

## Effects of guided imagery with relaxation training on anxiety and quality of life among patients with inflammatory bowel disease†

Maya C. Mizrahi<sup>ab</sup>, Rebecca Reicher-Atir<sup>b</sup>, Sigal Levy<sup>b</sup>, Sara Haramati<sup>c</sup>,  
Dov Wengrower<sup>a</sup>, Eran Israeli<sup>c</sup> and Eran Goldin<sup>a\*</sup>

<sup>a</sup>Department of Gastroenterology, Shaare Zedek Medical Center, Digestive Disease Institute, Affiliated with the Hebrew University School of Medicine, Jerusalem, Israel; <sup>b</sup>Academic College of Tel-Aviv-Yafo, Tel-Aviv, Israel; <sup>c</sup>Department of Gastroenterology, Hadassah Hebrew University Medical Center, Jerusalem, Israel

(Received 17 October 2011; final version received 1 May 2012)

**Background:** Inflammatory Bowel Disease (IBD) impacts quality of life (QoL). Psychological factors influence the course of the disease and should be targeted for intervention.

**Methods:** Our study was a prospective, randomised control trial. Fifty-six outpatients were randomly chosen and allocated to a treatment group or a waiting-list control group. Treatment group patients attended three relaxation-training sessions and received an audio disc for home practice. Evaluations performed pre and post-treatment: state anxiety was assessed with the State-Trait Anxiety Inventory, QoL with the IBD Questionnaire. The Visual Analogue Scale assessed pain, depression, stress and mood. Patients completed a symptom monitoring diary. The control group's symptoms were monitored without study-related treatment.

**Results:** Thirty-nine subjects completed the study and were included in the data analysis. Following the relaxation-training intervention, the treatment group's ( $n=18$ ) measured results showed a statistically significant improvement as compared to the control group ( $n=21$ ) (time by treatment interaction): anxiety levels decreased ( $p < 0.01$ ), QoL and mood improved ( $p < 0.05$ ), while levels of pain and stress decreased ( $p < 0.01$ ).

**Conclusions:** Findings indicate IBD patients may benefit from relaxation training in their holistic care. New studies as well as further investigation of the subject are warranted.

**Keywords:** Crohn's disease; ulcerative colitis; relaxation; quality of life; anxiety; IBD

### Introduction

Inflammatory bowel disease (IBD) is a chronic inflammatory disease of the gastrointestinal tract that appears in the form of Crohn's disease (CD) or ulcerative colitis (UC). IBD is characterised by periods of exacerbation and remission whilst the

---

\*Corresponding author. Email: erang@szmc.org.il

†This study was derived from a master's thesis by M.C. Mizrahi under the supervision of R. Reicher-Atir.

symptoms include abdominal pain, diarrhoea, weight loss, vomiting and fever (Achkar, 2001; Moses, Moore, Ferrentino, Bensen, & Vecchio, 1998; Mussell, Bocker, Nagel, Olbrich, & Singer, 2003; Thompson, 1993). Disease onset often occurs between the ages of 15–25, thus IBD is a most significant childhood and adolescence (MacPhee, Hoffenber, & Feranchak, 1998) illness suggesting that patients' management of the disease continues throughout most of their adult life. Another peak in incidence of IBD often occurs between the ages of 60–80 (Tojek, Lumley, Corlis, Ondersma, & Tolia, 2002). The aetiology of IBD is still unknown, although current literature supports the claim that interactions of genetic, immune and environmental factors trigger the inflammatory process (Mittermaier et al., 2004; Sainsbury & Heatley, 2005; Searle & Benett, 2001; Smolen & Topp, 2001). Thus, implying IBD patients' chronic disease requires psychological and social adjustments to cope with numerous complications; with treatments requiring recurrent hospitalisations; surgical interventions and the possible side effects of drug therapy (Podolsky, 1991).

#### **Mind/body–Stress/disease relationship**

The vicious mind/body–stress/disease cycle can be interpreted in a bidirectional manner: the disease and the disease symptoms may promote stress and distress (Schwarz & Blanchard, 1991) or the psychological stress and distress may exacerbate symptomatology and disease activity (Dudley-Brown, 2002; Maunder, 2005; Searle and Benett, 2001). Duffy et al. (1991) investigated the impact of stress on recurrence of IBD. They found that patients' exposure to major stressful events led to a 20% greater risk of developing an active disease or exacerbation of the symptoms. Furthermore, stressful events often predicted an increase in disease activity (Duffy et al., 1991). Stress has been defined as any influence that disturbs the natural equilibrium of the body, and includes a variety of illnesses and emotional disturbances (Cox, 1978). Individuals respond to new and challenging environmental information cognitively and physiologically by activating the sympathetic nervous system and the hypothalamic–pituitary–adrenal-axis. This response may have an effect on health in the following manner: stress stimulates the sympathetic nervous system which results in release of norepinephrine. Norepinephrine increases the heart rate and the force of cardiac contractions, thus causing blood pressure to rise. Simultaneously, adrenocorticotrophic hormone from the anterior pituitary gland stimulates the adrenal cortex to release aldosterone and cortisol, also known as 'stress hormones' (Fukudo, Nomura, & Hongo, 1998). Clearly, stress impacts the body's responses directly. This response to stress, also called 'fight or flight', is an effective short-term reaction to an immediate threat, not intended to be a constant state. When the 'fight or flight' response becomes constant, as in the case of a chronic and prolonged illness, the physiological components of the response produce harmful results, such as increased blood pressure, or exacerbation of diseases such as IBD (Jansen, Nguyen, Karpitskiy, Mettenleiter, & Loewy, 1995). IBD symptomatology has an effect on the intestinal system caused by the 'fight or flight' response (Mayer, 2000). An intervention aiming at reducing the body's stress reaction or moderating its arousal may reduce the intensity or the frequency of these symptoms (Mawdsley & Rampton, 2005). Furthermore, the literature indicates that stress

increases the risk of IBD exacerbation (Levenstein et al., 2000). Therefore, reducing anxiety and stress may serve as a preventive treatment.

### **Psychological aspects of IBD**

#### ***Psychological distress***

The role of psychological distress in the aetiology of patients with IBD, as it precipitates and exacerbates the disease symptoms, has been previously researched, as well as the correlation between psychological distress and disease states (Casati & Toner 2000; Dudley-Brown, 2002). Seventy four percent of IBD sufferers believe that psychosocial factors contribute to the course of their disease (Moser, Maier-Dobersberger, & Vogelsang, 1993).

