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Exposure and mindfulness based therapy for irritable bowel syndrome – An open pilot study

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ABSTRACT

We conducted a study of a group therapy based on exposure and mindfulness in the treatment of irritable bowel syndrome (IBS). Out of 49 outpatients, most of whom were referred from gastroenterological clinics, 34 entered into the 10-week treatment. Patients were assessed before, immediately after and 6 months after treatment. The assessments consisted of a gastrointestinal symptom diary, self-report questionnaires covering quality of life, gastrointestinal specific anxiety, general functioning, and a psychiatric interview. At post-treatment, the mean reduction in symptoms was 41% and 50% of patients showed clinically significant improvement in symptom level. Patients also showed marked improvement on other outcome measures. Treatment gains were maintained at follow-up. The results support the use of exposure and mindfulness based strategies in the treatment of IBS, but further randomised studies are needed to confirm the efficacy of the treatment.

1. Introduction

Irritable bowel syndrome (IBS) is the most common of the functional gastrointestinal disorders, affecting 5–11% of the adult population in most countries (Spiller et al., 2007). The IBS-diagnosis is based on the Rome III criteria which include abdominal pain or discomfort combined with diarrhea and/or constipation (Longstreth et al., 2006). Medical treatments for IBS are focused on alleviation rather than cure of symptoms (Lacy & Lee, 2005), and the illness has a major impact on quality of life (Halder et al., 2004). The societal costs of IBS are high. Compared to normal controls IBS-patients are three times more likely to be absent from work (Drossman et al., 1993) and utilize health care at almost double the cost (Talley, Gabriel, Harmsen, Zinsmeister, & Evans, 1995). At least half of patients with IBS suffer from co-morbid psychiatric illness (Spiller et al., 2007), the most common being depression, generalized anxiety disorder, and panic disorder (Whitehead, Palsson, & Jones, 2002).

In a series of small trials during the 80s and 90s cognitive behavior therapy (CBT) demonstrated strong effects on IBS symptoms (Blanchard, 2001; Lackner, Mesmer, Morley, Dowzer, & Hamilton, 2004). However, the outcomes of two recent large scale controlled trials of CBT for IBS were not as positive (Blanchard et al., 2007; Drossman et al., 2003). In light of the inconsistent effects of traditional CBT, Naliboff and colleagues suggested that CBT approaches targeted at other mechanisms than altering the content of thoughts, specifically mindfulness meditation and acceptance and commitment therapy (ACT), should be tried as treatments for IBS (Naliboff, Frese, & Rapgay, 2008). The goal of ACT and mindfulness meditation is to decrease "experiential avoidance", defined as the unwillingness to experience aversive bodily sensations, emotions, and thoughts (Hayes, Wilson, Gifford, Follette, & Strosahl, 1996). Experiential avoidance is assumed to result in long-term mental suffering – such as psychiatric disorders – when it is used as a strategy to control private events that are not controllable by will, or where the process of avoidance increases the strength of the undesired experience, or when the means of avoidance create additional suffering (Hayes et al., 1996).

For IBS-patients the experience of the bodily sensations associated with the illness is often aversive and anxiety-provoking, a phenomenon referred to as GI-specific anxiety (GSA). GSA is defined as "the cognitive, affective, and behavioral response stemming from fear of GI sensations, symptoms, and the context in which these visceral sensations and symptoms occur" (Labus,

Abbrevations: ACT, Acceptance and commitment therapy; GI, Gastrointestinal; GSA, GI-specific anxiety; VSI, Visceral sensitivity index; IBS-QOL, Irritable bowel syndrom quality of life instrument; MADRS-S, The montgomery åsberg depression rating scale – self report; CGI, Clinical global impression scale.

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Mayer, Chang, Bolus, & Naliboff, 2007, p. 89). Anxiety can in itself cause altered motility and increase awareness of pain, and GSA is therefore proposed to be a perpetuating factor in IBS through positive feedback loops (Mayer, Naliboff, Chang, & Coutinho, 2001). The behavioral consequences of GSA, i.e. attempts to decrease or avoid it, are also likely to maintain the disorder. For example, avoiding social or work-related situations when experiencing symptoms can cause social isolation and depression, worsening the symptoms through increased anxiety (Naliboff et al., 2008). A common behavior like distraction from the associated pain is probably not very effective and might even increase the awareness of pain (Cioffi, 1991; McCracken, 1997). This interplay between GSA and avoidance behaviors maps well onto the concept of how experiential avoidance can cause long-term suffering.

