



Effects of a self-management oriented education program (MEDIAS 2) on glycemic control and body weight in type 2 diabetic patients

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Introduction:

The review of Norris et al. (2001) summarizes that, despite the popularity of the self-management concept for education of type 2 diabetic patients, there is a lack for thoroughly evaluated diabetes education concepts, according to methodological criteria like randomization, intention to treat analysis and prospective trials. In a randomized, prospective trial, sponsored by the German Federal Ministry of Education and Research (BMBF), we tested whether two newly developed behavioral medical treatment programs were more effective than a formerly evaluated structured treatment and teaching program for type 2 diabetes (STANDARD treatment; 4 lessons). According to the National Standards for Diabetes Self-management Education Programs of the American Diabetes Association (ADA) and the guidelines for education of the German Diabetes Association (DDG), the newly developed programs were designed to enhance self-management abilities of type 2 diabetes patients to cope with the demands of diabetes treatment (e.g. modification of eating behavior, physical activity, home monitoring of urine glucose or blood glucose, diabetic foot care, blood pressure, weight reduction, and maintenance of reduced body weight). One of the two treatments was performed in a group setting (MEDIAS 2; 12 lessons), whereas the other program was designed to individualize the therapeutic approach by a mixture of 6 single and 6 group lessons (COMBINATION; 12 lessons). The hypotheses were that MEDIAS 2 is more effective than STANDARD, and COMBINATION is more effective than MEDIAS 2 respectively. Outcome measures included (1) physiological variables, (2) behavioral parameters, (3) processes measures, (4) psychosocial well-being and (4) economic measures.

Methods:

All type 2 diabetic patients (age between 40 and 65 years) in a German district around Würzburg with 463000 inhabitants were offered the participation in this study. 480 persons were screened and 193 type 2 diabetic patients decided to participate, meeting the following inclusion criteria: age 40-65 years; no insulin treatment, stimulated C-peptide level >0,8 nmol/l; Body Mass Index (BMI) > 26,7 kg/m²; no known psychiatric diagnosis. These patients were randomized (for sample characteristics see table 1). In spite of the relatively short diabetes duration and comparatively young age, the baseline examination disclosed a surprisingly high prevalence of diabetes associated complications (15,2% retinopathy, 6,4% CHD, 2,3% stroke, 37,7% reduced sensitivity in legs, 87% hypertension). Dependent variables were:
 - *Physiological measures:* HbA1c, fasting blood glucose, triglycerides, total cholesterol, body mass index (BMI);
 - *Behavioral parameters:* physical activity and foot self care (self report);
 - *Process variable:* knowledge test for type 2 diabetic patients (W2D);
 - *Psychological well-being:* depression (Zerssen DS) and anxiety (trait version of STAD);
 - *Economic measures:* diabetes related direct costs (inpatient treatment costs, costs for antidiabetic drugs and cost saving through prevention of insulin therapy).
 The crucial measurement for testing the above hypotheses was 12 months after the end of the programs. For statistical analysis, t-tests or Man Whitney Tests were used, if variance homogeneity or normal distribution were not given.

Results:

Physiological measures: According to the first hypothesis, there were significant differences between group STANDARD and MEDIAS 2 in HbA1c (figure 1), fasting blood glucose (figure 3), and triglyceride levels (figure 5). The effect on HbA1c was clinically meaningful (figure 2). BMI improved most in MEDIAS 2, but this effect did not reach statistical significance (figure 4). There was no significant effect on cholesterol levels (figure 6).
Process variables: The process variable knowledge did not differ between the two groups (figure 7).
Psychological well-being: A significant reduction in anxiety scores and a reduction of the depression score (figure 8 and 9) are indicating, that there were no signs of a deterioration of psychosocial well-being as a possible negative consequence of the life style modification.
Behavioral measures: Behavioral measures demonstrated a significant advantage for MEDIAS 2 in physical activity and foot care (figure 10 and 11).
Economic measures: Economic analysis (figure 12 and 13) revealed a total cost savings of 216 USD per year for MEDIAS 2.
 Surprisingly, there was no further benefit of the more individualized approach (COMBINATION) compared with MEDIAS 2. Furthermore, the improvement of HbA1c was not a consequence of a different treatment with antidiabetic drugs. At the end of the study the proportion of patients treated with oral antidiabetic agents were equivalent in all three groups (60,6% vs. 62,5% vs. 67,2% p=.736).

Conclusion:

In a comprehensive evaluation, MEDIAS 2 proved to be as an effective and cost efficient program. There were benefits in physiological, psychosocial, behavioral, and economic outcomes. With an annual saving of 216 USD per patient, there are financial resources for a reimbursement for training type 2 diabetic persons with MEDIAS 2. In this study the group, lessons proved to be more effective than a combination of an individualized and group approach (COMBINATION). Therefore it seems sensible to integrate MEDIAS 2 in the regular outpatient treatment of middle aged type 2 diabetes patients who will profit from tight glycemic control.

