Prevention of Diabetes Self-Management Program (PREDIAS): Effects on Weight, Metabolic Risk Factors, and Behavioral Outcomes

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OBJECTIVE — To evaluate the efficacy of the group program PREDIAS for diabetes prevention.

RESEARCH DESIGN AND METHODS — PREDIAS consists of 12 lessons and aims at lifestyle modification. The control group received written information about diabetes prevention. In this study, a total of 182 persons with an elevated diabetes risk participated (aged 56.3 ± 10.1 years, 43% female, and BMI 31.5 ± 5.3 kg/m^2).

RESULTS — After 12 months, weight loss was significantly higher ($P = 0.001$) in PREDIAS than in the control group (−3.8 ± 5.2 vs. −1.4 ± 4.09 kg). There were also significant effects ($P = 0.001$) on fasting glucose (control group 1.8 ± 13.1 mg/dl vs. PREDIAS −4.3 ± 11.3 mg/dl), duration of physical activity per week (control group 17.9 ± 63.8 min vs. PREDIAS 46.6 ± 95.5 min; $P = 0.03$), and eating behavior.

CONCLUSIONS — PREDIAS significantly modified lifestyle factors associated with an elevated diabetes risk.

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The prevalence of type 2 diabetes is increasing worldwide. Diabetes is associated with an increased risk for morbidity and mortality (1,2). Meta-analyses have shown that type 2 diabetes can be effectively prevented or delayed by lifestyle modification (3,4). We developed a group program (PREDIAS) for the prevention of type 2 diabetes that is based on the Diabetes Prevention Program (5,6). The aim of this randomized controlled trial was to evaluate in a 12-month follow-up the efficacy of PREDIAS with regard to the primary outcome variable, weight reduction, as well as behavioral, metabolic, and psychological outcomes as secondary variables.

RESEARCH DESIGN AND METHODS

— PREDIAS was compared with a control group whose members received the PREDIAS group intervention written information and patient materials. Inclusion criteria were those aged 20–70 years with BMI ≥26 kg/m^2, impaired glucose tolerance or impaired fasting glucose, and an ability to read and understand German. Exclusion criteria were manifest diabetes or diagnosis of a serious illness (e.g., cancer). All patients gave informed consent. The study was approved by the local ethics committee.

Individuals with an elevated diabetes risk based on a high score (>10) on the Diabetes Risk Score (7) or according to the assessment of a primary care physician were invited to a baseline examination. After a pool of 12–20 patients was created, a centrally performed block randomization (1:1) assigned subjects randomly to the PREDIAS or the control group.

The results refer to changes between baseline and the 12-month follow-up measurement. Patients underwent an oral glucose tolerance test. Weight, height, waist circumference, and blood pressure were assessed by study nurses, who were blinded to the treatment assignment of the subjects. Also, lipids and A1C were measured. Glucose was measured from capillary blood samples.

Physical activity was assessed by a physical activity questionnaire used in a representative federal health survey in Germany (8). Physical activity is reported as minutes per week. The Three Factor Eating Questionnaire, with the three scales cognitive restraint of eating, disinhibition, and hunger, was used to measure psychological determinants of eating behavior (9,10). Trait anxiety was measured by the State-Trait Anxiety Inventory (11). High scores on the scales always indicate a high parameter value.

The World Health Organization-Five Well-Being Index (WHO-5) assessed psychological well-being (12), and the Center for Epidemiologic Studies Depression Scale (CES-D) measured depressive symptoms (13). Low scores on the WHO-5 indicate reduced psychological well-being, whereas high scores on the CES-D indicate elevated depressive symptoms.

Statistical analysis

A power analysis showed that, assuming an additional weight reduction of 2.5 ± 4.6 kg and a power of $1-\beta = 0.90$ (two–sided $\alpha = 0.05$), 73 participants per group were appropriate. Calculating with a nonevaluable rate of maximum 20%, a total of 182 individuals (91 in each treatment group) was needed.