In the present study we developed and evaluated a CBT-protocol aimed at decreasing experiential avoidance in association with IBS. The protocol consisted of mindfulness exercises and exposure to GSA and IBS symptoms. Mindfulness can be described as "the intentional process of observing, describing, and participating in reality non-judgmentally, in the moment" (Robins, Schmidt, & Linehan, 2004, p. 37), and has shown promising effects in the treatment of disorders such as stress, chronic pain, depression and anxiety (Grossman, Niemann, Schmidt, & Walach, 2004). Exposure therapy can be defined as facilitating and encouraging the individual to expose him or herself to an aversive stimulus and simultaneously engaging in a behavior that is inconsistent with the emotion that the stimulus elicits (Farmer & Chapman, 2008). We hypothesized that engaging in exposure and mindfulness exercises would decrease IBS-symptom, improve quality of life and global functioning and lessen GI-specific anxiety. We also hypothesized that willingness to be in contact with negative experiences would lead to a general increase in mental health.

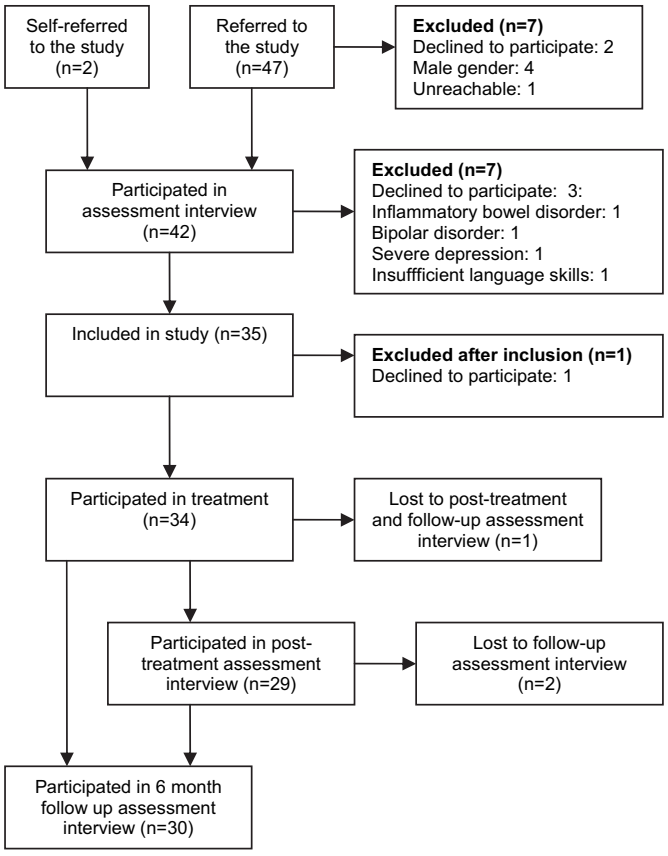

Fig. 1. Patient flow through the study.

2. Method

2.1. Participants

The study was approved by the local ethics committee. Information about the study was spread to gastroenterological clinics in the local area and patients were referred to the study psychiatrist (S. A.). Most patients were referred from their gastroenterologist ($n = 45$). Self-referrals ($n = 2$) or referral from GP ($n = 1$) or psychiatric outpatient clinic ($n = 1$) were accepted when the patient had an IBS-diagnosis verified from a gastroenterological clinic. The study psychiatrist judged eligibility for the study, confirmed that patients fulfilled IBS diagnostic criteria (Longstreth et al., 2006) and obtained informed consent. Inclusion criteria were female gender and age 18–65 years. Patients were excluded if any somatic or psychiatric disorder deemed to interfere with treatment was present. Fig. 1 displays an overview of the number of patients at the different stages of the study. A total of 49 patients were referred or self-referred to the study and 34 participated in treatment. The mean age of participants was 34.6 years (SD = 11.0) and the reported mean time of suffering from IBS symptoms was 11.2 years (SD = 7.8).

2.2. Assessments

Patients were assessed through psychiatric interview and self-report questionnaires before treatment, immediately after treatment and 6 months after treatment. Some questionnaires administered at the interviews were lost, a total of 6 self-report questionnaires were missing for 4 patients at data analysis.

