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The Potential Role of a Self-Management Intervention for Ulcerative Colitis: A Brief Report From the Ulcerative Colitis Hypnotherapy Trial

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Abstract

Inflammatory bowel diseases (IBD) are chronic inflammatory illnesses marked by unpredictable disease flares, which occur spontaneously and/or in response to external triggers, especially personal health behaviors. Behavioral triggers of flare may be responsive to disease self-management programs. We report on interim findings of a randomized controlled trial of gut-directed hypnotherapy (HYP, $n = 19$) versus active attention control (CON, $n = 17$) for quiescent ulcerative colitis (UC). To date, 43 participants have enrolled; after 5 discontinuations (1 in HYP) and 2 exclusions due to excessive missing data, 36 were included in this preliminary analysis. Aim 1 was to determine the feasibility and acceptability of HYP in UC. This was achieved, demonstrated by a reasonable recruitment rate at our outpatient tertiary care clinic (20%), high retention rate (88% total), and our representative IBD sample, which is reflected by an equal distribution of gender, an age range between 21 and 69, recruitment of ethnic minorities (~20%), and disease duration ranging from 1.5 to 35 years. Aim 2 was to estimate effect sizes on key clinical outcomes for use in future trials. Effect sizes (group × time at 20 weeks) were small to medium for IBD self-efficacy (.34), Inflammatory Bowel Disease Questionnaire (IBDQ) total score (.41), IBDQ bowel (.50), and systemic health (.48). Between-group effects were observed for the IBDQ bowel health subscale (HYP > CON; $p = .05$) at 20 weeks and the Short Form 12 Health Survey Version 2 (SF-12v2) physical component (HYP > CON; $p < .05$) at posttreatment and 20 weeks. This study supports future clinical trials testing gut-directed HYP as a relapse prevention tool for IBD.

Keywords

inflammatory bowel disease; ulcerative colitis; self-efficacy; hypnotherapy; self-management

Inflammatory bowel diseases (IBD), the most common of which include Crohn's disease (CD) and ulcerative colitis (UC), affect as many as 3 million people in North America (Loftus, 2004; Shanahan & Bernstein, 2009) and cost more than $25,000 per person, per year in medical expenditures, absenteeism, and lost productivity (Gibson et al., 2008;

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Longobardi & Bernstein, 2007). The course of IBD is chronic and marked by unpredictable disease flares, which may occur either spontaneously or in response to external triggers (Hanauer, 2004; Keefer, Keshavarzian, & Mutlu, 2008; Levenstein et al., 2000). Medical therapy seeks to manage painful and disabling symptoms, increase cancer surveillance, ward off surgery, and avoid hospitalization whenever possible (Bernstein et al., 2010).

Disease activity, general well-being, quality of life, and health costs in IBD are associated with personal health behaviors such as: (a) adherence to a medication regimen, including maintenance medications (Higgins, Rubin, Kaulback, Schoenfield, & Kane, 2009); (b) management of acute and chronic stress (Keefer et al., 2008; Mawdsley, Macey, Feakins, Langmead, & Rampton, 2006; Mawdsley & Rampton, 2005); (c) establishment and maintenance of a collaborative and communicative patient–physician relationship (Moser et al., 1996; Shoor & Lorig, 2002); (d) quitting smoking (Andrews, Mountifield, Van Langenberg, Bampton, & Holtmann, 2009); (e) obtaining restorative sleep and managing fatigue (Keefer, Stepanski, Ranjbaran, Benson, & Keshavarzian, 2006; Ranjbaran et al., 2007); and (6) maintaining up-to-date knowledge of disease and individual treatment options (Kiebles, Doerfler, & Keefer, 2010; Moser et al., 1996). We have previously demonstrated that IBD patients who have difficulty adapting to disease-related demands report more bowel and systemic symptoms, more pain, less engagement in activities, higher perceived stress, an emotional representation of illness, and higher health care use (Kiebles et al., 2010).

