Objective. This randomized trial evaluated the therapeutic effect of emotional awareness training on the severity and frequency of pain in patients with irritable bowel syndrome (IBS). Patients' level of alexithymia was also measured. Method. The study involved 100 patients diagnosed with IBS according to the Rome-III criteria. Patients' mean age was 34.98 years (standard deviation 10.22 years) and 60% of the patients were female. Seventy eligible patients were assigned randomly to one of two treatment groups. One group received standard symptom-oriented medical treatment only (MT group), while the second group, termed the emotional awareness group (EMT), was educated to increase conscious awareness of eight primary emotions in addition to receiving standard symptom-oriented medical treatment. This study was conducted over 20 months. All patients received 5 weeks of symptom-oriented medical treatment; patients in the EMT group also had two emotion awareness training sessions and recorded their emotions in a daily diary. Sixty patients completed the study. Results. Patients with IBS scored significantly higher on all aspects of alexithymia compared with healthy controls. The severity of pain decreased significantly in both groups, with a larger percentage of the patients in the EMT group who completed the study having a significant decrease in pain (54% in the EMT group vs. 36% in the MT group); this finding was replicated in an intent-to-treat analysis. The same results were observed for frequency of pain in patients who completed the study (59% in the EMT group vs 43.4% in the MT group), but this finding was not replicated in an intent-to-treat analysis. These patterns were not influenced by level of alexithymia, age, or gender. Conclusion. Adding emotional awareness training to medical treatment resulted in a better therapeutic response in abdominal pain in patients with IBS. (Journal of Psychiatric Practice 2014;20:xxx–xxx)

KEY WORDS: irritable bowel syndrome, alexithymia, pain, psychotherapy, emotion

Irritable bowel syndrome (IBS) is a disorder characterized by episodic abdominal pain, cramps, and changes in bowel habits. Although the etiology of IBS remains unclear, this disorder is commonly considered to be influenced by psychological factors and somatization.1 Evidence for the role of psychological factors in IBS is found in characteristics, such as certain personality traits, of patients with IBS,2 in the effect of psychiatric conditions such as depression in precipitating symptoms,3 and the effectiveness of psychological treatments such as cognitive-behavioral therapies for the disorder.4 Although several efforts have been made to identify effective psychotherapeutic and pharmacologic treatments for IBS,4–6 results are not yet conclusive.7 In addition, a substantial number of patients suffer from refractory symptoms and require additional treatment methods. Thus a combination of lifestyle adjustment and pharmacologic and non-pharmacologic interventions seems to be the best solution.

IBS has been labeled a functional somatic syndrome in which somatization is an essential factor. Somatization has been viewed as a somatic proxy for psychosocial distress.8 In other words, somatization is the tendency to express psychological distress in a somatic (physical) rather than emotional form.9 Blocking of emotions is a common finding in soma-
tizing patients. It is believed that such emotional blocking functions as a defense mechanism to mask the anxiety associated with intense or conflicted feelings.10 Previous studies have shown that patients with IBS may internalize negative emotions and thus increase their somatic problems.11

Patients with IBS may also have a general impairment in their conscious understanding of their own emotions, which is referred to as alexithymia. Alexithymia is a stable trait involving difficulty in experiencing, expressing and describing emotional responses, with a prevalence rate of less than 10% in various populations.12–15 The prevalence of alexithymia is slightly higher among men15 as well as in clinical samples with depression16 or substance abuse.17 Alexithymia is also common among patients with IBS.18 It has been assumed that alexithymia is associated with somatization independently from depression, anxiety, and somatic disorders.14,19

This study examined a novel method of increasing the level of conscious awareness of emotions in patients with IBS. We hypothesized that patients with IBS may have difficulty identifying and coping with their emotions. We also hypothesized that emotional awareness training may have its greatest therapeutic effect (compared to medical treatment per se) on pain, the key symptom of IBS. Thus, we first needed to determine whether the sample of patients in this study was deficient in their ability to identify emotions. We therefore first measured the level of alexithymia. We then taught the patients a process involving scheduled attempts to increase awareness of emotions and evaluated the therapeutic effects of this process.

