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**Effect of prebiotic oligosaccharides on bowel habit and the gut microbiota in children with functional constipation: study protocol for a randomised, placebo-controlled, multi-centre trial using a validated modified Bristol Stool Form Scale.**

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## Abstract

**Background:** Functional constipation (FC) in children is a common gastrointestinal (GI) disorder with a worldwide pooled prevalence of 9.5%. Prebiotic oligosaccharides have been shown to result in softer stools and/or to increase stool frequency in infants and adults. However, sufficient evidence is lacking linking prebiotic intake to improve constipation symptoms in children with FC.

**Methods:** In the present randomised, double-blind, placebo-controlled, multi-centre trial, we study the effects of two prebiotic oligosaccharides in comparison to a placebo on constipation symptoms in Dutch children of 1-5 years of age diagnosed with FC according to the Rome IV criteria for functional GI disorders. The primary outcome measure is change in stool consistency which is assessed using the modified Bristol Stool Form Scale (m-BSFS). Validity of the m-BSFS for (non-)toilet trained Dutch toddlers was evaluated by means of rating stool pictures by (grand)parents and day childcare employees, and determining inter- and intra-rater reliability by respectively single-rater intraclass correlation coefficient and Cohen's kappa (Wegh CAM et al, 2021). Secondary and tertiary outcomes of the multi-centre trial include among others stool frequency, painful defecation, gut microbiome outcomes, and quality of life. After a one-week run-in period, participants receive one of the two prebiotic oligosaccharides or placebo for 8 weeks, followed by a 4-week wash-out period.

**Discussion and conclusion:** As the inter- and intra-rater reliability of the m-BSFS were above recommended minimal standards of 0.61, the m-BSFS is a reliable scale to evaluate stool consistency in both toilet- and non-toilet trained Dutch toddlers. The multi-centre trial will investigate the effectiveness of prebiotic oligosaccharides in children aged 1-5 years with FC. Findings of this study might have important implications for nutrition and supplementation guidelines for children with FC.

*Wegh CAM et al, JPGN 2021; 73: 210-216.*