2.2.1. The GI symptom diary

At each assessment patients completed four weeks of the GI symptom diary (Blanchard, 2001), with the exception of the first four patients included who only completed two weeks of symptom diary at pre- and post-treatment. The GI symptom diary is a measure of primary IBS symptoms (abdominal pain and tenderness, diarrhea, constipation, and bloating) and additional common gastrointestinal symptoms (flatulence, belching and nausea). Daily severity of each symptom is rated from 0 (not a problem) to 4 (debilitating).

2.2.2. Visceral sensitivity index (VSI)

The VSI (Labus et al., 2004) measures GI-specific anxiety (GSA), has 15 items and is scored between 0 (no GSA) and 75 (severe GSA). The VSI has good psychometric properties and has been shown to be a key explanatory variable of IBS diagnostic status (Labus et al., 2007). To our knowledge, the VSI has not yet been used as an outcome measure in studies on the effects of CBT for IBS.

2.2.3. Irritable bowel syndrom quality of life instrument (IBS-QOL)

The IBS-QOL (Patrick, Drossman, Frederick, DiCesare, & Puder, 1998) is used to assess the impact on quality of life specifically for patients with IBS. The IBS-QOL consists of 34 items and includes domains such as dysphoric thoughts, symptoms interference with activity, food avoidance, and impact on relationships. The score ranges between 0 (minimum quality of life) and 100 (maximum quality of life). The scale has good psychometric properties (Patrick et al., 1998) and is responsive to treatment effects (Drossman et al., 2000).

2.2.4. Secondary self-report outcome measures

The Montgomery Åsberg Depression Rating Scale – Self report (MADRS-S; Svanborg & Åsberg, 1994) is a well-established self-

report measure of depressive symptoms and is based on a structured interview. The MADRS-S has 9 items and a total score which ranges between 0 (minimum) and 54 (maximum) is calculated. The Sheehan Disability Scales (Sheehan, 1983, p. 151) assess symptom induced disability in three domains: social, work, and family, from 0 (no disability) to 10 (severe disability) and a total score between 0 and 30 is calculated.

2.2.5. Interview assessment

The psychiatric interview was conducted by the study psychiatrist and included the Mini-International Neuropsychiatric Interview (MINI; Sheehan et al., 1998) and the Clinical Global Impression Scale (CGI; Guy, 1976). The MINI reliably diagnoses the most common DSM axis I disorders and the CGI is widely used to assess global severity and response to treatment. The improvement scale of the CGI is scored between very much worse and very much improved. Patients were also inquired how many of the last 20 work days they had been absent from work because of IBS symptoms.

2.3. Treatment

The treatment consisted of 10 weekly 2-h group sessions lead by two psychologists, with 4–6 patients in each group. The treatment protocol was developed for this study and consisted of three main themes. The first theme was education about a psychological model of IBS where negative effects of behaviors that serve to control or avoid symptoms or negative affect related to symptoms was explained. The patients' own experiences of the apparent failure of symptom control strategies and the detrimental effects of avoidance behaviors on quality of life were discussed from this perspective. The second theme was mindfulness; patients were taught a 15 min mindfulness exercise to be practiced daily and a brief exercise aimed at bringing the patient into immediate awareness of current GI-symptoms, thoughts, feelings and behavioral impulses. The third theme was exposure, chiefly divided into three categories; (1) exercises that provoke symptoms, such as certain foods, physical activity, and stressful situations, (2) abolishment of behaviors that serve to control symptoms, such as distraction, excessive toilet visits, eating certain foods, resting, and taking unprescribed medications, (3) exposure to situations where symptoms were unwanted, such as attending a meeting when experiencing abdominal pain or riding the bus with fear of losing control of the bowels. The three categories of exposure exercises were most often combined, e.g. not going to the bathroom before a meeting while wearing tight clothes to provoke pain. The patients were also instructed on how to use mindfulness during exposure. By being mindful they would counter distraction and by attending to any impulses to flee the situation or decrease the intensity of symptoms they would be less inclined to act on these impulses. Throughout treatment, acceptance of aversive symptoms, thoughts and feelings through willful engagement in exposure exercises was emphasized. At the end of treatment the risk of relapse into strategies of symptom control and avoidance was discussed.