An intention-to-treat analysis was performed using the baseline observation carried forward method. Statistical analy-

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Table 1—*Baseline and 12-month follow-up results in the control group and the PREDIAS group*

	Control	PREDIAS	Between-group *P*-value
BMI (kg/m²)			
Baseline	32.0 ± 5.7	31.0 ± 4.7	
Endpoint	31.5 ± 5.8	29.7 ± 4.7	
Change from baseline to endpoint	−0.5 ± 1.4 ($P = 0.002$)*	−1.3 ± 1.7 ($P < 0.001$)*	0.002
Weight (kg)			
Baseline	93.6 ± 19.3	92.1 ± 16.5	
Endpoint	92.2 ± 19.4	88.3 ± 15.9	
Change from baseline to endpoint	−1.4 ± 4.0 ($P = 0.002$)*	−3.8 ± 5.2 ($P < 0.001$)*	0.001
Waist circumference (cm)			
Baseline	106.3 ± 13.7	106.8 ± 13.7	
Endpoint	105.9 ± 14.1	102.7 ± 12.5	
Change from baseline to endpoint	−0.4 ± 6.2 ($P = 0.559$)*	−4.1 ± 6.0 ($P < 0.001$)*	0.001
Fasting glucose (mg/dl)			
Baseline	105.5 ± 12.4	105.7 ± 12.4	
Endpoint	107.3 ± 14.3	101.4 ± 11.3	
Change from baseline to endpoint	1.8 ± 13.1 ($P = 0.211$)*	−4.3 ± 11.3 ($P = 0.001$)*	0.001
2-h postprandial OGTT (mg/dl)			
Baseline	138.5 ± 34.9	133.1 ± 36.2	
Endpoint	130.3 ± 36.1	125.8 ± 41.3	
Change from baseline to endpoint	−8.2 ± 36.9 ($P = 0.060$)*	−7.3 ± 30.8 ($P = 0.041$)*	0.865
A1C (%)			
Baseline	5.7 ± 0.6	5.7 ± 0.5	
Endpoint	5.8 ± 0.5	5.7 ± 0.4	
Change from baseline to endpoint	0.1 ± 0.4 ($P = 0.165$)*	0.0 ± 0.3 ($P = 0.203$)*	0.060
Physical exercise (min/week)			
Baseline	96.9 ± 76.3	104.2 ± 80.24	
Endpoint	114.0 ± 72.6	150.8 ± 75.18	
Change from baseline to endpoint	17.9 ± 63.8 ($P = 0.035$)*	46.6 ± 95.5 ($P < 0.001$)*	0.034
Total cholesterol (mg/dl)			
Baseline	209.9 ± 36.6	212.2 ± 43.8	
Endpoint	207.9 ± 36.8	201.9 ± 35.6	
Change from baseline to endpoint	−2.0 ± 35.1 ($P = 0.607$)*	−10.3 ± 35.9 ($P = 0.011$)*	0.144
HDL cholesterol (mg/dl)			
Baseline	53.5 ± 13.2	55.9 ± 14.1	
Endpoint	51.3 ± 14.5	54.6 ± 14.9	
Change from baseline to endpoint	−2.2 ± 9.4 ($P = 0.044$)*	−1.3 ± 6.9 ($P = 0.104$)*	0.479
Triglycerides (mg/dl)			
Baseline	144.1 ± 102.1	156.2 ± 151.0	
Endpoint	141.6 ± 99.5	120.6 ± 65.5	
Change from baseline to endpoint	−2.5 ± 100.3 ($P = 0.823$)*	−35.6 ± 136.8 ($P = 0.022$)*	0.087
Systolic blood pressure (mmHg)			
Baseline	139.1 ± 15.9	141.8 ± 18.6	
Endpoint	138.1 ± 15.3	137.2 ± 17.1	
Change from baseline to endpoint	−1.0 ± 16.7 ($P = 0.610$)*	−4.6 ± 19.1 ($P = 0.035$)*	0.217
Diastolic blood pressure (mmHg)			
Baseline	87.3 ± 9.7	88.5 ± 10.5	
Endpoint	85.2 ± 12.3	84.1 ± 10.4	
Change from baseline to endpoint	−2.1 ± 12.6 ($P = 0.151$)*	−4.4 ± 11.7 ($P = 0.001$)*	0.255
TFEQ			
Cognitive restraint			
Baseline	10.2 ± 4.3	10.0 ± 4.0	
Endpoint	11.7 ± 4.7	13.9 ± 4.2	
Change from baseline to endpoint	1.5 ± 3.0 ($P < 0.001$)*	3.9 ± 3.8 ($P < 0.001$)*	0.0011
Disinhibition			
Baseline	6.3 ± 3.9	6.1 ± 3.2	
Endpoint	5.8 ± 3.9	4.9 ± 2.6	
Change from baseline to endpoint	−0.4 ± 2.6 ($P = 0.247$)*	−1.2 ± 2.7 ($P < 0.001$)*	0.049