#### ***Anxiety***

Anxiety can be defined as ‘an inner emotional disquiet, which may be aroused by a threat to well-being’ (Davies, Blakeley, & Kidd, 2001) and regarding its components, ‘anxiety is made up of subjective feelings of tension and apprehension as well as autonomic arousal’ (Spielberger, 1983). State-anxiety is a transitory condition of the organism and varies in degree from moment to moment, whereas trait-anxiety refers to relatively stable differences in a person’s predisposition to respond with heightened anxiety to threatening stimuli. Several studies report anxiety in 25–50% of IBD patients (Kurina, Goldacrem, Yeates, & Gill, 2001; Larsson et al., 2003; Lyte, Li, Opitz, Gaykema, & Goehler, 2006) and IBD patients report a higher degree of anxiety and depression as compared to healthy controls (Addolorato et al., 1996; Kurina et al., 2001). Furthermore, up to 80% of IBD patients with an active disease suffer from state anxiety (Addolorato, Capristo, Stefanini, & Gasbarinni, 1997).

#### ***Quality of life***

The term ‘health-related quality of life’ (HRQoL) refers to the physical, psychological and social domains of health that are influenced by a person’s experiences, beliefs, expectations and perceptions (Irvine, Feagan, & Rochon, 1994). IBD are chronic, recurrent diseases which have a significant impact on the patients’ quality of life (QoL). Multiple studies demonstrate an impaired QoL among patients with IBD (Casati, Toner, De Rooy, Drossman, & Maunder, 2000; Cohen, 2002; Hall & Rubin, 2005; Larsson et al., 2003; Love, Irvine, & Fedorak, 1992; Sainsbury & Heatley, 2005; Smolen & Topp, 2001).

### **Psychological interventions among IBD patients**

Various intervention studies have been designed to focus on the psychological treatment of IBD patients. Schwarz and Blanchard (1991) tested the effectiveness of a multi-component behavioural treatment package, of cognitive coping strategies including: education, muscle relaxation, biofeedback and training as compared with the effectiveness of a symptom-monitoring package used as the control procedure, in patients with IBD (Schwarz & Blanchard, 1991). At post-treatment, the control

group showed improvement on a measure of total symptomatic change compared to the study group. The treated subjects perceived themselves as coping better with IBD, as feeling less IBD-related stress, and reported experiencing less depression and anxiety. Maunder and Espfen (2001) investigated the effect of supportive-expressive psychotherapy administered during 20 weekly meetings, in which emotional and interpersonal issues associated with IBD were discussed. Results showed no change in the group's mean rate of QoL, anxiety or depression over the course of treatment, although there was a reduction in the group's mean rate of maladaptive coping. Jantschek et al. (1998) examined the effects of psychodynamic psychotherapy with relaxation training on the course of IBD. The main analysis failed to show statistically significant differences between the study group that received psychotherapy and relaxation training and the control group. Smith (2002) examined a program involving coping mechanisms and relaxation techniques *versus* standard care. Whilst the program helped reduce anxiety and improved health related QoL, the effects were not sustained the following 12 months. As demonstrated, various forms of intervention were tested on patients with IBD, however, none of these studies provide compelling evidence for benefit. All of the aforementioned studies used interventions that were multi-component; they involved more than one technique and performed in-group settings. The present study aims at reducing these complexities, by designing an individual intervention that focuses strictly on relaxation techniques. These are easy to learn and require few resources thus making them highly feasible in hospital settings. Moreover, they have been proven as an effective intervention in other chronic diseases (Baird & Sands, 2006; Halpin, Speir, CapoBianco, & Barnett, 2002; Ilacqua, 1994; McCauley, Thelen, Frank, Willard, & Callen, 1983).

### **Relaxation techniques and guided imagery**

Relaxation is a state of both physiological and mental rest. Relaxation techniques comprise any method, process or activity that helps a person relax, attain a state of calm and reduce levels of anxiety, stress or tension (Dudley-Brown, 2002; Jacobson, 1967). During relaxation, neuromuscular activity is reduced, leading to decreased proprioceptive input into the hypothalamus. This results in decreased activation of the sympathetic nervous system and a reduction in the arousal state of the cerebral cortex (Kim & Kim, 2005). Subsequently, relaxation techniques can decrease muscle tension, lower blood pressure and slow heart and breath rates, in addition to providing other health benefits (Brewer, 1999; Northfield, 1973).

In diaphragmatic breathing individuals are instructed to expand their diaphragm as they inhale, and relax the diaphragm as they exhale, aiming to minimise or even stop chest and accessory muscle breathing (Calderon & Thompson, 2004). In progressive muscle relaxation, individuals learn to recognise tension changes in different muscle groups in the body, by first tensing or contracting a given muscle, then relaxing it. Thus, muscle groups are systematically tensed and released one at a time (Jacobson, 1938). Guided imagery is a technique that helps individuals to focus on mental images and scenes that evoke relaxation. The principle behind guided imagery is to provide a relaxing image for the mind to focus on, thereby interrupting stressful thoughts and images and replacing them with relaxing ones (Ilacqua, 1994). Whilst treating individuals with physical disabilities, the aim is to empower the

patient with their disease-related issues as well as enhance their self-control (Smolen & Topp, 2001).

The beneficial effect of relaxation training was exhibited in a meta-analysis of 48 studies evaluating relaxation in patient populations. The evidence demonstrates that this treatment improves hypertension, headaches and insomnia, and also has an effect, albeit to a lesser degree, on anxiety and chronic pain (Hyman, Feldman, & Harris, 1989). Several studies suggest that relaxation training is effective in a variety of physical illnesses, including: cardio-vascular diseases (Halpin et al., 2002), back pain (McCauley et al., 1983), oncological diseases (Kim & Kim, 2005; Smolen & Topp, 2001), arthritis (Baird & Sands, 2006) and perioperative pain (Halpin et al., 2002).

### **Aim of the study**

The aim of this study was to evaluate the effects of an individual, short term intervention combining relaxation training (diaphragmatic breathing and progressive muscle relaxation) and guided imagery, based on self-practice. The study examined the intervention's impact on anxiety, QoL, pain, depression, stress, mood and intestinal symptoms in patients with IBD.