2.4. Analysis

All statistical analyses were performed using SPSS 16.0. Dependent samples *t*-tests were performed to assess if changes from pre- to post-treatment and changes from post-treatment to follow-up were significant. Effect sizes of within-group changes between pre- and post-treatment were calculated using Cohen's *d*. In order to detect tendencies of later improvement on measures where no significant change was observed between pre- and post-treatment, follow-up results were compared to the pre-treatment results. Following the intent to treat principle (ITT) the post-assessment analyses on the self-assessments were rerun using the "last observation carried forward" method (LOCF) to see if treatment improvements remained significant. However, the tests were not rerun using LOCF from post-treatment to follow-up since this assumes that treatment gains were sustained. Significance testing of change in absent days from work was made with the Wilcoxon matched pairs test.

Effects on individual symptoms in the GI symptom diary were calculated including only patients who reported to have suffered (i.e. scoring above 0) from the respective symptom at least one day during any of the assessment periods. For each patient the mean daily level of each primary GI symptom during the post-treatment and follow-up periods was divided by the mean daily pre-treatment level. The average of these primary symptom means was calculated as the patient's Composite Primary Symptom Reduction score (CPSR; Blanchard et al., 2007) which ranges between −1 and 1 (−1 = 100% more symptoms, 0 = no change in symptoms, 1 = complete remission). The number of patients having a score ≥0.5, which means at least 50% reduction in primary symptoms and is considered clinically significant improvement (Irvine et al., 2006), is reported.

3. Results

3.1. Treatment compliance

On average patients attended 7.8 (SD = 2.1) of the 10 group sessions, 24 of the 34 patients attended 8 or more sessions and 3 patients attended 4 sessions or less.

3.2. Self-report assessments

Results of all self-report assessments are summarized in Table 1.

All 34 patients completed the pre-treatment diary, one patient did not complete the diary at post-treatment, and while this patient did complete the follow-up diary 5 patients did not, and thus 29 patients completed the follow-up diary. Patients were instructed to leave missed days empty rather than trying to recall their symptoms later and missing days were excluded when calculating mean symptom level per day. The first week of diary at follow-up was excluded from analysis for one patient who reported to have suffered from stomach flu during this week, in the following three weeks almost no symptoms were reported and the patient considered herself to have been in complete remission since post-treatment. On average, patients completed 23.9 (SD = 5.9) days of symptom diary at pre-treatment, 27.8 (SD = 4.1) at post-treatment and 27.6 (SD = 1.5) at follow-up.

Patients showed significant improvement on all symptoms at post-treatment, except for diarrhea. Abdominal pain and tenderness was combined into one score (total pain) and the improvement was moderate ($d = 0.64$). The treatment effects on bloating and belching were large ($d = 1.02$ and $d = 1.11$ respectively). The smallest significant effects were observed on constipation (small, $d = 0.35$) and nausea (moderate, $d = 0.48$). A primary symptom score was calculated as the sum of abdominal pain and tenderness, constipation, diarrhea and bloating, and the effects on this score were large ($d = 0.83$). No significant differences were found between the symptom scores at post-treatment and follow-up. However, when comparing follow-up to pre-treatment results, the effect on diarrhea was significant ($p < 0.001$) with a moderate effect size ($d = 0.64$). The mean daily rating of primary symptoms during treatment, post-treatment and follow-up is shown in Fig. 2.

The average change score for each patient, CPSR, was 0.41 (SD = 0.54) at post-treatment and 0.52 (SD = 0.38) at follow-up. The number of patients reaching a score above 0.5 were 17 (50%) at post-treatment and 15 (44%) at follow-up.

Table 1
Pre-treatment, post-treatment, and follow-up results on self-assessments.

Measurement	*d*	*p*	Pre-treatment			Post-treatment			Follow-up		
			n	*m*	sd	*n*	*m*	sd	*n*	*m*	sd
Symptom diary											
Total pain	0.64	**	34	2.16	1.42	33	1.22	1.53	29	1.05	1.25
Constipation	0.35	**	31	0.73	0.78	30	0.47	0.72	26	0.41	0.56
Diarrhea	0.43	ns.	33	0.68	0.66	32	0.40	0.67	28	0.28	0.59
Bloating	1.02	***	34	1.61	0.84	33	0.82	0.72	29	0.91	0.76
Nausea	0.48	**	32	0.81	0.87	31	0.41	0.83	29	0.26	0.34
Flatulance	0.71	***	34	1.36	0.97	33	0.70	0.90	29	0.70	0.91
Belching	1.11	**	24	0.51	0.56	23	0.10	0.17	22	0.07	0.12
Primary symptoms	0.83	***	34	5.11	2.66	33	2.86	2.76	29	2.59	2.46
VSI	1.40	***	34	47.7	18.3	33	24.0	15.6	29	23.4	16.8
IBS-QOL	1.30	***	34	52	20	33	79	19	29	79	21
MADRS-S	0.59	ns.	33	11.5	9.1	27	6.9	6.5	30	8.3	7.2
Sheehan Disability Scales	1.21	***	34	14.2	7.6	27	5.6	6.8	30	5.4	7.3

