

# CHANGES IN HEALTH RELATED QUALITY OF LIFE IN CROHN'S DISEASE PATIENTS FOLLOWING COGNITIVE BEHAVIORAL MINDFULNESS INTERVENTION: PRELIMINARY RESULTS OF A RANDOMIZED CONTROLLED TRIAL

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## BACKGROUND

Crohn's disease (CD) is idiopathic, chronic autoimmune inflammatory disorder of the gastrointestinal (GI) tract, caused by abnormal immune response in the body. CD significantly impairs patients' Health-Related Quality of Life (HRQoL) affecting physical, emotional and social domains.

## OBJECTIVE

We examined whether a tailored Cognitive Behavioral Mindfulness Intervention (CBMI) can improve HRQoL in adult CD patients.

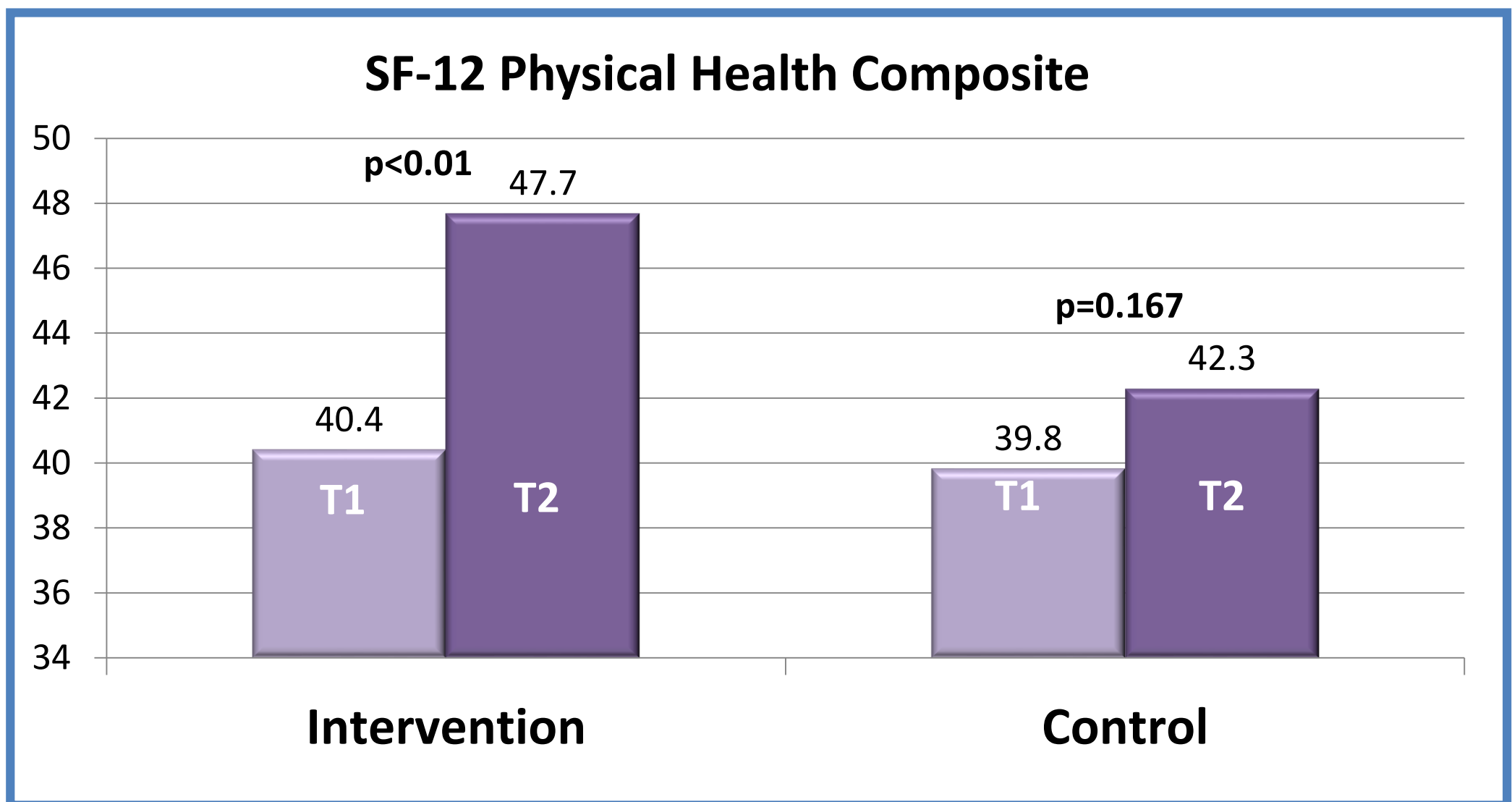
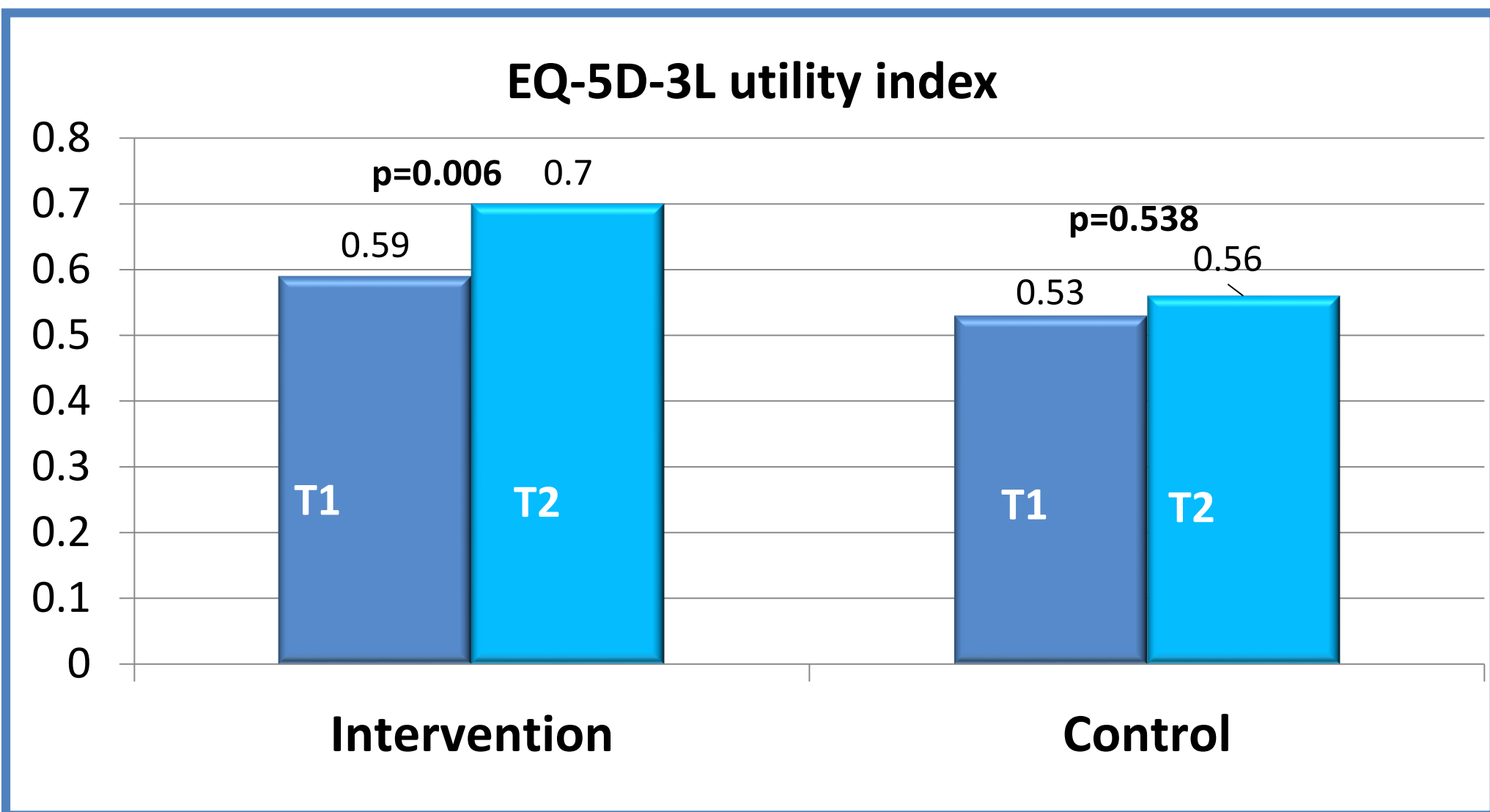
## METHODS