METHODS

This trial was registered with the Iranian Clinical Trials Registry (IRCT IRCT138810152999N1). The protocol was approved by the ethics committee of Tabriz University of Medical Sciences. Recruitment and follow-up lasted for 15 months.

Subjects

All participants in the study were patients who met the Rome III criteria for IBS as evaluated by an experienced gastroenterologist in the university outpatient clinics in Tabriz, Iran (Figure 1). The Rome criteria were developed to classify functional gastrointestinal disorders (e.g., irritable bowel syndrome, functional dyspepsia, functional constipation, functional heartburn) based on clinical symptoms.20,21 Functional gastrointestinal disorders are disorders of the digestive system in which symptoms cannot be explained by the presence of structural or tissue abnormality. The Rome III criteria, the most recent revision of the criteria, were published in 2006. The diagnosis was established after physical examination, hematology and serum biochemistry, stool examination (culture and microscopy), and proctosigmoidoscopy in all patients. Gastroduodenoscopy, colonoscopy (with biopsies), and abdominal ultrasound were done when clinically appropriate. Undergraduate patients were excluded (n = 9). A total of 100 patients completed a measure of alexithymia, the Toronto Alexithymia Scale.22 Their mean age was 34.98 years (standard deviation 10.22 years, range: 18–54 years); 60% were female.

Patients were then invited to participate in the study by the gastroenterologist, who explained that all participants would undergo a psychiatric evaluation and receive appropriate medications, and that they might or might not be trained to do some homework. Of the 100 patients, 16 refused to participate at this point, while the remainder gave written informed consent.

The Structured Clinical Interview for DSM-IV (SCID)23 was administered for the psychiatric evaluation. Nine patients did not meet the inclusion criteria for the study (Rome III criteria for IBS); a past or current symptom of a DSM-IV Axis I psychiatric diagnosis (bipolar spectrum disorder, generalized anxiety disorder, major depressive disorder, and obsessive-compulsive disorder) led to the exclusion of 5 additional participants to minimize the influence of uncontrolled conditions on the cognitive and emotional status of the sample. The remaining 70 patients were randomly assigned24 to receive medical treatment alone (MT, n = 34) or the emotional awareness protocol plus medical treatment (EMT, n = 36). No psychological intervention was provided to the MT group. The study flow chart is shown in Figure 1 and the sociodemographic characteristics of the intent-to-treat sample are presented in Table 1.
Sample Size

According to previous studies, an effect size of more than 0.5 for this self-management cognitive intervention was expected. Thus, for a power of 80% with an $\alpha$ level of 0.5, a minimum of 27 participants was needed in each group.

Measures

Toronto Alexithymia Scale. Alexithymia was evaluated with the self-report Toronto Alexithymia Scale (TAS-20) which includes the subscales difficulty identifying feelings, difficulty describing feelings, and externally oriented thinking. The TAS-20 contains 20 items that are rated on a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). Thus, possible total scores on the TAS-20 range from 20-100. The possible range of scores for the subscales is difficulty identifying feelings 7–35, difficulty describing feelings 5–25, and externally oriented thinking 8–40. The validated Farsi Version of the Toronto Alexithymia Scale-20 (FTAS-20) was administered by the gastroenterologist and completed at the first visit.

The FTAS-20 is internally consistent ($\alpha$ coefficients for the FTAS-20 difficulty identifying feelings, difficulty describing feelings, externally oriented thinking, and total score were 0.85, 0.82, 0.75 and 0.72, respectively) and the test-retest coefficients ranged from 0.80 to 0.87 in a sample of students. The psychometric characteristics of the FTAS-20 have also been reported in a clinical sample that included patients with major depressive, obsessive-compulsive, and generalized anxiety disorders ($N = 173$, 57% female, range: 18–60 years of age). The $\alpha$ coefficients were all $> 0.65$ and the test-retest coefficients ranged from 0.65 to 0.77 in this clinical sample.