Scientific advances may eventually yield safer, more tolerable or nonsurgical curative therapies for UC. In the meantime, we can optimize current therapy by promoting strong disease self-management skills. In this communication, we report on interim findings of an ongoing randomized controlled trial of a disease self-management program featuring gut-directed hypnosis for quiescent UC. Gut-directed hypnotherapy (HYP) has been an effective intervention in other gastrointestinal disorders, including irritable bowel syndrome, noncardiac chest pain, and acid reflux (Francis & Houghton, 1996; Palsson & Whitehead, 2002, 2006). Studies of mechanistic aspects of gut-directed HYP suggest that hypnosis affects gastrointestinal physiology (gut-transit time, acid secretion) as well as symptom perception and tolerance (Palsson, Turner, Johnson, Burnett, & Whitehead, 2002). Finally, this study is an extension of a previously published case series of gut-directed HYP for IBD that demonstrated improved quality of life (Keefer & Keshavarzian, 2007). Aim 1 is to determine the feasibility and acceptability of gut-directed HYP in quiescent UC. Aim 2 is to estimate effect sizes on key clinical outcomes for use in a future, large-scale trial aimed at IBD self-management more generally. We expected that gut-directed HYP would be a superior self-management tool for patients with UC when compared to a time and attention control group on several key outcomes, including quality of life, self-efficacy, and perceived stress.

Materials and Methods

Study Design

This study is a single-site randomized clinical trial comparing gut-directed HYP versus an active attention control condition (CON). The Institutional Review Board (IRB) at Northwestern University approved the study, and all participants to date have signed a consent form.

Participants

A study coordinator is currently recruiting adult men and women (aged 18–70) with UC, which has been confirmed by a gastroenterologist via endoscopic standards within the past

year following a routine well-visit to their gastroenterologist at our outpatient faculty practice group at Feinberg School of Medicine, Northwestern University. Inclusion criteria include a flare frequency of ≥ once per year, quiescent disease at time of baseline as determined by an adapted Mayo score <12 (Higgins, Schwartz, Mapili, & Zimmerman, 2005), and a stable medication regimen for >30 days. Exclusion criteria include active disease (Mayo score ≥ 12), history of severe or fulminant UC by chart review or physician report; CD, irritable bowel syndrome, renal or hepatic disease; history of colon resection, short bowel syndrome, or indeterminate colitis; steroid dependency, smoking cessation ≤30 days prior to baseline; or contra-indications for hypnosis (e.g., cognitive impairment, past sexual abuse, serious mental illness). Between September 2007 and February 2010, 43 participants were consented and enrolled; 5 participants discontinued participation following baseline (one of which was in the HYP group), while we excluded 2 from analysis due to excessive missing data. A total of 36 participants were included in the preliminary analysis. Upon randomization, we allocated participants to either seven sessions of standardized gut-directed HYP with one of the two trained hypnotherapists ($n = 19$) or to a time-equivalent attention control group ($n = 17$). See Table 1 for demographic and clinical characteristics by group.

Treatment Conditions

Both interventions were standardized and conducted on an individual, outpatient basis at a tertiary gastrointestinal(GI) clinic in an academic medical center. Gut-directed HYP is a session–session standardized treatment protocol derived and adapted from a previously validated treatment protocol for IBS (Keefer & Palsson, 2005; Palsson, 2006). Trained hypnotherapists (LK, JLK) facilitated treatment, which they delivered to participants in seven weekly, 40-min sessions. Facilitators then instructed participants on continued home-based practice of the technique on a weekly to biweekly basis during the year following enrollment. We provided all participants with an audio-file of their hypnotherapist's voice, facilitating a self-hypnotic state. Hypnotic suggestions and imagery reflect primary themes of disease self-management and include maintaining remission, monitoring disease routinely, early detection of flare activity, managing stress, engendering empowerment, minimizing extraintestinal symptoms, promoting general health and well-being, and enhancing self-care.

We developed the CON for this study to control for the effects of clinical attention (Keefer, Kwiatek, & Kiebles, 2008). A doctoral-level physiologist not formally trained in clinical psychology or the delivery of psychological treatments (MK) delivered CON. Sessions include nondirective discussions of the "link between the mind and body in UC" without reference to relaxation, medication adherence, maintaining remission, self-monitoring, or other theoretical "active ingredients" in the HYP condition.

Baseline and Process Measures

Baseline sociodemographic and clinical information—Participants were asked to report demographic and illness-related variables on our standard IBD Center-wide questionnaire. For this study, we were interested in disease duration, duration of most recent flare, medication regimen, and history of steroid use, hospitalizations, and smoking. Participants also reported on the frequency of complementary and alternative medicine (CAM) use (e.g., Have you ever used any of the following to manage your IBD: psychotherapy, prayer, meditation, acupuncture, herbal preparations, massage, yoga, other?) and provided a general medical history.

