Efficacy of an Education and Treatment Programme for People with Type 2 Diabetes on a non-intensive Insulin Regimen (MEDIAS 2 BOT+SIT+CT): Results of a Prospective Randomized Trial

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INTRODUCTION

Long-term studies show that type 2 diabetes is associated with a progressive deterioration of glucose tolerance. After a median time of approx. 9 years most people with type 2 diabetes require the addition of insulin to anti-diabetic oral agents to achieve optimal glycaemic control. Currently there is no strong evidence for a specific insulin regimen for initiating insulin treatment in type 2 diabetes. Therefore, different regimens for the initiation of insulin treatment are coexisting in clinical care: (1) Basal insulin supported Oral Therapy (BOT), (2) Supplementary Insulin Treatment with prandial insulin (SIT), and (3) Conventional Insulin Treatment with biphasic insulin (CT). These different insulin regimens are requiring new skills and knowledge in people with type 2 diabetes, previously treated with lifestyle modifications and oral anti-diabetic agents. Amongst these new skills are the correct injection and dosing of insulin, blood glucose self-control and the timing of insulin injection with carbohydrate intake in prandial or biphasic insulin regimens. MEDIAS 2 BOT+SIT+CT (More Diabetes Self-management for People with type 2 diabetes on a BOT, SIT or CT) is a newly developed diabetes education and treatment programme for people with type 2 diabetes. PWD-T2 on a non-intensive insulin treatment regimen. The development of MEDIAS 2 BOT+SIT+CT (MEDIAS 2 BSC) was based on the self-management and empowerment theory. The efficacy of the newly developed intervention MEDIAS 2 BSC was evaluated in a randomized trial with a 6-month follow-up period. The control group (CG) participated in an established education programme (treated-population without MEDIAS 2 BSC). The control group did not differ in terms of demographic, psychosocial and treatment characteristics.

Methods

Both interventions consisted of 6 lessons (see table 1 with the key topics of the lessons). At baseline and follow-up, HbA1c was measured in a central laboratory. Participants also completed questionnaires to measure diabetes distress, empowerment, diabetes knowledge and hypoglycaemia awareness.

Results

- 182 PWD-T2 participated in the study (see table 2 for baseline characteristics). There were no significant differences at baseline between MEDIAS 2 BSC and CG. At the 6-month follow-up, data of 160 participants could be analysed.
- 17 participants were lost to follow-up and 5 participants terminated insulin treatment (see figure 1). Patients who were lost to follow-up or terminated insulin treatment were significantly younger than participants of the per-protocol population.
- HbA1c was significantly more reduced in MEDIAS 2 BSC compared to CG (-0.7 ±0.1 vs. -0.3 ±0.1; p=0.02 (see figure 2)). Figure 3 shows the effect of MEDIAS 2 BSC in the per-protocol and intention-to-treat population (baseline HbA1c). Carried forward for participants who were lost to follow-up. All analyses showed a significant benefit of MEDIAS 2 BSC with regard to glycaemic control.
- There was no severe hypoglycaemic event reported (medical assistance required) in neither treatment group. Hypoglycaemia unawareness measured by questionnaire did not change significantly in both groups. Thus, reductions in HbA1c was not associated with an increased risk of severe hypoglycaemia (see figure 4).
- In both intervention groups there was an improvement of Diabetes Self Care, Knowledge, Diabetes Distress, Depression and Health Related Quality of Life. However, the differences between MEDIAS 2 BSC and CG were not significant (see table 3).
- Number of insulin injections or blood glucose self-tests as well as insulin doses were only slightly changed during the intervention and follow-up period in both groups. There was a moderate increase in weight in both groups. Between groups differences did not reach significance (see table 4).
- A sensitivity analysis evaluated whether treatment differences like insulin doses, number of insulin injections or change of insulin regimen had an impact on the observed HbA1c difference in both groups. The results of these sensitivity analyses are shown in figure 5.

Conclusion

Participation in the newly developed MEDIAS 2 BOT+SIT+CT treatment and education programme led to a significant improvement of glycaemic control without a measurable increase in risk for hypoglycaemia. An important component of the newly developed MEDIAS 2 BOT+SIT+CT was self-titration of insulin doses; this might have contributed to the positive impact of this programme on glycaemic control. There was a positive impact of diabetes education delivered either in the control group or in the MEDIAS 2 BSC group on Diabetes Self-Care activities, Diabetes Knowledge, Diabetes Distress, Depressive Symptoms and Health-Related Quality of Life. However, the impact of the different education programmes on these psychosocial outcomes was too small to reach significance with regard to between group differences. Participants in the study had a rather high age and long diabetes duration and were highly affected by diabetes complications. This might have limited beneficial effects of diabetes education on depressive symptoms, diabetes distress and health-related quality of life. Treatment factors did not differ substantially between MEDIAS 2 BSC and the control group. The sensitivity analysis controlling for mode of insulin treatment or insulin dose suggests that the beneficial impact of MEDIAS 2 BSC on glycaemic control was not explained by treatment intensification or mode of insulin treatment.

In summary, MEDIAS 2 BOT+SIT+CT has been proven as an effective treatment and education tool.

Table 1: Content of education programmes in CG and MEDIAS 2 BOT+SIT+CT

Table 2: Sample characteristics

Table 3: Impact of MEDIAS 2 BSC and CG on insulin treatment factors (adjusted for study centre and baseline values)

Table 4: Impact of MEDIAS 2 BOT+SIT+CT and CG on treatment factors (adjusted for study centre)

Table 5: Sensitivity analysis of the impact of treatment factors on HbA1c differences between both groups