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The Effects Of Emotional Awareness And Expression Training And Relaxation Training For People With Irritable Bowel Syndrome: A Randomized Trial

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THE EFFECTS OF EMOTIONAL AWARENESS AND EXPRESSION TRAINING AND RELAXATION TRAINING FOR PEOPLE WITH IRRITABLE BOWEL SYNDROME: A RANDOMIZED TRIAL

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CHAPTER 1

Study Overview

Irritable bowel syndrome (IBS) is a common, often debilitating gastrointestinal disorder that occurs in approximately 10% of adults in Europe and North America (World Gastrointestinal Disorder Global Guideline, 2009). The primary symptoms of IBS are chronic abdominal pain and discomfort associated with a change in bowel function (Rome III Diagnostic Criteria, 2012), but symptoms are often variable and do not have any evident peripheral pathology. Irritable bowel syndrome is thought to be multifactorial in its etiology, and it is best understood from a biopsychosocial perspective (Drossman, 1998). However, many facets of the disorder remain unclear, which makes it difficult to find successful treatments. As a consequence, many patients with IBS have high health-care costs (Longstreth et al., 2003), and struggle with daily functioning and quality of life (Frank et al., 2002).

There is a substantial body of literature indicating that stressful life events (e.g., abuse, divorce, relationship difficulties, and business failures) are common among patients with IBS (Bennett, Tennant, Piesse, Badcock, & Kellow, 1998; Roelofs & Spinehoven, 2007). In addition, daily hassles are associated with an increase in gastrointestinal symptoms (Levy, Cain, Jarrett, & Heitkemper, 1997). Stressors, whether significant life events or recurrent daily hassles, may dysregulate gastrointestinal functioning through the brain-gut axis, which links brain systems that mediate cognition and emotion to the gastrointestinal system (Chang, 2011; Mayer, Naliboff, Chang, & Coutinho, 2001; Mayer, 2000).

However, it is not likely that a stressor alone influences one's gut health; rather, it's the response to a stressor that determines how much psychological and physiological stress one

experiences. Some individuals develop psychological conflicts following difficult life events, especially those that originate early in life. Such conflicts are likely a response to deeply felt emotional pain. When people lack emotion regulation skills, they tend to avoid negative emotional experiences, and fail to process stress.

Difficulties identifying, experiencing, and processing negative emotions can have an adverse effect on one's health and functioning. For example, many individuals with IBS have elevated levels of alexithymia, which is defined as an inability to label and describe emotional experiences (Sayar, Solmaz, Trablus, Ozturk, and Acar, 2000). Further, disorders such as anxiety and depression are prevalent in this population (Hertig, Cain, Jarrett, Burr, & Heitkemper, 2007). In addition, individuals with overlapping stress-related disorders, such as fibromyalgia, have been shown to have high levels of emotional suppression (van Middendorp et al., 2008).

Thus, an intervention that enhances emotional awareness and expression may promote better adaptation for patients with IBS; however, to date, most interventions for IBS are aimed at symptom management (e.g., pharmacological treatments, diet, exercise, and cognitive behavioral therapy) and do not address unresolved stress and emotional suppression. For instance, one of the most widely studied behavioral treatments for IBS, relaxation training, has been shown to be an effective stress management technique (Blanchard, Greene, Scharff, & Schwarz-McMorris, 1993; Keefer & Blanchard, 2001; Lahman et al., 2010; Shinozacki et al., 2010) for some individuals. However, there is a subset of individuals who do not benefit from this approach. Perhaps, this is because behavioral interventions minimize negative emotions and arousal, rather than helping an individual experience and resolve stress and negative emotions.

Research suggests that identifying and processing emotions connected to stressful situations can improve pain and somatic symptoms. For instance, short-term psychodynamic

psychotherapy (Abbass, Kisley, & Kroenke, 2009) and brief dynamic interpersonal psychotherapy (Guthrie, Creed, Dawson, & Tomenson, 1991; Svedland, Sjodin, Ottoson, & Dotevall, 1983) are interventions that encourage patients to acknowledge and engage with avoided emotions and psychological conflicts. However, psychodynamic treatments are complex and multifaceted, and may not often involve active emotional processing of unresolved stressors or suppressed emotions, which makes it difficult to determine the active ingredient of change. Nonetheless, there is some evidence that supports written emotional disclosure, an emotional processing approach for individuals with chronic pain (Lumley, Sklar, & Carty, 2012). In addition, in a previous study, our team found that anger awareness and expression training—an intervention that helps individuals identify and express anger appropriately—was as effective as relaxation training for individuals with chronic headaches, and both interventions were superior to a wait-list control condition (Slavin-Spenny, Lumley, Thakur, Nevedal, & Hijazi, 2013).

Taken together, this preliminary research indicates that an intervention that helps people experience and express their emotions related to stressful life experiences may be an important approach for people with IBS. In this study, a 3-session intervention, emotional awareness and expression training (EAET), was compared to a protocol that teaches the conceptually opposite approach – relaxation training (RT) – and a wait-list control condition. It was hypothesized that individuals in the EAET group would demonstrate greater improvement in their IBS-related outcomes at the 4 and 12-week follow up time points as compared to the RT group. It was also hypothesized that both of the active interventions (EAET and RT) would be more efficacious than the wait-list control conditions.

CHAPTER 2

Literature Review

The prevalence of IBS among adults in Europe and North America is approximately 10% (World Gastrointestinal Disorder Global Guideline, 2009), and women are twice as likely to have the disorder as men (Mayer, Naliboff, Lee, Munakata, & Chang, 1999). The primary symptoms of IBS include chronic abdominal pain and discomfort associated with a change in bowel function, such as diarrhea and constipation (Rome III Diagnostic Criteria, 2012). Traditionally, IBS has been viewed as a diagnosis of exclusion because symptoms do not have any evident peripheral cause. More recently, it has been described as a disorder of the brain-gut axis that is multifactorial in its etiology. It is best understand from a biopsychosocial perspective in which biology (e.g., genetic predisposition, possibly diet), psychology (e.g., emotional and cognitive processes), and sociocultural factors influence the development and maintenance of the disorder through their interaction with each other and early life experiences (Drossman, 1998).

Many facets of the disorder remain unclear, which makes it difficult to find successful pharmacological and psychological treatments. As a result, patients with IBS are often left with unsatisfying treatment results and high healthcare costs. One large-scale epidemiological study found that healthcare costs were 51% higher among patients with IBS as compared to non-IBS patients because of an increased number of outpatient visits, hospitalizations, and medical prescriptions (Longstreth et al., 2003). Irritable bowel syndrome has also been shown to have a negative impact on quality of life and daily functioning (Frank et al., 2002), making it difficult for many individuals to engage in school and/or work activities (Drossman et al., 1993).

The Role of Stress and Emotion Regulation in IBS

There is a substantial literature that suggests that stressful life events are common among patients with IBS. For instance, a history of trauma is elevated in individuals with IBS (Roelofs & Spinehoven, 2007), and is associated with greater pain, psychological distress, behavioral dysfunction, and health care utilization (Drossman, 1999). In addition, patients with gastrointestinal symptoms that have no peripheral pathology tend to have a more severe abuse history than patients with peripheral gastrointestinal pathology (Drossman, 2011). Other stressful life events, such as divorce, relationship difficulties, and business failures also predict greater IBS symptoms (Bennett, Tennant, Piesse, Badcock, & Kellow, 1998). In addition, daily hassles have been associated with gastrointestinal symptoms (Levy, Cain, Jarrett, & Heitkemper, 1997), and daily diary studies have shown that symptoms are related to the accumulation of stress over time (Blanchard et al., 2008; Dancey, Taghavi, & Fox, 1998).

Stressors, such as significant life events or recurrent daily hassles, may influence gastrointestinal functioning through the brain-gut axis, which links brain systems that mediate cognition and emotion to the gastrointestinal system. When stressors are chronic, they may trigger IBS symptoms in genetically predisposed individuals by altering pain processing in the central and peripheral nervous system and dysregulating the brain-gut neuroenteric system (Chang, 2011; Mayer, Naliboff, Chang, & Coutinho, 2001; Mayer, 2000). Furthermore, many individuals with IBS experience excessive sensitivity to both painful and nonpainful stimuli, which is a common symptom shared among individuals with other medically unexplained syndromes (e.g., fibromyalgia, chronic pelvic pain, headaches). Yunus (2008) describes this experience as "central sensitization" and attributes it to alterations in the central nervous system.

However, it is not likely that a stressor alone influences one's gut health; rather, it's the response to a stressor that determines how much psychological and physiological stress one experiences. Some individuals develop psychological conflicts following difficult life events, especially those that originate early in life. Such conflict may result from environmental scenarios (e.g., societal issues), spiritual issues (e.g., religion), or personal struggles (e.g., issues with sexual orientation). However, people most commonly experience conflicts in relationships. Such conflicts are likely a response to deeply felt emotional pain. When people lack emotion regulation skills (i.e., cognitive and affective processes that impact how one responds to stressors and experiences and manages emotions), they tend to avoid negative emotional experiences, and fail to process stress.

Difficulties identifying, experiencing, and processing negative emotions can have an adverse effect on one's health and functioning. For instance, many individuals with IBS have elevated levels of alexithymia, which makes it difficult for them to label and identify their own emotions (Sayar, Solmaz, Trablus, Ozturk, & Acar, 2000). Furthermore, Lackner (2005) found that patients with IBS who had deficits in emotional awareness also had difficulty recognizing and describing emotion in others, which was linked with greater distress, somatization, interpersonal problems, fear of arousal symptoms, and worry.

It is reasonable to suspect that difficulty with emotional expression is also a problem for patients with IBS, given that individuals with overlapping stress-related or central sensitization disorders, such as fibromyalgia, have been shown to have high levels of emotional suppression (van Middendorp et al., 2008). Regulation of anger has been studied among individuals with chronic pain, and suppression of anger has been linked with interpersonal stress and physical symptoms (Burns, Quartana, & Bruehl, 2008; Quartana, Bounds, Yoon, Goodin, & Burns, 2010).

Interestingly, Beesley, Rhodes, and Salmon (2010) found that trait and suppressed anger was greater in patients with IBS than individuals with Crohn's disease (an autoimmune bowel disease); however, the link between suppression of anger and other emotions and IBS symptoms has not yet been investigated. Thus, these preliminary findings suggest that the inability to express anger and other emotions might elevate stress and perpetuate symptoms for individuals with IBS, and it is worth considering this possibility when developing treatments for this population.

Another population that experiences high levels of negative emotion (e.g., fear, anger, shame) are patients with post-traumatic stress disorder (PTSD). In this population, these emotions often feel threatening, which contributes to avoidance of thoughts and experiences associated with their trauma. Foa and Kozak's (1991) exposure treatment for PTSD, which involves exposing individuals to negative emotions and memories associated with the traumatic event in session, has received substantial empirical support. Emotional processing is facilitated through exposure, as patients are able to modify existing memories with new cognitive and affective information. In turn, negative emotions are resolved, and PTSD symptoms are reduced. Given that elevated levels of trauma, anxiety, and mood problems are present in many individuals with IBS, it seems reasonable to use a similar approach for this population.

Some individuals appear to engage in emotional expression, but they are actually expressing secondary emotions or even emotional defenses rather than fundamental primary emotions. Thus, such people are maladaptively expressing emotions, which can be detrimental to their health. For instance, Lackner and Quigley (2005) found that catrastrophizing mediates the relationship between worry and pain suffering in patients with IBS. In their discussion, they raised an interesting clinical consideration, suggesting that worry may be a strategy of

"experiential avoidance" that impedes emotional processing of threatening emotional or somatic information linked with pain. That is, worrying can be viewed as a defense that guards against the experience of more painful, primary emotions for these individuals. This furthers the notion that it is important to learn to *adaptively* experience and express primary emotions for optimal mental health, which is line with the previous literature that demonstrates the psychotherapeutic value of accessing and expressing primary, adaptive emotions to replace maladaptive emotions (Greenberg & Bolger, 2001; McCullough & Andrews, 2001).

Given that individuals with IBS have difficulties with emotional awareness and expression, it is no surprise that many individuals with IBS are reluctant to engage in social interactions, even with those with whom they are ostensible close. For example, Bevan (2009) found that individuals with IBS often have interpersonal communication apprehension and topic avoidance when it comes to communicating with their closest relational partner. These difficulties were related to increased abdominal and bowel symptoms, as well as increases in healthcare utilization. Research also suggests that unresolved stress can prompt some individuals to develop rebellious behaviors – that is, they become overly dominant, or overly accommodating or pleasing, as a way to cope. Previous research that has focused on examining patterns of interpersonal problems among IBS patients, suggests that women with disorder are prone to a submissive interpersonal style characterized by problems with assertiveness and social inhibition (Lackner & Gurtman, 2005), whereas men are more prone to hostile-dominant interpersonal problems (Thakur, Gurtman, Keefer, Brenner, Lackner, 2015). Such problems have been linked to longer disease duration when left untreated (Hyphantis, Guthrie, Tomeson, Creed, 2009). These findings suggest that it is not only important to experience and express emotions, but it is also critical for individuals to use these skills when engaging in social

interactions. This is in line with the broader assertiveness literature, which suggests that asserting oneself to others has positive health benefits (Rakos, 1991).

Psychiatric disorders such as anxiety and depression are also prevalent in this population (Hertig, Cain, Jarrett, Burr, & Heitkemper, 2007), and research has demonstrated that these disorders precede the onset of IBS symptoms (Sykes, Blanchard, Lackner, Keefer, & Krasner, 2003), suggesting that mood and anxiety disorders may influence the development of the disorder. Moreover, Crane and Martin (2004) found that elevated levels of anxiety and depression in patients with IBS are associated with a high level of passive coping, which furthers the notion that individuals with IBS have difficulty regulating their emotions and engaging with appropriate emotional expression.

Taken together, many patients with IBS are exposed to stressful life events or recurrent daily hassles, and a lack of emotional awareness and expression likely maintains an excessive stress response. As a consequence, these patients often experience anxiety and other mood problems, as well as autonomic and central processing problems that influence pain and other somatic symptoms. This preliminary research suggests that an intervention that targets emotional awareness, expression, and processing may promote better adaptation for patients with IBS. To date, however, most interventions for IBS are aimed at symptom management and do not address unresolved stress and emotional dysregulation.

Current IBS treatments

Specific IBS symptoms have been successfully treated by some pharmacological therapies (e.g., antidepressants, antispasmodics); however, no single medication has been shown to alleviate the full range of IBS symptoms (Chang & Talley, 2010). In addition, Yoon, Grundmann, Koepp, and Farrell (2011) reported that there is mixed evidence for the

effectiveness of complimentary and alternative medicine techniques for IBS, such as herbal medicine, acupuncture, dietary modifications, probiotics, and exercise. Given that psychological and social factors have been shown to be important contributors to the development and maintenance of IBS, it is no surprise that these treatments alone have been inadequate to treat it.

In light of these shortcomings, there has been increasing interest in psychological interventions for IBS, based on the hypothesis that one can manage and reduce IBS symptoms by targeting psychological processes. Cognitive-behavioral therapy (CBT) is the most widely studied psychological treatment for IBS. It is important to note that "cognitive-behavioral therapy" is a rather broad term and is often used to describe multicomponent treatment packages that include a variety of techniques. For example, behavioral interventions, such as contingency management, skills training (e.g., assertiveness training), and techniques aimed to reduce physiological arousal (e.g., hypnosis, relaxation training, biofeedback) are often coupled with cognitive interventions designed to modify appraisal and thought patterns. Most of the techniques in the CBT family include the common component of relaxation training. Relaxation training is an arousal reducing and attention diverging strategy, which involves teaching individuals how to purposefully relax. Techniques such as progressive muscle relaxation, relaxed breathing, and guided imagery are often used and are thought to decrease stress, pain, and anxiety if consistently practiced. As a treatment for IBS, relaxation training has been shown to be a useful intervention in several randomized, controlled trials.

For example, in a study of progressive muscle relaxation, patient with IBS (n = 8) underwent an 8-week, 10-session, progressive muscle relaxation treatment, and comparable patients (n = 8) monitored their gastrointestinal symptoms. Daily diaries collected 4-weeks pre-treatment and 4-weeks post-treatment revealed that participants in the relaxation condition had

significant reductions in gastrointestinal symptoms, as compared to those who only monitored their symptoms, and clinical improvement was found for 50% of patients at the end of treatment (Blanchard et al., 1993). Similarly, Lahmann and colleagues (2010) found that participants (n =39) who underwent functional relaxation (i.e., focusing on body perception while simultaneously moving one's joints and breathing outward) with two sessions per week over a 5-week period, had significant improvements in bodily impairment at the 3-month follow-up time point, as compared to those (n =39) who had enhanced medical care (i.e., treatment as usual in addition to two counseling interviews). Results also indicated that functional relaxation was superior to enhanced medical care with a standardized effect size of 0.85. Progressive muscle relaxation and relaxed breathing have also been shown to be useful in a group intervention for patients with IBS. In a study by Van der Veek, Van Rood, and Masclee (2007), patients received four, 90-minute relaxation training sessions (RT) in small groups combined with standard medical care (n = 46) or standard medical care alone (n = 52). Patients who received RT with treatment as usual had improvements in IBS symptom severity, general health, and medical consumption (i.e., number of doctor visits in the past 3 months, and the number of analgesics and laxatives/antidiarrheals used in the previous 14 days) post-treatment as well as 6 and 12 months following the intervention.

Visualization and meditative relaxation techniques have also been found to be beneficial for this population. For instance, Shinozacki and colleagues (2010) examined autogenic training, a technique that involves brief, visualizations for patients with IBS. Patients who participated in an 8-session, 8-week trial of autogenic training (n = 11) had a significantly greater proportion of adequate relief at post-treatment (81.1%), compared to patients (n =10) who underwent control therapy (i.e., discussions about patients' meal habits and lifestyles) who only slightly improved

(30%). In addition, social functioning and bodily pain were significantly improved in the autogenic training group, but not in the controls. Along the same lines, Keefer and Blanchard (2001) tested Benson's (1975) Relaxation Response Meditation (RRM) program, which involves a quiet environment, a comfortable position, focusing on the word "one", and a passive attitude. Participants (n = 16) were stratified by Axis I disorder, primary IBS symptoms, demographic characteristics, and matched into pairs, before they were randomized into either a 6-week meditation condition or a 6-week wait list symptom monitoring condition. Daily diaries, at 2 weeks post-treatment, revealed that participants in the meditation condition had significant improvements in flatulence, belching, bloating, and diarrhea, as compared to individuals who only monitored their symptoms. Keefer and Blanchard (2002) then conducted a follow-up study and found that significant reductions in abdominal pain, diarrhea, flatulence, and bloating were maintained 1 year after baseline. These findings suggest that meditation and visual imagery is a useful treatment for IBS with long-term benefits.