Visual analogue scale. The visual analogue scale (VAS), which was administered by the gastroenterol-
ogist before treatment, was used to assess the overall intensity of pain. All patients who completed the study and were seen for follow-up rated the VAS for a second time 1 month later under the supervision of the psychiatrist.

The VAS is a horizontal line that is 100 mm in length. It is anchored by the phrases “no pain” and “very severe pain” at each end. Patients were asked to mark on the line the point representing their perception of their current state of pain. The VAS was then measured in millimeters from the “no pain” end to the point that the patient marked. This scale has a high test-retest reliability, with correlation coefficients ranging from 0.97 to 0.99 in different studies and has demonstrated some validity in measuring both acute and chronic pain.

Frequency of pain. Frequency of pain was initially assessed with a direct question during the first visit. Each page of the booklet that patients in the study completed contained the item “number of pain episodes today.” These data, which were collected at the final session, were used to calculate the mean pain frequency over the final week of the trial.

Treatment

Medical treatment. All patients regularly (approximately every 2 weeks) visited the same gastroenterologist, who was blind to the participants’ group assignment. In addition to a supportive doctor-patient relationship, patients received symptom-oriented pharmacotherapy and medication effects were observed. The regimen could consist of loperamide, protein glycol, psyllium, imipramine, lactulose, peppermint oil capsules, lactol, hyoscine hydrobromide, dicyclomine, clidinium-C, metoclopramide and/or short-term antibiotics (metronidazole, ciprofloxacin), according to the patients’ symptoms. The medication treatment component of the study lasted for 5 weeks.

Emotional awareness training. The emotional awareness protocol focused on eight primary emotions: anger, fear, joy, sadness, disgust, acceptance, surprise, and anticipation. Each patient had two 30-
minute sessions with a psychiatrist in the gastroenterology clinic, and one additional session was available for consultation if requested. These individual psychoeducational sessions included the use of schematic faces, role-playing, semantic examples, and discussion. Eight schematic faces were used, each of which showed a specific emotional expression. The semantic examples were used to explain and make distinctions among these emotional states. The first session was held at the same time that pharmacotherapy was begun. After the first training session, patients began using the emotion diary (see below for a description) for 1 week of practice. The second session was a booster visit 1 week later to complete the training and evaluate the efficacy of the training and patients’ compliance in completing the diary. Patients were asked to remember and describe the situations for which they had recorded emotions and their observations were discussed.

During the two training sessions, patients were educated to focus on their level of arousal three times a day (morning, noon, and evening) and to pay attention to their mixture of emotions in order to identify the percentage of each primary emotion felt. Patients then recorded their observations in booklets labeled “My Emotion Diary” for 1 month after the second session. The booklets had a page with the schematic faces at the beginning. Each of the following pages represented 1 day and provided a place to record the date at the top and three eight-row tables to be scored three times that day. The names of the emotions were written in each row and patients were asked to score each emotion right at that moment. They were also asked to record the frequency of abdominal pain on that day at the bottom of the page. Contact information was provided at the end of the booklet in case patients wanted assistance.

A day’s homework was considered acceptable if ratings were recorded at least two times that day. If a patient missed fewer than 4 consecutive days or a total of 7 days of ratings, this was ignored. Otherwise the patient was asked to start over (this happened in the case of 3 patients, for whom no further education was required) or was excluded. Patients were seen for a follow-up 1 month after the second training session and were reminded of this appointment by telephone. The follow-up included face-to-face measurement of pain severity using the VAS; the patients’ ratings in the booklet were used to calculate the mean frequency of pain over the last week of the study.

