

Multicenter, randomised, double-blind, crossover trial. Patients with IBD & fatigue were randomized to 5-hydroxytryptophan (5-HTP) 100mg twice daily or placebo followed by a crossover to the other treatment arm for an additional 8 weeks without intermediate washout.

**Primary endpoint:** Proportion of patients reaching  $\geq 20\%$  reduction in fVAS at week 8.

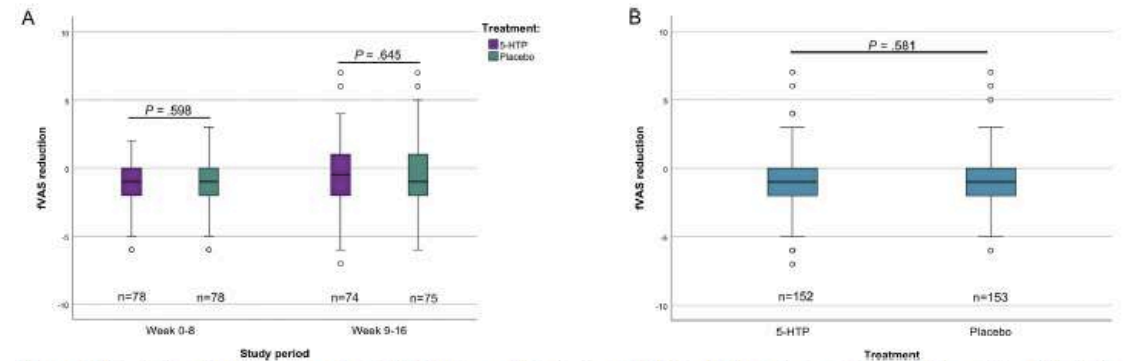
#### Results: N=166

- $\geq 20\%$  reduction in fVAS at w8: 37.6% placebo vs 35.6% 5HTP,  $p=0.83$
- The fVAS and Functional Assessment of Chronic Illness Therapy Fatigue scale increase were comparable between groups.
- During 5HTP treatment, significant increase in serum 5HTP and serotonin levels were observed compared to placebo.

#### Conclusion:

Despite a significant increase in serum 5-hydroxytryptophan and serotonin levels, oral 5-HTP did not modulate IBD-related fatigue better than placebo.

### Effect of 5-Hydroxytryptophan on Fatigue in Quiescent Inflammatory Bowel Disease: A Randomized Controlled Trial



**Figure 2.** Reduction in fVAS score after 5-HTP treatment. Reduction of fVAS at (A) weeks 8 and 16 and (B) combined for both study periods. Box-and-whisker plot: The *horizontal line* in the middle of each *box* indicates the median; the *top and bottom borders* of the box mark the 75th and 25th percentiles, respectively, the *whiskers* mark the minimum and the maximum value, and the *circles* indicate outliers.