Variable	all groups	Standard	MEDIAS 2	Combination	P
n	193	64	63	66	-
age (yr)	55.6 ±6.3	55.1 ±5.6	56.1 ±6.8	55.5 ±6.5	.68
gender (% female)	49.7	43.8	52.4	53	.56
disease duration (yr)	6.6 ±6.2	6.1 ±5.5	6.6 ±6.6	7.0 ±6.5	.72
HbA1c (%)	7.9 ±1.6	7.7 ±1.6	8.1 ±1.8	7.8 ±1.6	.36
BMI (kg/m ²)	32.3 ±3.9	32.1 ±3.6	32.2 ±3.9	32.6 ±4.1	.74
% OAD	68.4	68.7	61.9	74.2	.32

table 1: sample characteristics

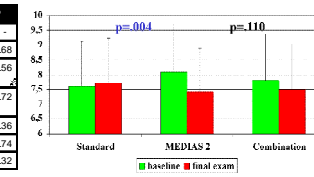


figure 1: HbA1c

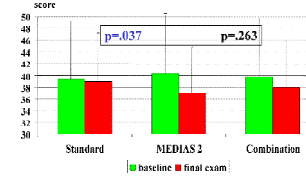


figure 8: trait anxiety

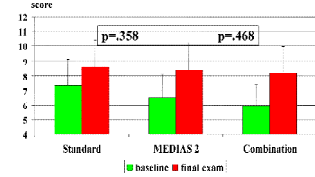


figure 9: depression

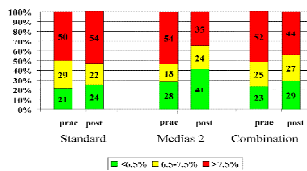


figure 2: clinical relevance according to national guidelines

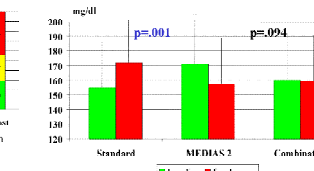


figure 3: fasting blood glucose

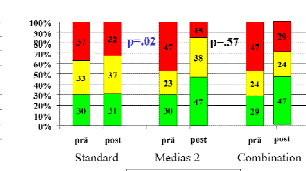


figure 10: physical activity

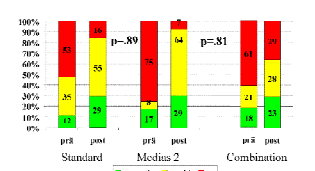


figure 11: diabetic foot care

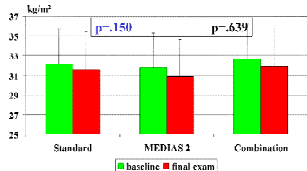


figure 4: BMI

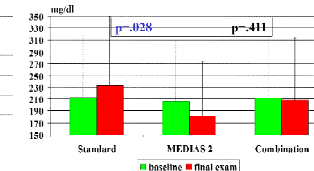


figure 5: triglyceride

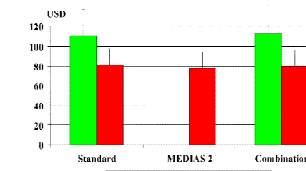


figure 12: costs inpatient treatment and OAD

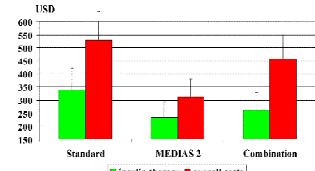


figure 13: prevention of insulin therapy and overall costs

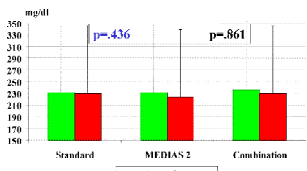


figure 6: cholesterol

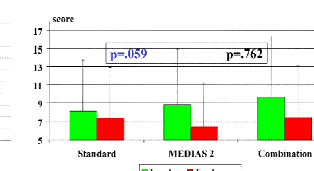


figure 7: knowledge

Abstract: We studied the efficacy of three different outpatient education programs for middle aged non-insulin-dependent type 2 diabetic persons: (1) self-management oriented program, performed in group lessons (MEDIAS 2); (2) combination treatment with group lessons and individual counseling (combination); (3) conventional structured education program aiming at knowledge transfer (standard). In a prospective randomized trial we tested the efficacy of these programs. The key outcome variables were glycemic control and body weight 12 months after the end of the different treatments. Eligibility criteria were: manifest diabetes type 2, no insulin treatment, stimulated C-peptide 0.8 nmol/L, age between 40 and 65 years, obesity (BMI 26.7 kg/m²), no psychiatric diagnosis. Subjects: 193 type 2 diabetic subjects (age 55.5 ± 7.2 years; HbA1c 7.8 ± 1.7%, BMI 32.1 ± 3.9 kg/m²) were randomized. Baseline examination revealed no relevant differences in the main outcome variables. According to intention to treat analysis 181 subjects could be re-examined at the decisive measurement-point 12 months after the end of the treatments (dropout rate 6.2%). The oral diabetes medication was equivalent in all three groups. There was a significant advantage of MEDIAS 2 (p=0.14) with respect to glycemic control (DHbA1c -0.7 ± 1.4%), compared with the combination (DHbA1c -0.3 ± 0.6%) and with the standard treatment (DHbA1c 0.1 ± 1.5%). Body weight improved most in MEDIAS 2 (BMI -0.9 ± 1.5 kg/m²) compared with the standard (BMI -0.5 ± 1.6 kg/m²) and with the combination treatment (BMI -0.7 ± 1.5 kg/m²; p=.32). The self-management oriented group program (MEDIAS 2) achieved the best effects on metabolic control for middle aged non-insulin-dependent type 2 diabetic persons. Therefore the integration of this program in the regular outpatient diabetes education should be considered.