

The real-life use of the Crohn's disease exclusion diet (CDED) in adults with mild-to-moderate Crohn's disease activity: an interim analysis of an open-label randomized controlled trial

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Background and aims: Crohn's Disease Exclusion Diet (CDED) is a validated dietary intervention with a highly restrictive food regime to induce remission in Crohn's disease (CD). We aim to provide an additional real-world evidence-based validation.

Methods: Interim analysis of an open-label randomized controlled trial of CD patients with mild-to-moderate clinical activity assessed by Harvey-Bradshaw Index (HBI) was performed. Demographical characteristics and medical history were collected at enrollment while weight, body mass index (BMI), HBI, fecal calprotectin (FC) and serum inflammatory indices were assessed at baseline and after 12 and 24 weeks. Bioelectrical impedance analysis (BIA) was performed every 12 weeks in CDED group to test the safety. The primary endpoint was clinical remission and was assessed in the intention-to-treat population.

Results: Twenty-four patients were randomized to CDED diet while 21 were controls: no significant differences among all parameters considered were observed at baseline. Five patients in CDED group discontinued diet because of intolerance at median of 5 weeks. At week 12, median HBI was lower in CDED patients than controls (3 vs 5, respectively) resulting in more patients achieving clinical remission (17/24, 70.8% vs 8/21, 38.1%, respectively; $p=0.027$). No differences of FC and systemic inflammation were observed. CDED was associated with weight loss (72 to 69 kg, $p=0.003$) although BIA analysis showed a decrease in fat mass (18.2% to 15.5%, $p<0.0001$), while fat-free mass increased (81.9% to 83.7%, $p=0.001$).