Although these findings are positive overall there are a number of limitations in the literature that make them difficult to interpret with confidence. For instance, in a review of the CBT literature, Toner (2005) evaluated several arousal-reducing, cognitive and behavioral interventions and found that there is some support for this treatment approach in improving IBS symptoms and related psychological distress. However, many of these studies had methodological weaknesses (e.g., small sample sizes, insufficient control conditions, failure to identify primary versus secondary outcome measures). Thus, more methodologically sound, randomized, controlled trials are needed to be able to confirm the usefulness of this technique for patients with IBS.

In addition, high placebo response rates have been demonstrated in individuals with IBS (Spiller, 1999), which lends support to the "dodo bird effect" (Luborsky, Singer, & Luborsky, 1975) and suggests that *any* active intervention might work for this population. One explanation for equivalence among treatments is the notion that common factors, such as support and feedback (Lambert & Bergin, 1994) might be driving these findings. Interestingly, when Kaptchuk and colleagues (2008) examined the placebo effect in a randomized, controlled trial for patients with IBS, they found placebo-treatment combined with a supportive patient-provider interaction to be especially potent. On the other hand, another explanation is that equivalence among treatments might be artificial, and main effects of treatments may be masking individual differences among subgroups. For example, Patel et al. (2005) conducted a meta-analysis that examined the placebo effect in clinical trials that measured a global IBS outcome, and found a large-range of variability (the placebo response ranged from 16.0% to 71.4%). When they examined differences among subgroups, they found that more stringent inclusion criteria and a greater number of office visits decreased the placebo response. This suggests that individual factors might influence treatment responses differently, and more individual differences and treatment approaches need to be evaluated to determine for whom certain treatments are more or less effective.

Along these lines, there is a subset of individuals with IBS who do not benefit from cognitive behavioral therapy. For instance, in one randomized, controlled trial, Drossman and colleagues (2003) found that 70% of patients with moderate to severe abdominal pain without peripheral pathology responded to CBT (versus 37% who responded to education alone); however, individuals with co-morbid depression did not make significant improvements following treatment. This is in line with previous literature, which has found that individuals

with IBS and co-morbid Axis I psychopathology do not respond well to CBT interventions (Blanchard, et al., 1992).

Taken together, cognitive-behavioral therapy and arousal reducing techniques may provide some benefit to managing symptoms of IBS. However, these techniques might also be limited. Perhaps this is because arousal-reducing interventions aim to minimize negative emotions and arousal, rather than help an individual experience and resolve negative emotions. Therefore, more research is needed to test alternative therapy approaches and determine what treatment approaches are most effective for this population. Perhaps an intervention that helps patients with IBS identify and label their emotions and teaches them how to express them appropriately might be an effective treatment approach.

Interventions based on emotional awareness and expression

Research suggests that identifying and processing emotions connected to stressful experiences can improve pain and other symptoms. For instance, short-term psychodynamic psychotherapy, an intervention that encourages patients to acknowledge and engage with avoided emotions and psychological conflicts, has many positive benefits for individuals with somatic system disorders and somatic complaints. Abbass, Kisley, and Kroenke (2009) conducted a systematic review of 23 studies (13 randomized controlled trials, and 10 case series with pre-post outcome assessment), in which they examined the effectiveness of short-term psychodynamic psychotherapy (STPP) in patients with somatic symptom disorders. The majority of the studies reported significant effects on physical symptoms, psychological symptoms, social-occupational functioning, and healthcare utilization for these individuals. A meta-analysis of 14 studies revealed significant effects (ES = 0.58 – 0.78) for individuals in the STPP group compared to controls on physical symptoms, psychiatric symptoms, and social adjustment, which were

maintained at the long-term follow-up. Along these lines, brief psychodynamic interpersonal psychotherapy that focuses on helping a person explore interpersonal and psychological conflicts related to bowel dysfunction has been shown to reduce somatic symptoms in individuals with IBS (Guthrie, Creed, Dawson, & Tomenson, 1991; Svedlund, Ottoson, Sjodin, & Dotevall, 1983). Furthermore, this approach has been shown to be cost-effective and improve health-related quality of life for patients with severe IBS (Creed et al., 2003). However, these are the only studies, to date, that have empirically examined psychodynamic therapy for this population. In addition, psychodynamic treatments are complex and involve a range of techniques. Many of them include insight-oriented and experiential components; however, they do not often involve active emotional processing of unresolved stressors or inhibited emotions. Consequently, it is difficult to interpret what the active component of treatment is and identify the mechanism of change. Therefore, research that empirically tests more focused interventions that involve emotional processing techniques is needed to fill an important gap in the literature.

There is a paucity of research that involves emotional processing techniques for patients with IBS; however, there is some support for a conceptually similar but simpler approach, written emotional disclosure (WED), for individuals with chronic pain and related disorders. Although there has been some variation in this technique, most studies instruct participants to write about unresolved stressful experiences for three or four, 20-minute sessions (Pennebaker & Beall, 1986). Written emotional disclosure has shown to decrease disease activity in patients with rheumatoid arthritis or asthma (Smyth et al., 1999), as well as improve symptoms in individuals with chronic pelvic pain (Norman, Lumley, Dooley, & Diamond, 2004). Additionally, WED has been shown to reduce pain and fatigue and increase psychological well being in individuals with fibromyalgia (Broderick, Junghaenel, & Schwartz, 2005), as well as

improve sleep quality and health care utilization in this population (Gillis, Lumley, Mosley-Williams, Leisen, & Roehrs, 2006). Moreover, in adolescents with recurrent abdominal pain, WED is linked with reduced activity-limiting gastrointestinal pain experiences and health care utilization (Wallander, Madan-Swain, Klapow, & Saeed, 2011). In patients with IBS, WED has received little attention. However, there was one exploratory study in which WED was followed by improved IBS symptom severity and cognition in participants with longer-term duration of the syndrome (Halpert, Rybin, & Doros, 2010); however, this was an uncontrolled study, and therefore, it is not possible to infer causation.

Despite these positive findings, a meta-analysis of 146 published and unpublished studies revealed a small effect size for WED (Cohen's d = .15) (Fratterolli, 2006), and a review of WED for chronic pain disorders suggests that the benefits of this technique for pain are very modest overall (Lumley, Sklar, & Carty, 2012). Written emotional disclosure might be limited because it does not help individuals identify emotional conflicts. In addition, it does not provide a framework to help them adequately access, experience, and express feelings, especially suppressed emotions, such as anger. As a result, these patients do not make necessary cognitive changes or learn how to appropriately communicate their thoughts and feelings with others.

To successfully engage in emotional expression, patients with IBS must also understand how life stress and emotional processes influence their physical symptoms. A lack of awareness between stress, emotions, and health can perpetuate pain, bowel dysfunction, and psychological stress. Thus, an emotional awareness component is also needed for these individuals to benefit from emotional disclosure and insight-oriented interventions. In a previous study, we found that anger awareness and expression training, an intervention that helps individuals identify and express anger appropriately, was as effective as relaxation training for individuals with chronic

headaches, and both interventions were superior to a wait-list control condition (Slavin-Spenny et al., 2013). These findings provide preliminary support for the usefulness of an intervention that targets both emotional awareness *and* expression for individuals with chronic pain. However, psychoeducation that builds awareness may not be sufficient, and individuals may need more guidance and individualized feedback to learn how their specific experiences are related to their physical symptoms. Abbass (2005) introduced the notion of emotion-focused interviewing in a healthcare setting as a way to facilitate this process. In order for a clinician to diagnose somatization and related disorders, he suggests that they ask about specific recent events to activate emotions and consequent somatic symptoms during an emotion-focused interview. Based on his theory, there are four main patterns of somatization that have to do with how one experiences stressful life events. With each pattern, different muscle groups are impacted (e.g., smooth muscle, striated muscle), and different symptoms are manifest. Throughout this process, the clinician identifies patterns of particular somatic symptoms related to stressful life events and helps the patient identify and recognize them. If a patient has difficulty, Abbass (2005) suggests that a clinician could discuss defenses used for emotional avoidance with the patient during their interaction. At the end of the interview, findings are reviewed with the patient, in a similar fashion as one would share a laboratory finding, such as a blood test. If the interviewer finds that symptoms increase with an emotional focus and decrease when emotions are not the focus, then the diagnosis is likely somatization, and emotion-focused psychotherapy is recommended. Although individuals with IBS already have a diagnosis, a similar approach would be useful to enhance emotional awareness before individuals engage with emotional expression and processing techniques. If patients are able to identify particular life events and conflictual experiences that trigger emotional avoidance and consequent

symptoms, they will be able to make the necessary changes to process and express avoided emotions.

Taken together, this preliminary research suggests that stressful life experiences, emotional avoidance, and failure to process negative emotions related to these experiences contribute to pain and symptoms of IBS. To fill a gap in the current literature and enhance clinical outcomes, novel treatment approaches that directly target these processes need to be developed and tested in randomized, controlled studies.

Goals of this Study

The primary goal of this study was to test the efficacy of an emotional awareness and expression training intervention for people with IBS. The aim of this intervention was to help people with IBS enhance their emotional awareness and expression and process unresolved stress. To facilitate this, participants learned how to label and identify their emotions associated with stressful life experiences and their IBS, as well as how to engage in appropriate emotional expression. It is important to note that primary emotions, such as anger or intimacy/closeness, were key targets to facilitate adaptive, emotional processing.

Individuals first reported their IBS symptoms, psychological distress, and quality of life, and then were randomly assigned to receive either of two active interventions, or to a wait-list control condition. Emotional awareness and expression training was compared to a well-established intervention, relaxation training, which was also individualized, and took place over the same timeframe. A wait-list control condition was included so both interventions could be tested against no treatment. Participants completed follow-up assessments 4 and 12-weeks after randomization.

It was hypothesized that the EAET condition would demonstrate greater improvement in their IBS symptom severity, psychological functioning, and quality of life at the 4 and 12-week follow up time points than the RT condition. It was also hypothesized that both of the active interventions (EAET and RT) would be more efficacious on these outcomes than the wait-list control condition.

CHAPTER 3

Methods

Participants

Participants were 106 men and women between the ages of 18 and 70 with IBS. They were recruited from both the university and local community. Most participants had a diagnosis confirmed by a physician (79%), with symptoms that were present for many years (*M* = 22.9 years, *SD* = 12.8 years). At baseline, most participants endorsed moderate symptoms of IBS (IBS-SSS, *M* = 270, *SD* = *80*). The majority of participants were female (80.2%); and their mean age was 36.1 years (*SD* = 16.4). Most identified themselves as European American (65.1%), whereas 22.6% identified as African American, 3.8% as Middle Eastern or Arab, 2.8% as South Asian, 1.9% as East Asian, and 3.8% as other. Over half of the participants were never married (57.0%), whereas a third were either married (27.4%) or living with their significant other (4.7%). The other participants were divorced (7.5%), separated (1.9%) or widowed (0.9%). Participants were well educated, with a mean education of 15.65 years (*SD* = 2.0).

Procedures

The study was approved by the Wayne State University Human Investigation Committee and registered with Clinicaltrials.gov (NCT01886027) prior to recruitment. Recruitment occurred from June 2013 through January 2015, and post treatment assessments were completed in March 2015. Prospective participants were recruited through newspaper and internet advertisements, as well as through the distribution of fliers in waiting rooms at local health clinics, particularly those of collaborating gastroenterologists. Students and staff at Wayne State University were also recruited. Undergraduate students enrolled in psychology classes responded to the Psychology Department mass screening survey at the start of each semester. Students who

took the mass screening survey and indicated that they had a diagnosis of IBS were contacted through e-mail or the telephone and invited to participate in this study. In addition, in past several semesters, students reported whether or not they had a diagnosis of IBS on the Psychology Department mass screening survey. We also invited those students to participate in the study, by contacting them by e-mail and/or telephone. Other mechanisms to announce the study to the university community (e.g., Pipeline, other web announcements, word of mouth) were also used.

Interested individuals were asked to call the laboratory for an initial screening. During the initial telephone screening, a research assistant verified the potential participant's interest and eligibility for the study by asking them more detailed screening questions (see Appendix E, p. 98). To be eligible to participate, individuals must have met the Rome III Diagnostic Criteria for Functional Gastrointestinal Disorders – specifically for IBS (Rome III Diagnostic Criteria, 2012). That is, that they have had recurrent abdominal pain or discomfort, or a change in stool frequency or form, at least three days per month, in the last three months. Because this was a clinical trial, people were also required to have symptoms at least two days per week at the time of screening. Individuals who reported having post-infectious IBS, organic gastrointestinal diseases (e.g., inflammatory bowel disease), immunodeficiency, a current psychotic disorder, drug or alcohol dependence within the past two years, or the inability to communicate in English were excluded.

Respondents who met the screening criteria were then told about the study over the phone. If those individuals remained interested and were able to participate (e.g., had time, transportation, and were willing to participate in all aspects of the study), they were invited to the laboratory to review the study procedures with their potential therapist and provide written,

informed consent (see Appendix F, p. 103). They also signed a release of their medical records if they reported that a physician had diagnosed them with IBS, so we could send a diagnostic form to their primary care physician or gastroenterologist's office to confirm the diagnosis. We asked their physicians' office to mail or fax it back. We then proceeded based on patient's self-reported symptoms at screening (i.e., based on the Rome III criteria asked by the research assistant) and used the physician confirmation, if available.

Participants filled out several baseline questionnaires that assessed their IBS health and functioning, psychological distress, and quality of life. All data were entered by participants using a web-based computer system (Qualtrics). After the baseline questionnaires were complete, the therapist confirmed that the participant remained willing to be randomized and proceed with the study. If so, the therapist consulted a randomization scheme to determine to which of the three intervention conditions the participant was assigned. Randomization was stratified by therapist and participant gender and conducted in randomized blocks of 3 and 6, so that the three conditions would have equal proportions of men and women and equal sample sizes after each block. All randomization envelopes were created before recruitment by someone not involved with patient contact and sealed in envelopes.

Participants assigned to either of the two active interventions (EAET or RT) began their first session immediately following their baseline assessment. Sessions were conducted at the Wayne State Stress and Health lab and at various external locations that are part of Wayne State (i.e., Oakland Center and Macomb Center). After the first visit, participants were scheduled to return in one week for their second session. They returned for their third session one week after that. Following the third session, participants completed follow-up measures two weeks later (i.e., 4-weeks after randomization/session 1), either at home or in the laboratory using Qualtrics.

These measures were the same measures that participants filled out at baseline (with the addition of an overall change measure and an assessment of reactions to treatment). Following their first follow-up visit, participants completed their second follow-up assessment 8 weeks later; that is, 12-weeks after randomization. Participants who were in the waitlist control group completed follow-up questionnaires 4 and 12-weeks after randomization. They were also given the opportunity to participate in RT or EAET, if they desired, at the end of the study. At that time, we described both interventions in some detail and then scheduled a time for them to complete the intervention of their choice. All participants were paid $20 for completing each of the 3 assessment sessions. In addition, intervention sessions were provided for free, and participants were not remunerated for the intervention sessions.

All three sessions for either intervention were conducted in an individualized format, run for 50 minutes, on a weekly basis. All intervention sessions were run by one of five therapists, who were either graduate students in clinical psychology or a master's educated nurse. All therapists were trained and supervised by a licensed clinical psychologist (Mark Lumley, Ph.D.), and sessions were audio recorded to facilitate supervision. Sessions were conducted in private rooms. At the end of each session, homework was provided so participants could practice the skills learned in session (see Appendix B, p. 66). Regardless of condition, all participants were instructed to maintain their usual care (i.e., pharmacological, dietary, or behavioral interventions) throughout the study. The following provides a more detailed discussion of each intervention and the three sessions (see Appendix A, p. 56).

Emotional Awareness and Expression Training

Emotional awareness and expression training (EAET) is an emotional processing intervention, based on the principle that emotional unawareness and suppression can lead to

chronic overarousal, symptoms including pain, and a dysregulated brain-gut neuroenteric system. The goal of the intervention is to help patients reduce stress by: a) having them learn about connections between their stressful life experiences and physical symptoms; b) teaching them to identify, experience, and express their emotions related to these stressful situations; and c) encourage them to engage in healthy emotional and interpersonal behaviors in their daily lives, including assertive and genuine communication. Ultimately, this intervention is intended to reduce IBS symptoms by promoting cognitive and affective changes that improve an individual's ability to experience, express, and resolve their emotions and relate to others. To facilitate this process, patients first had a life history interview, which helped them connect their IBS episodes to their life experiences. Subsequently, the therapist conducted experiential exercises to help patients engage with their avoided feelings, behaviors, memories and relationships. Finally, patients were encouraged to communicate more genuinely in their relationships.

Session One. A rationale for treatment was given, and the relationship between stress and IBS was explored. The therapist focused on the role that emotional avoidance plays in the relationship between stress and health. Next, the participant was given a life history interview to learn about their life experiences, particularly those that have been stressful and that continue to be unresolved. To help participants recognize how life stress and emotional processes have contributed to their IBS, the therapist created a detailed timeline of the participant's experiences during the interview. The therapist also pointed out indicators of emotional avoidance, and explained how this perpetuates both stress and symptoms. At the end of the session, the therapist and participant discussed the participant's timeline and reaction to the interview. A writing exercise that allows participants to freely write about their stressors related to their IBS episodes was given as homework.

Session Two. The therapist and participant reviewed the homework assignment and discussed what stressors the participant identified and wrote about. Barriers to homework were explored. After that, the therapist discussed the importance of expressing emotions. The participant learned that emotional suppression can cause stress, which can exacerbate pain and alter bowel functioning. They also learned that emotional expression of certain emotions (e.g., anger, sadness, intimacy) is often avoided because of fear or potential rejection by others. The bulk of the session involved experiential exercises in which the therapist encouraged the participant to experience and express emotions relevant to their stressful life experiences. These exercises also encouraged patients to experience affect in their body, and then communicate these emotions directly, out loud, with voice, face, tone and physical expression. The therapist took a balanced stance that is both supportive but also directive to facilitate this process. After this exercise, the therapist encouraged the participants to reflect on their experience. Participants were assigned a homework assignment that asked them to monitor their emotional avoidance and suppression, and asked them what they would communicate if they could.

Session Three. The final session began by discussing the participant's homework, and barriers to homework were explored. The therapist reviewed what the participant learned in the previous session, and the participant engaged in more emotional expression during interactive, experiential exercises. The bulk of the session was devoted to helping the patient learn how to honestly and directly communicate feelings to others in an adaptive, responsible manner. For example, assertive communication and the expression of care or love was examined and taught. The participant practiced such honest communication during role-plays in session. At the end of the session, there was a discussion of what the participant had learned throughout the intervention. The participant also generated goals for the future and discussed how they could

continue to implement emotional expression and assertive communication skills into their everyday lives.