*Hypotheses:* (1) The state-anxiety levels of patients participating in the relaxation-training intervention will be lower than those of the control group. (2) The QoL ratings of patients participating in the relaxation training will be higher than those of the control group. (3) The Visual Analogue Scale (VAS) measurements of pain, depression, stress and mood will improve in patients receiving the relaxation training compared to the controls. (4) The intestinal symptoms of patients participating in the relaxation-training intervention will be lower than those of the control group.

### **Method**

#### ***Subjects***

Participants were selected from the patient database of the IBD Centre, at the Hadassah Medical Centre in Jerusalem. A randomised controlled trial was used. Recruitment was via telephone, and participation in the study was offered to 119 randomly selected patients. Seventy-five accepted and 56 met the study inclusion criteria, which consisted of: (1) confirmed diagnosis of IBD for at least six months prior to recruitment; (2) age over 18 years; (3) suffering from an 'active' disease according to the 'Disease Activity Questionnaire', by meeting one of the following criteria: more than five bowel movements a day, more than one hospitalisation a year over the previous 2 years, and either had suffered a fistula during the previous year or was using corticosteroids; (4) provided informed consent and (5) fluent in the Hebrew language. The exclusion criteria comprised of: (1) expected surgery in the following two months; (2) diagnosed as suffering from an active psychosis or from active major depression (due to the hazard of psychotic-symptom-abreactions this would be contra-indicative for relaxation); (3) undergoing psycho-pharmacotherapy (anti-anxiety, anti-depression or anti-psychotic); (4) already participating in another research study and (5) acquainted with, and already practicing relaxation techniques.

Fifty-six participants were randomly assigned to one of two groups: a treatment group and a waiting-list control group that was being monitored for symptoms.

### ***Instruments***

Participants' data was collected using several self-report questionnaires. *Demographic and medical* data included age, disease duration, diagnosis, gender, status and pharmacological treatment. Screening and assessment was done with the *Disease Activity Questionnaire*, an unpublished questionnaire developed by Dr Israeli and Dr Lan, senior gastroenterologists at Hadassah Medical Centre. The questionnaire is based on Lennard-Jones (1989) criteria for diagnosing IBD, and on Beaugerie, Seksik, Nion-Larmunier, Gendre and Cosnes (2006) criteria to define IBD course as active or in remission. All study subjects were assessed at pre- and at post-treatment whilst the controls were assessed at baseline and at the end of the waiting-list period. Assessment was performed using the following instruments:

*Anxiety* was assessed using Spielberger's State-Trait Anxiety Inventory (Spielberger, 1983). The state-anxiety that was used in the present study consisted of 20 short affirmative statements reflecting a transitory emotional state at a particular moment in time. Total scores ranged from 20 to 80, with a higher score reflecting higher levels of anxiety. Clinically, a score of 20–39 implied lack of anxiety, 40–59 – moderate anxiety and a score of 60–80 – severe anxiety. The original instrument has been validated and found to be reliable (Spielberger, 1983), as was its Hebrew version (Tychman & Melnick, 1979). In the current study, the Cronbach's alpha reliability was 0.924 and 0.941 for pre and post-treatment, respectively.

QoL was assessed using the IBD Questionnaire (IBDQ) which is a disease-specific quality-of-life assessment instrument for IBD (Guyatt et al., 1989). Adapted for clinical trials, the questionnaire includes 32 items that examine four aspects of a patient's life during the two weeks prior to assessment: intestinal symptoms, systemic symptoms, social functioning and emotional functioning. The response to each item is scored on a 7-point Likert scale, on which 7 corresponds to the highest level of functioning and 1 to the lowest. The overall scores of the IBDQ ranged from 32 to 224 (Guyatt et al., 1989). Guyatt et al. (1989) designed and validated the IBDQ: The Hebrew version has been validated by the Mapi Institute. In the current study, the Cronbach's alpha reliability was 0.925 and 0.929 for pre and post-treatment, respectively. The subscales reliability ranged between 0.657 and 0.902.

*VAS*, each with a 10 cm linear scale, used for measuring four domains: pain, depression, stress and mood. The time scale referred to the 24 hours prior to assessment. VAS measurements evaluate the changes in a person's subjective perception. The overall scores for each measurement ranged from 0 to 10, with a higher score reflecting a worse state as perceived by the patient.

*Symptom-monitoring diaries* were used throughout the study period to track daily gastrointestinal symptoms, including: number of bowel movements, fever, vomiting, abdominal pain and weight-changes. Patients were instructed to complete these diaries each and every evening to ensure accurate reporting.

*Log sheets of relaxation practice* were completed by the treated patients during the intervention period. They were asked to keep track of the frequency and time of day when they practiced relaxation, and each day to rate the level of relaxation they felt.

### **Study design**

*Recruitment:* All the participants were recruited and assigned via telephone to either the treatment or the control group. After a brief phone screening, all those recruited for the study were invited to a personal interview.

*Personal interview and pre-treatment assessment:* Each participant received a detailed explanation about the study and the procedures and signed the informed consent form. They completed the pre-treatment assessment questionnaires and underwent individual semi-structured interviews.

*Intervention stage:* For the treatment group, the intervention consisted of three individual relaxation-training sessions at two-week intervals. Relaxation training with guided imagery served as the basis for the three, 50-minute treatment sessions. Each treatment session included: (1) a relaxation exercise with guided imagery, (2) a brief review of the relaxation monitoring forms, used to assess difficulties and (3) a discussion of any problems the patient may have experienced whilst attempting to achieve relaxation. Each subject received an audio disc and was requested to continue practicing at home. They were advised to practice at least once a day, during the whole 5-week period of the study and to record the frequency of home practice in the provided log sheets. The control subjects on the waiting-list were assessed at baseline and approximately five weeks later, at the end of the waiting-list period. They completed symptom-monitoring diaries both at baseline and at the end of the trial. After completing the diaries and following analysis of the collected data, the control subjects were offered treatment in a group setting.

*Relaxation and guided imagery audio disc for the treatment group:* The researchers developed and designed an audio disc for home practice. This audio disc contained the therapist's familiar voice with soothing music in the background and was approximately 15 minutes in duration. The relaxation exercise consisted of deep breathing relaxation, progressive muscle relaxation and guided imagery (of a 'safe place').