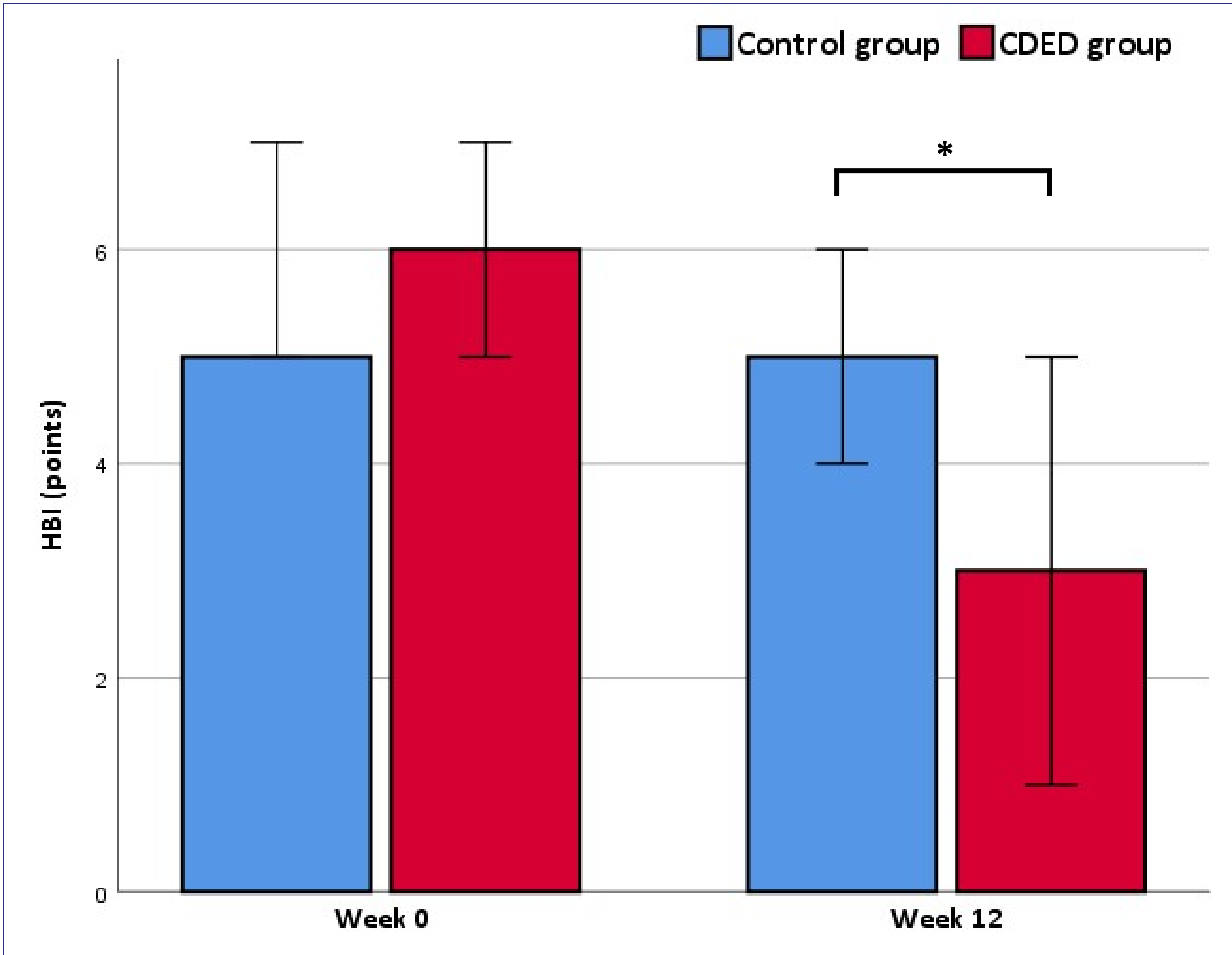


Figure 1. HBI at baseline and follow-up visit in control group and CDED group

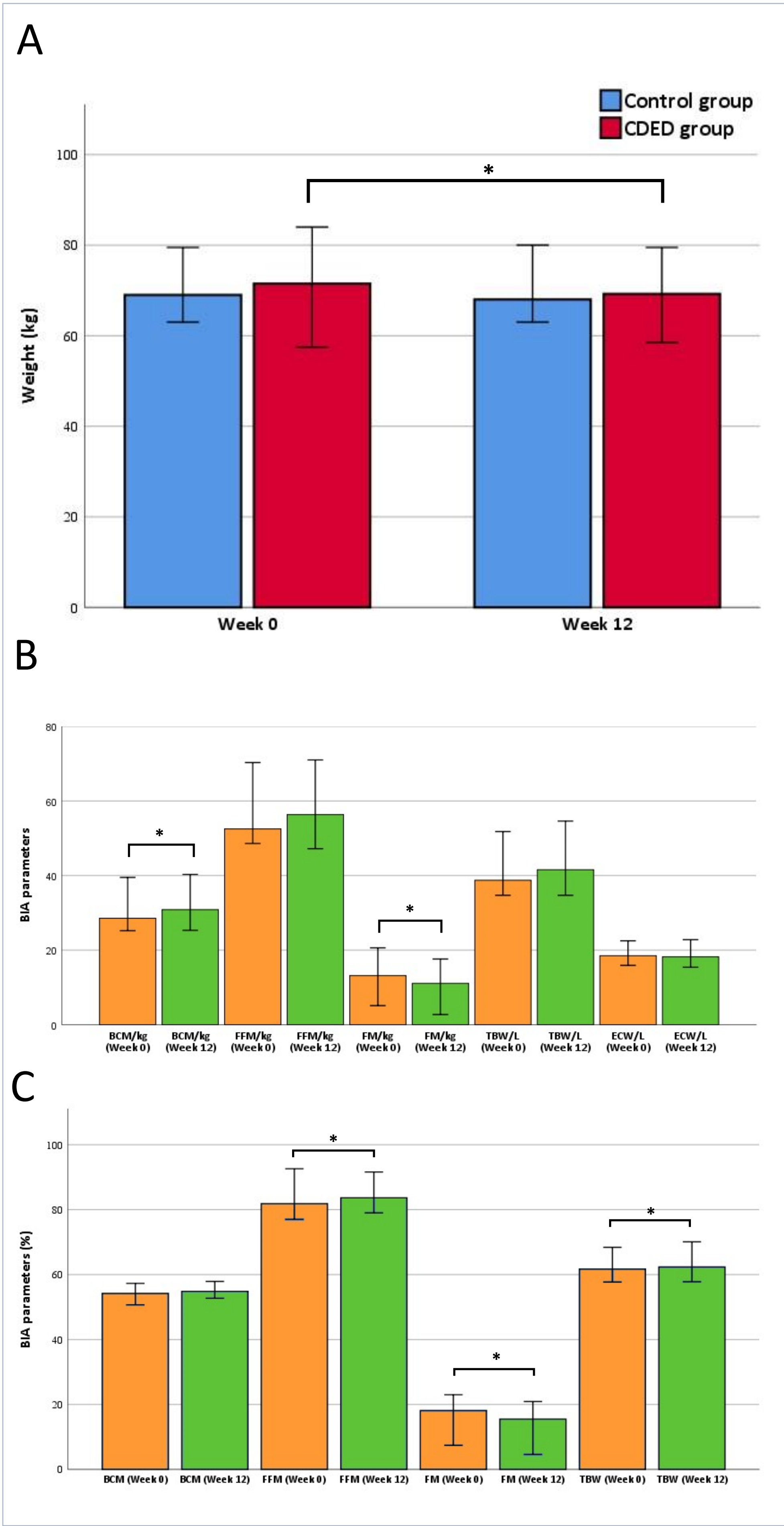


Figure 2. A) Fecal calprotectin, B) VES, C) CRP and D) Fibrinogen at baseline and follow-up visit in control group and CDED group