Relaxation Training

Relaxation training (RT) is an empirically supported, stress-management treatment for IBS. It is an emotion reduction approach, which is conceptually very different than EAET. It is based on the premise that long-term stress can elevate physiological arousal, exacerbate pain and dysregulate communication between the brain and the gut. The goal of RT is to reduce physiological arousal and minimize pain and discomfort. To facilitate this process, participants were taught different relaxation training skills (e.g., progressive muscle relaxation, applied relaxation, and guided imagery) to reduce their distress, pain, and discomfort. During each session, participants were guided through the relaxation exercise (see Appendix C., p. 76). They also learned variations of the techniques (e.g., relaxation mini-practices), so they can integrate them into their everyday lives. These exercises minimized IBS symptoms by instigating cognitive and behavioral changes that influence how one responds to stressors.

Session One. A rationale for treatment was given, which emphasized that stress causes arousal, which increases symptoms, and the goal of RT is to directly reduce arousal. In addition, the relationship between stress and IBS was explored. After discussing these ideas, the therapist guided the participant through a 20-minute relaxation exercise, Progressive Muscle Relaxation (PMR) (Jacobson, 1938). The therapist demonstrated how to do the exercise, and then the participant practiced. Following the exercise, the participant and the therapist discussed the participant's reaction to PMR. Then, for a homework assignment, the therapist asked participants to listen to an audio recording (on CD or mp3) that guided them through a PMR practice once per day.

Session Two. At the beginning of the session, the homework assignment was discussed. The participant and therapist discussed how often the participant listened to the audio recording, and evaluated how helpful it was at helping them relax. Barriers to practice were also explored. After that, the therapist introduced the participant to the concept of applied relaxation, and guided them through a 30-60 second relaxed breathing exercise (mini-practice). Next, the therapist taught the participant a 20-minute relaxed breathing technique. Following this exercise, the therapist and participant discussed the participant's reactions to this technique, and explored how much the participant liked this exercise compared to PMR. Another mini-practice was conducted at the end of this session, to give the participant an additional opportunity to practice. For homework, the participant was asked to practice this technique or PMR daily. They were also encouraged to build the mini-practice exercise into their daily routine.

Session Three. This session followed a similar format to session two. First, homework was discussed and barriers to practice were explored. After that, the therapist taught the participant a 20-minute guided imagery relaxation exercise. Following the exercise, the therapist and participant discussed the participant's reactions to this exercise, and explored how much the participant liked this exercise compared to the other relaxation training techniques. At the end of the session, the participant described their experience with relaxation training in general and reflected on their ability to manage stress. The final portion of the session was devoted to goal setting, where the participant described how they would be able to incorporate relaxation training into their daily routine in the future. The therapist encouraged the participant to continue to use the audio recordings to help them reach their goals.

Wait-list Control

After baseline and during the intervention phase of this study, participants in the wait-list control condition engaged only in standard medical care. After completing the 4 and 12-week follow-up assessments, participants in the wait-list control condition were given the opportunity to participate in RT or EAET. Both interventions were described in detail, and then participants indicated which one they preferred. Sessions were scheduled with a therapist and began immediately or shortly after their final assessment.

Measures (see Appendix D, p. 87)

Primary Outcome:

IBS symptom severity. This was assessed using the IBS Symptom Severity Scale (IBS-SSS), which contained five questions measured on a 100-point visual analogue scale. These questions assessed the severity and frequency of abdominal pain, the severity of abdominal distention, dissatisfaction with bowel habits, and interference with quality of life over the last 10 days (Francis, Morris, & Whorwell, 1997). All five items were summed to create a total IBS symptom severity score (range: 0 – 500). A higher score indicates greater symptom severity. According to previous research, scores ranging from 75 – 175 represent mild severity, 175 – 300 represent moderate severity, and 300 or greater represent severe IBS symptoms (Francis et al., 1997). This well-validated measure has been shown to be reproducible and sensitive to change (Francis et al., 1997). In this sample, this measure had moderate internal consistency at baseline (α=0.58), but good internal consistency at the 4-week (α =0.70) and 12-week follow-up assessments (α = 0.83).

Secondary Outcomes:

Global Change in IBS. This was assessed at the 4-week and 12-week follow-up time points using the Clinical Global Impressions (CGI) Improvement Scale – IBS version (Klein,

1999). Participants were asked to compare their symptoms of abdominal discomfort or pain and bowel symptoms, before entering the study to those during the past week, on a 1(substantially worse) to 7(substantially improved) scale.

Psychological symptoms. This was assessed using the 53-item Brief Symptom Inventory (BSI; Derogatis & Melisaratos, 1983). This measure assessed a range of psychological distress symptoms. For each item, participants rated their discomfort over the past 2 weeks on a 5-point scale that ranged from 0 (not at all) to 4 (extremely). This measure has well-established reliability and validity (Derogatis & Melisaratos, 1983). This study analyzed the Interpersonal Sensitivity, Depression, Anxiety, and Hostility subscales, which had high reliability in this sample. The anxiety subscale has 6 items (baseline α =0.78; 4-week follow-up α =0.85; 12-week follow-up α = 0.88), the depression subscale has 5 items (baseline α =0.84; 4-week follow-up α = 0.87; 12-week follow-up α = 0.89), the hostility subscale has 5 items (baseline α = 0.78; 4-week follow-up α = 0.81; 12-week follow-up α = 0.81), and the interpersonal sensitivity subscale has 4 items (baseline α = 0.85; 4-week follow-up α = 0.86; 12-week follow-up α = 0.86).

Quality of life. This was measured using the 34-item Irritable Bowel Syndrome Quality of Life measure that assessed how IBS impacts quality of life. Items were rated on a 5-point Likert scale, and participants were asked to report on how they generally feel. A total score was obtained by summing all items (range: 34 to 170); higher scores are indicative of worse quality of life (Drossman et al., 2000; Patrick et al., 1998). This measure has demonstrated high internal consistency (α = 0.95) and high reproducibility (ICC = 0.86). In addition, this measure has generally demonstrated good discriminant validity and convergent validity. In this sample, this measure had very strong reliability (baseline α =0.95; 4-week follow-up α = 0.95; 12-week

follow-up α =0.96).

Statistical Analysis

After data collection, analyses were conducted in SPSS 22.0. The data was screened for missing and out of range values, and frequency distributions of demographic and outcome variables were examined for outliers. Data was also examined for non-normal variables by examining skewness using histograms. Because no variables were highly skewed, only original variables were used in all analyses. Demographic information was analyzed using frequency distributions and measures of central tendency. Internal consistency of the outcome measures was evaluated using Cronbach's alpha measure of reliability.

To determine the success of randomization, preliminary analyses compared the three conditions on demographics and baseline levels of outcome measures using an analysis of variance (ANOVA) and chi-square analyses. Attrition analyses compared study completers to those who did not complete any post treatment assessment. An independent samples t-test was used to examine continuous variables. Chi-square analyses (Fisher's Exact Test) were used to examine categorical variables.

To conduct main effect analyses, intent-to-treat (ITT) analyses of the full randomized sample (N = 106) were used. ITT analyses were conducted using a multiple imputation procedure in SPSS 22.0 in which each missing outcome value was replaced with an imputed value, which takes into account other variables in the dataset (e.g., demographics, baseline levels of the outcome measures). The three conditions on each outcome measure were compared using analyses of covariance (ANCOVA), covarying for each measure's baseline value. If the overall ANCOVA was significant, LSD post-hoc tests were used to determine which pairs of groups differed. Analyses were done at the 4-week and 12-week time points separately. A global change

in IBS symptoms measure was also included at the 4-week and 12-week assessments. The three conditions were compared on this measure using an analysis of variance (ANOVA). If the overall ANOVA was significant, group differences were determined with LSD post-hoc tests. For each outcome, effect sizes (partial eta squared) are reported. These effect sizes are defined as the proportion of variance in the outcome accounted for by the three treatment groups while accounting for baseline scores. Another effect size (ES) – the standardized difference in change between conditions – was also indicated. This is calculated as the difference score in condition 1 minus the difference score in condition 2 (i.e., EAET –RT, EAET – control, or RT – control) divided by the pooled SD of change scores. Clinical significance was explored on the primary outcome (IBS-SSS), using a commonly accepted definition (30% improvement from baseline to 4 and 12-week follow-ups), and conditions were compared on improvement rates using chi-square analyses. All data analyses in this study used a two-tailed *p* value of .05.

CHAPTER 4

Results

Preliminary Analyses

The three conditions did not differ on age, gender, race, marital status, duration of symptoms (Table 1) or baseline levels of any outcome measures (Table 3) suggesting that randomization created equivalent groups on these variables. However, there was a statistically significant difference in years of education for the three conditions: F (2, 103) = 7.8, p = .001. Post-hoc comparisons using the LSD test indicated that the mean education for EAET (M = 16.65 years, SD = 2.00) was greater than that of RT (M = 15.17 years, SD = 1.90, p = .001) and controls (M = 15.06 years, SD = 1.78, p = .001). RT did not differ significantly from the controls.

Table 1. Comparison of Group Means on Demographic Measures at Baseline

		Full Sample (n = 106)	Emotional Awareness and Expression Training (n = 37)	Relaxation Training (n = 36)	Control Group (n = 33)	F/χ^2 Value	p - value
Age (years)	*M (SD)*	36.14 (16.42)	40.38 (17.64)	34.11 (15.22)	33.61(15.76)	1.94	.15
Gender						0.06	.97
Male	*n* (%)	21 (19.8)	7 (18.9)	7 (19.4)	7 (21.2)		
Female	*n* (%)	85 (80.2)	30 (81.1)	29 (80.6)	26 (78.8)		
Ethnicity						0.47	.79
European American	*n* (%)	69 (65.1)	23 (62.2)	23 (63.9)	23 (69.7)		
Other	*n* (%)	37 (34.9)	14 (37.8)	13 (36.1)	10 (30.3)		
Marital Status						4.13	.13
Partnered	*n* (%)	34 (32.1)	15 (40.5)	7 (19.4)	12 (36.4)		
Other	*n* (%)	72 (67.9)	22 (59.5)	29 (80.6)	21 (63.6)		
Years of Education	*M (SD)*	15.65 (2.03)	16.65 (2.00)[a]	15.17 (1.92)[b]	15.06(1.78)[b]	7.79	.001
Duration of Symptoms	*M (SD)*	22.90 (12.84)	22.89 (13.13)	23.58 (12.78)	22.17 (12.94)		

Note. All tests were 2-tailed. M = mean; SD = standard deviation;
Chi-square analysis for race was analyzed comparing only European American to Other, due to the small numbers in the other cells. Chi-square analysis for marital status was analyzed comparing only Partner (married or living together with a significant other) to Other (single, separated, divorced, widowed), due to the small numbers in the other cells. Means with different superscripts differ significantly according to Fisher's LSD post-hoc test.

Figure 1 demonstrates participant flow through the study. The majority of participants in both conditions completed all three treatment sessions. For RT, one participant did not complete any of the treatment sessions (due to lack of responding), and one participant had only two treatment sessions (withdrew). For EAET sessions, two participants only completed one treatment session (one participant withdrew, whereas the other stopped responding), and one participant had only two treatment sessions (due to scheduling difficulties). The mean number of relaxation training sessions attended (M = 2.89 SD = 0.52) did not differ from the mean number

of emotional awareness and expression training interventions attended (M = 2.86 SD = 0.48). All of the wait-list control participants were offered the opportunity to participant in an intervention of their choice following the 12-week assessment. Three participants opted to participate in RT, and one participant opted to participate in EAET.

Regarding attrition over the follow-up period, 5 participants were lost to follow-up at 4-weeks (EAET n = 2; Control, n = 3), and at 12-weeks, 11 participants were lost to follow-up (EAET, n = 2; RT, n = 3; Control, n = 6). Of the 106 participants, 5 (4.7%) did not complete any follow-up assessments and were considered "non-completers" (EAET, n = 2; RT, n = 0; Control, n = 3). Completers were defined as those who completed at least one follow-up assessment. As seen in Table 1, completers and noncompleters did not differ significantly on most demographic or outcome measures. However, there was a significant different between completers and non-completers on age (t (13.79) = -2.30, p = .04); completers were significantly older (M = 36.41, SD = 16.76) than non-completers (M = 30.80, SD = 3.96). A significant difference was also found for depression (t (104) = 3.35, p = .001), with completers having significantly lower depressive symptoms (M = 0.79, SD = 0.76) than non-completers (M = 2.00, SD = 1.26). There was also a significant difference between completers and non-completers on gender (χ^2 (1,N = 106) =11.97, p <.01), with women more likely to complete the study than were men.

Figure 1.

Flow of participants through the study

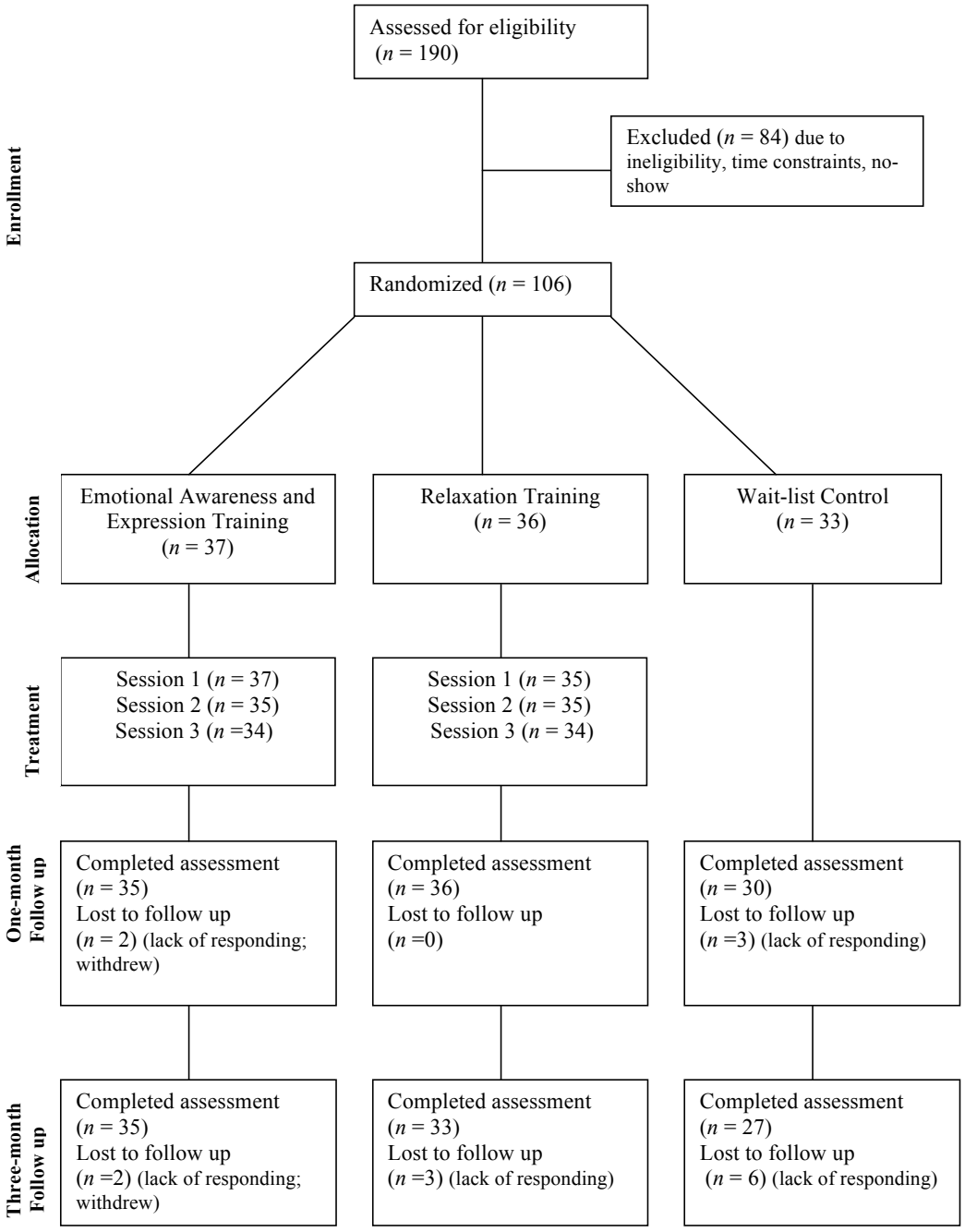


Table 2. Participants Who Completed the Follow-up Assessments Compared to Participants Who Were Lost to Follow-up on Demographic and Baseline Levels of the Outcome Measures

		Completers (n = 101)	Non-Completers (n = 5)	t/χ^2 Value	p - value
Age (years)	*M (SD)*	36.41 (16.76)	30.80 (3.96)	-2.30	.04
Gender				11.97	.01
Male	*n* (%)	17(16.8)	4 (80.0)		
Female	*n* (%)	84(83.2)	1 (20.0)		
Ethnicity				1.45	.34
European American	*n* (%)	67 (66.3)	2 (40.0)		
Other	*n* (%)	34 (33.7)	1 (60.0)		
Marital Status				0.35	1.0
Partnered	*n* (%)	33 (32.7)	1 (20.0)		
Other	*n* (%)	68 (67.3)	3 (80.0)		
Education (years)	*M (SD)*	15.70 (2.02)	14.60 (2.07)	-1.19	.24
Symptom Severity	*M (SD)*	5.27 (1.61)	6.28 (2.04)	1.35	.18
Anxiety	*M (SD)*	0.97 (0.83)	1.37 (0.70)	1.06	.29
Depression	*M (SD)*	0.79 (0.76)	2.00 (1.26)	3.35	.001
Hostility	*M (SD)*	0.75 (0.65)	1.36 (1.10)	1.24	.28
Interpersonal Sensitivity	*M (SD)*	0.98 (1.03)	1.40 (1.10)	0.89	.38
Quality of Life	*M (SD)*	2.50 (0.73)	2.53 (0.94)	0.10	.92

Note. All tests were 2-tailed. M = mean; SD = standard deviation; n = number of participants positive on variable in question; % = percent of participants positive on variable in question. Chi-square analysis for race was analyzed comparing only European American to Other, due to the small numbers in the other cells. Chi-square analysis for marital status was analyzed comparing only Partner (married or living together with a significant other) to Other (single, separated, divorced, widowed), due to the small numbers in the other cells.

Primary Analyses

Analyses of covariance were conducted to compare all three conditions on outcome measures (symptom severity, psychological distress, and quality of life) while controlling for baseline levels. The global change in IBS symptoms measure was not administered at baseline; therefore, covariance analyses were not conducted. Instead, an analysis of variance (ANOVA) was conducted. The outcome data for each condition is presented in Table 2, specifically, means

and standard deviations for each score at 4- and 12-week follow-up assessments. Adjusted means at both follow-up timepoints are also presented, which represent the original outcome means adjusted for the baseline scores.