Adult patients ( $\geq 18$  years) with active CD (Harvey-Bradshaw Index (HBI) in range of 5-16) attending for routine follow-up at a teaching hospital were enrolled consecutively and randomized to either Intervention (CBMI) or Control groups. The purpose of the CBMI intervention was to decrease stress levels of CD patients by teaching them new adaptive coping strategies and improve their quality of life. The intervention, combining cognitive behavioral and mindfulness techniques, was delivered in 8 weekly one-hour sessions by trained therapists on-line via SKYPE application; daily practice was monitored. No intervention was given to the Control Group. Both groups continued their ongoing medical therapy. Patients' HRQoL and utility weights were assessed using EQ-5D-3L and SF-12 at two time points: at study entry and after 3 months follow-up.

**Table 1: Baseline characteristics . All differences are non significant**

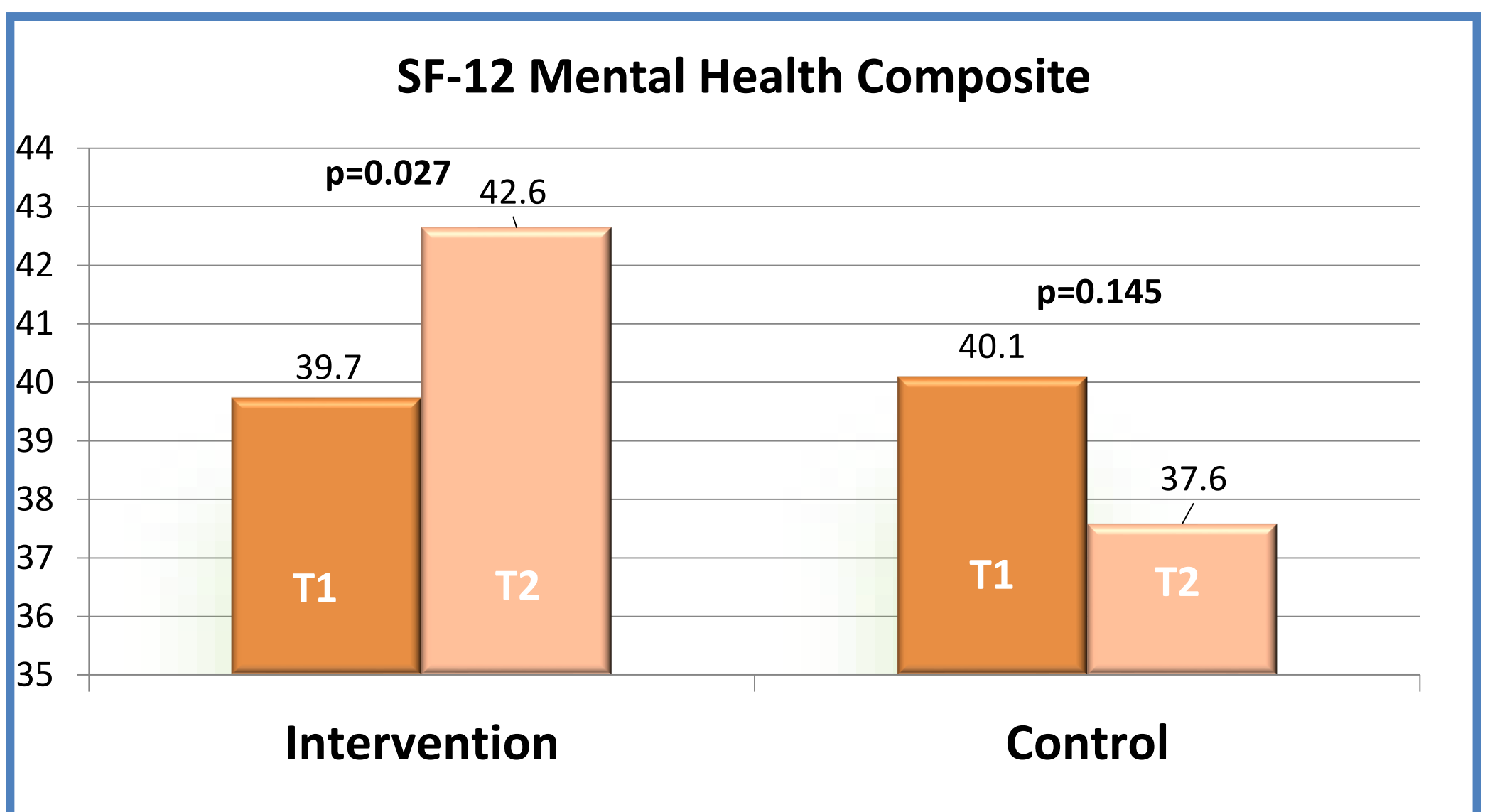
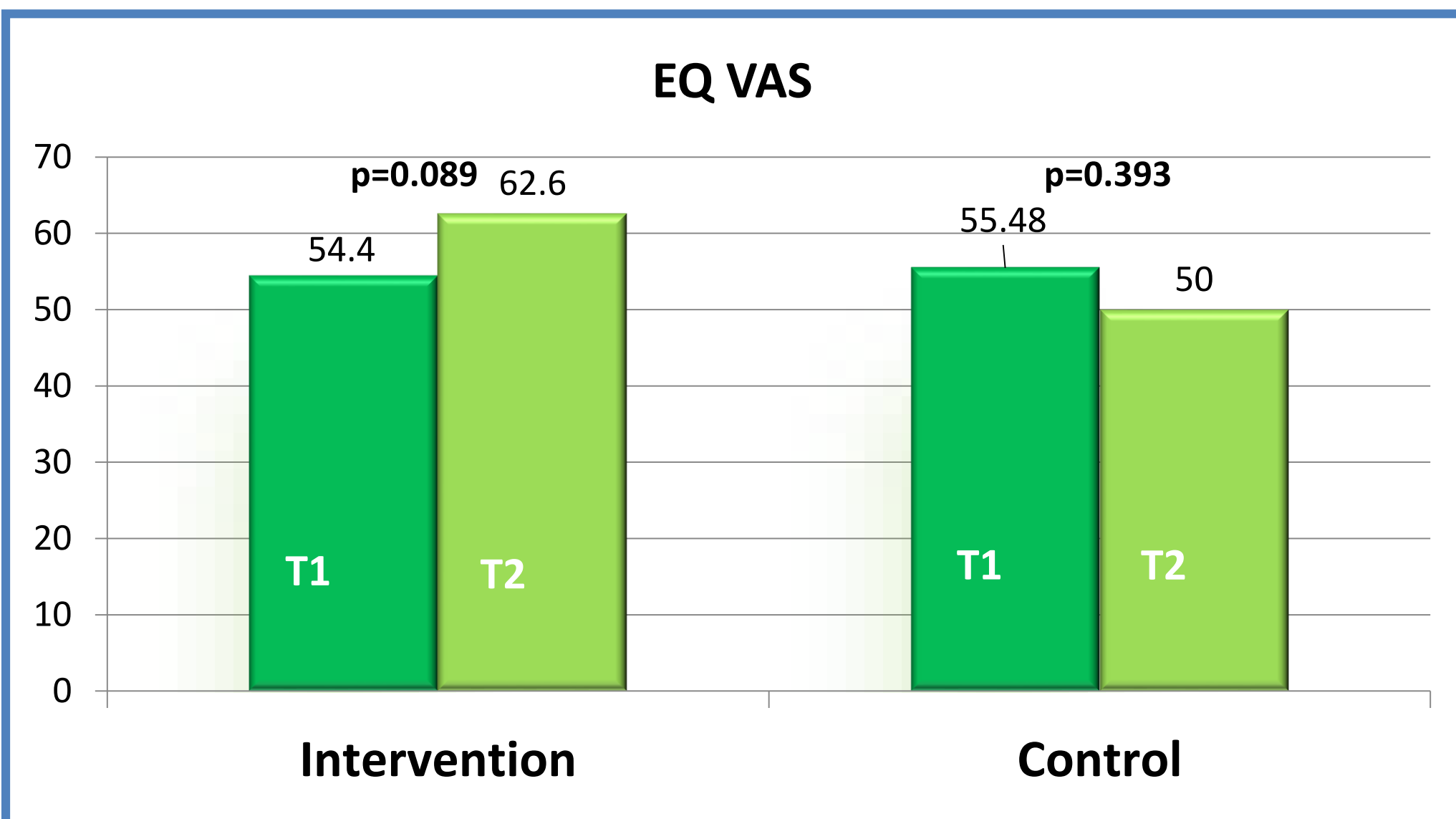
	Intervention Group (n=20)	Control Group (n=21)
Female, %	65%	62%
Age, mean (SD)	36(14.4)	34(10.8)
Disease duration, years, mean (SD)	9.7 (10.1)	9.7 (8.9)
Smokers, %	10%	14.3%
HBI, median (min-max)	8 (6-15)	8 (6-15)

