

Obesimed® Forte - Salas-Salvado Jordi, Xavier Farre, Xavier Luque, Silvia Narejos, Manel Borrell, Josep Basora, Anna Anguera, Ferran Torres, Monica Bullo, and Rafel Balanza. Effect of two doses of a mixture of soluble fibres on body weight and metabolic variables in overweight or obese patients: a randomised trial. British Journal of Nutrition (2008), 99, 1380–1387.

Authors (year published)	Study design	Total patients	Intervention	Reported outcomes/results	Adverse events	Appraisal	Level
Salas-Salvado J, et al., 2008	Parallel, double-blind, placebo-controlled clinical trial.	200	Glucomann 1g, plantago ovaga 3g 2-3 daily	Satiety induction and decreasing in plasma LDL-cholesterol concentrations..	No	D2 A1 P1 R1 T1 O1 F1 S1 C1	I

CASP Questions for making sense of evidence

1. Did the study ask a clearly focused question?	2. Was this a RCT, and was it appropriately so?	3. Were participants appropriately allocated to intervention and control groups?	4. Were participant, staff, and study personnel blinded to participants' study group?	5. Were all participants who entered the trial accounted for at its conclusion?	6. Were the participants in all groups followed up and data collected in the same way?	7. Did the study have enough participants to minimize the play of chance?	8. How are the results presented, and what is the main result?	9. How precise are these results?	10. Were all important outcomes considered so that the results can be applied?
Yes	Yes. Appropriate for this study	Yes. Participants randomly assigned to glucomannan 2-3g/d with plantago or placebo for 16 weeks.	Yes	Yes. 200 overweight or obese patients (n=200), 113 in placebo group.	Safety and efficacy data obtained on all patients	Yes-power analysis performed.	Weight loss was higher after both doses of fibre than placebo. The differences between groups in LDL-C levels were significant.	Statistical tests appropriately used can have confidence in results.	Efficacy and safety both considered.

Synopsis - Salas-Salvado Jordi, Xavier Farre, Xavier Luque, Silvia Narejos, Manel Borrell, Josep Basora, Anna Anguera, Ferran Torres, Monica Bullo, and Rafel Balanza. Effect of two doses of a mixture of soluble fibres on body weight and metabolic variables in overweight or obese patients: a randomised trial. British Journal of Nutrition (2008), 99, 1380–1387.

Aim: to compare the effect of the administration of a mixture of fibres *Plantago ovata* husk and glucomannan on body weight-loss, satiety and lipid profile

Study design: randomized, parallel, double-blind, placebo-controlled clinical trial.

Subjects: 166 patients (22% men and 78% women) between the ages of 18 and 70 years who were overweight or obese ($27 < \text{BMI} > 35 \text{ kg/m}^2$) with a high degree of motivation to achieve weight loss. Patients were given a mixed fibre dose (3 g *Plantago ovata* husk and 1 g glucomannan) twice (b.i.d. group) or three times daily (t.i.d. group) or placebo times daily or placebo for 16 weeks. Weight change was the primary efficacy endpoint. Satiety, dietary compliance, lipid profile, glucose tolerance, insulin resistance and high-sensitivity C-reactive protein were secondary endpoints.

Results: weight loss tended to be higher after both doses of fibre (-4,52 (SD 0,56) and -4,60 (SD 0,55) kg) than placebo (-0,79 (SD 0,58) kg); the differences in changes between groups were not statistically significant. Postprandial satiety increased in both fibre groups compared to the placebo. The differences between groups in LDL-cholesterol levels were significant ($p = 0,03$), with greater reductions in the two fibre-supplemented groups (0,38 (SD 0,10) and 0,24 (SD 0,09) mmol/l in the b.i.d. and t.i.d. groups v. -0,06 (SD 0,09) mmol/l in placebo group). A similar pattern was observed for changes in total cholesterol: HDL-cholesterol and HDL-cholesterol: LDL-cholesterol ratios. Interventions were well tolerated and had no effects on HDL-cholesterol, glucose and insulin concentrations, glucose tolerance or high-sensitivity C-reactive protein. No serious adverse event was reported during the study. No significant differences in total adverse events were observed between groups.

Authors' conclusion: a 16-week dietary supplement of soluble fibre in overweight or obese patients was well tolerated, induced satiety and had beneficial effects on some cardio-vascular diseases risk factors, the most important of which was a significant decrease in plasma LDL-cholesterol concentrations.