The primary outcome, IBS symptom severity, differed among the three conditions at the 4-week follow-up (F (2, 102) = 4.39, p = .02, partial eta^2 = 0.08). EAET had lower symptom severity than the controls (ES = -0.65, p = .004), but did not differ from RT (ES = - 0.40, p = .13). RT did not differ from the controls (ES = -0.29, p = .15). There were no group differences among conditions at 12-weeks. At this timepoint, all groups continued to improve, particularly the controls, which were no longer significantly different than EAET.

At 4 weeks, 59.5% of EAET participants had clinically significant reductions in symptom severity (at least 30% reduction), whereas 38.9% of RT participants and 33.3% of controls had clinically significant reductions in symptom severity. These percentages, however, did not differ significantly (χ^2 *(2,N = 106)* =5.48, p = .07). At 12-weeks, 54.1% of EAET and 55.6% of RT participants had clinically significant reductions in symptom severity, whereas 30.3% of controls had clinically significant reductions in symptom severity. Again, these percentages did not differ significantly (χ^2 *(2,N = 106)* =5.49, p = .06).

Global change in IBS symptoms was also assessed. There was a significant difference between groups at 4-weeks (F (2, 97) = 3.09, p = .05, partial eta^2 = 0.06), with EAET (M = 4.83, SD = 0.22, p = .05*)* and RT (M = 4.91 SD = 0.22, p = .02*)* having "slight improvements" that were significantly greater than controls who had "no change" (M = 4.17, SD = 0.24*)*. At 12 weeks, however, the three conditions did not differ; although EAET (M = 4.81, SD = 1.66*)* and RT (M = 4.85, SD = 1.58*)* maintained their "slight improvements," the controls shifted toward slight improvement (M = 4.46, SD = 1.43*)*.

Participants in both interventions improved on some psychological symptoms relative to controls at the 4-week follow-up. More specifically, the three conditions differed on anxiety (F (2, 102) = 7.27, p = .001, partial eta^2 = 0.13), with both EAET (ES = -0.50, p = .003) and RT (ES = -0.58, p = .001) having lower anxiety than controls; but EAET did not differ from RT (ES = 0.16, p = .55). Hostility was similar. Again, the three conditions differed (F (2, 102) = 3.76, p = .03, partial eta^2 = 0.07), with EAET (ES = -0.43, p = .01) and RT (ES = -0.41, p = .03) having lower hostility than controls; but EAET did not differ from RT (ES = 0.13, p = .75). Depression had a slightly different outcome pattern. There was a significant difference among conditions (F (2, 102) = 5.30, p = .006, partial eta^2 = 0.09), but only RT had significantly lower depression than controls (ES = -0.60 p = .002). EAET did not differ from RT (ES = 0.52, p = .10) or the controls (ES = -0.14, p = .12). There were no group differences for interpersonal sensitivity. At 12 weeks, the three conditions did not differ on any psychological symptoms.

The three conditions differed on quality of life at the 4-week follow-up F (2, 102) = 12.19 p <.01, partial eta^2 = 0.19). Both EAET (ES =-0.90, p <.001) and RT (ES = -0.92, p <.001) led to significant improvements in quality of life as compared to controls; again, EAET did not differ from RT (ES = -0.06, p =.35). Similarly, at 12 weeks, group differences emerged (F (2, 102) = 4.84 p =.01, partial eta^2 = 0.09), with EAET (ES = -0.56, p =.004) and RT (ES = -0.62, p =.02) having higher quality of life than controls; and, EAET did not differ from RT (ES =0.10, , p = .66).

Table 3. Comparison of Group Means and Adjusted Means on Outcome Measures at 4-week and 12-week Follow-up Timepoints

Outcome Measure	Time Point	Emotional Awareness and Expression Training (n = 37)	Relaxation Training (n = 36)	Control Group (n = 33)	F-value	p-value
Symptom Severity	Baseline M (SD)	5.49(1.74)	5.24(1.50)	5.22(1.68)	0.30	.74
	4-week M (SD)	3.69 (1.66)	4.13 (1.46)	4.64 (1.81)		
	12-week M (SD)	3.57 (2.18)	3.61(1.95)	4.33 (2.15)		
	4-wk Adj. M (SE)	3.62 (0.25)[a]	4.16 (0.25)[a,b]	4.68 (0.26)[b]	4.39	.02
	12-wk Adj. M (SE)	3.48 (0.32)	3.65 (0.32)	4.39 (0.33)	2.15	.12
Anxiety	Baseline M (SD)	0.89 (0.88)	0.97 (0.76)	1.10 (0.84)	.561	.57
	4-week M (SD)	0.67 (0.66)	0.62 (0.62)	1.22 (0.92)		
	12-wk M (SD)	0.73 (0.87)	0.61 (0.60)	0.98 (0.86)		
	4-wk Adj. M (SE)	0.71 (0.10)[a]	0.62 (0.11)[a]	1.16 (0.11)[b]	7.27	<.01
	12-wk Adj. M (SE)	0.78 (0.11)	0.61 (0.11)	0.92 (0.12)	1.81	.17
Depression	Baseline M (SD)	0.61 (0.62)	0.93 (0.87)	1.03 (0.93)	2.53	.09
	4-week M (SD)	0.62 (0.66)	0.57 (0.68)	1.13 (1.09)		
	12-week M (SD)	0.53 (0.64)	0.56 (0.72)	0.87 (0.93)		
	4-wk Adj. M (SE)	0.77 (0.11)[a,b]	0.52 (0.11)[a]	1.02 (0.11)[b]	5.30	.01
	12-wk Adj. M (SE)	0.66 (0.10)	0.52 (0.10)	0.77 (0.11)	0.39	.68
Hostility	Baseline M (SD)	0.68 (0.66)	0.79 (0.60)	0.86 (0.79)	0.61	.54
	4-week M (SD)	0.50 (0.57)	0.61 (0.51)	0.94 (0.90)		
	12-week M (SD)	0.51 (0.68)	0.49 (0.44)	0.64 (0.77)		
	4-wk Adj. M (SE)	0.56 (0.09)[a]	0.60 (0.09)[a]	0.89 (0.10)[b]	3.76	.03
	12-wk Adj. M (SE)	0.55 (0.09)	0.48 (0.09)	0.60 (0.09)	0.39	.68
Interpersonal Sensitivity	Baseline M (SD)	0.74 (0.80)	1.09 (1.27)	1.19 (0.93)	1.89	.16
	4-week M (SD)	0.69 (0.78)	0.75 (0.98)	1.22 (1.08)		
	12-week M (SD)	0.54 (0.66)	0.58 (0.68)	0.83 (0.94)		
	4-wk Adj. M (SE)	0.82 (0.13)	0.71 (0.13)	1.13 (0.14)	2.62	.08
	12-wk Adj. M (SE)	0.62 (0.12)	0.55 (0.12)	0.77 (0.12)	0.85	.43
Quality of Life (Poor)	Baseline M (SD)	2.41 (0.56)	2.65 (0.80)	2.43 (0.83)	1.23	.30
	4-week M (SD)	2.05(0.51)	2.34(0.73)	2.56(0.82)		
	12-week M (SD)	1.93(0.55)	2.11(0.78)	2.34(0.70)		
	4-wk Adj. M (SE)	2.12(0.07)[a]	2.22(0.72)[a]	2.61(0.07)[b]	12.19	<.01
	12-wk Adj. M (SE)	1.98(0.10)[a]	2.04(0.10)[a]	2.39(0.10)[b]	4.84	.01

Note: Note. All tests were 2-tailed. M = mean; SD = standard deviation; n = number of participants positive on variable in question; % = percent of participants positive on variable in question.

[a, b]: Adjusted means with different superscripts differ significantly according to Fisher's LSD post-hoc tests

CHAPTER 5

Discussion

This clinical trial has several key findings. First, a brief emotional processing intervention that enhanced emotional awareness, experiencing, and expression reduced IBS symptom severity at 4 weeks above and beyond no treatment; however, EAET did not differ than RT. Next, emotional awareness and expression training was as effective as relaxation training, in reducing anxiety, hostility, and improving quality of life, which not only supports previous research that has shown relaxation skills to be beneficial for people with IBS (Blanchard, et al., 1993; Keefer & Blanchard, 2001; Lahman et al., 2010; Shinozacki et al., 2010), but also suggests that an emotional processing intervention has the potential to be a viable treatment alternative. Third, on most measures, both EAET and RT maintained their gains at 12 weeks, but neither EAET nor RT surpassed the controls, due to the improvement reported by the controls. However, quality of life is the single measure that continued to show longer-term advantage of both treatments over controls at 12 weeks.

The finding that EAET had significantly greater improvements on IBS symptom severity, at 4-weeks, compared to the controls, is notable. This suggests that emotional awareness and expression training is effective in reducing the primary symptoms of IBS. These findings also reflect meaningful changes given that approximately 20% more EAET participants had clinically significant improvement in IBS symptoms, as compared to RT. However, it is important to interpret these findings with caution, given that the difference between the two active interventions (EAET vs. RT) was not statistically significant. Further, RT was not significantly different than the controls. It may be that an intervention that helps people confront, rather than avoid emotionally laden experiences, better targets core factors (e.g., emotional avoidance,

failure to process and resolve stress) that are responsible for maintaining and prolonging stress-related symptoms. This is in line with research that has demonstrated a relationship between life stressors (e.g., divorce, relationship difficulties, business failures) and IBS symptom exacerbation (Bennet et al., 1998).

The data on IBS symptom severity at 12 weeks were less clear. The EAET group maintained its early gains with some slight improvements and the RT condition continued to improve; however, for some unknown reason, the controls improved quite a bit, leading to no differences among the three conditions. There are several possible explanations for the improvement shown by controls. First, the passage of time simply leads to improvements, particularly regression to the mean, where people enter a study at a high point of symptom / distress, and then over time, move toward the mean. Or, these findings may be a "relief" effect of being done with the study, or a response to the upcoming option to participate in treatment. It is also plausible that these findings reflect the natural fluctuation in symptoms often seen in IBS, given that it is an episodic disorder. However, despite the unexpected improvement seen among controls, it is notable that participants in both treatment conditions had 20% more clinical improvement in IBS symptom severity at 12 weeks than the controls, suggesting that those who underwent an active treatment had more meaningful changes as compared to their wait-list control counterparts.

A global assessment of symptom change was used as a secondary measure to examine participant's perceptions of change in their IBS symptoms over time. It was not surprising that participants in both of the active interventions reported significantly greater improvement in IBS symptoms as compared to the controls. This suggests that participants felt like they improved following these interventions, and demonstrates that the active interventions were well received.

However, improvements were rated as "slightly improved," on average, as opposed to the moderate to marked improvements that were expected. These more limited ratings may reflect the measure used to assess global improvement. Some critics of adequate or satisfactory relief measurements argue that global measurements of change are confounded by initial symptom severity. For example, Whitehead and colleagues found that patients with IBS who experienced more severe symptoms at baseline, had the largest reductions of symptom severity, but were the least likely to report satisfactory relief (Whitehead, Palsson, Levy, Feld, VonKorff, & Turner, 2006). This may be true of this sample given that patients reported, on average, moderately severe IBS symptoms at baseline. At 12 weeks, the three groups did not differ on change in IBS symptoms; however, the participants in the EAET and RT groups continued to report "slight improvements" as compared to the controls who shifted towards "slight improvement." These data parallel the findings seen on the primary outcome measure, IBS symptom severity, and demonstrate that both of the active interventions maintained their gains, but the controls also improved, leading to no differences between groups at this timepoint.

Psychological distress and quality of life was also assessed. Both of the active interventions were effective at improving anxiety, hostility, and quality of life at 4 weeks, as compared to the wait-list control. Although it was hypothesized that the emotional awareness and expression training intervention would have the greatest improvements, these findings are not surprising. This data corroborates research that has shown relaxation training to be a useful approach for patients with IBS (Blanchard, Greene, Scharff, & Schwarz-McMorris, 1993; Keefer & Blanchard, 2001; Lahman et al., 2010; Shinozacki et al., 2010). However, it is notable that a conceptually opposite intervention designed to enhance emotional awareness and expression achieved comparable benefits. Therefore, emotional awareness and expression training may also

be effective at reducing negative emotions, such as anxiety and hostility, and improving overall well-being.

There are several possible explanations for this data. The finding of treatment specificity but equivalent outcomes is common in the psychological treatment literature (Lambert & Ogles, 2004), and it is possible that both EAET and RT had specific effects in this study. Both RT and EAET had comparable effect sizes (medium to large) on these measures, which suggests that both treatments were equally effective. One plausible interpretation is that only a subset of people responded to a single treatment approach, and individual differences influenced who was most likely to benefit from EAET versus RT. IBS is a heterogeneous disorder influenced by multiple factors (Drossman, 1999). Beyond biological factors, psychological and social factors have also been shown to play a role (Drossman, 1998; Tanaka, Kanazawa, Fukudo, & Drossman, 2011). Therefore, participants may have had different needs, which moderated treatment outcomes. For some patients, unhealthy behavioral patterns and lack of self-care (e.g., poor diet, disturbed sleep patterns, sedentary behavior) may have contributed to IBS symptoms and related distress, whereas for others, maladaptive communication styles, personality factors (e.g., neuroticism), and/or deficits in emotional processing (e.g., alexithymia, ambivalence over emotional expression, and a lack of assertiveness) may have been the most important factors.

It is also important to consider the individual differences in readiness to change and/or motivation to engage in treatment. Based on the transtheoretical model of change, people may be more or less ready depending on whether they are in the precontemplation, contemplation, preparation, action, maintenance, or termination phase (Prochaska & Vellicer, 1997). Although the participant's readiness for change was not assessed, clinical observations of the people in this trial suggest that many participants were in the precontemplation or contemplation stages rather

than prepared or ready for action with respect to engaging in EAET, which required a great deal of openness, courage, and motivation on the part of the participant. It is possible that EAET led to significant gains for those who were highly ready and able. For example, one participant noted, "This program helped me to be able to cope with my IBS so much better than my prior ways of just feeling so defeated. Also the therapy sessions were so ground breaking in my life for the fact that finally allowed myself to become angry and enraged and reassuring that I am able to express how I truly feel." In addition, participants who could easily identify sources of conflict appeared to have an easier time engaging in EAET. The types of conflicts varied, however, participants appeared to commonly report conflict associated with a parental relationship (e.g., anger versus love towards a parent who mistreated them). Conversely, those who were not ready and motivated to engage in something new likely had fewer gains. Clinical observations suggest that participants who were unaware of avoided emotional experiences, satisfied with their current relationships, or otherwise not ready and/or motivated for change appeared to have the least success with the EAET intervention. It is also important to note that participants who did not "buy" the treatment rationale did not appear to respond as favorably to EAET. For example, some participants felt that EAET may help others, but could not benefit them in any way. One participant noted, "I feel this treatment program would benefit those sufferers who have recently experienced increase in symptoms coincidental with crises (emotional or physical) and/or have not yet developed balance self-perception or confidence when dealing with other people." Another commented, "While I really liked my therapist and can acknowledge that this type of therapy may help others with IBS, I don't really think it helped me much. Though I am the first to admit that my stomach problems get worse with stress, I have had so many stomach issues even when I am calm as can be that an emotional therapy like this can only help me to a certain

extent." Although EAET and RT generally had similar attendance, a few participants did not like EAET and quit. This is further evidence that participants were at different stages of change, and/or had varying degrees of motivation to engage in treatment. Clinical observations suggest that RT was easier for participants to engage in, and participants generally reported that they enjoyed the relaxation exercises. Therefore, most who underwent RT appeared to benefit, although perhaps to a more modest degree than the changes achieved by a smaller number of EAET patients. More research is needed to determine what patient characteristics are associated with patient outcomes for this population, and how to best target these in treatment.

Another possibility is that each treatment could have improved on the same health outcomes through different mechanisms. Emotional awareness and expression training is thought to target avoidance of negative emotional experiences, and processing of unresolved stress. This source of stress is often not addressed by conventional treatment approaches that minimize emotional arousal. Previous research has shown that emotional expression can directly target psychological symptoms by helping to regulate internal states (Ekman & Davidson, 1993), which may help to explain why participants in the emotional awareness and expression training group experienced reductions in anxiety and hostility. Further, identifying, experiencing, and expressing emotions can be both liberating and/or empowering, which may have contributed to changes in overall well being. Anecdotally, one participant noted, "Overall my IBS symptoms have improved, as well as the nausea I've experienced off and on for years. I feel lighter, and after the exercise to deal with a particularly traumatic event I feel less angry and less tense. I can't say that my IBS is completely gone, but the symptoms have definitely gotten better."

Relaxation has been shown to reduce anxiety and stress by targeting different processes, such as downregulating and/or controlling negative emotions and arousal. As a result, relaxation

skills may help patients feel calmer, and less hostile, and as participants began to implement these skills into their daily routine, this may have enhanced their quality of life. Anecdotal reports suggest that participants felt better and less tense following relaxation training, even if their symptoms did not shift. For example, one patient commented, “I thought the skills I learned were helpful and they helped me relax, but I am still unsure if being more relaxed is having a direct effect on my IBS symptoms.” Another participant noted, "It taught me a new way to try to cope with my stress and focus on ways to relieve my tension in a positive way.” However, more process research needs to be conducted to determine exactly what mechanisms were responsible for these findings.

It is also possible that the finding of equivalent outcomes between the active interventions is due to an insufficient sample size (i.e., there were only about 35 patients per condition). There may not have been enough statistical power to find differences between the two active conditions. Another possibility is that non-specific factors account for this finding. For example, obtaining treatment, enhancing awareness about the relationship between physical and emotional health, mastery of new skills, and regular contact with a supportive therapist, may be driving these health outcomes. Some suggest that these factors account for more variance in treatment outcome as compared to specific treatment techniques (Wampold, 2001).

A measure of depressive symptoms had a different pattern of data. At 4 weeks, participants in the relaxation training group had significant improvements in mood following treatment, above and beyond those who underwent emotional awareness and expression training, or no treatment. The finding that participants in the emotional awareness and expression training group did not improve on a measure of depressive symptoms was unexpected, albeit in retrospect, not surprising. Emotional processing interventions, such as written emotional

disclosure and psychodynamic therapy, often negatively impact the moods of people, at least in the short term, as patients deal with their newfound awareness of their conflicts. Further, the experiential exercises in emotional awareness and expression training likely brought up painful memories that provoked sadness in people, which likely contributed to higher scores on a measure of depressive symptoms.