Inflammatory Bowel Disease Self-Efficacy Scale (IBD-SES)—The IBD-SES (Keefer, Kiebles, & Taft, 2010) is a 29-item validated disease-specific self-efficacy measure.

Responses are rated on a 10-point Likert scale ranging from not sure at all to totally sure. Questions are grouped into four theoretical subscales: managing stress and emotions, managing medical care, managing symptoms and disease, and maintaining remission. The overall score of the IBD-SES ranges from 29 to 290, with a higher score suggesting greater disease-specific self-efficacy.

Perceived Health Competence Scale (PHCS)—The PHCS (Smith, Wallston, & Smith, 1995) is a domain-specific, validated measure that examines the degree to which an individual perceives his or her ability to effectively manage his or her own health outcomes (general health self-efficacy). The PHCS includes eight questions on a 5-point Likert scale ranging from strongly disagree to strongly agree. Higher scores indicate higher perceived competence.

Perceived Stress Questionnaire-Recent (PSQ-Recent)—The PSQ-Recent (Levenstein et al., 1993) is a 30-item validated measure of stress in the past month across seven factors: harassment, overload, irritability, lack of joy, fatigue, worries, and tension. Items are rated on a 4-point Likert scale ranging from almost never to usually. Higher scores suggest greater perceived stress. Researchers have previously reported norms in IBD (Levenstein et al., 2000).

Rating Form of IBD Patient Concerns (RF-IPC)—The RF-IPC (Drossman, Leserman, & Li, 1991) is a disease-specific 25-item measure assessing magnitude of specific current and future worries/concerns related to IBD along a visual analog scale (0–100). Factors include impact of disease, sexual intimacy, complications of disease, and body stigma. Total score is the average of all items, with higher scores indicating greater worry and concern. Drossman and colleagues found higher scores on the RF-IPC to be related to greater disease severity, female gender, and lower socioeconomic status.

The Medication Adherence Scale (MAS)—The MAS (Morisky, Green, & Levine, 1986) is a widely used (Sewitch et al., 2003) 4-item questionnaire that quantifies adherence to an IBD medication regimen (Sewitch et al., 2003; Sewitch, Leffondre, & Dobkin, 2004). The four domains of adherence assessed are (a) forgetting to take medications; (b) being careless around timing of medications; (c) stopping medication when feeling better; and (d) stopping medication when feeling worse. A sum score of 0 reflects 100% adherence in the past month and a sum score of 4 reflects complete lack of adherence.

Outcome Measures

Inflammatory Bowel Disease Questionnaire (IBDQ)—The IBDQ (Irvine, 1999) is a 32-item validated questionnaire designed to assess disease severity and quality of life in IBD, which yields four subscale scores: bowel health, systemic health, emotional functioning, and social functioning. Responses are given on a 7-point Likert scale, ranging from worst function to best function. Lower scores indicate greater disease severity and lower quality of life.

Short Form 12 Health Survey Version 2 (SF-12v2)—The validated SF-12v2 (Ware, Kosinski, Turner-Bowker, & Gandek, 2002) includes 12 items from the Short-Form 36 Health Survey (Ware, 1993) and yields physical and mental composite scores as well as eight subscale values: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. Lower scores correspond with poorer health-related quality of life.

Data Integrity

For obvious reasons, neither therapists nor participants could be blinded to study condition. We did take several steps, however, to maximize the integrity of the data and to decrease the potential for therapist and participant characteristics to threaten the internal validity of this study. First, a study coordinator collected all of the measures to maintain therapist blinding to baseline data and follow-up progress, including if/when a flare occurred. Second, we measured the expectancy and credibility of each condition at pretreatment and posttreatment (Devilly & Borkovec, 2000), and these measures did not differ, suggesting that participants were effectively blinded to the hypothesis. Finally, our statistician (ZM), who was otherwise unfamiliar with the characteristics of the participants, provided block randomization.

