Introduction: Many people with IBD experience fatigue, pain and faecal incontinence (FI), impacting quality of life (QoL). We developed an interactive digital online self-management intervention (IBD-BOOST) based on a theoretically informed logic model and cognitive behavioural techniques.

Methods: We conducted a multi-centre two-arm parallel group randomised controlled trial (RCT) comparing IBD-BOOST with Care as Usual (CAU), recruiting patients from clinics and national registries who rated the impact of fatigue and/or pain and/or FI as ≥5/10. Those in the IBD-BOOST arm received 6 months access to the 12-session IBD-BOOST programme, a 30-minute telephone support call and weekly in-site email messages for 3 months. The UK Inflammatory Bowel Disease Questionnaire (UK-IBDQ) and global rating of symptom relief (GRSR) at 6 months were dual primary outcomes (alpha=0.025 was considered statistically significant with two primary outcomes). Other secondary outcomes, including individual symptoms, were measured at 6 and 12 months. Complier-averaged causal effects (CACE), sensitivity and pre-specified subgroup analyses were conducted.

Results: 780 participants were randomised, 432 with Crohn's disease; 520 (66.7%) were female, mean age 49 years. At 6 months, both UK-IBDQ and GRSR were similar between the BOOST and CAU arms, p=0.19 for IBDQ and p=0.39 for GRSR. Adverse events were similar between groups. FI score and EQ5D utility score (secondary outcomes) were in favour of IBD-BOOST at 6 months, but pain and fatigue were no different. 57% of the intervention group completed a pre-defined minimum "dose" of 4 sessions (i.e. compliers). The CACE analysis suggested that compliers were more likely to report better QoL (p=0.03). Subgroup analysis of those meeting criteria for irritable bowel syndrome (IBS) at baseline, showed that IBD-BOOST was more effective in improving IBDQ and GRSR at 6 months when compared with CAU for the IBD-IBS group ($p_{interaction}$=0.015 and 0.046, respectively).

Conclusions: This large RCT found that IBD-BOOST did not improve IBDQ and GRSR in patients with IBD and fatigue and/or pain and/or FI relative to CAU. Participants reported less FI at 6 and 12 months. Those with IBD-IBS improved more than those without.