

# The Effect of an Education Program (MEDIAS 2 ICT) for Type 2 Diabetic Patients with Intensive Insulin Therapy

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**Introduction:** We developed a new diabetes education program for people with type 2 diabetes that involves intensive insulin treatment (MEDIAS 2 ICT: **More Diabetes Self-management for Type 2 Diabetes** – Intensive Conventional Insulin Therapy). The objectives of MEDIAS 2 ICT are to enhance the self-management abilities in people with type 2 diabetes to perform intensive insulin therapy effectively into their daily routine, reduce diabetes-related distress, and improve self-care behavior. Patients who have type 2 diabetes and utilize an intensive insulin treatment should be enabled to improve glycaemic control by integrating the task of insulin treatment into daily routine, thus maintaining an optimal quality of life. The aim of this study was to evaluate the efficacy of MEDIAS 2 ICT in a randomized, prospective trial. In order to compare the efficacy of MEDIAS 2 ICT we have chosen a combination of two established education programs that were of equal length than MEDIAS 2 ICT as an active comparator condition (ACC). Because meta-analyses have shown the efficacy of diabetes education per se, the primary objective of the study was to demonstrate the non-inferiority of MEDIAS 2 ICT compared with the ACC control group regarding improvement of glycaemic control. Secondary objectives were the analyses of the impact of this program on diabetes-related distress, diabetes knowledge, self-care behavior, quality of life, and metabolic risk factors (lipids, blood pressure, body mass index).

**Methods:** The MEDIAS 2 ICT program was based on a self-management/empowerment approach. It was conducted as a group program comprising 10 lessons of 90 minutes each. MEDIAS 2 ICT was designed to help patients perform multiple-injection insulin therapy and adjust their insulin doses depending on carbohydrate consumption, physical exercise, and pre-prandial glucose levels. In addition, MEDIAS 2 ICT focused on controlling metabolic risk factors such as elevated lipids and blood pressure. A key element of the empowerment/self-management approach of MEDIAS 2 ICT is shared decision making between patients and diabetes educators concerning realistic treatment goals. The active comparator condition consisted of a combination of two previously established and evaluated education programs - a diabetes education program to initiate mealtime insulin and a hypertension education program for treatment of hypertension. These education programs were developed in the 1980s and 1990s and were more didactic-oriented, focusing primarily on the acquisition of knowledge, skills, and information about the correct treatment of diabetes and hypertension. Patients who participated in this study had a relatively long diabetes duration with an average insulin treatment of 5 years. The daily injections were frequent and thus indicated a rather intensified insulin regimen. In spite of the intensified insulin treatment, glycaemic control was unsatisfactory. The number of diabetes-related complications indicated a rather high co-morbidity. Except for gender distribution, demographic and other clinical baseline characteristics were much the same between the two groups at baseline (see Table 1).

- Results:** After the 6-month follow-up the following results could be observed:
- A1c could be reduced by 0.37 percentage points in the control group and by 0.63 percentage points in MEDIAS 2 ICT. The mean difference between both groups was -0.26 in favor of MEDIAS 2 ICT, with a 95% confidence interval from -0.63 percentage points to 0.14 percentage points. Thus, non-inferiority of MEDIAS 2 ICT could be demonstrated clearly because the confidence interval stayed under the non-inferiority threshold of 0.4 percentage points (see Figure 1 and 2).
  - Diabetes-related distress could be significantly reduced in MEDIAS 2 ICT, whereas diabetes-related distress remained largely unchanged in ACC. The adjusted between group difference was significant in favor of MEDIAS 2 ICT (Figure 3).
  - Participants in MEDIAS 2 ICT showed a significant improvement in the Physical Composite Score of the SF-12, indicating a significant improvement in health-related quality of life, whereas members of the ACC group did not report a significant improvement. Adjusted between group differences did not reach the significance level (Figure 4).
  - As expected, both interventions led to a significant improvement in diabetes knowledge, with remarkable effect sizes of Cohen's d = 0.4 (control group) and Cohen's d = 0.5 (MEDIAS 2 ICT). This improvement did not differ between the two groups (Figure 5).
  - Self-reported self-care behavior was significantly increased in MEDIAS 2 ICT, whereas it remained unchanged in members of the control group. However, adjusted between group differences were not significant (Figure 6).
  - At baseline, mean lipid values and blood pressure were, except for triglycerides, in a rather favorable range. There were no adjusted between group differences regarding lipids or systolic as well as diastolic blood pressure (Table 2).

**Conclusion:** MEDIAS 2 ICT was associated with a clinically relevant reduction of A1c. A randomized trial proved non-inferiority of A1c reduction compared to the control group. Furthermore, diabetes related distress was significantly more reduced in MEDIAS 2 ICT than in ACC. Diabetes self-care behavior, quality of life, and diabetes knowledge were also significantly improved in MEDIAS 2 ICT compared to baseline. The MEDIAS 2 ICT program provides an alternative for education of people with type 2 diabetes treated by multiple injection therapy.

