects of changes in medication regimens on HbA_{1c} levels. However, there was a significantly greater reduction in HbA_{1c} level for control patients who had their dosage of antihyperglycemic drugs increased or the type of medication changed—a -0.9 reduction in HbA_{1c} level vs a -0.04 reduction for intervention patients who also had changes in their antidiabetes drug regimen ($P=.02$). In addition, 22% of intervention patients were at a 6.0 or lower HbA_{1c} level at the end of the study vs 17% for controls.

CHANGES IN ENERGY INTAKE

The intervention group reduced total self-reported energy (kilocalorie) intake by a mean of 907 kcal/wk (8.3%) per patient vs a 547 kcal/wk (4.4%) reduction for controls ($P = .06$). However, self-reported dietary and physical activity measures are susceptible to inaccuracies and reporting bias.²⁶⁻²⁹ A subgroup analysis of broad categories of energy intake and energy expenditure was conducted to assess the relationship between self-reported lifestyle change and change in weight and HbA_{1c} level. This analysis revealed that patient self-reported lifestyle changes from baseline to 12 months were related to changes in body weight and HbA_{1c} level.

COMMENT

Motivating patients to adopt a healthy lifestyle during brief office visits is a major challenge facing clinicians. Traditional approaches to patient education and counseling usually rely on advice giving and direct persuasion, which have limited effectiveness.³⁰ Hence, we tested a patient education and brief health behavior change counseling intervention process that is based on patients selecting self-management goals in advance of meeting with their physician. This brief intervention is based on principles of effective health behavior change intervention and can be successfully used in brief primary care physician-patient encounters.³¹ Patients reported that support from their physician was the most important component of the intervention. The patients showed continued weight loss between 6 and 12 months, indicating that an approach encouraging modest lifestyle changes can produce sustained benefits over 1 year of intervention.

This brief motivational approach is well suited to the daily practice of a busy primary care clinic, where improved patient adherence to treatment recommendations is a priority. Motivational interviewing techniques provide patients with an opportunity to take a more active role in the change process. Use of motivational interviewing techniques by clinicians encourages patients to reflect on and express their own motivation for change.³² This process reduces or sidesteps patient resistance and is usually more satisfying to both the patient and the clinician.

Patients succeeded in using the computer-assisted patient assessment and identifying self-management goals during usual care clinic visits with a scheduled duration of 20 minutes. The modest intervention was well accepted and well used by both clinicians and patients. Intervention patient attendance rate with study-related visits was 90% or higher. The intervention appeared to help a subset of patients make meaningful behavior changes associated with clinically significant increases in physical activity and weight loss. In fact, the rate of clinically successful weight loss in the intervention group was 50% higher than in the control group or what would be expected by individuals attempting to lose weight through self-management alone.³³

Recent American Diabetes Association guidelines on physical activity/exercise found evidence to recom-

mend encouraging individuals with type 2 diabetes who are already exercising at moderate intensity to consider increasing the intensity of their exercise to obtain additional benefits.⁹ Because baseline activity levels were so low, this intervention primarily focused on getting patients to begin exercise and to try to achieve 150 minutes of activity per week at moderate levels. With the emergence of new evidence related to protective effects of more intense physical activity, additional opportunities to use this type of intervention could be very useful in busy clinical settings.

In regard to study limitations, group assignments (ie, intervention vs control) could not be blinded because intervention patients were engaged with discussions of their self-management goals with their physicians. All physicians had been trained in brief motivational counseling, so it is possible that physicians also improved their counseling methods for patients assigned to the control group. Evidence for this comes from the fact that subjects gained a mean of 5 lb (2.25 kg) in weight over the year prior to the study, but they gained much less, even in the control group, during the study. There were also 34 patients who dropped out of the study for whom end points and outcomes could not be assessed. Because there were more dropouts in the control group, and since dropping out is often correlated with poor intervention compliance, dropouts were not likely to have accounted for the positive findings we observed.

In summary, an intervention using patient self-management goal setting and brief physician health lifestyle counseling may be useful in producing positive behavioral change in patients with diabetes. Because the intervention was simple and the burden on physicians was low, it is conceivable that the core components of this simple intervention process could be adopted in other clinical settings.

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Author Contributions: Mr J. G. Christian had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* J. G. Christian, Bessesen, K. K. Christian, Goldstein, and Bock. *Acquisition of data:* J. G. Christian, Bessesen, and K. K. Christian. *Analysis and interpretation of data:* J. G. Christian, Bessesen, Byers, and Goldstein. *Drafting of the manuscript:* J. G. Christian, Bessesen, Byers, K. K. Christian, and Bock. *Critical revision of the manuscript for important intellectual content:* J. G. Christian, Bessesen, Goldstein, and Bock. *Statistical analysis:* J. G. Christian and Byers. *Obtained funding:* J. G. Christian, K. K. Christian, and Bock. *Administrative, technical, and material support:* J. G. Christian, Bessesen, and K. K. Christian. *Study supervision:* J. G. Christian and Bessesen.

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