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Fecal calprotectin response to Tasty&Healthy dietary intervention in asymptomatic children and young adults with biologically active Crohn's disease: results of the "TASTI-E" randomized controlled trial

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Background: Tasty&Healthy™ (T&H) is a whole food diet aimed at alleviating inflammation in Crohn's disease (CD). It excludes processed food, gluten, red meat, and dairy (except for plain yogurt), but does not include mandatory ingredients or partial enteral nutrition with formula as does the CD Exclusion Diet. In this RCT we evaluated T&H diet as an intervention for persistent subclinical inflammation compared with continuing habitual diet. (NCT#04239248; TASTI-E).

Methods: Patients with CD, aged 6-40 years, in clinical remission or with minimal symptoms (wPCDAI<20/CDAI<200), were randomized if their MINI-index was ≥8 (i.e. bowel inflammation), to receiving either T&H or continuing their habitual diet for 8 weeks. Patients in the latter group were also offered T&H after completing the initial 8 week randomization period. The primary outcome was calprotectin-defined response (i.e. reduction of >50%). Secondary outcomes included adherence, MINI-index, and CRP. Due to COVID-19-related slow enrolment, the study was terminated early, and thus analyses are exploratory on a per-protocol basis.

Results: 46 patients were randomized (mean age 18.2±7.6 years; median disease duration 9.01 months, IQR 2.9-17.1); 19 were assigned to T&H and 27 to the habitual group. The primary endpoint was achieved, with 7 patients (37%) in the T&H group achieving calprotectin response, vs 4 (15%) in the habitual group (RR 3.23 [95% CI 1.15-9.01]; p=0.028). A pre-post comparison of 15 patients who completed 8 weeks of habitual diet and crossed-over to T&H, showed higher rates of calprotectin<250 mcg/g at week 16 compared with their baseline at week 8 (47% vs. 17%, p=0.005) and MINI<8 (60% vs 20%, p=0.0013). Additionally, compared with the habitual diet, the improvement in CRP 0.48 (0.18-0.81) vs. 0.36 (0.1-0.36); p=0.0012) and MINI (10 (9-13) vs. 7 (5-10.5); p=0.047) was higher in the T&H arm, respectively.

The absence of gluten levels in stool was used as a measure of adherence to the T&H diet. At week 8, only 2/13 patients (15%) in the T&H group tested positive for stool gluten, compared to 18/20 patients (90%) in the habitual diet group (p=0.002), demonstrating high adherence to T&H.

Patients in the T&H arm met over 95% of Dietary Reference Intakes (DRI) for key macro- and micronutrients. No significant differences were found between the groups except for higher potassium and fiber in the T&H group (p=0.018 and p<0.001, respectively).

Conclusion: The T&H diet is effective in reducing inflammation in children and adults with CD who have subclinical inflammation. The flexibility of T&H without the need for formula feeds or mandatory ingredients is associated with high adherence.