At the 12-week follow-up, participants in both EAET and RT had significantly greater improvements in quality of life relative to the controls. Thus, it appears that both interventions were helpful in enhancing overall well-being and these benefits were sustained over time. Perhaps engaging in a psychological treatment was helpful because participants gained new knowledge, enhanced their self-awareness, and took time for self-care. It is also possible that improvements in self-efficacy contributed to these findings; however, self-efficacy was not explicitly measured. The findings on measures of psychological functioning were less clear. Participants in both of the active interventions generally had lower symptoms relative to baseline; however, the controls also improved.

Strengths and Limitations

This study has many strengths and some important limitations. First, participant attrition was low and intervention sessions were well attended. In addition, participants were followed 12 weeks post-randomization so long-term benefits could be assessed. It is also important to note that participants were recruited from the community and local gastroenterology clinics, which increases the generalizability of the findings. This sample likely represents the wide range of people who are characterized as having IBS in the community, given that some are treatment seeking and others are not.

One limitation, however, is that medical confirmation of an IBS diagnosis (by a physician) was not received on all participants. Therefore, the relevance of effects to treatment-seeking patients versus non-treatment seeking individuals could not be ascertained. It is possible that a sample recruited solely from a medical setting may have different outcomes. Despite this limitation, it is important to note that all of the participants in this study met the Rome III criteria of IBS as diagnosed by study staff at the time of screening, and the majority had a diagnosis confirmed by a physician (79%). Another limitation is that the sample in this study, although larger than many studies of psychological treatments for IBS, still had only about 35 patients per condition and may have lacked the statistical power to find relatively small differences between two active conditions. The sample also included many more women (80.2%) than men. Although distribution tends to reflect the population of IBS patients in general (Mayer et al., 1999), these findings will not necessarily generalize to males with the disorder. A discrepancy was also found between completers and non-completers. Completers were older, had lower depressive symptoms, and were more likely to be female than the relatively few people who did not complete the study. This further limits the generalizability of the sample.

Next, in this sample, the IBS-SSS measure had only moderate internal consistency at baseline, but good internal consistency at the 4-week and 12-week follow-ups. The moderate value seen at baseline is slightly lower than previous studies, which have reported at least adequate internal consistency (e.g., α = 0.65; Kelley et al., 2009). It is unclear why internal consistency was lower at baseline and increased over time. Possible explanations may include the small size of the measure, which only included 5 items (Cortina, 1993). Others have suggested that values less than 0.7 can be expected given the diversity of constructs measured (Kline, 1999).

Next, randomization did not create equivalent groups on years of education. Participants in emotional awareness and expression training had more education, on average, than those in relaxation training and the controls. Thus, it appears that randomization failed to create equivalent groups on this baseline variable. Thus, a limitation of the study is that it is possible that the higher education of the EAET condition facilitated the benefits of this condition, given that greater education is often linked to better treatment outcomes. Although this baseline difference between groups was unfortunate, it is important to note that it is typically not recommended to control for a variable that differs among groups (Field, 2013). Therefore, I chose to run my primary analyses without controlling for education.

This study had a nice range of measures, which captured physical and psychological symptoms, as well as quality of life. However, data was only collected on self-report measures, which can be problematic. Participants may not be able to accurately recall their experiences over time, which may have biased these findings. Other types of assessments (e.g., symptom diaries, physician rated measures, biological measures) may have provided more accurate or extensive information. In addition, data on a limited number of outcomes was analyzed. These interventions may have had effects on health outcomes that were not captured.

Another strength of this study is that it used a comparison condition (e.g., wait list control condition), which controlled for many threats of internal validity (e.g., maturation, history, statistical regression to the mean). However, a wait-list control did not control for non-specific aspects of treatment (e.g., attention, support). A credible placebo control (e.g., psychoeducation) would have helped to determine whether or not nonspecific factors influenced treatment outcomes.

Lastly another strength of this study is that multiple therapists were involved, which reduces the risk of the effects being due to a single therapist, and randomization was stratified by therapists, so that each therapist worked with patients in all three conditions. However, there were 5 therapists involved, and some worked with a relatively small number of cases, rendering statistical tests of therapist effects unreliable. Fidelity data was not collected and there was likely a learning curve for therapists, especially for the complex EAET intervention, which involved various nuances, and required some degree of flexibility to tailor it to the individual needs of each participant. Further, EAET was a difficult intervention to learn, master, and implement. There were various factors that may have influenced treatment fidelity (e.g., previous experience conducting emotional processing interventions, personality/temperament of the therapist, therapists' values). However, therapists received weekly supervision by a licensed clinical psychologist who has expertise in stress, emotional processes, and emotional exposure approaches to intervention. Supervision was group-based and involved didactics, a review of audiotaped samples, and extensive feedback. All of these efforts likely improved knowledge, competence, and adherence of the therapists.

Clinical Implications and Future Directions

Although research has demonstrated that psychological treatments as a class are effective in treating symptoms of IBS (Lackner et al., 2004); few studies have examined whether a particular type of psychological treatment is more effective than another. Research on psychological interventions for IBS has focused primarily on cognitive and behavioral approaches to intervention, which seek to decrease arousal and manage symptoms. For example, a recent meta-analysis examining various therapeutic techniques for IBS found that interventions that utilized both cognitive and behavioral techniques led to better symptoms and overall well-

being, compared to those that did not (Henrich et al., 2015). There has been some preliminary work demonstrating the value of other techniques, such as exposure for patients with IBS; however, the focus has been on exposure to gastrointestinal symptom-specific anxiety (Ljottson et al., 2013), rather than targeting avoided emotional experiences. This is the first study to systematically assess a brief, emotional awareness and expression intervention for this population.

The results of this study are encouraging. It appears that that an emotional awareness and expression intervention has the potential to be a viable treatment alternative for people with IBS and is as least as effective as a more conventional skills-based approach, relaxation training. In addition, these findings suggest that EAET is particularly strong in its reduction of IBS-symptoms in the short-term, whereas RT did not show this effect. Thus, EAET may be a useful approach for people with IBS for a number of reasons. First, it is brief, requiring participants to attend only three sessions. Next, it provides people with various emotional skills that enhance their ability to become aware of their emotions, and experience and express them with greater comfort. Teaching people to experience and express emotions has the potential to not only improve health and functioning, but also is likely to enhance interpersonal communication and help individuals to develop and maintain more meaningful relationships. However, many questions remain unanswered, and given that this is the first test of this intervention, it is difficult to draw any firm conclusions.

It is important to replicate this study using a larger sample that is informed by a power analysis to ensure there is enough statistical power to detect a relatively small difference between two active conditions. Such a study should also include additional health outcomes that may be impacted by these interventions. For example, one might include measures examining positive

and negative affect, interpersonal communication, experience in close relationships, interpersonal functioning, and health care utilization. It is also unclear exactly how emotional awareness and expression training operates relative to cognitive-behavioral approaches, such as relaxation training. In order to better understand the active ingredients of change, process research examining potential mediators (e.g., self-efficacy, resolved stress symptoms, levels of emotional awareness and expression, mastery, locus of control) needs to be conducted. In addition, given the heterogeneity of IBS, it is likely only a subgroup of patients will benefit from a single treatment approach. Therefore, future research should examine patient characteristics that may be potential moderators of treatment outcomes, such as assertiveness, ambivalence over emotional expression, readiness for change, and motivation. This can help better direct clinical care by tailoring treatment to the needs of different individuals. Such studies might also include measures of nonspecific factors, or homework adherence, to determine if these factors might account for the data.

Next, only a three-session "dosage" of treatment was tested; however, it is possible that a longer EAET intervention (e.g., 10-12 sessions) would have a greater impact. It may be that EAET is more effective than RT in the long run, but it is a more difficult and time-demanding process. Therefore, three sessions may not have been long enough for participants to enhance their emotional awareness, release inhibited affect, and successfully resolve intrapsychic conflicts. Therefore, researchers should consider testing a longer version of EAET to identify the most beneficial length of treatment. It also may be helpful to assess readiness for change at the outset of treatment. If participants are in the preparation phase, then a three-session dosage might be enough. However, if participants are in the pre-contemplation or contemplation phases, longer treatment may be needed. Researchers might consider adding motivational interviewing or

emotional awareness exercises to see if these strategies help people who are in the pre-contemplation or contemplation phases move forward to the preparation phase. It is also important to consider the possibility that a participant may have more than one intrapsychic conflict that needs to be addressed. For example, in this study one participant noted that she was molested as a child by a family member and raped by a stranger as an adult. These two scenarios brought up different sources of conflict for her that needed to be addressed. In this case, multiple sessions might be needed to resolve the patient's underlying issues. However, adding additional treatment visits may enhance participant burden and/or increase the chance of attrition. To meet the needs of the participants, researchers could consider adding a booster session one month after final treatment session to help the participant continue to work through issues that linger.

It is also important examine the impact of these interventions in different samples. Many patients with IBS do not seek medical treatment or stop consulting with medical providers because current treatments are often unhelpful. Therefore, it would be interesting to test such treatment approaches in a purely treatment-seeking sample to determine its efficacy with a different population. People with IBS also often have co-morbid medically unexplained disorders, such as fibromyalgia, chronic pelvic pain, and headaches. Some argue that these medically unexplained syndromes are all related (Yunus, 2008). It may be advantageous to apply such interventions to samples of patients who present with other medically unexplained conditions, to determine if such approaches are generalizable across conditions.

Although my focus was on identifying which intervention was superior, it may be that both interventions work best together. There is a movement towards more integrated, multicomponent treatment packages in research and practice. For example, there has been an initiative to increase the effectiveness of psychological treatment for generalized anxiety disorder

by integrating cognitive and behavioral therapy with interpersonal and experiential therapies (Borkovec, Newman, & Castonguay, 2003). A similar approach could be used for this population. One might develop a unified protocol, which combines cognitive-behavioral and emotional processing components. One way to carry out such an intervention might be to use a modular approach in which participants are provided with various different treatment modalities (e.g., motivational interviewing, cognitive and behavioral skills, emotional awareness and expression training). An integrated approach may be more patient-centered, enhance effect sizes, and reach a greater number of people, who have various different intervention needs.

Once the efficacy of EAET is well-established, effectiveness studies are needed to translate this work into real world settings. Given that psychological interventions are often underutilized in routine practice, we need to promote research that not only examines potential treatments in rigorous, randomized, controlled trials, but also produces effective, adoptable, and sustainable interventions that could be easily disseminated to front line care. For example, a hybrid effectiveness-implementation trial (Curran, Bauer, Mittman, Pyne, & Stetler, 2012) designed to test the effectiveness of a psychological intervention in a gastroenterological clinic would be able to examine patient and provider outcomes that could elucidate the costs and benefits of such approaches under real-world conditions. For this population, one challenge pertains to who might administer the intervention, given that psychologists are not routinely present in gastorentological clinics, or other specialty care settings, where IBS patients often present. It could be that a psychologist would train other medical providers (e.g., nurses, physician assistants, dieticians) to carry out these interventions. A competency-based training program might include an experientially-based workshop in addition to supervision, feedback, and regular consultation with an expert. These elements have been shown to increase provider's

knowledge and skills (Herschell, Kolko, Baumann, & Davis, 2010) and have been used to train medical providers to implement other evidenced-based practices in primary care settings (Karlin et al., 2010). However, such training programs come with unique challenges that should not be ignored. They may be time-consuming and costly, and clinics may not have the space to carry out this work. More effectiveness and implementation data is needed to determine how to embed these interventions into routine practice, and the most efficient and effective way to train providers to disseminate evidence-based practices.

In conclusion, these findings provide preliminary evidence that emotional awareness and expression training is an efficacious treatment for IBS. Thus, a novel, emotional processing intervention has the potential to be a beneficial treatment alternative to more traditional cognitive and behavioral approaches, for people with IBS. These findings may inform evidence-based practice, improve health outcomes for patients, and reduce health care costs for this chronic and often debilitating condition. Future efficacy-based research with greater methodological rigor is needed to confirm my findings and advance the understanding of emotional processing interventions for IBS. Research should also move towards translating best practices to front line care.

APPENDIX A: Intervention Protocol

Emotional Awareness and Expression Training

Session 1:

1. Have patients complete **"Before Session Ratings"**
2. **Discuss ground rules for sessions** ***(5 min)***

    a. There are many things to cover each session, and I will keep you on track
    b. Remind the participant about confidentiality & audio recording (for supervision purposes)
    c. Encourage / remind about the importance of attendance—and being on time

3. **Introduction** ***(10 min)***

    a. **What causes IBS? What have you heard? What do you believe?**
        i. Possible answers: Diet, Biology – genetic predisposition, Stress

    b. **What is stress?**

        i. "Stress" is defined as a biological (fight or flight) & emotional reaction to an event that you find difficult to cope with
        ii. Stress can make IBS symptoms worse, and IBS symptoms trigger stress.

    c. **What are some of your bodily reactions to stress?**

        i. Possible answers: Diarrhea/Constipation, Headaches

4. **Emotion-focused interview** ***(30 min)***

    GOAL: to help the patient develop an awareness that their physical symptoms are linked to their emotions

    a. **Create a timeline with patient**
        i. Health issues/symptoms
        ii. Stressful life experiences

            1. Focus on:
                a. Issues that continue to haunt patient, Relationships

            2. Point out indicators of emotional avoidance

a. When you avoid emotional experiences, you don't have a chance to change yourself, your relationships, or your beliefs. This is a major source of stress, and more likely to create physical symptoms.

5. **How did you feel about the interview? What were your reactions?**

   a. Help patient recognize value of emotions – provide rationale for treatment

      i. Isn't it interesting that your body responds to the struggles you have with stress?
         1. Normal part of human functioning (consider disclosing personal experience), but is problematic when chronic over time
      ii. What types of experiences in your life did you recall most powerfully? Negative emotional ones!
         1. Humans are built to remember negative emotional experiences – learn what is dangerous and avoid in the future.
      iii. Becoming aware, experiencing, and expressing your emotions will help you become healthier.
         1. Next week you will try and access all of those emotions.
            a. Some of this work will occur here in session, but you will also be asked to do some work at home, like writing or monitoring things
         2. To start this process, I am going to have you do a homework exercise

6. **Homework Assignment *(5 min):***

   a. Hand out/explain EAET homework 1
      i. When/where will you write?
      ii. What sorts of distractions will you have?

7. **Discuss the next session**

   a. Does this time work for you? What might get in the way of you coming back next week? Any concerns about working with me or with what we are doing?
   b. Shall I call you next week to remind you? I'd like to do that if I could.

8. Have patients complete **"After Session Ratings"**

Session 2:

1. Have patients complete **"Before Session Ratings"**
2. **Reflect on last week's session**

    a. What was it like for you to go through the interview last week?

3. **Review of homework and discussion** ***(10 min)***

    a. How often were you able to write?
    b. Who did you write to? What stressors did you come up with?
    c. Problem solve if barriers to writing
        i. What made it difficult to write? What would make it easier?
        ii. Tell me about times that you thought about writing, or you ran out of time.
        iii. Would it be possible? Could you prioritize this?

4. **Intervention** ***(30 min)***

    GOAL: Help patient express avoided emotions

    a. **Experiential exercises**
        i. Introduction/rationale
            1. Now, that we have identified your stressors, we will discuss how to deal with these stressors differently. The goal of this program is to have you reduce your stress and physical symptoms by having new – corrective – emotional experiences that are healthy.
            2. This will take emotionally, challenging work on your part - in session and at home. I will encourage and push you to try new things, and will also support you (*show two-handed model).*
            3. Ultimately, it is up to you to grow and change – I want you to commit, rather than quit when it gets hard.
        ii. Questions? Concerns?

        iii. Encourage the patient to experience and express avoided emotions relevant to their stressful life experiences
            1. Go back in time & have patient have a conversation (empty chair) - tone, words, body language
                a. Express something that has not been expressed before
            2. Look for ways to make this more powerful over multiple repetitions
            3. Look for relief
            4. If needed, repeat, using different scenarios/relationships from previous session and/or homework

5. **How did you feel about our work today? What were your reactions?**
    - **a.** Reiterate rationale: Becoming aware, experiencing, and expressing your emotions will help you become healthier.

6. **Homework Assignment *(5 min)***
    - a. Hand out/explain EAET homework 2
        - i. When will you fit this in?
        - ii. What challenges will you encounter? How will you handle them?

7. Have patients complete **"After Session Ratings"**

Session 3:

1. Have patient complete **"Before Session Ratings"**
2. **Reflect on last week's session**

    a. What was it like for you last week? What did you learn?

3. **Review of homework and discussion *(10 min)***
    - **a.** Who/what did you typically avoid?
    - **b.** How did that impact your emotions and IBS symptoms?
    - **c.** What would you communicate if you could?
    - **d.** Problem solve if barriers to completing homework
        - **i.** What made it difficult?

4. **Intervention**

    GOAL: express emotions in an adaptive way in relationships

    a. You probably also need to deal with people or situations in your life differently – more directly and honestly. I will teach you skills to do that.

    b. Experiential exercises

        i. Encourage the patient to experience and express avoided emotions, honestly and directly to important people in their lives – role play
            1. Teach assertiveness skills
                - **a.** Assertiveness involves asking for what you want or saying no to something in a simple, direct, and honest manner.
                - **b.** Being assertive means that you state exactly what you want (or don't want) in a straightforward and calm manner, without excuses or apologies. Assertiveness also involves non-verbal behavior – keeping an open pose with your body. Assertiveness also means that you are willing to listen to.
                - **c.** Assertiveness involves three parts:

i. Expressing thoughts and feelings to someone, especially disagreeing or saying something negative
ii. Asking for what you want
iii. Saying no to something you do not want

d. Which of these do you think you might have trouble with?
e. How could you express your thoughts and feelings?

2. And, encourage patient to express care/love
   a. How would could express your thoughts and feelings?

c. **Plan**
   i. When are you going to do this?

5. **How did you feel about our work today? What were your reactions?**

6. **Reactions to treatment as a whole** ***(10 min)***

   a. What did you learn?
   b. Set goals: How can you continue to implement emotional expression and communication skills into your everyday life?
   c. Say goodbye & remind participants about follow-up in two weeks. Also, remind them about follow-up two months after that.

7. Have patient complete **"After Session Ratings**

Relaxation Training

Session 1:

- Have participant complete **"Before Session Ratings"**
- **Discuss ground rules for sessions *(5 min)***
    - Remind the participant about confidentiality and audio recording (for supervision purposes)
    - There are many things to cover in each session, and I will keep you on schedule
    - Encourage/remind participant about the importance of attendance—and being on time

- **Introduction and Rationale for treatment *(15 min)***

    - What causes IBS? What have you heard? What do you believe?
        - Possible answers: Diet, Biology – genetic predisposition
        - If they do not say "stress," then ask, "what about stress?"
    - What is stress? (do NOT ask them about life stressors)
        - "Stress" is defined as a biological (fight or flight) & emotional reaction to an event that you find difficult to cope with
        - Stress can make IBS symptoms worse, and IBS symptoms trigger stress.
    - What are some of your bodily reactions to stress?
        - Possible answers: Diarrhea/Constipation, Headaches
    - What do you do normally when you experience a stressor and/or have an IBS episode?
        - Discuss how participants currently cope with stressors
        - Stress and IBS symptoms can be made better or worse depending on how you respond to them
    - Learning stress management techniques can improve your IBS symptoms and give you a greater sense of control

    - One way to do that is through relaxation training
        - Learning how to quiet your body and minds response to stress is the key to feeling calm and relaxed
        - Learning how to purposefully relax and let go of the things bothering us, even if only for short periods of time, lets the body recover from tension to ease
        - The goal of the intervention is to reduce your arousal and stress, and we will teach you skills to do that (PMR, Relaxed Breathing, Guided Imagery) – one or more of these skills might be useful for you – RT works!

