

**Efficacy of a behavioral lifestyle intervention group program (PREDIAS) for the prevention of type 2 diabetes.**

Bernhard Kulzer (PhD)<sup>1</sup>, Norbert Hermanns (PhD)<sup>1</sup>, Daniela.Gorges (MA)<sup>1</sup>, Peter. Schwarz (MD)<sup>2</sup>, Thomas Haak (PhD)<sup>1</sup>

<sup>1</sup>Research Institute of the Diabetes Academy Mergentheim & Diabetes Centre Mergentheim, Bad Mergentheim, Germany

<sup>2</sup>Department of Medicine, University of Dresden, Carl Gustav Carus, Dresden, Germany

**Correspondence Address**

Prof. Dr. Norbert Hermanns

E-mail: [hermanns@diabetes-zentrum.de](mailto:hermanns@diabetes-zentrum.de)

Clinical Trials Reg. No: NCT00707447, [clinicaltrials.gov](http://clinicaltrials.gov)

Submitted 2 December 2008 and accepted 6 March 2009.

This is an uncopyedited electronic version of an article accepted for publication in *Diabetes Care*. The American Diabetes Association, publisher of *Diabetes Care*, is not responsible for any errors or omissions in this version of the manuscript or any version derived from it by third parties. The definitive publisher-authenticated version will be available in a future issue of *Diabetes Care* in print and online at <http://care.diabetesjournals.org>.

*Introduction:* The objective of this randomized, prospective trial was to evaluate the efficacy of a group program (PREDIAS) for diabetes prevention.

*Design and Methods:* PREDIAS consists of 12 lessons and aims at the modification of lifestyle. The control group (CG) received written information about diabetes prevention. In this study, a total of 182 persons with an elevated diabetes risk participated (age  $56.3 \pm 10.1$  yrs; 43% female; BMI  $31.5 \pm 5.3$  kg/m<sup>2</sup>).

*Results:* After 12 months, weight loss was significantly higher ( $p = .001$ ) in PREDIAS than in the CG ( $-3.8 \pm 5.2$  kg vs.  $-1.4 \pm 4.09$  kg). There were also significant effects ( $p = .001$ ) on fasting glucose (CG  $+1.8 \pm 13.1$  mg/dl vs. PREDIAS  $-4.3 \pm 11.3$  mg/dl), duration of physical activity per week (CG  $+17.9 \pm 63.8$  minutes vs. PREDIAS  $+46.6 \pm 95.5$  minutes;  $p = .03$ ), and eating behavior.

*Conclusion:* PREDIAS significantly modified lifestyle factors associated with an elevated diabetes risk.

**Clinical Trials ID: NCT00707447**

The prevalence of type 2 diabetes is increasing worldwide. Diabetes mellitus 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 (CG), whose members received the written information and written patient materials of the PREDIAS group intervention.

**Sample:** Inclusion criteria were age between 20 and 70 years, BMI  $\geq 26$  kg/m<sup>2</sup>, impaired glucose tolerance *or* impaired fasting glucose, and ability to read and understand German. Exclusion criteria were manifest diabetes mellitus 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 to 20 patients was created, a centrally performed block randomization (1:1) assigned subjects randomly to PREDIAS or the CG.

**Measures:** 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 about 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 WHO-Five Well-being Index assessed psychological well-being (12) and the Center for Epidemiologic Studies Depression Scale 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 kg ( $\pm 4.6$  kg) and a power of  $1-\beta=.90$  (two sided  $\alpha = .05$ ), 73 participants per group were appropriate. Calculating with a non-evaluable 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 analyses 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 approximately 90 minutes each. During the first eight weeks, eight core lessons were given—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 7 persons). 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 IMAGE-project (14).

## RESULTS

A total of 182 participants were randomized (age  $56.3 \pm 10.1$  yrs; 43% female; education  $13.2 \pm 4.1$  years; BMI  $31.5 \pm 5.3$  kg/m<sup>2</sup>; fasting glucose  $105.7 \pm 12.8$  mg/dl; 2 hours post oral glucose  $135.7 \pm 35.8$  mg/dl). There were no significant baseline differences between PREDIAS and the CG. At follow-up, 17 participants (9.3%) were lost to follow-up. A dropout analysis showed no significant differences between participants who remained in the study and those who dropped out.

