Food4Gut multicenter randomized placebo-controlled trial.

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1 *Works for me* dx.doi.org/10.17504/protocols.io.baidica6

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ABSTRACT

Objectives:We describe the methodology of a trial designed to highlight the interest of vegetables rich in ITF-prebiotics in obese adults.

DESIGN:150 obese subjects (BMI> 30 kg.m^{-2}; 18–65 years) recruited in three different university hospitals in Belgium will be selected with at least one of the following criteria: (pre-)diabetes, hypertension, dyslipidemia, liver steatosis. They will be randomly assigned to receive either 16 g/day of inulin (Fibruline, Cosucra) with dietary advice to promote the consumption of vegetables rich in ITF or 16 g/day placebo (maltodextrin, Cargill) with dietary advice provided nutrients to promote the consumption of vegetables poor in ITF for 3 months. Review of literature, analysis of ITF content in vegetables and satisfaction and digestive tolerance tests (on healthy volunteers) will be performed to propose adequate receipts.

Results: The primary outcome is to evaluate the impact of a higher consumption of ITF-prebiotics on the gut microbiota composition. The secondary outcome of this trial was the effect of the prebiotic intervention on the BMI. Other secondary endpoints were anthropometric and clinical parameters.

Conclusions:The goal of this intervention study is to establish the proof of concept that nutrients which selectively stimulate the growth of beneficial bacteria in the human colon might offer protection against metabolic disorders associated to obesity on an adequate target population.

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