- **Progressive Muscle Relaxation** ***(20 min)***

    - Get patient's 0 – 10 rating of current pain / discomfort
    - The therapist demonstrates the exercise with samples
        - If you find yourself falling asleep, I will gently bring you back.
    - The therapist leads the participant through the exercise using the script (see and use RT script 1)

- **Reactions to exercise & Homework Assignment** ***(10 min)***

    - Get patient's 0 – 10 rating of current pain / discomfort
        - Discuss changes (or not) in rating
    - What did you think of the exercise?
        - Did you like it?
        - Do you feel more relaxed now?
    - Homework
        - Distribute audio recording
        - Practice PMR four times per week (20 minutes)
            - What sorts of things will get in your way?
        - For this intervention to work most effectively, you will need to commit to practicing on your own
            - When will you practice? Where will you practice? What sort of distractions will there be?
            - Practice does not have to be while you are having IBS symptoms – can be at any time
            - However, let's talk about challenges to homework, what might get in the way, and what to do if you can't do as much as desired.

- **Discuss the next session**

    - Does this time work for you? What might get in the way of you coming back next week? Any concerns about working with me or with what we are doing?
    - Shall I call you next week to remind you? I'd like to do that if I could.

Have patient

<u>Session 2:</u>

1. Have participant complete **"Before Session Ratings"**
2. **What was it like for you last week? How did you find it?** ***(5 min)***
3. **Review of homework and discussion** ***(10 min)***

    a. How often were you able to practice?
        - Tell me about it.
    b. Where did you practice?
    c. What was it like? Did you feel more relaxed?

d. Problem solve if barriers to practice
    - What made it difficult to practice? What can you do differently in the future to help make practice part of your everyday routine?
    - Tell me about times you thought about doing it, or you ran out of time. Get a sense for daily life and capacity to prioritize exercises.
        - Would it be possible to? Could you prioritize this?

4. Relaxed Breathing *(20 min)*

a. Get patient's 0 – 10 rating of current pain / discomfort
b. Breathing is a fundamentally important connection that often goes awry in people and is usually triggered by life events and stress.
    - If you find yourself falling asleep, I will gently bring you back.
c. The therapist leads the participant through the exercise using the script (see and use RT script 2)

5. Reactions to the exercise *(5 min)*

a. Get patient's 0 – 10 rating of current pain / discomfort
b. What did you think of the exercise? Did you like it?
c. Do you feel more relaxed now?
d. Did you like this one or PMR more? Which one do you think will be more helpful for you?

6. Mini-practice *(10 min)*

a. For relaxation to be most effective, you also need to know how to relax and calm yourself whenever needed
b. This skill can be very helpful when you are feeling IBS symptoms, pain, or tension, but can't go to a secluded area to do the longer exercises
    - Mini-practice (practice 2-3 times for 30 seconds)
        - Stop what you're doing
        - Take a long breath and exhale
        - Take another deep breath
        - Say the word RELAX to yourself while you slowly exhale
        - Allow yourself to relax and focus on relaxed sensations
        - Allow your jaws to relax, and allow sensations of heaviness to flow downward from your shoulders throughout your body
        - After 30 seconds, return to what you were doing – regardless of how well you have succeeded in relaxing
    - How was it? Questions? Problems?
    - Useful to do several times per day
        - When could you do these? (e.g., standing in a check-out line, stopped at a red light, after hanging up the phone, etc.) Have the patient identify a source of how they can remember.

7. **Homework Assignment** ***(5 min)***

    a. Remember: practice, practice, practice
        - Practice makes relaxation more automatic
    b. Homework
        - Practice track two (relaxed breathing) four times per week
            - The relaxed breathing exercise on the CD is different than what you did in session today, we want to show you various types of exercises, so you can pick and choose which works best for you
        - Practice doing the mini-practice as much as possible
        - Practice does not have to be while you are having IBS symptoms – can be at any time

8. **Discuss the next session**

    a. Does this time work for you? What might get in the way of you coming back next week? Any concerns about working with me or with what we are doing?
    b. Shall I call you next week to remind you? I'd like to do that if I could.

9. Have participant complete **"After Session Ratings"**

Session 3:

1. Have participant complete **"Before Session Ratings"**
2. **Review of homework and discussion** ***(10 min)***

    a. How often were you able to practice? How often did you do the mini-practice?
    b. Where did you practice?
    c. What was it like? Did you feel more relaxed?
    d. Problem solve if barriers to practice
        - What made it difficult to practice? What can you do differently in the future to help make practice part of your everyday routine?
    e. Do mini-practice

3. **Guided Imagery** ***(20 min)***

    a. Get patient's 0 – 10 rating of current pain / discomfort
        - If you find yourself falling asleep, I will gently bring you back.
    b. The therapist leads the participant through the exercise using the script

4. **Reactions to exercise** ***(5 min)***

    a. Get patient's 0 – 10 rating of current pain / discomfort
    b. What did you think of the exercise? Did you like it?
    c. Do you feel more relaxed now?
    d. Did you like this one, relaxed breathing, or PMR more? Which one do you think will be most helpful for you?

5. **Reactions to treatment as a whole** ***(15 min)***

    a. Do you think you know more about managing stress? How do you think you can incorporate these exercises into your daily life?
    b. Do mini-practice
    c. Set goals: What else can you do to help you relax/reduce your IBS symptoms? How will these exercises be a part of that?
    d. Say goodbye & remind participants about follow-up in two weeks. Also, remind them about follow-up two months after that.

6. Have participant complete **"After Session Ratings"**

APPENDIX B: Homework Practice Sheets for EAET

Week 1: Emotional Awareness and Expression Training Homework

As you are becoming aware, holding emotions inside rather than expressing them can cause or worsen Irritable Bowel Syndrome. The most important stressful feelings are usually related to people in our lives. We often are unable to express some of these emotions verbally for a variety of reasons. The person we need to talk to may be gone from our lives, unavailable, or simply difficult to talk to. There are some things that one simply can't express to a boss, neighbor, or relative. Many emotions stem from many years ago, and the person involved may have changed. Yet we still may be hanging on to feelings that have been bothering us for years. One way to express these feelings in a safe and useful way is to write letters that we do not plan to send.

Unsent letters are useful to express our genuine feelings that we have been harboring and that are causing us harm. These feelings are often unexpressed anger or resentment, but the feelings also can be guilt, sadness, pride, or love.

Create a list of possible people (recipients) to whom you might write a letter, even though you don't plan to send it. These letters will allow you to explore whatever you need to explore regarding your relationships and deepest feelings. You may need to write to a parent, relative, current or former spouse, significant other, child, friend, neighbor, colleague, boss, or coworker. You may need to write to someone who has died or a person from whom you are estranged, as well as to people who are present in your life today. You can write to groups of people or to a president, a Pope, or God.

My list of possible "recipients" of an unsent letter includes:

_____

_____

_____

_____

_____

_____

_____

_____

_____

For your four writing sessions this week, you will choose one or more of the recipients listed above to write a letter to. Take a look at your list now, and circle the people that you think it might be most helpful for you to write to first. Once you begin writing, you may discover you need to send several letters to the same person. Feel free to do this if necessary. You can also choose to write a letter to four different people.

When you write, feel free to allow your mind and hand to write whatever needs to be said to the person or entity you have chosen to address. Since the letter will not be sent, you should say anything that comes to your mind without censoring it. You might choose to use profanity, for example, or to express extreme emotion. This is perfectly acceptable and can help to relieve tension in your mind and body.

Trust that you are safe in writing this letter and that you can express any thoughts or feelings that cross your mind. Write as long as you need to, but typically 10-20 minutes is reasonable.

When you start writing, you may be surprised by the strength of the emotions you have been holding in. This is normal and important. Allow yourself to express ALL of the feelings that you have, and do NOT hold back any feelings.

The Unsent Letter

Date and write a letter below to a person or entity from your unsent letter list. Express your thoughts and feelings fully, especially those related to anger, resentment, hurt, guilt, sadness, and love. Use the back of the paper if needed. Remember to sign your name.

Dear _____:

The Unsent Letter

Date and write a letter below to a person or entity from your unsent letter list. Express your thoughts and feelings fully, especially those related to anger, resentment, hurt, guilt, sadness, and love. Use the back of the paper if needed. Remember to sign your name.

Dear _____:

The Unsent Letter

Date and write a letter below to a person or entity from your unsent letter list. Express your thoughts and feelings fully, especially those related to anger, resentment, hurt, guilt, sadness, and love. Use the back of the paper if needed. Remember to sign your name.

Dear _____:

The Unsent Letter

Date and write a letter below to a person or entity from your unsent letter list. Express your thoughts and feelings fully, especially those related to anger, resentment, hurt, guilt, sadness, and love. Use the back of the paper if needed. Remember to sign your name.

Dear _____:

Week 2: Emotional Awareness and Expression Training Homework

Monitor what you typically avoid. At the end of four days this week, spend 20 minutes reflecting on what you avoided that day.
You can use additional paper if you need more space.

Day One

Who I avoided:

Why Avoided (e.g., fear/anxiety, guilt, pain)?

How did this affect your emotions and physical symptoms?

What would you communicate if you could? That is, what would you honestly be able to say and do with this person? Be sure to describe your words, tone of voice, and body language.

Day Two

Who I avoided:

Why Avoided (e.g., fear/anxiety, guilt, pain)?

How did this affect your emotions and physical symptoms?

What would you communicate if you could? That is, what would you honestly be able to say and do with this person? Be sure to describe your words, tone of voice, and body language.

Day Three

Who I avoided:

Why Avoided (e.g., fear/anxiety, guilt, pain)?

How did this affect your emotions and physical symptoms?

What would you communicate if you could? That is, what would you honestly be able to say and do with this person? Be sure to describe your words, tone of voice, and body language.

Day Four

Who I avoided:

Why Avoided (e.g., fear/anxiety, guilt, pain)?

How did this affect your emotions and physical symptoms?

What would you communicate if you could? That is, what would you honestly be able to say and do with this person? Be sure to describe your words, tone of voice, and body language.

APPENDIX C: Relaxation Training Scripts

Relaxation Training Session One: Progressive Muscle Relaxation
Sit back and relax. Make sure your legs are uncrossed and your arms are free to relax.
First, I will show you what to with your body – that is, I am going to show you how to tense and relax your different muscle groups (samples). After that, we will do the full progressive muscle relaxation exercise.

Let's start with your hands.

Allow your right arm to rest limply by your side, palm down. Keeping your arm by your side, raise your hand until it is bent back tightly at the wrist. Pull it back really hard, and feel the tension in your hand and arm. Then, relax and let it go.

Now, allow your left arm to rest limply by your side, palm down. Keeping your arm by your side, raise your hand until it is bent back tightly at the wrist. Pull it back really hard, and feel the tension in your hand and arm. Then, relax and let it go.

Now become aware of your hands. Make a fist with your hands. Hold that tension and feel it, then relax.

Now tense your forearms. Feel the tension, then relax.

Now tense your upper arms – your biceps. This may involve a little of your shoulder. Feel the tension. And, now relax.

Now lift your shoulders up toward your ears so that you are shrugging your shoulders, notice the tension. Release, and relax your shoulders.

Now tense the muscles in your feet – curl your toes. Feel the tension. Then, release, and notice the relaxation.

Now tense the muscles of your ankle and heel and calves – point your toes upwards. Feel the tension. Now, relax.

Now tensing the muscles of your thighs – roll your legs in, push your knees together. And, relax.

Now tense your butt muscles – feel the tension. Now relax.

Now arch your back gently, as though you are bending backwards slightly. Now, relax.

Now tense the muscles of your stomach and abdomen. And, relax.

Now tense the muscles in your neck by arching your neck as if to look up. Relax.

Now pull your chin down toward your chest and feel that tension, bending your whole head forward. Now, relax.

Now clench your teeth together, so you can feel the tension in your jaw muscles. Now, relax.

Now open your mouth wide. Feeling the tension in the muscles that do that. Relax.

Now tense the muscles in your forehead, as though you are worried. Feel the tension. Release.

Now raise your eyebrows, as though you are surprised. Feel the tension. Release.

Clenching your eyes closed tightly. Feeling the tension. Then, relax.

And let your eyes open wide, feeling the tension in the muscles that hold them open. And, relax.

Any questions? Are you ready to go through the full progressive muscle relaxation exercise?

Now allow your right arm to rest limply by your side, palm down. Keeping your arm by your side, raise your hand until it is bent back tightly at the wrist. Pull it back really hard, and feel the tension in your hand and arm. When I say "release" let the relaxation be immediate, as if your hand was being held up by thread and the thread is being cut. Now release.

Now allow your left arm to rest limply by your side, palm down. Keeping your arm by your side, raise your hand until it is bent back tightly at the wrist. Pull it back really hard, and feel the tension in your hand and arm. When I say "release" let the relaxation be immediate, as if your hand was being held up by thread and the thread is being cut. Now release.

Take a deep breath in, and as you let it out, allow your body to begin to let go. Let yourself become aware of any area of your body in which you can detect stress. You may notice this stress as a feeling of tension in certain muscles or groups of muscles of your body. In a few minutes, when you've become more relaxed, you will have an opportunity to release this stress and let your muscles relax completely.

Now become aware of your hands. And allowing all the rest of your body to remain comfortably still, tense your hands. Make a fist with each hand. Hold that tension and feel it. Now release – letting the tension drain away. And each time you release the tension, allow it to be a passive release. Make sure the relaxation is not a contraction of the opposing muscles, but passive relaxation.

Now tense your forearms. Feel the tension, letting all the other muscles of your body remain relaxed. Release. Feel the relaxation.

Now tense your upper arms – your biceps. This may involve a little of your shoulder. Feel the tension. Release. And feel the relaxation.

Now lift your shoulders up toward your ears so that you are shrugging your shoulders, and feel where there is tension. Release. Feeling the relaxation.

Now tense the muscles in your feet – curl your toes. Feel the tension. Release. Feel the relaxation.

Now tense the muscles of your ankle and heel and calves – point your toes upwards. Feel the tension. Release. Feel the relaxation.

Now tensing the muscles of your thighs – roll your legs in, push your knees together. Feeling the tension, allowing all the other muscles of your body to remain relaxed. Now releasing. Letting the tension drain away. Feeling the relaxation.

Now tense your butt muscles. Feel the tension. Now, release, really letting go. Feel the relaxation.

Now arch your back gently, as though you are bending backwards slightly. Feel the tension in your back. Releasing. Really letting go. And feeling the relaxation.

Now tense the muscles of your stomach and abdomen. Feeling the tension. Releasing. And feeling the relaxation.

Take a deep breath in. Hold your breath, feeling the tension. Now release the air and let your chest passively collapse. Now feeling the relaxation.

Now tense the muscles in your neck by arching your neck as if to look up. Feel the tension in the muscles as you do that. And release. Really releasing, and feeling the relaxation.

Now pull your chin down toward your chest and feel that tension, bending your whole head forward. And releasing. And feeling the relaxation.

Now roll your neck to the left, then forward, then to the right. Roll forward, to the left, then back. Feel the relaxation.

Now clench your teeth together, so you can feel the tension in your jaw muscles. Releasing. And feeling the relaxation.

Now open your mouth wide. Feeling the tension in the muscles that do that. Releasing. And feeling the relaxation.

Now tense the muscles in your forehead, as though you are worried. Feel the tension. Release. And feel the relaxation. Now raise your eyebrows, as though you are surprised. Feel the tension. Release.

Clenching your eyes closed tightly. Feeling the tension. Releasing. Feeling the relaxation.

And let your eyes open wide, feeling the tension in the muscles that hold them open. Now releasing, letting your eyelids close, feel the relaxation. And as you look into the comfortable darkness behind your eyelids, picture the word “relax” or some other word or symbol or scene that can be your own personal symbol of relaxation.

Let that relaxation flow into your forehead, your scalp, the muscles of your face, your jaw and neck, your shoulders, arms, the muscles of your back. Relaxed, more and more relaxed with each rising and falling of your abdomen. The air breathes for you. Your abdomen becoming more and more relaxed, letting that relaxation continue to flow down, your thighs, your knees, your legs, your ankles, and your feet, flowing right out the soles of your feet.

And each time you do this, you will be building up a new response to stress within your body. A relaxing response. And soon you will notice that your body automatically releases stress and tension without your having to become consciously aware of it at all. Now look within your body and find the part of your body that feels the most comfortable. The most pleasant. And as I count from 1 to 5, imagine letting this feeling begin to spread from this part of your body to all the other parts of your body. And as I count, and the pleasant feeling spreads, you will slowly let yourself turn entirely to an awareness of the outside, as though you have been asleep for a while, becoming more and more awake. Each time you enter the relaxed state, you will be able to relax yourself more and more fully, and more rapidly.

One, slowly let that pleasant feeling expand and travel into each muscle and to each bone, to each organ, through every part of you. Two, and as you are feeling this spreading, feeling yourself becoming a little more awake. Three, letting your awareness return to the world around you, as the pleasant feeling continues to spread throughout all your body. Four, letting your eyelids open as you take a deep breath in, and let it out. Five, Wide awake now, ready to respond to the world around you, your body still feeling pleasant and comfortable.

Take a moment to enjoy that feeling as you stretch your body. Carry that feeling with you, as you let your body return to its wide awake state of movement. Letting your arms and hands move, your feet. Wide awake. And take a moment to notice how comfortable you feel.

Relaxation "1 to 10"
Dr. John Heil
Training Script
(Heil, 2009)

The following is a script that may be used to guide relaxation training. It simplicity renders it particularly suitable for beginners.

Close your eyes and focus your attention on your breathing. Begin by simply observing the way you are breathing. Notice whether your breathing is fast or slow, whether your breathing shallow or deep, whether your breathing is rough or irregular or smooth and regular.

Slowly, gradually allow yourself to move to a way of breathing that is slow, deep, and regular; slow, deep, and regular. You will find that as you breathe in this way you become more relaxed, more composed, more focused. Breathing in a way that is slow, deep, and regular; slow, deep, and regular.