**Body weight and waist circumference:** After 12 months, there was a significant effect on body weight. Participants in PREDIAS had lost 3.8 kg of weight, whereas members of the CG had reduced their weight by 1.4 kg ( $p = .001$ ). An intention to treat analysis yielded similar results (CG:  $-1.3 \pm 3.9$  kg vs. PREDIAS:  $-3.6 \pm 5.1$  kg;  $p < .001$ ).

A significantly higher proportion of weight was lost in PREDIAS than in the CG ( $4\% \pm 5.4\%$  vs.  $1.6\% \pm 4.1\%$ ;  $p = .002$ ). Similar results were obtained regarding BMI and waist circumference.

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

**Metabolic risk factors:** There was a significant effect of PREDIAS on fasting glucose, however, the 2-hour 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 PREDIAS, whereas in the CG there was no substantial change in these risk factors. However, the difference between the groups failed to reach significance.

Psychological well-being

In both groups, psychological well-being increased, whereas anxiety and depressive symptoms decreased, but, except anxiety, there was no significant difference between the two groups.

## CONCLUSION

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).

## ACKNOWLEDGMENT

The conduct of this study was supported by an unrestricted grant from Roche Diagnostics, Germany. We also want to thank the Siemens AG, Erlangen, the cities

of Erlangen and Wuerzburg as well as the Association of Primary Care Physicians in Wuerzburg and the “Main Tauber Country”, Germany, for their collaboration.

**Conflict of Interest Statement:**

There is no potential conflict of interest related to this article of any authors.

**REFERENCES**

1. Zimmet P, Alberti KG, Shaw J: Global and societal implications of the diabetes epidemic. *Nature* 414:782-787, 2001
2. Schwarz PE, Schwarz J, Schuppenies A, Bornstein SR, Schulze J: Development of a diabetes prevention management program for clinical practice. *Public Health Rep.* 122:258-263, 2007
3. Gillies CL, Abrams KR, Lambert PC, Cooper NJ, Sutton AJ, Hsu RT, Khunti K: Pharmacological and lifestyle interventions to prevent or delay type 2 diabetes in people with impaired glucose tolerance: systematic review and meta-analysis. *BMJ* 334:299, 2007
4. Orozco LJ, Buchleitner AM, Gimenez-Perez G, Roque IF, Richter B, Mauricio D: Exercise or exercise and diet for preventing type 2 diabetes mellitus. *Cochrane.Database.Syst.Rev.* CD003054, 2008
5. Diabetes Prevention Program Research Group: Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med* 346:393-403, 2002
6. Diabetes Prevention Program Research Group: The Diabetes Prevention Program (DPP). Description of lifestyle intervention. *Diabetes Care* 25:2165-2171, 2002
7. Lindström J, Tuomilehto J: The diabetes risk score: a practical tool to predict type 2 diabetes risk. *Diabetes Care* 26:725-731, 2003
8. Mensink GBM: Körperliche Aktivität [Physical activity]. *Gesundheitswesen* 61 Sonderheft 2:S216-S131, 1999
9. Pudel V, Westenhöfer J: *Fragebogen zum Ernährungsverhalten (FEV) [Questionnaire about eating behavior]*. Hogrefe: Göttingen 1989.
10. Stunkard AJ, Messick S: The three factor eating questionnaire to measure dietary restraint, disinhibition and hunger. *Journal for Psychosomatic Research* 29:71-83, 1985
11. Laux L, Glanzmann P, Schaffner P, Spielberger D: *Das State-Trait-Angstinventar. Theoretische Grundlagen und Handanweisung [The State Trait Anxiety Inventory. Theoretical principles and manual]*. Beltz, Weinheim, 1981
12. Psychiatric Research Unit and WHO Collaborating Center for Mental Health. WHO-Five Well-being Index (WHO-5). <http://www.who-5.org/>. 1998. (last accessed 01/15/2009)
13. Hautzinger M, Bailer J: *Allgemeine Depressions-Skala [General Depression Scale]*. Göttingen, Hogrefe, 1993
14. IMAGE Project Management. IMAGE (Development and Implementation of a European Guideline and Training Standards for Diabetes Prevention). <http://www.image-project.eu/download.aspx> . 2009.
15. Tuomilehto J, Lindström J, Eriksson JG, Valle TT, Hämäläinen H, Ilanne-Parikka P, Keinänen-Kiukaanniemi S, Laakso M, Louheranta A, Rastas M, Salminen V, Uusitupa M: Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med* 344:1343-1350, 2001