**Figure 1: All parameters significantly improved after CBMI in the Intervention Group but not in the Control Group.**



**Table 2: At baseline, EQ-5D-3L utility index, EQ VAS, SF-12 Physical and Mental Health components in Intervention and Control groups do not differ**

	Intervention Group (n=20)	Control Group (n=21)
EQ-5D-3L utility index , mean (SD)	0.59(0.13)	0.53(0.19)
EQ VAS, mean (SD)	54.4(13.6)	55.5(17.7)
SF-12 Physical Health, mean (SD)	40.3 (6.3)	39.8 (7.7)
SF-12 Mental Health, mean (SD)	39.7(4.9)	40.1(5.8)



## RESULTS

The preliminary analysis included a cohort of 41 patients: 20 in the Intervention and 21 in the Control group. Patients' mean (SD) age was 36 (14.4) and 34 (10.8), mean (SD) disease duration was 9.7 years (10.1) and 9.7 years (8.9), mean HBI was 9.1 and 8.5, for the Intervention and Control groups, respectively. Both utility scores significantly improved over 3 months of follow-up in the Intervention group while showing decrease or slight increase in the Control group. EQ-5D-3L utility weights increased by 0.11 in the Intervention group ( $p<0.01$ ) vs 0.03 in the Controls ( $p=0.54$ ). EQ VAS increased from 54.4 to 62.6 in the Intervention group ( $p=0.09$ ) while decreased from 55.5 to 50 in the Controls ( $p=0.39$ ). SF-12 Mental Health Composite increased by 2.9 points in the Intervention group ( $p=0.03$ ) vs. 2.5 decrease in Controls ( $p=0.15$ ). SF-12 Physical Health Composite increased by 7.3 in the Intervention group ( $p<0.01$ ) vs 2.5 increase in Controls ( $p=0.17$ ).

## CONCLUSIONS

An interim analysis of this randomized controlled trial demonstrated a trend for improved HRQoL following Cognitive Behavioral Mindfulness Intervention. The full study results involving 200 patients could likely demonstrate a clinically and statistically significant improvement in HRQoL in adult CD patients receiving CBMI.