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Table 1—*Continued*

	Control	PREDIAS	Between-group *P*-value
Hunger			
Baseline	4.9 ± 3.8	4.5 ± 3.4	
Endpoint	4.7 ± 3.8	3.4 ± 3.1	
Change from baseline to endpoint	−0.2 ± 2.7 (P = 0.434)*	−1.1 ± 3.1 (P = 0.002)*	0.066
Psychological well-being by WHO-5			
Baseline	14.3 ± 4.9	15.3 ± 5.1	
Endpoint	14.3 ± 5.1	16.7 ± 4.8	
Change from baseline to endpoint	0.0 ± 4.2 (P = 0.901)*	1.4 ± 3.9 (P = 0.015)*	0.101
Depression by CES-D			
Baseline	13.7 ± 8.2	12.0 ± 9.5	
Endpoint	11.4 ± 7.8	9.8 ± 7.5	
Change from baseline to endpoint	−2.3 ± 6.8 (P = 0.009)*	−2.2 ± 7.7 (P = 0.031)*	0.876
Trait Anxiety by STAI			
Baseline	39.5 ± 9.8	38.5 ± 10.4	
Endpoint	38.5 ± 9.5	34.5 ± 9.5	
Change from baseline to endpoint	−1.0 ± 6.1 (P = 0.142)*	−3.5 ± 7.1 (P = 0.001)*	0.023

Data are means ± SD. *P = within group test. OGGT, oral glucose tolerance test; STAI, State-Trait Anxiety Inventory; TFEQ, Three Factor Eating Questionnaire.

ses were performed by paired *t* tests for within-group differences and independent *t* tests for between-group differences.

Program

The prevention program consisted of 12 lessons lasting ~90 min each. During the first 8 weeks, eight core lessons were given with one per week; the last four lessons were bimonthly booster lessons. The PREDIAS program, which is based on self-management theory, was conducted in small groups (median size seven people). PREDIAS was delivered by either diabetes educators or psychologists. The program comprised a set of transparencies for the lessons and a curriculum for the prevention manager. Each participant received an exercise book, which contained information about diabetes prevention. This book also contained resources for the participants such as a table of caloric values and worksheets (e.g., eating diaries and logbooks for physical activity) for each lesson. More details about PREDIAS can be accessed at the homepage of the European Union Project: Development and Implementation of a European Guideline and Training Standards for Diabetes Prevention (IMAGE) at http://www.image-project.eu/pdf/praedias (14).

RESULTS — A total of 182 participants were randomized (aged 56.3 ± 10.1 years, 43% female, education 13.2 ± 4.1 years, BMI 31.5 ± 5.3 kg/m^2, fasting glucose 105.7 ± 12.8 mg/dl, and 2-h postprandial postoral glucose 135.7 ± 35.8 mg/dl). There were no significant baseline differences between those in the PREDIAS and the control group. The study lost 17 participants (9.3%) to follow-up. A dropout analysis showed no significant differences between participants who remained in the study and those who dropped out.

After 12 months, there was a significant effect on body weight (Table 1). Participants in the PREDIAS group had lost 3.8 kg of weight, whereas members of the control group had reduced their weight by 1.4 kg (P = 0.001). An intention-to-treat analysis yielded similar results (control group −1.3 ± 3.9 kg vs. PREDIAS group −3.6 ± 5.1 kg; $P < 0.001$). A significantly higher proportion of weight was lost by those in the PREDIAS than in the control group (4 ± 5.4 vs. 1.6 ± 4.1%, respectively; P = 0.002). Similar results were obtained regarding BMI and waist circumference.

Both groups increased their physical activity significantly, but the increase was significantly greater in the PREDIAS than in the control group. Cognitive restraint of eating behavior was significantly more increased in the PREDIAS than in the control group, and eating disinhibition was significantly more decreased in the PREDIAS than in the control group. Members of the PREDIAS group showed a significant within-group reduction on the hunger scale, but there was no significant between-group difference.

There was a significant effect of PREDIAS on fasting glucose; however, the 2-h postprandial glucose values and A1C did not change significantly between the groups. Total cholesterol and triglycerides, as well as systolic and diastolic blood pressure, were significantly reduced in the PREDIAS group, whereas in the control group there was no substantial change in these risk factors. However, the between-group difference failed to reach significance.

In both groups, psychological well-being increased, whereas anxiety and depressive symptoms decreased. However, except for anxiety, there were no significant differences between the two groups.

CONCLUSIONS — The PREDIAS prevention program was able to reduce weight and modify eating behavior and physical activity significantly; thus, diabetes risk was reduced. The magnitude of these effects and the observed metabolic changes were in the range of previously published results of diabetes prevention programs (3–5,15).

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