Statistical Analysis

The level of alexithymia in the patients with IBS in the study was compared to the level of alexithymia in a sample of 587 university students (59% female) 18–27 years of age in which the questionnaire was validated.

The principal statistical analysis involved the severity and frequency of pain using a 2 × 2 repeated analysis of variance (ANOVA) design with a group factor (MT vs. EMT), and a repeated-measures factor (pre- vs. post-treatment). Effect sizes were calculated by the difference between the outcomes of the groups divided by the pooled standard deviation. An intent-to-treat analysis with the last observation carried forward was also conducted.

Other statistical comparisons were made with the univariate $\chi^2$-test and Student’s t-tests when appropriate. That a normal distribution was present was tested and confirmed prior to all analyses. The $p$-value was set at 0.05 for statistical significance and all comparisons were two-tailed.

RESULTS

One hundred patients with IBS participated in the first stage of this study in which alexithymia was measured. Table 2 shows the mean alexithymia scores in these patients compared to the normal population sample. IBS patients scored higher in all three aspects of alexithymia, which was consistent with our hypothesis.

Seventy patients were eligible to participate in the second stage of the study. After the initial interview, they were randomly assigned either to MT alone or to MT plus the emotional awareness training protocol (EMT). When seen for the booster visit, almost all of the patients (95%) were following the directions without difficulty. Four patients from the MT group and 6 from the EMT group dropped out, so that more than 85% completed the trial. Reasons for dropping out are shown in Figure 1. Sixty patients completed the 1-month follow-up.

Analysis of variance of the pain severity score revealed a significant group × time interaction ($F = 8.99; p = 0.004$), with the EMT group showing a decrease in severity from $66.87 \pm 23.45$ mm at pre-
treatment to 26.10 ± 25.93 mm at posttreatment. Pain severity in the MT group decreased from 61.36 ± 23.52 mm to 41.67 ± 31.20 mm over this same time period, indicating that these treatments differed in their effect on pain severity (Figure 2) (effect size = 0.5). The intent-to-treat analysis showed similar results ($F = 6.22, p = 0.015$). In the patients who completed the study, pain severity decreased by 54% in the EMT group and by 36% in the MT group.

In the analysis of variance of pain frequency, the within-subjects test showed a significant time effect ($F = 57.60; p < 0.005$); specifically, pain frequency decreased in both groups over time. Moreover, the interaction of group × time ($F = 4.10; p = 0.048$) showed a difference in the change in pain frequency between the two groups (Figure 3). Pain frequency decreased from 5.41 ± 1.91 per week pretreatment to 3.65 ± 2.55, post-treatment in the MT group, whereas it decreased from 4.93 ± 2.12 to 1.88 ± 2.48 in the EMT group (effect size of 0.7). This result was not replicated in the intent-to-treat analysis ($F = 2.81$, ns). In the patients who completed the study, the frequency of pain decreased by 59% in the EMT group and by 34% in the MT group.

Alexithymia as a covariate did not have a significant effect on the overall outcome of pain severity ($p = 0.950$) or pain frequency ($p = 0.506$). Gender also had no effect on the outcome of pain severity ($p = 0.317$) or pain frequency ($p = 0.438$). Mean alexithymia scores by gender for each treatment group are shown in Table 1.

**Discussion**

Our study found a high mean score on alexithymia in this sample of patients with IBS. Similar results have been reported in other populations with IBS. Another study involving patients with functional gastrointestinal disorder also reported similar results. In conjunction with the theory that somatizing patients tend to experience psychological distress in the form of somatic symptoms, these results suggest that IBS was associated with abnormal cognitive processing of emotional stimuli, providing a theoretical basis for the emotion awareness training evaluated in this study.

