

# **BENEFICIAL EFFECT OF A LOW FODMAPs DIET IN DIFFERENT GASTROINTESTINAL DISORDERS**

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## **Study Protocol**

Each subject who respected the inclusion criteria was enrolled in the study and was submitted to a diet low in FODMAPs content, after filling out questionnaires on quality of life and symptoms (IBS-SSS and SF-36) (T0).

The IBS-SSS questionnaire consists of 5 questions on: the severity and frequency of abdominal pain, the severity of the bloating, the level of satisfaction in bowel habits and quality of life. Patients give an estimate from 0 to 100 and the results of each question are summed to obtain the final score (theoretical range of 0-500, with a higher score indicating worse condition). Previous studies have established that mild IBS symptoms corresponded to a score <175, moderate IBS symptoms corresponded to a score between 175–300, and severe IBS corresponded to scores more than 300.

The SF-36 is a questionnaire on the patient's state of health consisting of 36 questions related to eight health domains: AF-physical activity (10 questions), RP-role limitations due to physical health (4 questions) and RE-role limitations due to emotional problems (3 questions), BP-physical pain (2 questions), GH-perception of general health (5 questions), VT-vitality (4 questions), SF-social activities (2 questions), MH-mental health (5 questions) and a single question about the change in health status. All SF-36 questions, except one, are referred to a previous four-week period of the compilation of questionnaire. The eight-scaled scores are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale on the assumption that each question carries equal weight: the lower the score the more disability; the higher the score the less disability.

After the administration of the questionnaires and the collection of anthropometric measurements (weight and height), patients were put on a low FODMAPs diet (T0). Each regimen was specific for the patient's energy requirement (calculated by BMI) and for its content in FODMAPs, realized in conformity with the food reference tables. This low FODMAPs diet was prescribed by a dietitian for 12 weeks and patients were instructed to eat according to their appetite, received a summary diagram with substances to be taken and those to be avoided and were educated to interpret food labels/ingredients lists.

In order to cover the needs of micro and macronutrients, we guaranteed a minimum content of oligosaccharides, fructose and polyols (not more than 0.5 g): thereby the administered diet was a low FODMAPs regimen and not a free FODMAPs one.

The questionnaires and the clinical evaluation of the patients were repeated one month (T1) and three months (T3) after the beginning of the diet.

### **Statistical analysis**

All the data were analyzed using the SPSS (Statistical Package for Social Sciences v.15.0, Chicago, USA). Descriptive statistics included the determining of the mean value and standard deviation (SD) of the continuous variables, and the percentages and proportions of the categorical variables. Statistical analysis was performed using chi-square and T-student, when appropriate. The analysis of variance (ANOVA) was used with and without adjustment for covariates. All results were considered statistically significant when the p value was  $<0.05$ .