Within group effect sizes (Cohen's *d*) are given for difference between pre-treatment and post-treatment values. *N* denotes number of participants completing each self-assessment at each time of assessment. For every symptom in the symptom diary only patients who reported a symptom score of at least 1 on any day at any time of assessment were included in analyses. $^{*}p < 0.05$, $^{**}p < 0.01$, $^{***}p < 0.001$ for two-tailed dependent *t*-test of difference between pre-treatment and post-treatment values, with casewise deletion of missing data.

The effects on VSI and IBS-QOL were well above large at post-treatment ($d = 1.40$ and $d = 1.30$ respectively). The effects on work, family and social disability measured with the Sheehan disability scales were large ($d = 1.21$). Effects on MADRS-S were non-significant. No significant differences were found between post-treatment and follow-up on these assessments.

Analyses were rerun using the pre-treatment values as post-treatment values where data was missing. This means that data for the GI symptom diary, VSI, and IBS-QOL was carried forward for one patient and data for MADRS-S and Sheehan disability scales was carried forward for six patients. Improvements on the GI symptom diary, IBS-QOL, VSI, and Sheehan disability scales remained statistically significant while MADRS-S still did not demonstrate statistically significant improvement.

3.3. Interview assessment

All 34 patients participated in the pre-treatment interview, 29 patients participated in the post-treatment interview and 30 participated in the follow-up interview. Only one patient participated in neither of the two interviews after treatment. In accordance to the ITT-principle, patients were considered to be unimproved from pre-treatment if they did not participate in post-treatment or follow-up interviews. At pre-treatment, 14 (41%) of the patients fulfilled at least one DSM-diagnosis (e.g. dysthymia, panic disorder, agoraphobia, and generalized anxiety disorder). Of the 14 patients diagnosed with a disorder at pre-treatment, 6 (42%) and 9 (64%) no longer fulfilled diagnostic criteria at post-treatment and follow-up respectively. As judged by the clinical global impression scale (CGI) at post-treatment and follow-up (parenthesized), 2 patients (0) were considered minimally or much worse, 8 (7) patients were considered unchanged, 2 (6) were considered minimally improved and 22 (21) were considered much or very much improved.

On the measure of absent days from work, patients reported 3.7 (SD = 6.6) at pre-treatment, 3.2 days (SD = 6.7) at post-treatment, and 2.9 (SD = 7.2) at follow-up. Using the Wilcoxon matched pairs test, the difference between pre- and post-treatment was not significant, while the difference between post-treatment and follow-up was ($z = 2.0$, $p < 0.05$).

4. Discussion

The aim of this open study was to evaluate a treatment which included mindfulness and exposure instructions used within a frame of acceptance rather than control of negative experiences. The treatment was based on a conceptualization of IBS as an illness characterized by experiential avoidance of GI symptoms and related negative feelings and thoughts. Moreover, the treatment targeted the contexts in which IBS symptoms, related feelings and thoughts occur. To our knowledge this is the first trial of an acceptance-oriented treatment for IBS.

Participants experienced significant improvements on almost all outcome measures. Of the primary IBS symptoms, effects were most pronounced on bloating and pain. Although the effects on diarrhea and constipation were less convincing, bloating is often considered the most bothersome of the IBS symptoms (Houghton & Whorwell, 2005) and patients showed an overall large improvement on primary symptoms. At follow-up improvements were maintained and the reduction in diarrhea score was significant compared to pre-treatment. The treatment effects on quality of life and GI-specific anxiety were clear. According to the psychiatric assessment 9 of the 14 patients who had a diagnosable psychiatric disorder at pre-treatment no longer fulfilled diagnostic criteria at follow-up and 21 of the total sample were considered much improved. The participants also showed large improvements in social, familial and work-related functioning and a decreased number of days absent from work at follow-up. The negligible results on depressive symptoms measured by MADRS-S can probably be explained by the low mean pre-treatment score of 11.5, which is within the lower range of mild depressive symptoms (Svanborg & Ekselius, 2003).