*Post-treatment assessment:* The post-treatment assessment was completed approximately five weeks following the first assessment. At the end of the final session, each participant in the treatment group received a stamped envelope containing questionnaires and a symptom diary they were requested to fill out at home and send back after completion. The control group participants received a stamped envelope that contained the outcomes at the end of the waiting-list period consisting of questionnaires and symptom diaries.

### **Data analysis**

The Statistical Package for Social Sciences Software (SPSS version 10.0) was used for data analysis. The chi-square test was used to compare demographic characteristics between the control and treatment groups. The independent samples *t*-test was used to compare differences in the mean scores of the control and treatment groups with respect to age, disease duration and the scores on state-anxiety, IBDQ, VAS domains and the number of bowel movements. Repeated measure analysis of variance (R-ANOVA) was employed to identify differences over time between the control and

treatment groups in terms of the change in state-anxiety levels, IBDQ and its four domains, VAS domains (pain, depression, stress and mood) and the number of bowel movements. The within-subjects-factor used was time, and the between-subjects-factor was treatment procedure (treatment group *vs.* controls). In cases where the difference was found to be statistically significant, paired *t*-tests were applied to identify within-group changes from baseline to post-treatment or to end of the waiting-list period, respectively.

### ***Ethical considerations***

*Ethical approval* was obtained from the Ethics and Research Committees of the Hadassah Medical Centre, in accordance with the 1975 Helsinki Declaration. As aforementioned, all participants signed an informed consent form.

## **Results**

### ***Demographic data***

Fifty-six subjects were randomly assigned to either a treatment group ( $n=28$ ) or a control group ( $n=28$ ). The dropout rate was 30% ( $n=17$ ) failing to complete the study. Eight participants from the treatment group dropped out either due to medical reasons or time constraints, preventing them from attending the sessions; nine participants failed to return the questionnaires (two from the treatment group and seven from the control group). Thirty nine completed the study, 18 in the treatment group and 21 in the control group, provided complete data sets and were included in the data analysis.

Among the 39 participants, 17 (43.6%) were female and 24 (61.5%) had CD. The age range was 20–69 years ( $M=35.56$ ;  $SD=13.38$ ).

Selected demographic and medical characteristics of the participants who completed the study are summarised in Table 1. Comparisons across the groups showed no statistically significant differences with regard to demographic variables, namely, age, duration of disease, diagnosis, gender, status and pharmacological treatment. All patients were requested to continue their prior medication regimen whilst participating in the study.

### ***Baseline assessment***

*t*-Tests were used to analyse differences between the groups' baseline assessments for levels of state-anxiety, QoL index and its four domains, three of the VAS measurements and the number of bowel movements. No statistically significant differences were found between the two groups on these variables. However, statistically significant differences were found on the pain measurements between the groups at pre-treatment, with the treatment group demonstrating higher levels of pain. The control group reported more pre-treatment intestinal symptoms without statistical significance.

Table 1. Demographic variables for experimental and control groups.

Variables	Sample (n = 39)		Exp. group (n = 18)		Cont. group (n = 21)	
	Mean	SD	Mean	SD	Mean	SD
Age (years)	35.56	13.38	35.56	14.45	35.57	12.76
Disease duration (years)	8.82	8.88	7.89	7.09	9.62	10.27
	%		%		%	
Gender						
Male	56.4		50		61.9	
Female	43.6		50		38.1	
Status						
Single	41		33.3		47.6	
Married	53.8		61.1		47.6	
Divorced	5.2		5.6		4.8	
Diagnosis						
UC	38.5		44.4		33.3	
CD	61.5		55.6		66.7	
Medication treatment						
Without medication	15.8		11.1		20	
Corticosteroids	10.5		16.7		5	
5-ASA	63.2		72.2		55	
Immunosuppressive drugs	34.2		27.8		40	
Alternative treatment	39.5		27.8		50	

Table 2. Differences between experimental and control groups over time (group \* time).

Variable	F(1, 36)	Experimental group (n = 18)		Control group (n = 21)		$\eta_p^2$
		Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	
		Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	
State anxiety	8.291**	45.39 (9.38)	36.67 (10.65)	42.35 (12.82)	40.51 (12.57)	0.187
QoL index	6.628*	163.67 (28.22)	177.00 (28.62)	174.26 (21.08)	175.48 (20.53)	0.155
Intestinal symptoms	9.602**	51.83 (11.51)	56.56 (9.56)	58.32 (6.38)	56.95 (6.90)	0.211
Systemic symptoms	3.514***	22.56 (5.51)	25.00 (6.32)	22.70 ((5.04)	22.85 (4.55)	0.089
Social function	3.856***	29.17 ((5.80)	31.33 (6.08)	31.34 (4.19)	31.60 (5.08)	0.097
Emotional function	NS	60.11 (9.78)	64.11 (10.97)	62.15 (9.02)	64.25 (8.52)	0.021
Pain	12.308**	3.56 (2.41)	(2.23) 1.83	2.20 (2.09)	2.95 (2.44)	0.255
Depression	0.515	2.50 (2.64)	1.39 (2.23)	2.60 (2.37)	1.90 (1.99)	0.014
Stress	9.293**	5.28 (2.67)	2.83 (2.43)	4.45 (2.14)	4.10 (1.99)	0.205
Mood	10.269**	3.44 (2.41)	2.33 (2.38)	2.75 (2.07)	3.00 (1.95)	0.222
Bowel movements	NS	2.58 (1.71)	2.65 (1.70)	2.30 (1.31)	1.91 (0.64)	0.045

Notes: \* $p < 0.05$ .

\*\* $p < 0.01$ .

\*\*\* $0.05 < p < 0.07$ .

NS = non significant.

$\eta_p^2$  = effect size.

Table 3. Within-group differences from pre to post treatment.

