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

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/m²).

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.
Efficacy of a diabetes prevention group program

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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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.

months 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/pd/predias (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/m², 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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