



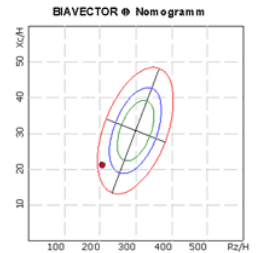
Medizinische
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Graz

Initial use of a VLCD programme using INSUmed® compared to conventional dietary advice on weight, body composition, and glucose control after 1 and 2 years in type 2 diabetic patients

E.Fließer-Görzer¹, A.Kellner², H.Toplak¹

¹Medical University, Department of Medicine, Diabetes and Metabolism, Graz, Austria

²Internist and Diabetologist, Saarbrücken, Germany



Background:

Weight reduction and stabilisation is quite difficult, especially in diabetic populations. HbA1c is strongly associated with diabetic related late complications but well influenced by reduction in weight and body fat mass, especially in early stages of diabetes.

Methodes:

28 diabetic patients were enrolled in this outpatient study (18 in the intervention group and 10 in the control group). The intervention group used INSUmed® products twice daily with one normal meal left (about 600kcal) for at least 3 months. Both groups received conventional dietary advices for diabetic patients. At baseline and thereafter 3, 6 and 12 months body composition (body fat mass, lean body mass, body water), blood samples and blood pressure were collected. We used bioelectrical impedance measurement (BIA 101, AKERN, Italy) for collecting body composition. Anti-diabetic agents were adjusted according to blood glucose measurements.

Results:

After 3 months a weight reduction of $-9.1 \text{ kg} \pm 5 \text{ kg}$ ($p < 0.01$) in the intervention vs $-2.8 \pm 0.9 \text{ kg}$ in the control group (ns, $p < 0.05$ for inter-group comparison) could be observed. Body fat mass decreased by $7.1 \pm 1 \text{ kg}$ vs. $1.8 \pm 0.3 \text{ kg}$ ($p < 0.05$). After 12 months, both groups under dietary advice, exhibited a weight reduction of $7.6 \pm 2.5 \text{ kg}$ vs. $1.0 \pm 0.8 \text{ kg}$ compared to baseline data ($p < 0.01$, ns). After 24 month we could still see a mean weight decrease of 6 kg in the intervention vs. 0.1 kg in the control group ($p < 0.05$, ns) and mean body fat mass reduction was 3.7 kg vs. 0.8 kg ($p < 0.05$, ns), respectively. The HbA1c was slightly decreased in the intervention group, whereas the control group increased slightly (all ns) which might in part be influenced by the antidiabetic treatment also.

Population

18 study patients

KG 109.7 ± 20.5

FM 44.3 ± 12.7

BMI 38.4 ± 5.7

HbA1c $6.8 \pm 0.9\%$

Male 10

Mean age 59 years

10 control patients

KG 103.2 ± 10.1

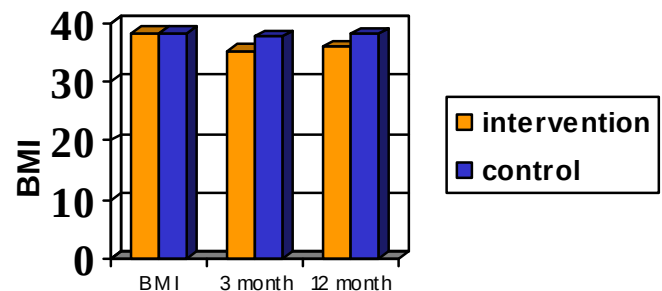
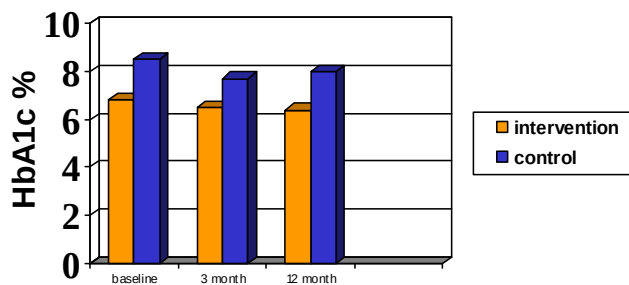
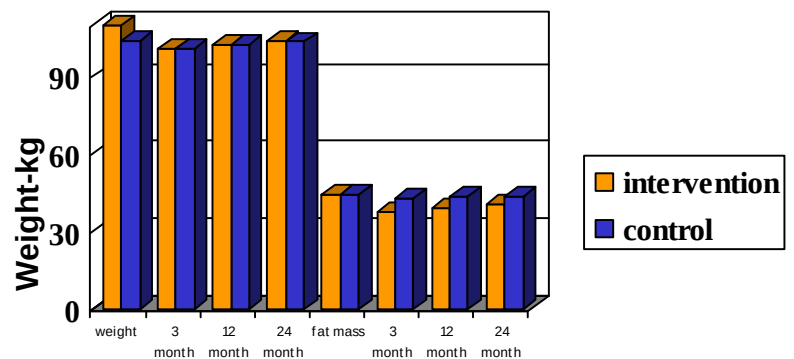
FM 44.3 ± 10.1

BMI 38.4 ± 6.0

HbA1c $8.5 \pm 2.5\%$

Male 4

Mean age 55.5 years



Conclusion:

Long term body fat mass and weight developed significantly better in the intervention group using INSUmed® products in the first 3 months than using a conventional diet only. Furthermore, HbA1c slightly decreased over a 12 month period with an opposite effect in the control group. So initial body fat reduction seems feasible and could have long term effects on metabolic control and event rate in these patients which should be further investigated.