Statistical Analysis

We used SPSS 18.0 for Windows (SPSS Inc., Chicago Illinois) to perform statistical analyses. Data were normally distributed across total scale scores. Data from the RF-IPC were positively skewed, with most reporting few-to-no IBD-related concerns. We calculated central tendency and variability, including frequencies, means, standard deviations, and ranges and used chi-square and Fisher's exact tests to evaluate differences in proportions of categorical variables across groups. We performed a 2 × 3 (group × time) mixed design analysis of variance (ANOVA) with planned contrasts (baseline to posttreatment; baseline to 20 weeks) to determine the effect of treatment on process and outcome measures. We also calculated effect sizes by dividing the difference in change means at 20 weeks by the average pooled baseline variance.

Results

Aim 1: Demonstrate Feasibility and Acceptability

Of 212 patients approached, 69 did not return our postclinic follow-up phone call, 30 were not interested (mainly due to time constraints), and 70 were not eligible. Of the 43 enrolled (=20% recruitment rate), 5 participants dropped out (only 1 of which completed a single session of HYP), yielding an 88% rate of retention over a 6-month period with repeated assessments. All remaining participants assigned to HYP completed all seven sessions of hypnosis (100% completion). The same was true in the CON, which speaks to the credibility and acceptability of both interventions. We recommended that participants engage in home-based practice of the skill five times per week during active treatment. Based on self-reported adherence to treatment recommendation for at-home practice, only four subjects were 100% adherent, with a range of 2–100% adherence and an average adherence (54% of participants) of 2–3 times per week. This rate is consistent with both therapists' independent observation.

We had an equal distribution of gender, an age range between 21 and 69 years, and a disease duration ranging between 1.5 and 35 years. Of our sample, 20% was non-White. Table 1 reports demographic characteristics of participants, demonstrating the feasibility and acceptability of this intervention to a broad range of patients. Only prior use of CAM, with 53% of HYP and 35% of CON reporting past usage ($\chi^2 = 10.22$, $p < .05$) differed significantly between the two groups. This difference may be reflective of a randomization failure, but as this is a pilot study, we have decided to control for this baseline difference rather than attempt to stratify participants on this variable. There were no additional differences between HYP and CON at baseline on any categorical or continuous variables.

Aim 2: Estimate Effect Sizes

We calculated the effect size scores based on the difference in change score means divided by the pooled standard deviation at baseline. This technique considers both groups across

time illustrating a group × time effect, commensurate with the ANOVA results. We observed small-to-medium effect sizes ($d > .30$) for self-efficacy (IBD-SES; $d = .34$) and for disease-specific quality of life: IBDQ total score ($d = .41$), IBDQ bowel health ($d = .50$), and systemic health ($d = .48$).

Between-Group Comparisons on Quality of Life

We conducted a 2 × 3 mixed design ANOVA with follow-up planned *t*-tests (baseline to posttreatment; baseline to 20 weeks). There was a statistically significant group-by-time interaction effect for the IBDQ bowel health subscale ($F(1) = 4.1$, $p < .05$) with the hypnosis condition improving more than the CON at 20 weeks ($p = .05$). There was also a significant group-by-time interaction effect for the SF-12v2 physical component summary score ($F(1) = 5.3$, $p < .05$) such that the hypnosis condition reported more improvement in physical quality of life over time at both posttreatment ($p = .04$) and 20 weeks ($p = .03$). See Table 2.

Discussion

Aim 1 of this report on interim findings of our ongoing NIH-funded randomized controlled trial of a self-management intervention for quiescent UC was to determine the feasibility and acceptability of gut-directed HYP in UC. Evidence that we have achieved this aim includes our reasonable recruitment rate at our outpatient tertiary care clinic (20%), a high retention rate (~88% total, only 1 dropout in HYP), and a range of IBD patients who participated. We had an equal distribution of gender, an age range between 21 and 69 years, 20% ethnic diversity, and a disease duration range of 1.5–35 years.

Aim 2 was to estimate effect sizes for key clinical outcomes for use in a future, large-scale trial aimed at IBD self-management more generally. Effect sizes are a useful way to estimate clinically relevant changes in health status and, supplemental to standard statistical estimates of significance, provide “a more complete and clinically relevant picture of health status change” (Kazis, Anderson, & Meenan, 1989). Cohen’s (1988, 1992) guidelines specify the following: minimal to no effect 00–.19, small .20–.49, medium .50–.79, and large effects ≥. 80. While Aim 2 was really designed to estimate effect sizes for future trials, we cannot help but notice that the majority of our effect sizes on key patient outcome variables were greater than .30 (average effect size across all measures = .31; range .12–.50). We are optimistic that with a larger sample, the modest effect sizes already seen in self-efficacy and disease-specific quality of life will warrant future studies aimed at improving disease self-management in IBD more generally.

