Efficacy and safety of mirikizumab in paediatric participants with moderately-to-severely active ulcerative colitis (SHINE-1): a multicentre, open-label, non-randomised phase 2 trial

Multicenter, parallel, randomised controlled trial in the UK.
Adult patients with IBD who rated he impact of fatigue.pain and faecal urgency or incontinence as >=5 on a 0-10 scale were invited.
Patients were randomly assigned to the online IBD-BOOST programme or care as usual for 6 months.

Primary endpoint: UK-IBDQ and Global Rating of Symptom Relief at 6 months.

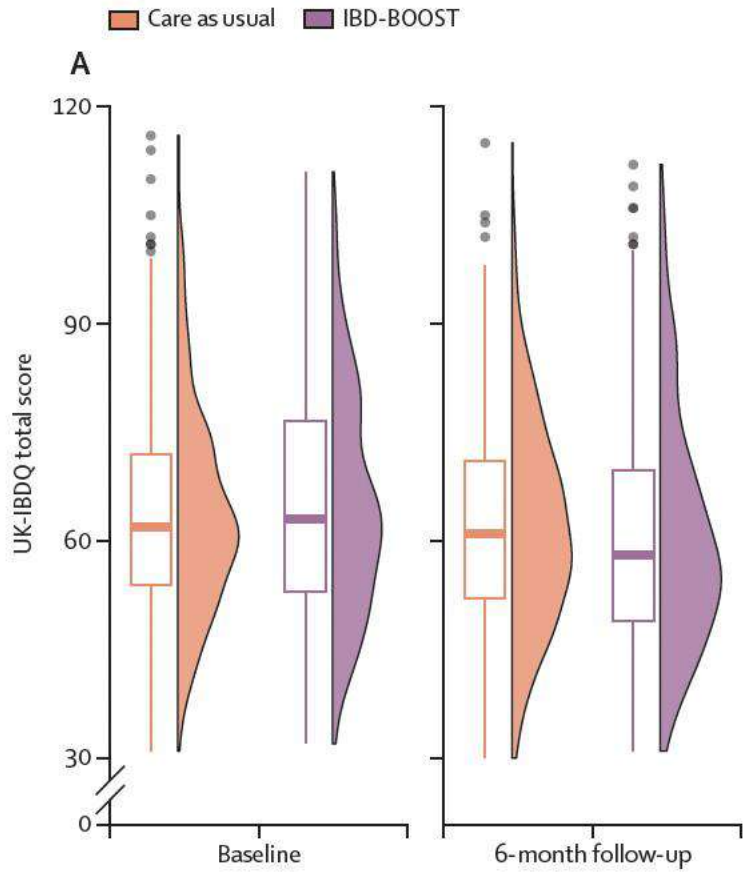
Results: N=780

- At 6 months there were no differences for UK-IBDQ between the IBD-BOOST group and usual care .
- Complier-averaged causal effects análisis demonstrated that participants who complied with IBD-BOOST reported lower UK-IBDQ scores.

Conclusion:
IBD-BOOST did not statistically significantly improve disease-specific quality of life or Global Rating of Symptom Relief in patients with IBD with fatigue, pain, or faecal urgency or incontinence compared with care as usual. People who complied with the intervention appeared to derive benefit.

*IBD-BOOST is a 12-session, interactive, digital, facilitator-supported intervention based on a model of gut–brain psychological mechanisms that contribute to symptom maintenance.

UK-IBDQ total score at baseline and 6-month follow-up



Moss-Morris R et al. Lancet Gastroenterol Hepatol.2025