

# Cognitive Behavioral and Mindfulness-Based Stress Reduction Intervention to reduce stress and improve the Quality of Life in Patients with Crohn's Disease

## A randomized interventional study: Preliminary Findings

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### Introduction

Patients with Crohn's disease (CD), a chronic inflammatory bowel disease, suffer from a host of physical and psychological symptoms that impair their ability to handle the disease and makes for poor performance in the social and work setting.

In recent years, Mindfulness Based Stress Reduction (MBSR) and Cognitive-Behavioral Interventions (CBI) have emerged as effective stress reduction interventions for patients with chronic physical illnesses.

The aim of this study was to examine the efficacy of cognitive, behavioral and mindfulness-based intervention in reducing perceived stress levels among patients with mild to moderately active CD.

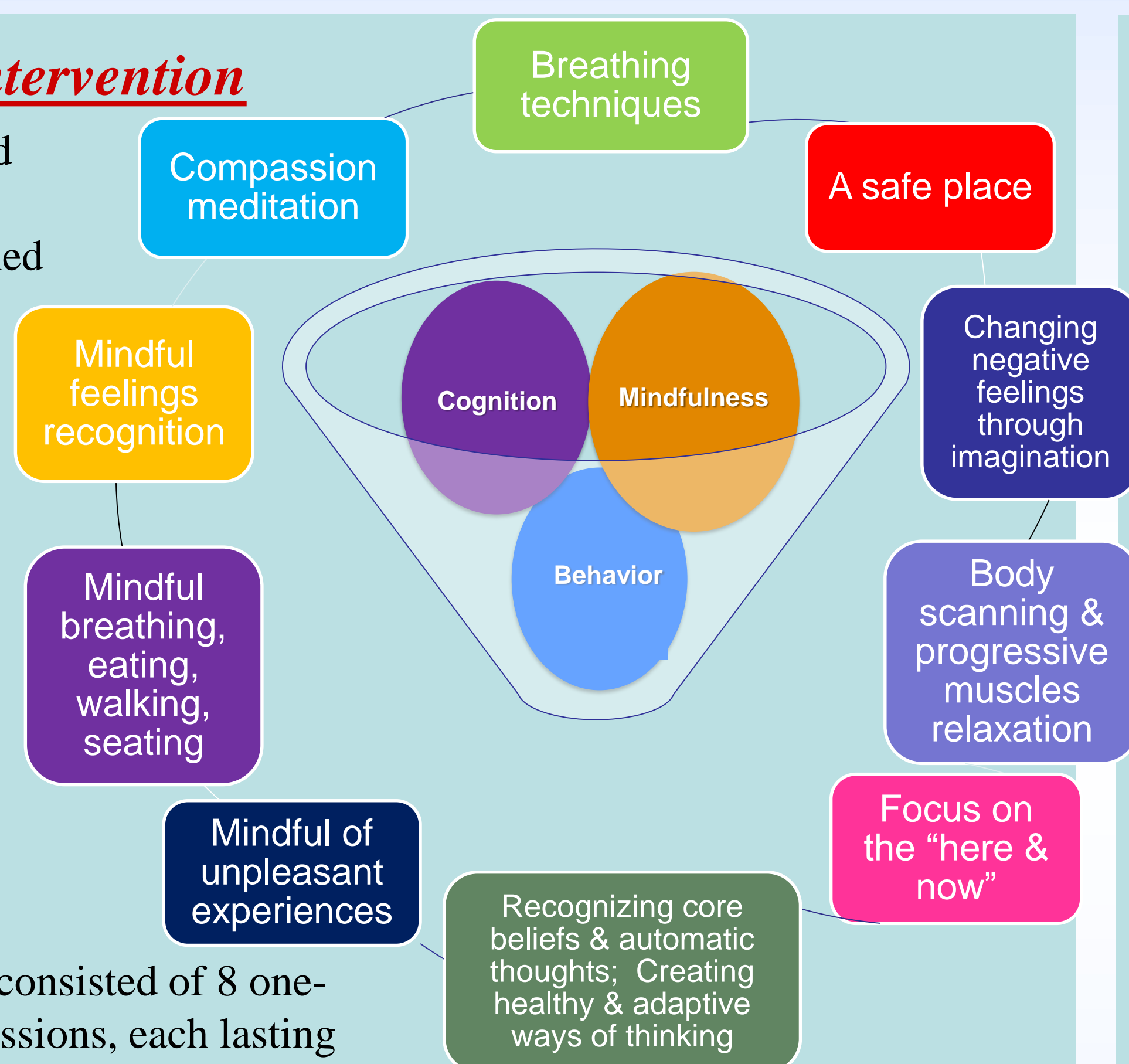
### Methods: Intervention

The standardized intervention program combined CBI & MBSR techniques.

Intervention was administrated by experienced social workers who had received additional training on study's protocol.

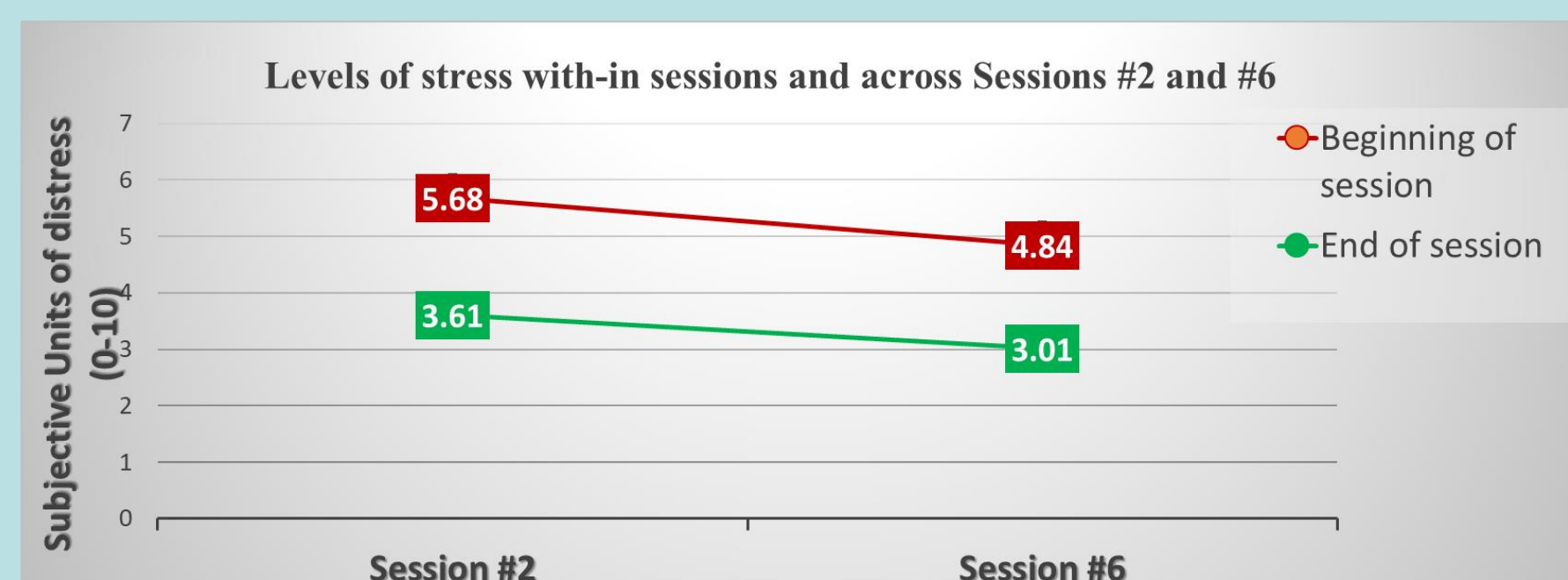
The intervention consisted of 8 one-on-one weekly sessions, each lasting for 60 min. Twice a day home practice with self-report was required.

All sessions were delivered via real-time Video conferencing (Skype™).

