The Effect of a Self-Management Oriented Education and Treatment Programme (PRIMAS) for Type 1 Diabetic Patients

B. Kulzer, N. Hermanns, D. Ehrmann, N. Bergis, T. Haak
Research Institute Diabetes Academy Bad Mergentheim (FIDAM), Germany

Background and Aims: In a randomised, multi-center trial the effect of a structured education and treatment programme to promote self-management and empowerment for type 1 diabetic patients (PRIMAS) was compared to an established education programme (structured education and treatment programme for type 1 diabetic patients) as an active control group (CG). Besides optimising insulin treatment by testing basal insulin doses and carbohydrate factors as well as avoiding acute and late complications, the PRIMAS programme also aims at motivational factors and the daily routine of living with diabetes.

Materials and Methods: The primary outcome was the impact of both interventions on overall glycaemic control six months after the end of the diabetes education programmes. Secondary outcomes were diabetes related distress (Diabetes Distress Scale, 17 items), extent of self-perceived empowerment (Empowerment Scale, 11 items), self-efficacy for diabetes management (Self-Efficacy Scale, 10 items), satisfaction with insulin treatment (Insulin Treatment Experience Questionaire), diabetes knowledge (Knowledge Test, 11 items), self-care behaviour (Summary of Diabetes Self-Care Activity Scale), hypoglycaemia awareness (Hypoglycaemia Unawareness Questionnaire) and incidence of severe hypoglycaemic episodes (required third party assistance). Statistical analyses were adjusted for baseline values. Intention to treat analyses were performed.

Results: A total of 160 patients with type 1 diabetes (see table 1) recruited in diabetologist practices were randomised to either PRIMAS or the CG (see figure 1). Main outcome was the HbA1c 6 months after participation in the respective programme. Baseline adjusted HbA1c was significantly more improved in PRIMAS than in the CG, whereas total insulin doses were highly comparable (see figure 2). Also empowerment and self-efficacy for diabetes management was significantly more increased in PRIMAS than in the CG (see figure 3). Participants in PRIMAS were also significantly more satisfied with their insulin therapy and reported less diabetes related distress than members of the CG (see figure 4). There was no specific impact of both education programmes on diabetes knowledge and self-care behaviour (see figure 5). There was also a comparable reduction of hypoglycaemia unawareness and on the incidence of severe hypoglycaemic episodes in both groups (see figure 6).

Conclusion: Although baseline HbA1c were remarkable lower than in former evaluation studies of type 1 diabetic education programmes, PRIMAS was more effective in lowering HbA1c than the established education programme. In addition, PRIMAS has proven its efficacy regarding the improvement of empowerment, self-efficacy and satisfaction with insulin treatment as well as regarding the reduction of diabetes related distress. The effects on knowledge and self-care behaviour are similar to those of the established education programme. The prevalence of severe hypoglycaemic episodes requiring third party assistance was rather low at baseline. However, both intervention groups were able to reduce the number of severe hypoglycaemic episodes even further. Thus, PRIMAS was able to improve glycaemic control, while also reducing the prevalence of hypoglycaemia problems. In summary PRIMAS has proven some advantages compared to the established diabetes education programme for type 1 diabetic patients with regard to glycaemic control, higher empowerment and self-efficacy of diabetes management as well as satisfaction with insulin treatment and reduction of diabetes related distress (see table 2). Thus, PRIMAS provides a good alternative for the treatment and education of type 1 diabetic patients.

Table 1: Sample characterstics

Characteristics	PRIMAS	CONTROL
N	81	79
Mean age ± SD (yrs)	45.9 ± 13.8	45.2 ± 13.4
Mean diabetes duration ± SD (yrs)	19.6 ± 12.8	19.4 ± 13.2
Mean BMI ± SD (kg/m²)	26.7 ± 4.6	27.6 ± 4.6
% female	38.3	49.4
Mean HbA1c ± SD (%)	8.3 ± 1.1	8.1 ± 0.9
Mean daily insulin dose ±SD (IU/Kg)	0.67 ± 0.28	0.63 ± 0.27
% with CSII	23.5	27.8
Number of daily injections	5.2 ± 1.1	5.2 ± 1.1
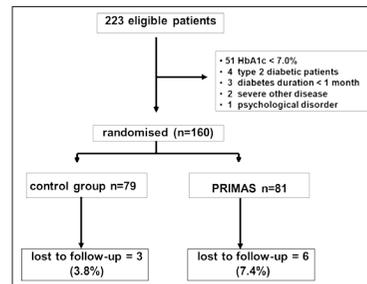
Figure 1: Consort statement
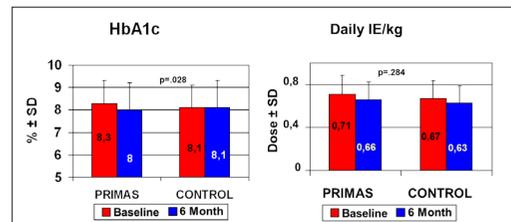
Figure 2: HbA1c and daily insulin dose
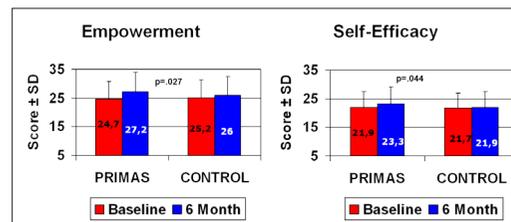
Figure 3: Empowerment and self-efficacy of diabetes management
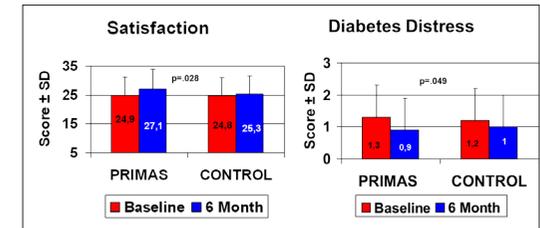
Figure 4: Satisfaction with insulin therapy and diabetes distress
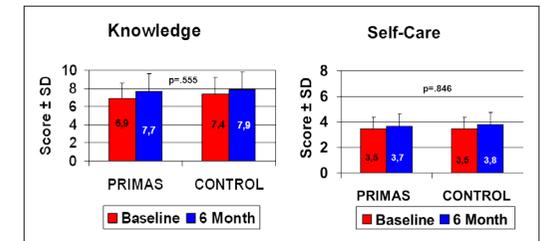
Figure 5: Diabetes knowledge and self-care behaviour
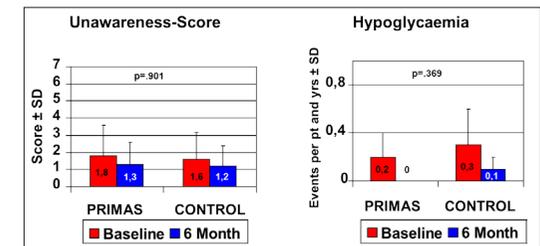
Figure 6: Hypoglycaemia unawareness and incidence of severe hypoglycaemic episodes

Table 2: Summary of results

	PRIMAS	CONTROL
HbA1c	✓	-
Diabetes Distress	✓	-
Empowerment	✓	-
Self-Efficacy	✓	-
Satisfaction with Insulin therapy	✓	-
Knowledge	✓	✓
Self-care	✓	✓
Insulin dose	-	-
Hypogylcaemia unawareness	✓	✓
Severe Hypoglycaemia	✓	✓