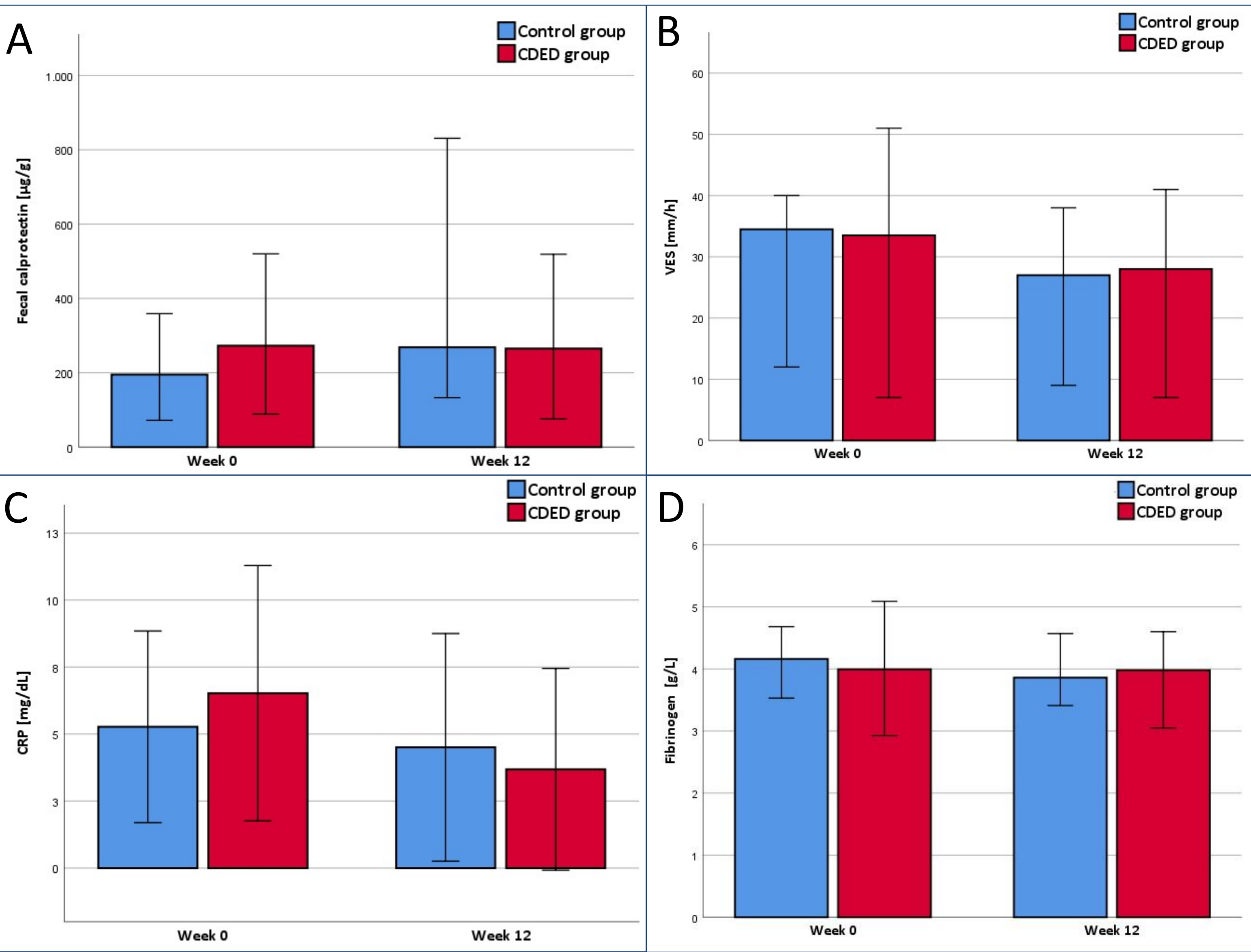


Figure 3. A) Weight at baseline and follow-up in control group and CDED group and B) BIA parameters (kg) and C) BIA parameters (%) in CDED group at baseline and follow-up

Conclusion: The CDED is effective in inducing remission in mild-to-moderate clinical activity CD patients and seems to be safe and well-accepted. Although the CDED is an elimination diet, it did not lead to risk of malnutrition.