Limitations

Our sample was in remission; thus participants were relatively well and their quality of life was reasonably intact. Despite this, we did see improvements in quality of life and well-being, suggesting that patients in remission still benefit from disease management skills. This observation is important because patients are often highly adherent and motivated to manage their disease during flare but take a more lax approach during remission.

There was a difference between groups on CAM use, which we think may be related to a randomization failure. Rather than stratify on this variable, we have controlled for prior CAM use in our analyses. CAM use in IBD is high in general and unlikely to have significantly influenced our sample (Bernstein, 2004; Burgmann, Rawsthorne, & Bernstein, 2004).

As is usually the case when one reports preliminary data, this study is underpowered (we would need 23 more subjects to detect true efficacy between groups). However, an estimate

of effect sizes suggests that efficacy of HYP over CON will be established with an increased sample size, recruited during the final year of the trial.

We rely solely on self-report measure of outcome in this study. However, future trials aimed at determining the effects of self-management on disease activity more directly through standard biomarkers (fecal calprotectin, C-reactive protein, etc.) would further speak to the impact of such interventions on disease outcome. Finally, the intervention reported here reflects only a few components of traditional self-management interventions—while these can be effective, certain patients may require a more comprehensive approach to disease management.

Summary

Consistent with a social-learning theory view of disease self-management (Bandura, 1977, 2004; Lorig & Holman, 2003), this study demonstrates that when an individual successfully adopts new health behaviors (e.g., self-hypnosis or stress reduction), they can feel improvement in the experience of their disease, especially in the areas of self-efficacy and quality of life. Nursing has an important role in educating and empowering patients with chronic diseases to use self-management skills to meet the challenges of their disease. This pilot study suggests that gut-directed HYP may be one aspect of a more comprehensive disease-management program for IBD.

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Table 1

Baseline Demographic and Clinical Characteristics From the Ulcerative Colitis Relapse Prevention Trial (UCRPT) for Hypnotherapy (n = 19) and Control (n = 17) Conditions

Variable	Hypnotherapy	Control	p Value[a]
Demographics			
Age (mean [*SD*, range])	38.6 (11.5, 23–65)	41.5 (13.3, 21–69)	NS
Female gender (frequency [%])	13 (68%)	8 (47%)	NS
Race: non-Hispanic White (frequency [%])	15 (79%)	16 (94%)	NS
Marital status: single (frequency [%])	9 (47%)	6 (35%)	NS
Education: college + (frequency [%])	16 (84%)	11 (65%)	NS
Use of CAM: sometimes + (frequency [%])	10 (53%)	6 (35%)	<.05
Disease characteristics			
Duration of last flare (weeks; mean [*SD*, range])	6.1 (4.9, 1–16)	6.6 (6.0, 0.1–24)	NS
Frequency of hospitalizations (mean [*SD*, range])	1.4 (.8, 0–4)	1.4 (1.5, 0–7)	NS
Disease duration (years; mean [*SD*, range])	11.0 (8.8, 1.5–35.3)	10.7 (8.6, 1.6–29.5)	NS
Past use of steroids: yes (frequency [%])	12 (63%)	11 (65%)	NS
Process measures			
IBD Self-Efficacy Scale (mean [*SD*, range])	219.9 (48.8, 111–288)	219.8 (36.6, 156–290)	NS
Perceived Health Competence Scale (mean [*SD*, range])	30.4 (6.0, 16–38)	29.6 (4.5, 22–37)	NS
Perceived Stress Questionnaire (mean [*SD*, range])	63.7 (18.5, 31–96)	60.6 (13.5, 41–89)	NS
Overall sleep quality: very good (frequency [%])	5 (26%)	5 (29%)	NS
Daytime energy: no problem (frequency [%])	7 (37%)	6 (35%)	NS
Duration of sleep (hr; mean [*SD*, range])	6.9 (1.2, 4–9)	7.1 (.9, 5–9)	NS
Rating Form of IBD Patient Concerns (mean [*SD*, range])	30.6 (22.6, 4–80)	34.1 (17.7, 1–69)	NS
Outcome measures			
IBDQ total score (mean [*SD*, range])	190.6 (19.3, 147–220)	192.9 (20.1, 139–216)	NS
IBDQ bowel health (mean [*SD*, range])	62.3 (6.3,43–70)	61.1 (6.6,47–70)	NS
IBDQ systemic health (mean [*SD*, range])	25.5 (6.6,13–34)	26.2 (5.0,14–32)	NS
Short Form Health Survey Version 2 (mean [*SD*, range])			
Physical component summary	53.9 (4.6, 40–60)	51.1 (7.6, 27–59)	NS
Mental component summary	46.9 (10.2, 27–59)	49.0 (9.0, 31–60)	NS