Imagining your lungs like balloons that fill up with air each time your breath in and that empty the air out as you breathe out. Notice the feeling of fullness, of energy as you breathe in, notice the feeling of relaxation, of letting go as you breathe out.

You can relax even further by relaxing your muscles one group of muscles at a time. You can do this by counting from 1 to 10, and for each number you count focusing on the particular area of your body that you would like to relax. You can do this by taking in a full deep breath, counting the number silently to yourself, and holding your breath for a moment as you focus on the area of the body you would like to relax. Then as you breathe out, focus on the feeling of relaxation, of letting go.

To begin take a nice long full deep breath, hold it for a moment, not too long, and then when ready breathe out and relax, being sure to let all the air out. As you breathe out and let go of the breath, focus on letting go of any tension you feel in your muscles.

With your next breath in, silently to yourself, count, 1 and focus on the muscles in your belly. Focus on the muscles as you hold your breath for a moment. Then when ready, breathe out, let go of the breath, and let go of any tension you feel in the muscles in your belly.

Next, breathe in count 2 silently to yourself, and focus on the muscles in your chest. Say the number, feel the muscles, hold your breath for a moment, and then when ready breathe out and relax.

Next breath in count 3 silently to yourself, focus on the muscles in your back from your hips to your knees. Say the number, feel the muscles, hold your breath for a moment, and when ready breathe out and relax. Each time you breathe out, focus on letting go of the breath and letting go of tension in your muscles.

Next breath count 4, focus on your upper legs from your hips to your knees. Say the number, feel the muscles, hold your breath for a moment, and when ready breathe out and relax.

Breath in count 5, focus on your lower legs from your knees to your toes. Say the number, feel the muscles, hold your breath for a moment, and when ready breathe out and relax. Focus on a pleasant relaxing feeling that goes all the way out to the tips of your toes.

Next breathe in count 6, focus on your upper arms from your shoulders to your elbows. Say the number, feel the muscles, hold your breath for a moment, and when ready breathe out and relax.

Breathe in count 7, focus on your lower arms from your elbows to your fingertips. Say the number, feel the muscles, hold your breath for a moment, and when ready breathe out and relax. Focus on a pleasant relaxing feeling that goes all the way out to the tips of your fingers.

Next breath in count 8, focus on your neck and shoulder. Say the number, feel the muscles, hold your breath for a moment, and when ready breathe out and relax.

Breathe in count 9, focus on your face, forehead, and head. Say the number, feel the muscles, hold your breath for a moment, and when ready breathe out and relax. Focus on a pleasant relaxing feeling that goes all the way out to the top of your head.

In a moment you will take in a nice long full deep breath, count 10 silently to yourself and focus on relaxing your entire body all at once. As you breathe in you will notice the feeling of fullness, of energy - and as you breathe you will imagine a wave of relaxation moving along the the length of your body from the top of your head to the tips of your fingers and toes.

Now breathe in count 10 silently to yourself and focus on relaxing your entire body all at once. As you breathe out you will imagine a wave of relaxation moving along the length of your body from the top of your head to the tips of your fingers and toes. Feeling relaxed, composed and focused.

Turning your attention again to your breathing, breathing in a way that is slow, deep and, regular; slow, deep, and regular. Imagining your lungs like balloons that fill up with air each time your breath in and that empty the air out as you breathe out. Notice the feeling of fullness, of energy as you breathe in, notice the feeling of relaxation, of letting go as you breathe out.

Pause

In a moment you will do a body scan, tuning in to your muscles, and letting them relax as you count from 1 to 10. In this brief relaxation method you will simply count from 1 to 10, focus briefly on each of the muscle groups and relax. Count 1 relax your belly; count 2 relax your chest; count 3 relax your back; count 4 relax your upper legs; count 5 relax your lower legs; count 6 relax you upper arms; count 7 relax your lower arms; count 8 relax neck and shoulders; count 9 relax face and head; count 10 relax your entire body.

In a moment you will take a centering breath, count 10 silently to yourself and focus on relaxing your entire body all at once. As you breathe in you will notice the feeling of fullness, of energy - and as you breathe out you will imagine a wave of relaxation moving along the length of the length of your body from the top of your head to the tips of your fingers and toes.

Now breathe in count 10 silently to yourself and focus on relaxing your entire body all at once. Turning your attention again to your breathing, breathing in a way that is slow, deep and, regular; slow, deep, and regular. Imagining your lungs like balloons that fill up with air each time your breath in and that empty the air out as you breathe out. Notice the feeling of fullness, of energy as you breathe in, notice the feeling of relaxation, of letting go as you breathe out.

In a moment you will count backward silently from 10 to 1 – and open your eyes. As you count backward you will fell yourself grow more alert and focused on your surroundings, even as you remain relaxed and composed. Counting 10, 9, 8,7,6,5,4,3,2,1. Open your eyes.

RelaxActivScriptAug09;jheil;7/9/09;8/2/09

Relaxation Session 3: Guided Imagery

Become aware of where you are right now and of the fact that there is no place you need to go and nothing that you need to respond to for a while.

Take two or three long, deep breaths. And as you do, let your body relax.

And feel the weight of your feet, allowing your feet and toes to feel heavy and warm. Your feet may feel far away, or it may even feel as though the borders around your feet and toes are growing more and more indistinct as your feet relax. And as you feel that relaxation, imagine you are on an elevator.

It can be any kind of elevator you want – perhaps it's made of lacy wrought iron and you can half-see the landscapes of imagination slide by as it passes from level to level. Or perhaps its made of polished wood, lined with soft pillows. And you can have any kind of decoration or lighting in it that you want. Or if you wish, you can just let it be dark in your elevator as you feel the warmth and relaxation of your toes and feet. And in a moment I'm going to count from ten down to one. And as I count, you might begin to imagine what it might feel like if your elevator slowly begins to descend. And as I count from ten down to one, you can imagine that with each number the elevator travels down another floor. And as it travels down, your entire body is becoming more and more relaxed. And more and more comfortable with each breath. And as I count, and as you feel the elevator begin to travel down, slowly let the relaxation from your feet begin to travel up your calves and the lower part of your legs.

Ten, feel the gentle floating down. Warm, heavy as the relaxation moves from your feet into your legs and knees. Growing more and more comfortable and more and more quiet.

Nine, and as you travel down deeper and more comfortably, feel the relaxation floating up into your thighs, relaxing your thighs as your muscles become soft and relaxed.

Eight, and let that relaxation and warmth flow up through your pelvis.

Seven, traveling down, deeper and deeper down, as the relaxation flows up into the muscles of your lower back and abdomen. Feeling the rising and falling of your abdomen with each breath. Letting each breath be a feeling of letting go, as you let the air breath for you.

Six, with each breath, feel relaxation filling and emptying your lungs. More and more calm. More and more comfortable with each breath, feeling all the muscles of your chest relax as you travel down deeper and deeper.

Five, let that relaxation fill the upper part of your back and flow into your shoulders and the back of your neck, feeling heavy and warm.

Four, and as the back of your neck and your shoulders relax, let that feeling flow into your upper arms, like honey flowing slowly through your elbows, your forearms, your wrists, and your hands, all the way down into the very tips of your fingers. Feel as the relaxation reaches the tips of your fingers.

Three, your whole body filled with relaxation. Letting that relaxation flow through your neck, into the back of your head and your ears, flowing around the back of your head, relaxing all the muscles of your scalp. A warm, comfortable, feeling of relaxation.

Two, feeling the muscles around your mouth and your jaw muscles, relaxing. Feeling the muscles of your lips relaxing. Let that relaxation flow through the muscles of your cheeks and your forehead. More and more relaxed as your elevator goes down, deeper and deeper down, more and more comfortable with each breath.

One, and as you feel the elevator gently stopping, and resting at this level, let that heavy relaxed feeling flow into your eyelids. Feeling your eyelids so relaxed and comfortable, they just don't want to move at all. Imagine letting your eyelids feel so heavy and warm and relaxed, that you can test them. And feel they just don't want to budge at all. And as you imagine this feeling, let the air breathe for you. And notice the breathing in and the letting go. And with each letting go, picture the number 1 in your mind's eye. Or perhaps imagine an internal voice speaking the number 1 with each breathing out. In some way, whatever way is easiest for you, being aware of the number one with each breathing out.

With each breathing out, you think the number one. With each breathing out there a letting go as the tension drains from your body.

Repeating with each breathing out, with each letting go. And as you continue to let the air breathe for you, you may stop repeating, and just feel the relaxation in your eyelids. Now gently let the relaxation flow from your eyelids throughout all the rest of your body. All the way down to your feet. And let your awareness follow that relaxation as it spreads from your eyelids, flowing through your body, gently guiding your awareness as you follow that relaxation all the way down through your chest and abdomen, through your pelvis, all the way down through your thighs and your knees, your legs, all the way down into your feet. And feel your feet and toes feeling warm and relaxed, as relaxed and as warm as though you are standing on the warm sand of a beach.

And you can feel the warmth of the sand and the dryness of the warm sand beneath your feet. And as you move first one foot and then the other from side to side, you can feel the warm sand on the sides and on top of your feet. And as you push your toes gently into it, you can feel the dry granules of sand between your warm toes. And as you are enjoying the warmth of the sand, you might imagine letting yourself open your eyes and see the warm, bright, golden light sand beneath your feet. And let your eyes follow the sand as you lift your eyes and look down the golden white sandy beach. Bright in the sunlight. And turning your head you begin to see the deep blue green of the ocean. And let yourself hear the sounds of the ocean. Waves rolling slowly to shore, breaking into fingers of foam that glide over the sand.

And you may want to walk over to the edge of the wet sand and see bright reflection of the sky and the thin film of water left behind as each wave strokes the wet surface and then rushes back down the slope. Feel the damp sand beneath your feet. Feel its coolness. Feel its moistness. And its firmness as you watch each wave foam towards you on the sand and then rush back into the ocean.

White crests of waves slowly follow each other in toward the shore. And as you enjoy the deep rich color of the ocean, perhaps you can feel the salty breeze blowing in, gently cool on the surface of your body. Taking a deep breath in, savoring the pleasant fragrance, the smell of the sea, perhaps even tasting the slightly salty taste on your lips and tongue. And let your eyes look up and out over the expanse of the ocean, following the waves to their source. Bright reflections dancing on the ocean's surface, looking far off across the ocean now, to the distant horizon. A long, slightly curved line in the distance. And above the horizon, patches of white cloud in a blue sky. And as you continue to look up, follow the clouds in the blue sky, and notice how the clouds that are closer to you look softer, puffy, fleecy white. And there's more and more deep bright blue sky, and floating above you, you can see cottony fluffs of pure white cloud, and a bird gliding through the vast expanses of blue.

And let yourself be aware of the bright sun behind you. Shining and warming, pleasantly warming the skin of your back. And feel the warmth on the surface of your back, sinking in deep into all the muscles of your back. The backs of your arms, the backs of your thighs and your calves. And as that warmth seeps into the muscles of your body, you look to your side and see a very comfortable place where you would like to lie down and rest for a while.
And as you lie down in the warm pleasant sun, you feel your body sinking deep into the surface beneath you and letting your eyelids close, you drift into a comfortable, relaxing sleep. Comfortable, relaxing, pleasant, sleep.

And as you are sleeping, you are beginning to have a dream. A dream about standing on a warm, pleasant beach. Looking out at the ocean. And as you are standing there, you are feeling strong, healthy, your body looks and feels just like you want it to be. Feel how good your body feels as you stand there. And let your eyes look down and discover your body looking just the way you want it to look. You can see your thighs and your abdomen and your arms. They're strong yet relaxed. Your skin is healthy and has a rich, glowing color. Perhaps you'd like to do something active. Perhaps you'd like to go for a walk or a run down the beach. Perhaps you'd like to run on the firm damp sand, or on the soft warm sand. Or, if you wish, you might like to wade into the water and feel its pleasant temperature. Immerse your body in it. Maybe you'd like to swim. Whatever you'd like to do, let yourself do it now. And feel how pleasant it is to be moving your body in this way.

And as you are enjoying the movement of your comfortable, strong, healthy body, you are thinking to yourself and repeating within, My body is healthy, strong, and relaxed. My body is healthy, strong, and relaxed.

And gradually, the dream is fading away. Slowly fading. And as you open your eyes, in the comfortable place where your body is comfortably lying, you notice the words still echo within your mind, My body is healthy, strong, and relaxed. And as you look around, you notice the sand is now a deeper red golden color. It's late in the day. The sky is a deep turquoise, and the clouds glow in soft rows, in orange and crimson. And the sun is low on the horizon. And the sun slowly sinks out of sight, the clouds about where it disappeared fade magenta and purple, and violet. And as you begin to stand up, you notice that the evening air is slightly cooler. Standing, beginning to walk back across the beach, the darkening sky washing everything in deep blue. And as you walk, becoming aware that it's time to return to your elevator.

Let yourself be on that elevator again. Still feeling yourself comfortably relaxed, yet feeling yourself stronger, more energized.

One, as the elevator gently begins to rise and you feel yourself being lifted. It's as though you are becoming lighter and lighter.

Two, feeling of floating up.

Three, becoming more and more alert and responsive to the sounds around you.

Four, your body feeling more and more like moving.

Five, just as though you are becoming more and more awake.

Six, as though you have been asleep for a long time, coming up feeling refreshed and clear.

Seven, become aware of where you are. The room, the approximate time of day.

Eight, taking a deep breath in and letting it out.

Nine, letting your eyes open. Feeling wide awake and comfortable.

Ten, letting your body stretch and move. Perhaps stretching first your hands and then your arms. Or maybe beginning with your feet and legs, gradually letting your entire body stretch itself. Take another deep breath in. Let it out. And let your body begin to move around. Feeling good and ready to go wherever you want to go. And to do whatever you want to do next.

APPENDIX D: Measures

Patient Health Evaluation
Pre-treatment

ID Number: _____
Date:_____

Sex: male / female

Date of Birth: _____ / _____ / _____ **Age**: _____

Ethnic Category:

_____ Hispanic or Latino
_____ Not Hispanic or Latino

Racial Category:

_____ American Indian or Alaskan native
_____ Asian
_____ Native Hawaiian or Other Pacific Islander
_____ Black or African American
_____ White
_____ Other (please describe: _____)

Education:

Number of Years of Education: _____ (e.g. 12=HS or GED; 16=BA/BS)

Highest Diploma/Degree Earned:_____ 18=MA; 20=Doctorates)

Marital Status

_____ Never Married
_____ Living Together
_____ Married
_____ Separated
_____ Divorced
_____ Widowed

Duration of above status:_____

Give the ages and relationships of all the people with whom you currently are living:
_____ (age)_____
_____ (age)_____

_____ (age)_____
_____ (age)_____

Employment Status:
Currently Employed? _____Yes _____No
Full or Part Time (please circle one)

Occupation: _____Current or Former (please circle one)
Medical Disability: ____Yes ____No
For what?_____

Health Insurance Status: (Check all that apply)
___ Private (BCBS, HMO, PPO)
___ Medicare
___ Medicaid
___ None

Occupation of Spouse:_____
Occupation of Father:_____Mother:_____

Have you ever participated in a pain or stress management class or program, where you learn skills or behaviors to control pain or stress? _____Yes _____No
When? _____ Describe: _____

Have you ever been in counseling or therapy? _____Yes _____No
When? _____ Describe: _____

II. MEDICAL INFORMATION

Is your health affected by any of the following medical problems?

_____Heart disease
_____Diabetes
_____Hypertension
_____Chronic lung disease
_____Cancer
_____Gout
_____Stroke
_____Syncope/Fainting
_____Kidney disease
_____Liver disease
_____Ulcer or other stomach disease
_____Lupus
_____Scleroderma
_____Rheumatoid Arthritis
_____Osteoarthritis
_____headaches
_____migraine?
_____other
_____Irritable Bowel Syndrome
_____Crohn's Disease
_____Ulcerative Colitis
_____Chronic Pelvic Pain

_____Anemia or other blood disease	_____Interstitial Cystitis
_____Psychiatric Illness or mental disorder	_____Vulvodynia
_____Alcohol or drug use	_____Asthma

Other Medical Conditions?_____

Height (in feet and inches): _____ **Weight** (in pounds): _____

IRRITABLE BOWEL SYNDROME INFORMATION AND HISTORY

Onset of IBS: _____ / _____ / _____

Date of First Diagnosis of IBS: _____ / _____ / _____

Since you developed IBS, what is the longest amount of time you have gone without experiencing symptoms due to IBS?
_____ (hours, days, weeks, months, years)

What type of physician diagnosed your IBS?_____

Have you experienced IBS symptoms today? ___ Yes ___ No
In past 2 months? ___ Yes ___ No

What medications are you currently taking?

Medication	Reason	How long?
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Have you received any other type of treatment for IBS?

Treatment	Response
_____	_____
_____	_____
_____	_____

Alternative Treatments Questionnaire

Many people try a lot of different things to help with their health. Tell me if you have ever used or tried each of the following things to improve your IBS.

	In the past	Presently
Eating healthier or changing your nutrition	_____	_____
Eating herbal remedies	_____	_____
Using over-the-counter or non-prescription medications	_____	_____
Using street drugs such as marijuana, cocaine, or others	_____	_____
Praying, reading the Bible, or other religious things by yourself	_____	_____
Attending religious services (includes revival, laying on of hands, etc.)	_____	_____
Acupuncture	_____	_____
Biofeedback	_____	_____
Talking with a counselor or psychotherapist	_____	_____
Physical therapy	_____	_____
Exercise	_____	_____
Imagery, relaxation, or meditation	_____	_____
Support group	_____	_____
Self-help treatments	_____	_____
Magnets or copper bracelets	_____	_____
Other_____	_____	_____

06-15-10
QLW0156(IBSOS1)/04-10-10

IBS - SYMPTOM SEVERITY SCALE

IRRITABLE BOWEL SYNDROME STUDY

Patient Number

Protocol Number

Date of Study Participant Visit/Contact mmm dd yyyy

Institution Code

Form Week *Seq No. **Step No. Key Operator Code

This area completed by Clinic Staff only.

* Enter a '1' if this is the first of this form for this date. Designate subsequent forms on the same date with a 2, 3, etc.
** Enter the study participant's current study step number. Enter '1' if the study does not have multiple steps.

INSTRUCTIONS:
This form will help you describe the nature of your IBS. It is to be expected that your symptoms might vary over time, so please try and answer all the questions based on how you currently feel (i.e., over the last 10 days or so). All information will be kept in **strict** confidence.

1. For questions where a number of different responses are possible please circle the response appropriate to you.
2. Some questions will require you to write in an appropriate response.
3. Some questions require you to put a cross line which enables us to judge the severity of particular problem(s).

   For example:

   How severe was your pain?

   Please place your "x" anywhere on the line between 0 - 100% in order to indicate as accurately as possible the severity of your symptom.

   This example shows a severity of approximately 90%, with 100% representing "very severe" pain.