Variable	Experimental group ( $n = 18$ )		Control group ( $n = 21$ )	
	Pre to post difference		Pre to post difference	
	Mean	SD	Mean	SD
State anxiety	8.72**	6.79	1.84	7.83
QoL index	-13.33**	15.45	-1.22	13.54
Intestinal symptoms	-4.72*	7.19	1.37	4.80
Systemic symptoms	-2.44*	3.35	-0.15	4.11
Social function	-2.17*	3.24	-0.26	2.74
Emotional function	-4.00*	7.55	-2.10	5.62
Pain	1.72**	2.49	-0.75	1.83
Depression	1.11*	1.78	0.70	1.75
Stress	2.44*	2.25	0.350	1.98
Mood	1.11**	1.28	-0.25	1.33
Bowel movements	-0.07	0.97	0.39	1.19

Notes: \*\* $p < 0.01$ .

\* $p < 0.05$ .

### Treatment outcomes

Variables were measured at two time-points (pre and post treatment) during the study. Statistical significance of changes was first evaluated by R-ANOVA followed by paired- $t$  test to determine the significance of the changes between individual times of measurement. Table 2 summarises the differences between the groups and over time, for each variable. Table 3 demonstrates the within-group changes from pre- to post-treatment.

*Effect of the intervention on state-anxiety:* Repeated-measure analysis indicates a statistically significant difference between the two groups in state-anxiety throughout the five week study period ( $F(1, 36) = 8.291$ ;  $p = 0.007$ ;  $\eta_p^2 = 0.187^2$ ), with the treatment group reporting a statistically significant lower state-anxiety level compared to the control group (Table 2). Paired sample  $t$ -tests were used to compare pre- to post-treatment scores for state-anxiety. These demonstrated statistically significant within-subject improvements in the treatment group ( $t(17) = 5.451$ ,  $p < 0.001$ ) and no change in the control group ( $t(19) = 1.051$ ,  $p > 0.05$ ) (Table 3).

*Effect of the intervention on QoL:* A statistically significant difference was found between the two groups, in the effect of the intervention over-time, on the QoL index ( $F(1, 36) = 6.628$ ;  $p = 0.014$ ;  $\eta_p^2 = 0.155^2$ ) and on the intestinal symptoms ( $F(1, 36) = 9.602$ ;  $p = 0.004$ ;  $\eta_p^2 = 0.211^2$ ). The improvement in the general QoL index score was statistically significant higher in the treatment group than in the control group. However, in systemic symptoms and social functioning the statistically significant differences were only marginal ( $F(1, 36) = 3.514$ ;  $p = 0.06$ ;  $\eta_p^2 = 0.089^2$  and  $F(1, 36) = 3.856$ ;  $p = 0.057$ ;  $\eta_p^2 = 0.097^2$ , respectively). There was also no statistically significant difference in effect for the emotional functioning domain ( $F(1, 36) = 0.789$ ;  $p > 0.05$ ;  $\eta_p^2 = 0.021^2$ ) (Table 2). Paired sample  $t$ -tests were used to analyse and compare pre- and post-treatment scores for QoL, demonstrating statistically significant within-subject improvements in the treatment group for each

domain: QoL index ( $t(17) = -0.660$ ;  $p = 0.002$ ); intestinal symptoms ( $t(17) = -2.785$ ;  $p = 0.013$ ); systemic symptoms ( $t(17) = -3.099$ ;  $p = 0.007$ ); social functioning ( $t(17) = -2.837$ ;  $p = 0.011$ ) and emotional functioning ( $t(17) = -2.249$ ;  $p = 0.038$ ). No changes were found in the control group (Table 3).

*Effect of the intervention on VAS measures and bowel movements:* Repeated measure analysis revealed statistically significant differences between the two groups in effect over-time on three variables: pain ( $F(1, 36) = 12.308$ ;  $p = 0.001$ ;  $\eta_p^2 = 0.255^2$ ); stress ( $F(1, 41) = 9.293$ ;  $p = 0.004$ ;  $\eta_p^2 = 0.205^2$ ) and mood ( $F(1, 41) = 10.269$ ;  $p = 0.003$ ;  $\eta_p^2 = 0.225^2$ ). In the treatment group, a statistically significant reduction in pain and stress levels appeared and a statistically significant improvement was observed in mood. No significant improvements in depression and number of bowel movements were noted (Table 2). Paired sample  $t$ -tests were used to analyse changes from pre- to post-treatment for each group, demonstrating statistically significant within-subject improvements in the treatment group for each domain of VAS: pain ( $t(17) = 2.932$ ;  $p = 0.009$ ); depression ( $t(17) = 2.650$ ;  $p = 0.017$ ); stress ( $t(17) = 4.599$ ;  $p < 0.001$ ) and mood ( $t(17) = 3.688$ ;  $p = 0.002$ ). No statistically significant within-subject improvement was found for the number of bowel movements (Table 3).

*Correlations between variables in the treatment group:* In order to examine possible correlations between the different parameters in the treatment group, Pearson tests were calculated between the following variables: levels of anxiety, QoL index and its four dimensions, gender, disease duration, age and number of relaxation exercises per week.

Positive correlation was found between disease duration and the intestinal symptoms of the IBDQ scores ( $r = 0.472$ ;  $p = 0.048$ ). Namely, the intervention was more effective in reducing the intestinal symptoms, as measured by the IBDQ, for patients with a prolonged disease. Another positive correlation was found between the number of relaxation exercises per week and the social functioning domain scores in the IBDQ ( $r = 0.522$ ;  $p = 0.026$ ). Hence, the more often the treatment group participants exercised, the greater the improvement in social functioning. These findings imply that for other indices, the improvement is not related to frequency of practice.

The fact that no correlations were found with other measures justifiably reinforces the study results, demonstrating the intervention itself had an effect on each measure separately.

## Discussion

In the present study, patients underwent five weeks of treatment, during which they received training in relaxation techniques with guided imagery, and assistance implementing regular practice of the techniques. This treatment protocol proved to be superior to a waiting-list symptom-monitoring procedure in reducing state-anxiety and improving health-related quality-of-life ratings and pain, mood and stress levels in IBD patients, with large effect sizes ( $\eta_p^2$ ).

As mentioned earlier, a number of studies have examined the effect of relaxation training combined with other techniques on IBD patients (Jantschek et al., 1998; Maunder & Esplen, 2001; Schwarz & Blanchard, 1991; Smith, 2002). Several studies

compared the effect of implementing only relaxation techniques in groups of patients with other illnesses (Baird & Sands, 2006; Ilacqua, 1994; Kim & Kim, 2005; McCauley et al., 1983; Sloman, 2002). The present study provides additional evidence for the effectiveness of these techniques, as well as suggests that individual relaxation training, without an addition of other components, is beneficial and effective in IBD patients.