**Table 1:** Baseline and 12-month follow-up results in CG and PREDIAS

|   | Control                 | PREDIAS                  | p between groups |
|---|-------------------------|--------------------------|------------------|
| <b>BMI (kg/m<sup>2</sup>)</b>           |                         |                          |                  |
| Baseline                                | 32.0 (±5.7)             | 31.0 (±4.7)              |                  |
| Endpoint                                | 31.5 (±5.8)             | 29.7 (±4.7)              |                  |
| Change baseline endpoint                | - 0.5 (±1.4) (p=.002)*  | - 1.3 (±1.7) (p<.001)    | .002             |
| <b>Weight (kg)</b>                      |                         |                          |                  |
| Baseline                                | 93.6 (±19.3)            | 92.1 (±16.5)             |                  |
| Endpoint                                | 92.2 (±19.4)            | 88.3 (±15.9)             |                  |
| Change baseline endpoint                | - 1.4 (±4.0) (p=.002)   | - 3.8 (±5.2) (p<.001)    | .001             |
| <b>Waist circumference (cm)</b>         |                         |                          |                  |
| Baseline                                | 106.3 (±13.7)           | 106.8 (±13.7)            |                  |
| Endpoint                                | 105.9 (±14.1)           | 102.7 (±12.5)            |                  |
| Change baseline endpoint                | - 0.4 (±6.2) (p=.559)   | - 4.1 (±6.0) (p<.001)    | .001             |
| <b>Fasting glucose (mg/dl)</b>          |                         |                          |                  |
| Baseline                                | 105.5 (±12.4)           | 105.7 (±12.4)            |                  |
| Endpoint                                | 107.3 (±14.3)           | 101.4 (±11.3)            |                  |
| Change baseline endpoint                | + 1.8 (±13.1) (p=.211)  | - 4.3 (±11.3) (p=.001)   | .001             |
| <b>OGTT 2 hour pp (mg/dl)</b>           |                         |                          |                  |
| Baseline                                | 138.5 (±34.9)           | 133.1 (±36.2)            |                  |
| Endpoint                                | 130.3 (±36.1)           | 125.8 (±41.3)            |                  |
| Change baseline endpoint                | - 8.2 (±36.9) (p=.060)  | - 7.3 (±30.8) (p=.041)   | .865             |
| <b>A1c (%)</b>                          |                         |                          |                  |
| Baseline                                | 5.7 (±0.6)              | 5.7 (±0.5)               |                  |
| Endpoint                                | 5.8 (±0.5)              | 5.7 (±0.4)               |                  |
| Change baseline endpoint                | + 0.1 (±0.4) (p=.165)   | 0.0 (±0.3) (p=.203)      | .060             |
| <b>Physical exercise (min per week)</b> |                         |                          |                  |
| Baseline                                | 96.9 (±76.3)            | 104.2 (±80.24)           |                  |
| Endpoint                                | 114.0 (±72.6)           | 150.8 (±75.18)           |                  |
| Change baseline endpoint                | + 17.9 (±63.8) (p=.035) | + 46.6 (±95.5) (p<.001)  | .034             |
| <b>Total cholesterol (mg/dl)</b>        |                         |                          |                  |
| Baseline                                | 209.9 (±36.6)           | 212.2 (±43.8)            |                  |
| Endpoint                                | 207.9 (±36.8)           | 201.9 (±35.6)            |                  |
| Change baseline endpoint                | - 2.0 (±35.1) (p=.607)  | - 10.3 (±35.9) (p=.011)  | .144             |
| <b>HDL-cholesterol (mg/dl)</b>          |                         |                          |                  |
| Baseline                                | 53.5 (±13.2)            | 55.9 (±14.1)             |                  |
| Endpoint                                | 51.3 (±14.5)            | 54.6 (±14.9)             |                  |
| Change baseline endpoint                | - 2.2 (±9.4) (p=.044)   | - 1.3 (±6.9) (p=.104)    | .479             |
| <b>Triglycerides (mg/dl)</b>            |                         |                          |                  |
| Baseline                                | 144.1 (±102.1)          | 156.2 (±151.0)           |                  |
| Endpoint                                | 141.6 (±99.5)           | 120.6 (±65.5)            |                  |
| Change baseline endpoint                | - 2.5 (±100.3) (p=.823) | - 35.6 (±136.8) (p=.022) | .087             |
| <b>Systolic blood pressure mmHg</b>     |                         |                          |                  |
| Baseline                                | 139.1 (±15.9)           | 141.8 (±18.6)            |                  |
| Endpoint                                | 138.1 (±15.3)           | 137.2 (±17.1)            |                  |
| Change baseline endpoint                | - 1.0 (±16.7) (p=.610)  | - 4.6 (±19.1) (p=.035)   | .217             |
| <b>Diastolic blood pressure mmHg</b>    |                         |                          |                  |
| Baseline                                | 87.3 (±9.7)             | 88.5 (±10.5)             |                  |
| Endpoint                                | 85.2 (±12.3)            | 84.1 (±10.4)             |                  |
| Change baseline endpoint                | - 2.1 (±12.6) (p=.151)  | - 4.4 (±11.7) (p=.001)   | .255             |
| <b>TFEQ: cognitive restraint</b>        |                         |                          |                  |
| Baseline                                | 10.2 (±4.3)             | 10.0 (±4.0)              |                  |