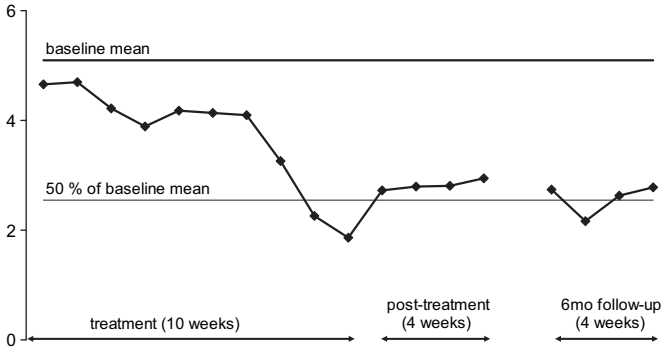

Fig. 2. Mean daily rating of primary symptoms (total pain, diarrhea, constipation and bloating) during treatment, post-treatment and follow-up.

Since this treatment included only minimal cognitive restructuring it is interesting to compare the results with a group treatment with more emphasis on changing the content of thoughts. In this study the mean effect size on primary symptoms at post-treatment was $d = 0.61$ and mean CSPR score was 0.41, and in the previously mentioned large scale study of group cognitive therapy for IBS (Blanchard et al., 2007) the mean effect size was $d = 0.37$ (our calculation) and the CPSR ranged between 0.09 and 0.16 for different treatment sites. This suggests that a mindfulness and exposure based treatment could be as effective as cognitive therapy.

However, the study does not allow for any firm conclusions to be drawn about the proposed mechanisms of treatment and whether these mechanisms actually differ from more cognitively oriented treatments. Although the clinical impression was that patients that engaged in the treatment exercises did improve, no formal measure was used to assess adherence to the exposure and mindfulness recommendations. Nor did we use any assessments on how the mindfulness exercises used improved the patients' skills in being mindful (cf. Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006). The emphasis on mindfulness and exposure does not preclude the possibility that cognitive changes partly mediated the improvement in IBS symptoms. Both the VSI and IBS-QOL contain items that measure cognitive distortions about IBS and the strong effects on these scales indicate that the treatment did indeed result in cognitive changes. In summary, more research is needed to assess to what extent exposure and mindfulness exercises, combined and individually, lead to treatment gains and how these effects are mediated.

This study has several limitations. Most importantly no control group was used, which limits the validity of the trial. However, in a review of CBT for IBS Blanchard found that in 15 of 16 trials that used waitlist or treatment as usual as control, CBT was superior (Blanchard, 2005), indicating that active treatments have effects beyond those of time. An active control group, such as psychoeducational support or relaxation therapy, would have been more appropriate, since the placebo effect is considered to be large in IBS (Patel et al., 2005). Until directly compared with a condition that delivers a credible control for effects of attention, the support for our treatment must be considered tentative. Additionally, although all patients included in the study were referred by gastroenterologists or self-referred outpatients from gastroenterological clinics, their diagnostic status was not confirmed by a gastroenterologist but by the study psychiatrist. It is also difficult to judge if the results from this study can be generalized to the whole population of IBS patients. It is possible that the gastroenterologists referring patients to the study applied idiosyncratic selection criteria when choosing patients to refer. The criteria could have been based on e.g. severity of symptoms, presence of avoidance behaviors, or psychiatric symptoms, introducing bias and making the study patients more amenable to this treatment than the average IBS patient. Finally, although we believe that the comprehensive assessments of the patients' psychiatric and global status gave valuable information, the results from the interviews must be interpreted with caution. The interviewing psychiatrist is a member of the research team and the assessments are therefore at risk of being biased toward a positive treatment outcome. The use of an independent assessor would have been preferable..

In conclusion, the hypotheses of the study were corroborated, supporting the notion that IBS can be treated with mindfulness and exposure. The treatment given was straightforward and congruent with well-established theories on the role of GI-specific anxiety and avoidance behaviors in IBS. The effects were evaluated both by self-assessment and clinician ratings and all patients but one participated in either post-treatment or follow-up assessment.

Further studies investigating therapies based on acceptance instead of control of symptoms in the treatment of IBS are warranted. A comparison with a credible active control is necessary and it would be of interest to examine whether more patients would benefit from the treatment if given individually or to patients that were selected on the basis of GSA and the presence of avoidance behaviors.

Disclosure statement

The authors report no conflicts of interest.

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