The bio-psycho-social model (Drossman, 1998) is superior for demonstrating the relationship between psycho-social factors and gastrointestinal illness. This model proposes that symptoms and consequent behaviours result from interacting systems rather than from a single, linearly determined cause. Stress appears to have an effect on gut motility, visceral sensation and possibly immune regulation of inflammatory activity in the gut (Sainsbury & Heatley, 2005). Therefore, in order to move the clinical practice from a bio-medical model to a bio-psycho-social model (Drossman, 1998), suitable and effective techniques and clinical interventions for physically ill patients (Porcelli, Leoci, & Guerra, 1996) are required, such as those proposed in the present study.

Our study demonstrates the intervention was successful in reducing state anxiety among IBD patients. The interpreted results support Spielberger's state-trait theory, claiming brief anxiety reduction techniques are effective for treating state anxiety (Spielberger, 1983). In addition to the statistically significant improvement, a clinical improvement was apparent: the baseline mean of the treatment group represented 'moderate anxiety' ( $M = 45.4$ ;  $SD = 9.4$ ), whilst the post-treatment mean indicated 'lack of anxiety' ( $M = 36.7$ ;  $SD = 10.6$ ) (Spielberger, 1983). The study supports Jacobson's theory stating relaxation training may reduce anxiety levels among physically ill patients (Jacobson, 1967), and refutes Stem's study (Stem, 1997) claiming relaxation training alone has no impact on anxiety levels.

The HRQoL measures showed an initial mean of QoL index similar to that of other studies with matched criteria (Larsson et al., 2003; Maunder & Esplen, 2001), approximately  $M = 165$ . Guyatt et al. (1989) emphasise that an index score of less than 170 implies poor QoL. This further strengthens the significance of the improvement recorded in the post-treatment assessment that indicated clinical remission according to the questionnaire's ratings (Guyatt et al., 1989). Gill and Feinstein (1994) claim that QoL is a state of mind, not a state of health. Some patients report an excellent QoL although their inflammation indices are high, whilst others, with relatively low inflammation indices report low QoL. Therefore, the improvement indicated in the results, possibly caused by changes in the patient's perception of health, may have contradicted his or her physical functioning, which had not changed.

The lower pain levels after intervention, support former study conclusions regarding the efficacy of relaxation training in pain reduction among IBD patients (Joachim, 1983; Shaw & Ehrlich, 1987). However, an initial difference was found for the pain measure assessment at baseline. One possible explanation is that patients on a waiting list may have either positive expectations or build-up of frustration causing them to misperceive or misreport their actual pain. Another probable explanation is that patients anticipating to participate in a clinical intervention report their pain more freely. A further plausible explanation would be regression to the mean, resulting in both groups having the same pain level after the treatment, despite a random initial difference.

Changes in the physiological symptoms were assessed using the symptom-monitoring diaries and the quality-of-life questionnaire (IBDQ) which examines the intestinal and the systemic symptoms. According to the diaries no statistically significant improvements were noted in number of bowel movements, namely, the intervention did not have an effect on the number of bowel movements. However, an interesting finding emerged: objectively, the number of bowel movements did not improve. Subjectively however, according to the IBDQ, symptoms improved following the intervention. Thus one may conclude that the improvement in the intestinal and in the systemic symptoms shown by the questionnaire responses did not result from an objective change but rather from a change in the patients' perceptions (Drossman, 1998). This finding supports the argument that a patient's perception is a better predictor of his or her QoL and experience of health than the objective data. In addition it implies that QoL is a state of mind rather than a state of health (Gill & Feinstein, 1994).

The dropout rate of 30% is consistent with dropout rates of 17–57% reported in other psychological-therapy studies (Jantschek et al., 1998; Maunder & Esplen, 2001; Smith, 2002). Arguably, such a short term and focused intervention would be expected to have a lower dropout rate.

### **Limitations and future research**

Despite the positive results, several limitations should be considered when interpreting the results of the present study. All stages of the study were conducted by the same research therapist. This fact may have restricted the generalisation of the study by impairing its external validity. Another issue to be considered is that a non-blind-design study increases the potential for investigator bias. Participants were aware they were taking part in a randomised controlled trial that involved random assignment to either the control or treatment group. The treatment subjects received more attention, which on its own may have been therapeutic in nature, however, it had an effect on data validity. Additionally, the sample size was relatively small. A fact that strengthens the findings, despite the high risk of committing a type II error, the results were positive, however, a larger sample would have increased the generalisation of the study. Furthermore, a waiting list control group, in which patients do not receive any treatment until the trial commences, may generate negative expectations and thus make them less inclined to report improvement. Finally, no long-term follow up was performed to examine the lasting effects of the results.

In view of the encouraging results of this study, it seems warranted that future research replicates this study with a larger sample size whilst considering these limitations. A larger sample size could be divided into smaller groups in order to test covariates in the analyses, such as age, gender or disease duration as control variables. In addition to symptom reports, future research may include measurements of objective data, i.e. inflammation indices, in order to objectively test the effects of the intervention. We also suggest adding other groups, i.e. an attention control group; a group of patients in remission with a long term follow up in order to test the intervention as a preventive treatment; or an additional study group undergoing relaxation training in a group setting. These measures and variables will enable testing for mediations and allow for further examination of the effects of

relaxation training on symptom reduction (real or perceived) and their true causes (due to improvement of QoL, reduction of anxiety, support group or merely receiving attention). In addition, it may be advisable to test the control group after their relaxation training as well, in order to examine differences between the groups. In the present study, they were measured only at the end of the waiting list period, after which they were trained. Finally, a one-year follow up would tremendously strengthen the study outcomes, to allow confirming maintenance of the results.

### **Recommendations and implications for practice**

The goal of therapists who treat patients suffering from a chronic disease is to provide them with both physical and mental tools and techniques to relieve their pain. The intervention based on relaxation training with guided imagery has produced encouraging results in this study, however further research is necessary prior to offering it as a routine therapy for patients with active IBD. Whereas many of the psychosocial interventions that were previously investigated were complex and required highly skilled therapists, relaxation training is a relatively easy and cost-effective treatment that can have numerous positive effects. With respect to the important role of psychological factors in IBD and their impact on health related outcomes, the present findings suggest the need to continue testing new relaxation techniques for the treatment of IBD.