The main result from the second stage of this study was that patients who participated in a protocol in which they were trained to give scheduled attention to, and be aware of, their emotions showed significant improvement, with a decrease in the severity and frequency of their pain. Alexithymia, which is considered a stable personality trait, literally means “without words for emotions.” The protocol of emotional awareness in this study described the main emotions experienced in life and asked the participants to pay attention to their inner experience so that they would acknowledge the existence of their emotions and be helped to associate their emotions with relevant “words.” This procedure was easy for the participants to follow and there was a low drop-out rate. The beneficial effects were observed for both severity and frequency of abdominal pain. However, the level of alexithymia did not influence this process, which is inconsistent with previous reports that found that level of alexithymia was a predictor of treatment outcome in functional gastrointestinal disorders. This difference could be explained by the high level of alexithymia in all of the patients in our study, so that the sample was not appropriate for estimating the possible effect of severity of alexithymia (see later discussion of the limitations of the study). The promising results of our study suggest that emotional awareness training may overcome the negative effect of alexithymia in patients with IBS.

Alexithymia may influence the severity of IBS symptoms via several potential pathways. These include a possible tendency to have a biased perception of emotional arousal, strengthening the somatic sensations associated with these states. In addi-
tion, the limited ability of individuals with alexithymia to cope with stressful situations\textsuperscript{37,38} may result in a sustained high level of arousal in the emotional response system.\textsuperscript{33,35} Thus, somatic symptoms may be generated not only by motility disturbances and integration of sensory inputs from the gut, but the “brain-gut axis” may also recognize these symptoms as unregulated states of emotional arousal.\textsuperscript{3} Accordingly, patients with alexithymia may experience more severe and frequent symptoms because of the physiological component of the emotional response system. Our study mediated this process by increasing patients’ awareness of the emotions they experienced and their level of arousal. Training was limited to the eight main emotions. The results suggest that patients who received the emotion awareness training could identify what they were experiencing and could distinguish their emotions as an independent component and, therefore, were more likely to be able to make a distinction between emotions and somatic symptoms. The emotion awareness process resulted in better therapeutic outcomes (in terms of frequency and severity of pain) in patients who were also receiving standard medical care compared with those who received only standard medical care.

This study had a number of limitations. One of the main limitations was that the scheduled method for increasing emotional awareness may also have a positive effect on other forms of functional pain besides those associated with IBS. We did not evaluate for such an effect, which could have been done by including another group of patients suffering from functional pain not associated with IBS. Second, the patient sample in this study was recruited from a tertiary clinic and thus may have consisted of patients with the most severe type of IBS as well as patients with a high level of alexithymia. These characteristics of this sample may limit the ability to generalize the results to other populations, because such patients are reported to have more psychological distress and psychological disorders than patients with milder IBS.\textsuperscript{39} However we tried to overcome this limitation by excluding patients with a comorbid psychiatric disorder. Third, this study did not include a third group of “contact control” patients who had the same amount of contact with the clinician while engaging in a sham intervention. To some extent this
challenges our ability to confirm our hypothesis but a practical clinical conclusion can still be made. Given that no definite treatment approach for IBS has been established yet and a combination of different strategies are typically employed, the results of our study may have important clinical implications. This study was also limited by the short duration of the treatment, nor did we follow up to assess the stability of the results after cessation of the designed intervention. Moreover, the treatment target was restricted to pain, although it is important to note that it is one of the most devastating symptoms of IBS.

Most previous studies of IBS have reported a high drop-out rate with traditional cognitive-behavioral treatments \(^4,40\) that may be explained by the more inflexible nature of these therapies compared with a self-management approach, which had a very low drop-out rate. \(^25\) Three patients in our study stopped their medication but were still very satisfied with the emotional awareness protocol. The emotional awareness approach might make psychological therapy more acceptable to patients with IBS.

In conclusion, the findings of this study suggest that alexithymia is common among patients with IBS who live in the region where this study was conducted. A better clinical outcome was achieved for patients with IBS in our tertiary clinic who were treated with a combination of symptom-oriented medical treatments and a simple protocol for emotional awareness compared to those who received medical treatment alone. Further studies are needed to confirm and extend these findings.

References