Note: CAM = complementary and alternative medicine; IBD = inflammatory bowel disease; IBDQ = Inflammatory Bowel Disease Questionnaire; *SD* = standard deviation.

[a]Differences observed between two groups using crosstabulations and chi-square statistic across all categories. No differences were observed between hypnotherapy and control groups using independent samples t-test (continuous variables).

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Table 2

Group Mean (*SD*) Scores Across Baseline, Posttreatment and 20 Weeks for Hypnotherapy (HYP) and Control (CON) Conditions

Variable/Group	Baseline	Posttreatment	20 Weeks	ANOVA *F*-Ratio, *p*-Value[*]	Between-Group Difference in Change Score Effect Size (*d*)[a]	Sample Size Estimate for Future Studies by Measure *N*
IBD Self-Efficacy Scale				NS	**.34**	62
HYP	219.9 (48.8)	230.5 (54.1)	234.5 (43.8)			
CON	219.8 (36.6)	219.5 (37.2)	220.0 (37.2)			
Perceived Health				NS	.17	124
Competence Scale						
HYP	30.4 (6.0)	32.3 (5.7)	32.3 (5.4)			
CON	29.6 (4.5)	29.6 (4.5)	30.6 (4.6)			
Perceived Stress				NS	.12	124
Questionnaire						
HYP	63.7 (18.5)	61.9 (20.4)	61.8 (20.6)			
CON	60.6 (13.5)	60.1 (12.9)	60.6 (15.3)			
Rating Form of IBD				NS	.24	68
Patient Concerns						
HYP	30.6 (22.6)	18.7 (17.1)	20.7 (22.0)			
CON	34.1 (17.7)	27.8 (16.2)	29.1 (21.8)			
Medication				NS	.22	
Adherence Scale						
HYP	1.1 (1.0)	.7 (1.0)	.8 (1.1)			
CON	.9 (1.1)	.9 (1.0)	.6 (0.7)			
IBDQ total score				NS	**.41**	36
HYP	190.6 (19.3)	192.8 (23.9)	198.2 (20.6)			
CON	192.9 (20.1)	188.9 (19.3)	192.4 (14.5)			
IBDQ bowel score				**4.1,** p = **.05** [*]	**.50**	24
HYP	62.3 (6.3)	63.5 (6.1)	64.5 (6.0)			
CON	61.1 (6.6)	58.6 (7.9)	60.1 (6.4)			
IBDQ systemic score				NS	**.48**	24
HYP	25.5 (6.6)	27.8 (5.9)	28.7 (4.8)			
CON	26.2 (5.0)	25.5 (6.3)	26.6 (4.8)			

Variable/Group	Baseline	Posttreatment	20 Weeks	ANOVA *F*-Ratio, *p*-Value*	Between-Group Difference in Change Score Effect Size (*d*)[a]	Sample Size Estimate for Future Studies by Measure *N*
Short Form Health Survey						
Physical component summary				**5.3,** p < **.05** *	.25	68
HYP	53.9 (4.6)	55.3 (4.4)	55.0 (4.3)			
CON	51.1 (7.6)	50.4 (7.8)	50.7 (7.4)			
Mental component summary				NS	.26	68
HYP	46.9 (10.2)	48.7 (11.0)	48.9 (9.2)			
CON	49.0 (9.0)	51.4 (6.4)	48.5 (6.5)			

Note: Text in bold reflects a clinically significant effect size. ANOVA = analysis of variance; IBD = inflammatory bowel disease; IBDQ = Inflammatory Bowel Disease Questionnaire; *SD* = standard deviation.

[a]Effect size interpretation (Cohen, 1988): no effect 0–.19, small .20–.49, medium .50–.79, and large effect ≥ .80; clinically significant effect size is estimated at ≥ .30.

*p-value < .05 is significant.

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