### **Acknowledgements**

The authors wish to thank Prof. R. Jacoby for teaching the relaxation techniques that served as basis for the intervention in this study.

### **References**

- Achkar, E. (2001). Common clinical manifestations of gastrointestinal disease. In T.E. Andreoli (Ed.), *Cecil essentials of medicine* (5th ed., pp. 301–365). New York, NY: Harcourt.
- Addolorato, G., Capristo, E., Stefanini, G.F., & Gasbarinni, G. (1997). Inflammatory bowel disease: A study of the association between anxiety and depression, physical morbidity, and nutritional status. *Scandinavian Journal of Gastroenterology*, *32*, 1013–1021.
- Addolorato, G., Stefanini, G.F., Capristo, E., Caputo, F., Gasbarrini, A., & Gasbarrini, G. (1996). Anxiety and depression in adult untreated celiac subjects and in patients affected by inflammatory bowel disease: A personality “trait” or a reactive illness? *Hepatogastroenterology*, *43*, 1513–1517.
- Baird, C.L., & Sands, L.P. (2006). Effect of guided imagery with relaxation on health-related quality of life in older women with osteoarthritis. *Research in Nursing & Health*, *29*, 442–451.
- Beaugerie, L., Seksik, P., Nion-Larmunier, I., Gendre, J.-P., & Cosnes, J. (2006). Predictors of Crohn’s disease. *Gastroenterology*, *130*, 650–656.
- Brewer, S. (1999). *Simply relax: An illustrated guide to slowing down and enjoying life*. London: Duncan Baird.
- Calderon, K.S., & Thompson, W.W. (2004). Biofeedback relaxation training: A rediscovered mind-body tool in public health. *American Journal of Health Studies*, *19*, 185–194.

- Casati, J., & Toner, B.B. (2000). Psychosocial aspects of inflammatory bowel disease. *Biomedicine & Pharmacotherapy*, *54*, 388–393.
- Casati, J., Toner, B.B., De Rooy, E.C., Drossman, D.A., & Maunder, R.G. (2000). Concerns of patients with Inflammatory Bowel Disease: A review of emerging themes. *Digestive Diseases and Sciences*, *45*, 26–31.
- Cohen, R.D. (2002). The quality of life with Crohn's disease. *Alimentary Pharmacology and Therapeutics*, *16*, 1603–1609.
- Cox, T. (1978). *Stress*. Oxford: Macmillan.
- Davies, A., Blakeley, A., & Kidd, C. (2001). *Human physiology*. Edinburgh: Churchill Livingstone.
- Drossman, D.A. (1998). Presidential address: Gastrointestinal illness and the biopsychosocial model. *Psychosomatic Medicine*, *60*, 258–267.
- Dudley-Brown, S. (2002). Prevention of psychological distress in persons with inflammatory bowel disease. *Issues in Mental Health Nursing*, *23*, 403–422.
- Duffy, L.C., Zielezny, M.A., Marshall, J.R., Byers, T.E., Weiser, M.M., Phillips, J.F., . . . Graham, S. (1991). Relevance of major stress events as an indicator of disease activity prevalence in inflammatory bowel disease. *Behavioral Medicine*, *17*, 101–110.
- Fukudo, S., Nomura, T., & Hongo, M. (1998). Impact of corticotropin-releasing hormone on gastrointestinal motility and adrenocorticotrophic hormone in normal controls and patients with irritable bowel syndrome. *Gut*, *42*, 845–849.
- Gill, T.M., & Feinstein, A.R. (1994). A critical appraisal of the quality of quality-of-life measurements. *JAMA*, *272*, 619–626.
- Guyatt, G., Mitchell, A., Irvine, E.J., Singer, J., Williams, N., Goodacre, R., & Tompkins, C. (1989). A new measure of health status for clinical trials in inflammatory bowel disease. *Gastroenterology*, *96*, 804–810.
- Hall, N.J., & Rubin, G.P. (2005). The fight for 'health-related normality': A qualitative study of the experiences of individuals living with established inflammatory bowel disease (IBD). *Journal of Health Psychology*, *10*, 443–455.
- Halpin, L.S., Speir, A.M., CapoBianco, P., & Barnett, S.D. (2002). Guided imagery in cardiac surgery. *Outcomes Management*, *6*, 132–137.
- Hyman, R.B., Feldman, H.R., & Harris, R.B. (1989). The effects of relaxation training on clinical symptoms: A meta-analysis. *Nursing Research*, *38*, 216–220.
- Ilaqua, G.E. (1994). Migraine headaches: Coping efficacy of guided imagery training. *Headache*, *34*, 99–102.
- Irvine, E.J., Feagan, B., & Rochon, J. (1994). Quality of life: A valid and reliable measure of therapeutic efficacy in the treatment of inflammatory bowel disease. *Gastroenterology*, *106*, 287–296.
- Jacobson, E. (1938). *Progressive relaxation*. Chicago: University of Chicago Press.
- Jacobson, E. (1967). *Tension in medicine*. Springfield, IL: C.C. Thomas.
- Jansen, A.S., Nguyen, X.V., Karpitskiy, V., Mettenleiter, T.C., & Loewy, A.D. (1995). Central command neurons of the sympathetic nervous system: Basis of the fight-or-flight response. *Science*, *270*, 644–646.
- Jantschek, G., Zeitz, M., Pritsch, M., Wirsching, M., Klor, H.U., Studt, H.H., . . . Keller, W. (1998). Effect of psychotherapy on the course of Crohn's disease. *Scandinavian Journal of Gastroenterology*, *33*, 1289–1296.
- Joachim, G. (1983). The effect of two stress management techniques on feelings of well-being in patients with inflammatory bowel disease. *Canadian Journal of Nursing Research*, *15*, 5–18.
- Kim, S.D., & Kim, H.S. (2005). Effects of a relaxation breathing exercise on anxiety, depression, and leukocyte in hemopoietic stem cell transplantation patients. *Cancer Nursing*, *28*, 79–83.
- Kurina, L.M., Goldacrem, M.J., Yeates, D., & Gill, L.E. (2001). Depression and anxiety in people with inflammatory bowel disease. *Journal of Epidemiology and Community Health*, *55*, 716–720.