Table 1: Sample characteristics

Characteristic	MEDIAS 2 ICT n=94	ACC n=92	P
age ± SD (yrs.)	63.9 ± 7.8	62.0 ± 8.7	.130
% female	37 (23)	52 (22)	.038
ys of education ± SD	10.1 ± 2.4	9.7 ± 2.1	.285
diabetes duration ± SD (yrs.)	13.6 ± 6.8	13.8 ± 8.3	.982
BMI ± SD (kg/m <sup>2</sup> )	33.4 ± 6.2	33.3 ± 5.6	.868
A1c ± SD (%)	8.3 ± 1.2	8.4 ± 1.5	.461
duration of insulin therapy ±SD (yrs.)	5.4 ± 5.0	5.3 ± 4.9	.939
# of insulin injections ±SD	3.7 ± 1.2	4.2 ± 3.2	.200
% with oral anti-diabetic medication	60.4	46.2	.054
# of complications ± SD	1.2 ± 1.2	1.2 ± 1.2	.790

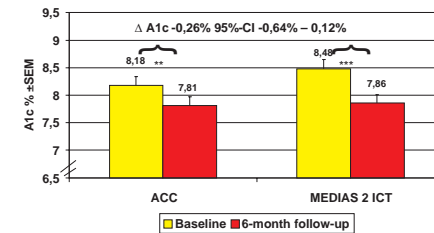


Figure 1: Effects on A1c

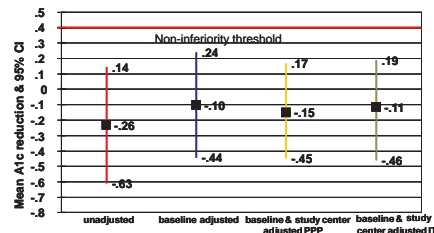


Figure 2: Non-inferiority adjusted for baseline, study centre

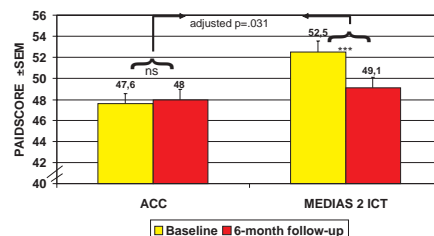


Figure 3: Effect on diabetes related distress

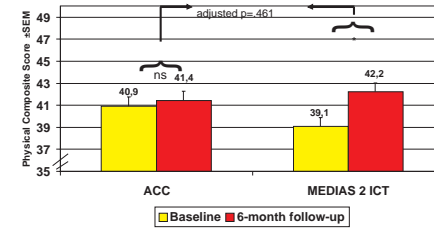


Figure 4: Effect on Physical Composite Score

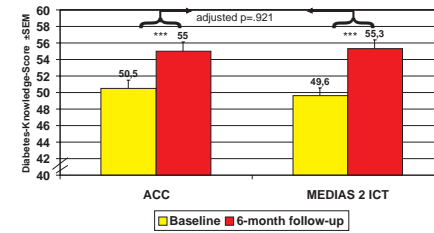


Figure 5: Effects on diabetes knowledge

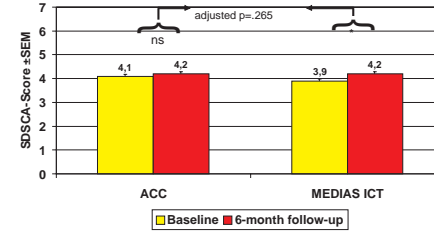


Figure 6: Effects on self-care behavior

Table 2: Effects on lipids and blood pressure

Characteristic	MEDIAS 2 ICT n=82	ACC n=85	P
cholesterol mg/dl ±SD	Baseline 193.4 (55.7) Follow-up 186.0 (49.4)	Baseline 196.5 (42.6) Follow-up 192.0 (44.6)	.506
triglycerides mg/dl ±SD	Baseline 166.0 (98.3) Follow-up 165.9 (107.1)	Baseline 198.0 (140.4) Follow-up 193.7 (136.1)	.995
HDL mg/dl ±SD	Baseline 49.0 (15.0) Follow-up 43.4 (13.2)	Baseline 47.0 (8.8) Follow-up 44.3 (12.0)	.545
LDL mg/dl ±SD	Baseline 107.4 (36.2) Follow-up 106.3 (35.5)	Baseline 111.6 (36.3) Follow-up 110.4 (38.5)	.371
systolic RR mm Hg	Baseline 138.9 (15.9) Follow-up 138.5 (17.6)	Baseline 137.7 (19.9) Follow-up 139.1 (16.6)	.671
diastolic RR mm Hg	Baseline 77.2 (8.6) Follow-up 78.3 (9.9)	Baseline 79.4 (10.0) Follow-up 80.9 (9.4)	.971