|                                       |                       |                       |       |
|---------------------------------------|-----------------------|-----------------------|-------|
| Endpoint                              | 11.7 (±4.7)           | 13.9 (±4.2)           |       |
| Change baseline endpoint              | + 1.5 (±3.0) (p<.001) | + 3.9 (±3.8) (p<.001) | .0011 |
| <b>TFEQ: disinhibition</b>            |                       |                       |       |
| Baseline                              | 6.3 (±3.9)            | 6.1 (±3.2)            |       |
| Endpoint                              | 5.8 (±3.9)            | 4.9 (±2.6)            |       |
| Change baseline endpoint              | - 0.4 (±2.6) (p=.247) | - 1.2 (±2.7) (p<.001) | .049  |
| <b>TFEQ: hunger</b>                   |                       |                       |       |
| Baseline                              | 4.9 (±3.8)            | 4.5 (±3.4)            |       |
| Endpoint                              | 4.7 (±3.8)            | 3.4 (±3.1)            |       |
| Change baseline endpoint              | -0.2 (±2.7) (p=.434)  | -1.1 (±3.1) (p=.002)  | .066  |
| <b>Psychological well-being WHO-5</b> |                       |                       |       |
| Baseline                              | 14.3 (±4.9)           | 15.3 (±5.1)           |       |
| Endpoint                              | 14.3 (±5.1)           | 16.7 (±4.8)           |       |
| Change baseline endpoint              | +0.0 (±4.2) (p=.901)  | +1.4 (±3.9) (p=.015)  | .101  |
| <b>Depression CES-D</b>               |                       |                       |       |
| Baseline                              | 13.7 (±8.2)           | 12.0 (±9.5)           |       |
| Endpoint                              | 11.4 (±7.8)           | 9.8 (±7.5)            |       |
| Change baseline endpoint              | -2.3 (±6.8) (p=.009)  | -2.2 (±7.7) (p=.031)  | .876  |
| <b>Trait Anxiety STAI</b>             |                       |                       |       |
| Baseline                              | 39.5 (±9.8)           | 38.5 (±10.4)          |       |
| Endpoint                              | 38.5 (±9.5)           | 34.5 (±9.5)           |       |
| Change baseline endpoint              | -1.0 (±6.1) (p=.142)  | - 3.5 (±7.1) (p=.001) | .023  |

Values are means (± SD); \* p in parentheses = within group test