- Larsson, K., Hjelm, M.S., Karlbom, U., Nordin, K., Auderberg, U.M., & Loof, L. (2003). A Group-based patient education program for high anxiety patients with Crohn's disease or ulcerative colitis. *Scandinavian Journal of Gastroenterology*, *7*, 763–769.
- Lennard-Jones, J.E. (1989). Classification of inflammatory bowel disease. *Scandinavian Journal of Gastroenterology*, *170*, 2–6, (discussion 16–19).
- Levenstein, S., Prantera, C., Varvo, V., Scribano, M.L., Andreoli, A., Luzi, C.,... Marcheggiano, A. (2000). Stress and exacerbation in ulcerative colitis: A prospective study of patients enrolled in remission. *American Journal of Gastroenterology*, *95*, 1213–1220.
- Love, J.R., Irvine, E.J., & Fedorak, R.N. (1992). Quality of life in Inflammatory Bowel Disease. *Journal of Clinical Gastroenterology*, *14*, 15–19.
- Lyte, M., Li, W., Opitz, N., Gaykema, R.P.A., & Goehler, L.E. (2006). Induction of anxiety-like behavior in mice during the initial stages of infection with the agent of murine colonic hyperplasia *Citrobacter rodentium*. *Physiology & Behavior*, *89*, 350–357.
- MacPhee, M., Hoffenber, E.J., & Feranchak, A. (1998). Quality-of-life factors in adolescent inflammatory bowel disease. *Inflammatory Bowel Disease*, *4*, 6–11.
- Maunder, R.G. (2005). Evidence that stress contributes to inflammatory bowel disease: Evaluation, synthesis, and future directions. *Inflammatory Bowel Disease*, *11*, 600–608.
- Maunder, R.G., & Esplen, M.J. (2001). Supportive-expressive group psychotherapy for persons with inflammatory bowel disease. *Canadian Journal of Psychiatry*, *46*, 622–626.
- Mawdsley, J.E., & Rampton, D.S. (2005). Psychological stress in IBD: New insights into pathogenic and therapeutic implications. *Gut*, *54*, 1481–1491.
- Mayer, E.A. (2000). The neurobiology of stress and gastrointestinal disease. *Gut*, *47*, 861–869.
- McCauley, J.D., Thelen, M.H., Frank, R.G., Willard, R.R., & Callen, K.E. (1983). Hypnosis compared to relaxation in the outpatient management of chronic low back pain. *Archives of Physical Medicine and Rehabilitation*, *64*, 548–552.
- Mittermaier, C., Dejaco, C., Waldhoer, T., Oefflerbauer-Ernst, A., Miehsler, W., Beier, M.,... Moser, G. (2004). Impact of depressive mood on relapse in patients with inflammatory bowel disease: A prospective 18-month follow-up study. *Psychosomatic Medicine*, *66*, 79–84.
- Moser, G., Maier-Dobersberger, T., & Vogelsang, H. (1993). Inflammatory bowel disease: Patient's beliefs about the etiology of their disease – A controlled study. *Psychosomatic Medicine*, *55*, 131.
- Moses, P.L., Moore, B.R., Ferrentino, N., Bensen, S.P., & Vecchio, J.A. (1998). Inflammatory bowel disease: Origins, presentation and course. *Postgraduate Medicine*, *103*, 77–84.
- Mussell, M., Bocker, U., Nagel, N., Olbrich, R., & Singer, M.V. (2003). Reducing psychological distress in patients with inflammatory bowel disease by cognitive-behavioral treatment: Exploratory study of effectiveness. *Scandinavian Journal of Gastroenterology*, *38*, 755–762.
- Northfield, W. (1973). *How to relax*. Wellingborough: Psychologist Magazine.
- Podolsky, D.K. (1991). Medical progress: Inflammatory bowel disease – Part 1. *New England Journal of Medicine*, *325*, 928–937.
- Porcelli, P., Leoci, C., & Guerra, V. (1996). A prospective study of the relationship between disease activity and psychologic distress levels in patients with inflammatory bowel disease. *Scandinavian Journal of Gastroenterology*, *31*, 792–796.
- Sainsbury, A., & Heatley, R.V. (2005). Review article: Psychosocial factors in the quality of life of patients with inflammatory bowel disease. *Alimentary Pharmacology and Therapeutics*, *21*, 499–508.
- Schwarz, S.P., & Blanchard, E.B. (1991). Evaluation of a psychological treatment for inflammatory bowel disease. *Behaviour Research and Therapy*, *29*, 167–177.
- Searle, A., & Benett, P. (2001). Psychological factors and inflammatory bowel disease: A review of a decade of literature. *Psychology, Health & Medicine*, *6*, 121–132.

- Shaw, L., & Ehrlich, A. (1987). Relaxation training as a treatment for chronic pain caused by ulcerative colitis. *Pain, 29*, 287–293.
- Sloman, R. (2002). Relaxation and imagery for anxiety and depression control in community patients with advanced cancer. *Cancer Nursing, 25*, 432–435.
- Smith, G.D. (2002). Impact of a nurse-led counseling service on quality of life in patients with inflammatory bowel disease. *Journal of Advanced Nursing, 38*, 152–160.
- Smolen, D.M., & Topp, R. (2001). Self-care agency and quality of life among adults diagnosed with inflammatory bowel disease. *Quality of Life Research, 10*, 379–387.
- Spielberger, C.D. (1983). *Manual for the State-Trait Anxiety Inventory*. Palo Alto, CA: Consulting Psychologist Press.
- Stem, R. (1997). *The practice of behavioral and cognitive psychotherapy*. Cambridge: Cambridge University Press.
- Thompson, W.G. (1993). *The angry gut: Coping with colitis and Crohn's disease*. New York, NY: Plenum.
- Tojek, T.M., Lumley, M.A., Corlis, M., Ondersma, S., & Tolia, V. (2002). Maternal correlates of health status in adolescents with inflammatory bowel disease. *Journal of Psychosomatic Research, 52*, 173–9.
- Tychman J., & Melnick H. (1979). *Sheelon lehaarachat charade matsavit ve tchonat charade*. [Free translation: A questionnaire for the evaluation of state anxiety and trait anxiety.] Tel-Aviv: University of Tel-Aviv.

Copyright of Psychology & Health is the property of Routledge and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.