



PROMESA II Study

Study Title

PROMESA II: Measuring the Effectiveness and Safety of the PronoKal® Method after Two Years.

Study Objectives:

- Evaluate the effectiveness of the PronoKal® Method for short- and long-term weight loss.
- Analyse factors which can predict patient response to the treatment.
- Register the incidence of method-related side effects.

Study Design and Type

Epidemiological, prospective, multi-centre study.

Researching Doctors and Research Centres

700 research doctors throughout Spain participated in the study.

Study Population

Overweight and obese patients who followed the PronoKal® Method for controlled weight loss beginning in September 2008.

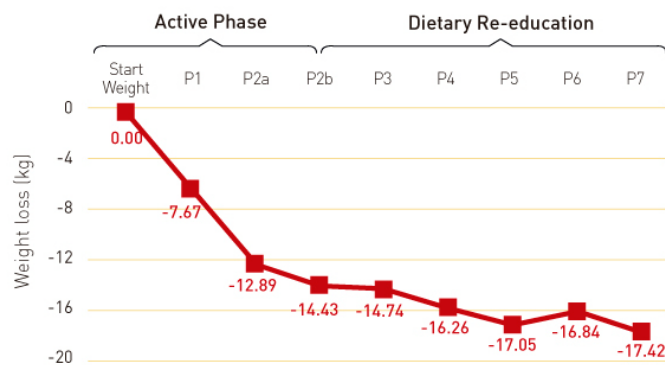
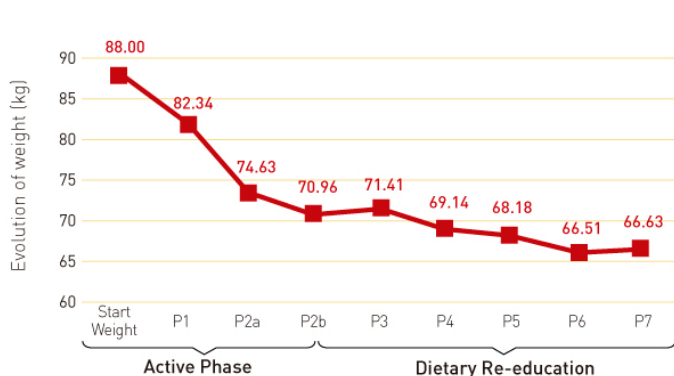
PRIMARY RESULTS

Sample Characteristics (3435 patients)

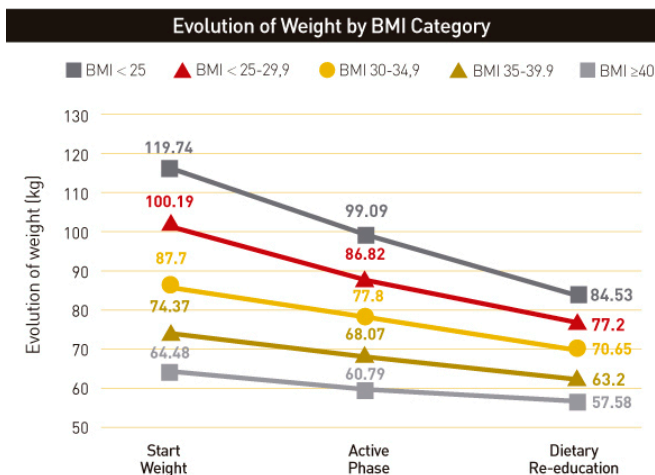
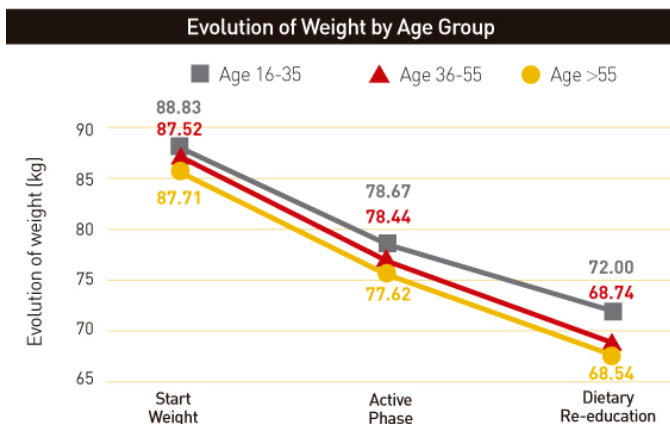
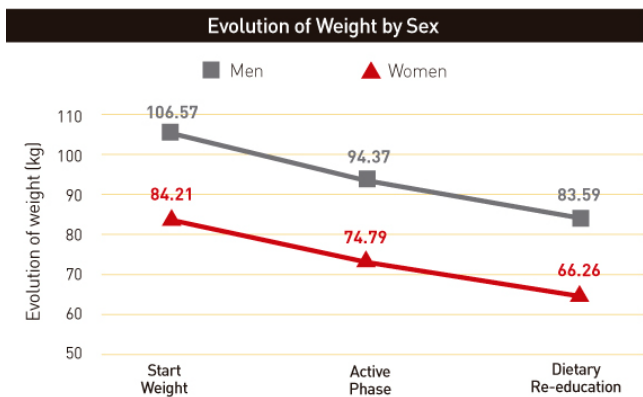
Total N=3435	%	average ± SD
Sex		
Male	16.99	
Female	83.01	
Age	-	41.72 ± 11.1
Initial Weight	-	87.96 ± 18.3
Waist Circumference	-	102.0 ± 14.6
BMI (KG/m²)	-	32.7 ± 5.8
BMI < 25	5.37	-
BMI: 25-29.9	30.50	-
BMI: 30-34.9	34.77	-
BMI: 35-39.9	18.95	-
BMI > 40	10.41	-
Medical History		
Type 2 Diabetes	3.46	-
AHT	12.58	-
Hypercholesterolaemia	19.51	-
Hypertriglyceridaemia	9.23	-
Gout	1.48	-
Cholelithiasis	2.18	-
Menopause	16.65	-



Data on the Effectiveness for Weight Loss during the Various Stages of the Treatment



Data on the Effectiveness for Weight Loss Depending on Various Factors



	Percentage of Weight Lost Compared to Start Weight			
	Active Phase		Dietary Re-education	
	%	p	%	p
SEX				
Men	16.1%		22.8%	
Women	16.4%	n.s.	19.9%	n.s.
AGE GROUP				
Age 16-35	17.6%		22.3%	
Age 36-55	16.5%	< 0.05	20.0%	n.s.
Age > 55	14.4%		17.4%	
BMI CATEGORY				
BMI < 25	9.5%		13.1%	
BMI 25-29.9	12.7%		16.5%	
BMI 30-34.9	17.0%	< 0.05	21.0%	< 0.05
BMI 35-39.9	19.2%		24.9%	
BMI ≥ 40	24.4%		30.3%	

Weight loss was greater among men, both in kg and in percentage of original weight. During the Active Phase, the percentage and number of kg of weight lost was greater among young people. Nonetheless, all groups evened out during the Dietary Re-education Phase, and no significant differences were observed at the end of the study. Kg and percentage of weight loss was greater in all phases of the method the greater the patient's initial BMI.