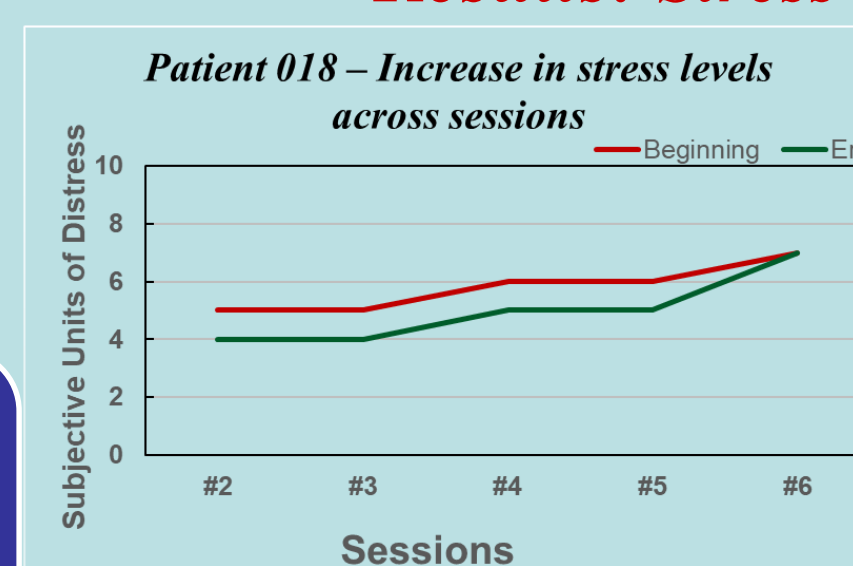


### Results: Stress levels reduced within each therapeutic session and as the patient progressed through the intervention.

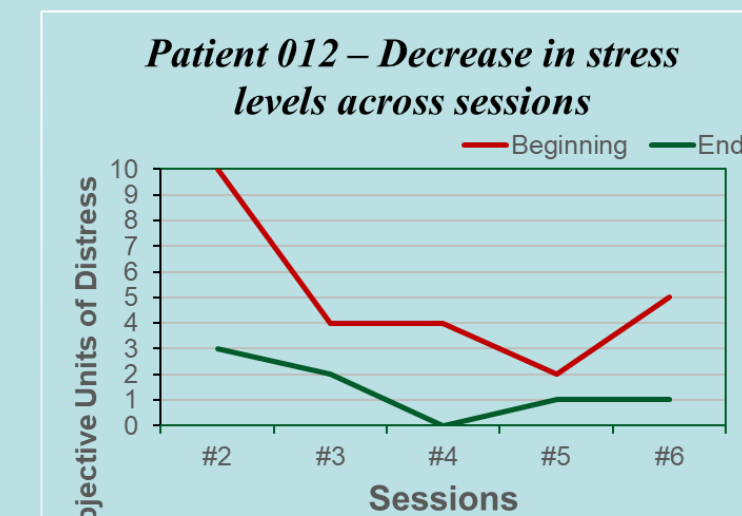
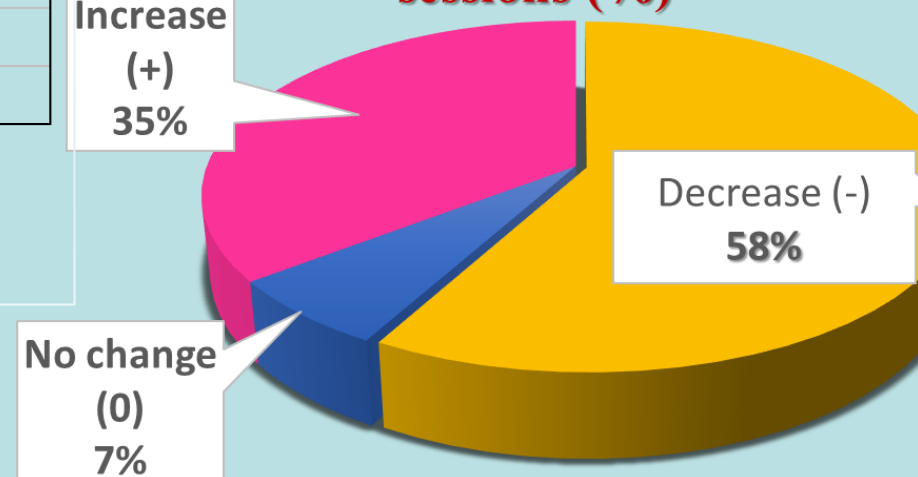
A 2-way ANOVA revealed significant main effects of within-session (pre-post session; {F(1,30)=54.3,  $p<.001$ }, and between-sessions (session #2 vs. session #6; {F(1,30)=4.3,  $p=.048$ }, and no significant interaction.



### Results: Stress levels reduced among the majority of patients



Decrease, no change and increase stress levels among patients across sessions (%)



### Results: Patient's disease activity and severity of mental health symptoms declined after the intervention.

Wilcoxon comparisons of HBI scores indicated a small, just significant, decline from Baseline to Time 2 for the Wait-list group (from 8.0 to 7.5; Wilcoxon  $Z = -1.96$ ,  $p=.050$ ), and a large significant decline in the Intervention group (from 8.0 to 5.0; Wilcoxon  $Z = -2.87$ ,  $p = 0.004$ ).

There was also a significant decrease in BSI scores for the Intervention group, in terms of general symptoms severity scale and depression subscale (e.g. for depressive symptoms: (Wilcoxon  $Z = -2.894$ ,  $p=.004$ ) No significant change was observed on any BSI scale for the Wait-List group.

### Methods: Study design

Patients recruited from gastroenterology clinic and consented to participate in the study were randomized into intervention and wait-list control groups. Wait-list group received the intervention 3 month after recruitment.

The inclusion criteria were (i) age over 18 years, (ii) verified CD diagnosis (iii) mild to moderately active ( $16 \geq \text{HBI} \geq 5$ ), (iiii) at least 3-month post diagnosis.

**Measures:** Levels of stress were assessed using the Subjective Units of Distress scale (SUDS, Wolpe, 1969) at the beginning and end of each individual session. Psychological symptoms were measured using the Brief Symptom Inventory (BSI, Derogotis & Melisaratos, 1983) and disease activity was monitored with Harvey-Bradshaw index, HBI) at entry and post-intervention.

### Methods: Statistical analysis

A 2-way repeated measures analysis of variance measured the changes in SUDS scores during treatment at session #2 vs. session # 6 at the beginning and end of each session. Wilcoxon signed rank test was used for comparing HBI and BSI scores at two time points within groups.

### Results: Sample's Characteristics

A cohort of 31 patients. Patients' characteristics were: Mean age=35.1 ( $SD=12.5$ , range 18-70) years, 68% females, 90% non-smokers, illness duration 9.4 ( $SD=9.0$ , range 0.5-39) years, past surgery in 2 patients. All patients had active disease: Mean HBI= 8.5 ( $SD=2.6$ ).

### Results: Patients' testimonies

"Because of the sessions with the social worker, I feel that the disease bothers me less. I've learned to accept my Crohn's." (A.D, 26 yrs)

"It's not as if I learned to evaporate the pain, but I feel that I learned how to manage the pain. To live with it and not run from it." (J.K, 31 yrs)

"After my first intervention session, it was the first time that I had slept through the entire night in a long time". (L.B, 29 yrs)

### Conclusions:

- ✓ The study shows that a videoconference-delivered Cognitive Behavioral Mindfulness intervention, among active CD patients is feasible in terms of participants' willingness to complete the sessions, daily practice and assessments.
- ✓ The preliminary results suggest that the Cognitive Behavioral Mindfulness based intervention, done by videoconferencing and accompanied by twice-daily home practice, is a promising tool to reduce stress among patients with chronic disease like Crohn's disease. Findings also underscore the health-promoting effects of stress-reduction intervention in terms of decline in patient's disease activity.
- ✓ Use of a larger cohort in a controlled study with year-long follow-up will be carried out to determine the precise efficacy and long-term effect.