CONTINUE ON NEXT PAGE

IBS - SYMPTOM SEVERITY SCALE

Pt. No. ☐☐☐☐☐ *Seq. No. ☐☐ **Step No. ☐☐ Date ☐☐☐ (mmm) ☐☐ (dd) ☐☐☐☐ (yyyy)

1. Do you currently suffer from abdomen or belly pain? ……
   If No, go to 'b.'
   If Yes, continue.

   Check One
   Yes ☐ (1) No ☐ (2)

   a. Indicate with an "**X**" on the line below the severity of your abdomen or belly pain:

   0% ——— **100%**
   no pain · not very severe · quite severe · severe · very severe

   b. Enter the number of days that you typically experience **abdominal pain *every 10 days:***
   (For example, if you enter 4, it means that you get pain 4 out of 10 days. If you get pain every day, enter 10.)

   Number of days with pain: …… ☐☐

2. Do you currently suffer from abdominal distension? ……
   (bloating, swollen or tight tummy)
   (*Women, please ignore distension related to your periods.)
   If No, go question 3.
   If Yes, continue.

   Check One
   Yes ☐ (1) No ☐ (2)

   a. Indicate with an "**X**" on the line below the severity of your abdominal distension/ tightness:

   0% ——— **100%**
   no pain · not very severe · quite severe · severe · very severe

3. Indicate with an "**X**" on the line below how satisfied you are with your bowel habits:

   0% ——— **100%**
   not at all satisfied · not too satisfied · somewhat satisfied · very satisfied

4. Indicate with an "**X**" on the line below how much your Irritable Bowel Syndrome affects or interferes with your life in general:

   0% ——— **100%**
   not at all interferes · not much · quite a lot · completely interferes

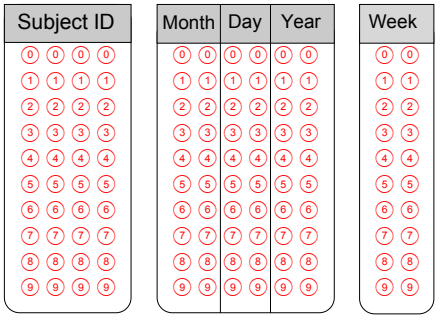
For office use only:

SCORE ☐☐☐

IBS SEVERITY SCORE: ☐☐☐

Date Form Keyed (DO NOT KEY): _____ / _____ / _____

GLOBAL IMPRESSION OF CHANGE



Compared to the way you usually felt before entering the study, how would you rate your symptoms of abdominal discomfort or pain, AND bowel symptoms during the PAST 7 DAYS? By bowel symptoms, we are referring to constipation and/or diarrhea, gas, a feeling of bloating, nausea, tenderness, urgent need to have a bowel movement, feeling that your bowel was not completely empty after a bowel movement, or other symptoms specific to the IBS problem that prompted you to seek treatment?

- (7) **Substantially Improved**
- (6) **Moderately Improved**
- (5) **Slightly Improved**
- (4) **No Change**
- (3) **Slightly Worse**
- (2) **Moderately Worse**
- (1) **Substantially Worse**

Subject ID	Month	Day	Year	Week
0 0 0 0	0 0	0 0	0 0	0 0
1 1 1 1	1 1	1 1	1 1	1 1
2 2 2 2	2 2	2 2	2 2	2 2
3 3 3 3	3 3	3 3	3 3	3 3
4 4 4 4	4 4	4 4	4 4	4 4
5 5 5 5	5 5	5 5	5 5	5 5
6 6 6 6	6 6	6 6	6 6	6 6
7 7 7 7	7 7	7 7	7 7	7 7
8 8 8 8	8 8	8 8	8 8	8 8
9 9 9 9	9 9	9 9	9 9	9 9

IBS-QOL INSTRUMENT

Please read the following statements and using the scale below, rate how characteristic the statement is of how you generally feel.

1	2	3	4	5
Not at all	Slightly	Moderately	Quite a bit	Extremely

	Not at all	Slightly	Moderately	Quite a bit	Extremely
1. I feel helpless because of my bowel problems.	1	2	3	4	5
2. I am embarrassed by the smell caused by my bowel problems.	1	2	3	4	5
3. I feel vulnerable to other illnesses because of my bowel problems.	1	2	3	4	5
4. I feel uncomfortable when I talk about my bowel problems.	1	2	3	4	5
5. I feel depressed about my bowel problems.	1	2	3	4	5
6. I feel isolated from others because of my bowel problems.	1	2	3	4	5
7. Because of my bowel problems, sexual activity is difficult for me.	1	2	3	4	5
8. I feel angry that I have bowel problems.	1	2	3	4	5
9. I feel irritable because of my bowel problems.	1	2	3	4	5
10. I feel sluggish because of my bowel problems.	1	2	3	4	5
11. I feel unclean because of my bowel problems.	1	2	3	4	5
12. Long trips are difficult for me because of my bowel problems.	1	2	3	4	5
13. I feel frustrated that I cannot eat when I want because of my bowel problems.	1	2	3	4	5
14. It is important to be near a toilet because of my bowel problems.	1	2	3	4	5
15. I feel that no one understands my bowel problems.	1	2	3	4	5
16. I am bothered by how much time I spend on the toilet.	1	2	3	4	5
17. I feel fat because of my bowel problems.	1	2	3	4	5
18. I feel like I am losing control of my life because of my bowel problems.	1	2	3	4	5
19. I feel my life is less enjoyable because of my bowel problems.	1	2	3	4	5
20. I have to watch the amount of food I eat because of my bowel problems.	1	2	3	4	5
21. I feel like I irritate others because of my bowel problems.	1	2	3	4	5
22. I worry that my bowel problems will get worse.	1	2	3	4	5
23. I worry that people think I exaggerate my bowel problems.	1	2	3	4	5
24. I feel I get less done because of my bowel problems.	1	2	3	4	5
25. I have to avoid stressful situations because of my bowels problems.	1	2	3	4	5
26. My bowel problems reduce my sexual desire.	1	2	3	4	5
27. My bowel problems limit what I can wear.	1	2	3	4	5
28. I have to avoid strenuous activity because of my bowel problems.	1	2	3	4	5
29. I have to watch the kind of food I eat because of my bowel problems.	1	2	3	4	5
30. Because of my bowel problems, I have difficulty being around people I do not know.	1	2	3	4	5
31. My life revolves around my bowel problems.	1	2	3	4	5
32. I worry about losing control of my bowels.	1	2	3	4	5
33. I fear that I won't be able to have a bowel movement.	1	2	3	4	5
34. My bowel problems are affecting my closest relationships.	1	2	3	4	5

BRIEF SYMPTOM INVENTORY

Below is a list of problems and complaints that people sometimes have. Please circle the response that best tells how much discomfort that problem has caused you in the past WEEK. Please remember, you are to indicate how much the problem has bothered you in the last two weeks, not how often it has happened.

		Not at all	A little bit	Moderately	Quite a bit	Extremely
1.	Nervousness or shakiness inside	0	1	2	3	4
2.	Faintness of dizziness	0	1	2	3	4
3.	The idea that someone else can control your thoughts	0	1	2	3	4
4.	Feeling others are to blame for most of your troubles	0	1	2	3	4
5.	Trouble remembering things	0	1	2	3	4
6.	Feeling easily annoyed or irritated	0	1	2	3	4
7.	Pains in your heart or chest	0	1	2	3	4
8.	Feeling afraid in open spaces	0	1	2	3	4
9.	Thoughts of ending your life	0	1	2	3	4
10.	Feeling that most people cannot be trusted	0	1	2	3	4
11.	Poor appetite	0	1	2	3	4
12.	Suddenly scared for no reason	0	1	2	3	4
13.	Temper outbursts that you could not control	0	1	2	3	4
14.	Feeling lonely even when you are with other people	0	1	2	3	4
15.	Feeling blocked in getting things done	0	1	2	3	4
16.	Feeling lonely	0	1	2	3	4
17.	Feeling blue	0	1	2	3	4
18.	Feeling no interest in things	0	1	2	3	4
19.	Feeling fearful	0	1	2	3	4
20.	Your feelings being easily hurt	0	1	2	3	4
21.	Feeling that people are unfriendly or dislike you	0	1	2	3	4
22.	Feeling inferior to others	0	1	2	3	4
23.	Nausea or upset stomach	0	1	2	3	4
24.	Feeling that you are watched or talked about by others	0	1	2	3	4
25.	Trouble falling asleep	0	1	2	3	4
26.	Having to check and double check what you do	0	1	2	3	4
27.	Difficulty making decisions	0	1	2	3	4
28.	Feeling afraid to travel on buses, subways, or trains	0	1	2	3	4
29.	Trouble getting your breath	0	1	2	3	4
30.	Hot or cold spells	0	1	2	3	4
31.	Having to avoid certain things, places, or activities because they frighten you	0	1	2	3	4

	Not at all	A little bit	Moderately	Quite a bit	Extremely
32. Your mind going blank	0	1	2	3	4
33. Numbness or tingling in parts of your body	0	1	2	3	4
34. The idea that you should be punished for your sins	0	1	2	3	4
35. Feeling hopeless about the future	0	1	2	3	4
36. Trouble concentrating	0	1	2	3	4
37. Feeling weak in parts of your body	0	1	2	3	4
38. Feeling tense or keyed up	0	1	2	3	4
39. Thoughts of death or dying	0	1	2	3	4
40. Having urges to beat, injure, or harm someone	0	1	2	3	4
41. Having urges to break or smash things	0	1	2	3	4
42. Feeling very self-conscious with others	0	1	2	3	4
43. Feeling uneasy in crowds	0	1	2	3	4
44. Never feeling close to another person	0	1	2	3	4
45. Spells of terror or panic	0	1	2	3	4
46. Getting into frequent arguments	0	1	2	3	4
47. Feeling nervous when you are left alone	0	1	2	3	4
48. Others not giving you proper credit for your achievements	0	1	2	3	4
49. Feeling so restless that you couldn't sit still	0	1	2	3	4
50. Feelings of worthlessness	0	1	2	3	4
51. Feeling that people will take advantage of you if you let them	0	1	2	3	4
52. Feelings of guilt	0	1	2	3	4
53. The idea that something is wrong with your mind	0	1	2	3	4

APPENDIX E: Recruitment Script and Screening Questions

Recruitment Script for Students at Wayne State

***Follow-up to initial recruitment e-mail:*

Hi <*insert the name of the individual*>, I am a doctoral student in the Psychology department here at Wayne State University, and I am conducting a study for people with irritable bowel syndrome. I recently sent you an e-mail asking if you were interested in a stress management study for irritable bowel syndrome because you reported having IBS on the Psychology Department's screening survey on the SONA system. I have not heard back from you and wanted to follow-up to determine if you were interested in this study. Can I tell you a bit more about the study?

This is a research study of stress management techniques for people with irritable bowel syndrome, which is being conducted at Wayne State University. In this study, we are testing whether two different stress management approaches help people reduce their IBS symptoms and improve their functioning. One approach involves learning how to relax and calm your body and mind, and the other approach involves becoming aware of and expressing your emotions related to stress.

At your first appointment, you will be provided with all of the information about the study, provide written consent, and sign a release for your medical records, so we can send a diagnostic confirmation form to your physician. After that, you will have an evaluation session during which you will fill out questionnaires about your current IBS symptoms, your mood, your functioning, and your personality. This will take approximately one hour. You will also be asked to return for two more evaluation visits, which will be held 4 weeks and 12 weeks after the first evaluation session. Each of these evaluations will also take about 1 hour, and you will complete the same questionnaires as you did at the first session.

After the first evaluation session, you will be randomly assigned to one of three intervention conditions. You have a 1 out of 3 chance of being assigned to the Relaxation Training condition, a 1 out of 3 chance of being assigned to the Emotional Awareness and Expression Training condition, or a 1 out of 3 chance of being assigned to a Waiting condition. If you are assigned to Relaxation Training or Emotional Awareness and Expression Training, you will attend three 50-minute sessions. The first one will be held immediately after the first evaluation session. Afterwards, you will be scheduled to return one week later for your second session, and then again in another week for your third session. During these sessions, you will meet privately with a therapist, who will teach you stress management skills. If you are assigned to Relaxation Training, you will learn progressive muscle relaxation, applied relaxation, deep breathing, and guided imagery. If you are assigned to Emotional Awareness and Expression Training, you will be taught to identify, experience, and express your feelings related to stress. You will be asked to practice the techniques at home in between the sessions. Also, at the beginning and end of each session, you will be asked to rate your mood and IBS symptoms. Is that something you are interested in and willing to do?

If you are assigned to the Waiting condition, you will wait for one of the interventions until after your evaluation session that is held at 12 weeks. At that time, you will be given the option to participate in the stress management intervention of your choice, for three sessions with a therapist.

The intervention sessions will be provided at no cost to you. You will be paid for each evaluation session that you complete, at $20 for each session; thus, you can be paid up to a total of $60.

What questions do you have?

Are you interested in participating?

Let's see if you are eligible….continue with screening questions below.

Leaving a voicemail if person does not answer:
Hi <*insert the name of the individual*>, my name is <*insert name of research assistant*>. I recently sent you an e-mail asking if you were interested in a stress management study for irritable bowel syndrome. I have not heard back from you and wanted to follow-up to determine if you were interested in this study. If you would like to learn more information about this study, you can call me back at (313)577-2773 or e-mail me at healthlab@wayne.edu. If you are not interested, please let me know, and I won't contact you further.
I will look forward to hearing from you, and potentially working with you in the future! Thank you!

Recruitment Script for People from the Community

The following will be stated over the phone or at intake.

***Answering a phone call:* Hi <*insert the name of the individual*>, thank you for your interest in our study, "Stress Management for Irritable Bowel Syndrome." Would you like me to tell you more information over the phone or send you an email? Next, I will ask you some questions to see if you are eligible. If so, we can discuss the study in more detail, and set up an appointment for you.

***Returning a phone call:* Hello <*insert the name of the individual*>. My name is <*insert your name*> from Wayne State University. I am returning your phone call/email about the study, "Stress management for irritable bowel syndrome." Are you still interested in participating in this study at this time?

> *If interested:* Would you like me to tell you more information over the phone or send you an email? Next, I will ask you some questions to see if you are eligible. If so, we can discuss the study in more detail, and set up an appointment for you.

Study Information:
This is a research study of stress management techniques for people with irritable bowel syndrome, which is being conducted at Wayne State University. In this study, we are testing whether two different stress management approaches help people reduce their IBS symptoms and improve their functioning. One approach involves learning how to relax and calm your body and mind, and the other approach involves becoming aware of and expressing your emotions related to stress.

At your first appointment, you will be provided with all of the information about the study, provide written consent, and sign a release for your medical records, so we can send a diagnostic confirmation form to your physician. After that, you will have an evaluation session during which you will fill out questionnaires about your current IBS symptoms, your mood, your functioning, and your personality. This will take approximately one hour. You will also be asked to return for two more evaluation visits, which will be held 4 weeks and 12 weeks after the first evaluation session. Each of these evaluations will also take about 1 hour, and you will complete the same questionnaires as you did at the first session.

After the first evaluation session, you will be randomly assigned to one of three intervention conditions. You have a 1 out of 3 chance of being assigned to the Relaxation Training condition, a 1 out of 3 chance of being assigned to the Emotional Awareness and Expression Training condition, or a 1 out of 3 chance of being assigned to a Waiting condition. If you are assigned to Relaxation Training or Emotional Awareness and Expression Training, you will attend three 50-minute sessions. The first one will be held immediately after the first evaluation session. Afterwards, you will be scheduled to return one week later for your second session, and then again in another week for your third session. During these sessions, you will meet privately with a therapist, who will teach you stress management skills. If you are assigned to Relaxation Training, you will learn progressive muscle relaxation, applied relaxation, deep breathing, and

guided imagery. If you are assigned to Emotional Awareness and Expression Training, you will be taught to identify, experience, and express your feelings related to stress. You will be asked to practice the techniques at home in between the sessions. Also, at the beginning and end of each session, you will be asked to rate your mood and IBS symptoms. Is that something you are interested in and willing to do?

If you are assigned to the Waiting condition, you will wait for one of the interventions until after your evaluation session that is held at 12 weeks. At that time, you will be given the option to participate in the stress management intervention of your choice, for three sessions with a therapist.

The intervention sessions will be provided at no cost to you. You will be paid for each evaluation session that you complete, at $20 for each session; thus, you can be paid up to a total of $60.

What questions do you have?

Are you still interested in participating?

If yes, continue with eligibility screening.

Screening Questions:

1) Has a physician diagnosed you with IBS?
   YES NO

2) Have you had recurrent abdominal pain or discomfort, or a change in stool frequency or form, at least three days per month, in the last three months?
   YES NO

3) Do you have pain and discomfort at least two days per week?
   YES NO

4) Do you have any physical or mental health problems that may prevent you from being able to participate in the study?
   a. Do you have post-infectious IBS, an organic gastrointestinal disease, or immunodeficiency?
      YES NO

   b. Do you have schizophrenia or bipolar disorder?
      YES NO

   c. Have you been dependent on drugs or alcohol within the past two years?
      YES NO

5) Is English your first language? (If not, can you read, write, and speak English fluently?)
   YES NO

6) Are you currently in another clinical research trial of an intervention for IBS?
YES NO

Circle:

ELIGIBLE NOT ELIGIBLE

If the participant is not eligible to participate: Thank you for your interest, but you do not meet criteria for the study at this time (you don't need to mention why to people in the community).

If eligible: Great! You are eligible to participate in our study.

Do you have the time to participate in this study and attend all sessions that you are assigned?

Are you planning on remaining in the area for at least the several months?

If the patient meets the study criteria and is interested and able to participate:

Great! Let's set up your first appointment now.

APPENDIX F: Consent Form

Stress Management for the Treatment of Irritable Bowel Syndrome

Behavioral Research Informed Consent

Title of Study: *Stress Management for Irritable Bowel Syndrome*

Principal Investigator (PI): Mark A. Lumley, Ph.D.
Department of Psychology, Wayne State University
(313) 577 – 2247

Purpose

You are being asked to be in a research study of stress management techniques for irritable bowel syndrome (IBS) because you have been diagnosed with IBS and you would like to learn more about stress management techniques to help you with your IBS. This study is being conducted at Wayne State University. The estimated number of study participants to be enrolled at Wayne State University is about 150. **Please read this form and ask any questions you may have before agreeing to be in the study.**

In this research study, we are testing whether two different stress management approaches help people reduce their IBS symptoms and improve their functioning. One approach involves learning how to relax and calm your body and mind, and the other approach involves becoming aware of and expressing your emotions related to stress.

Study Procedures

If you are eligible and agree to take part in this research study, you will first have a 1-hour evaluation session during which you will fill out questionnaires about your current IBS symptoms, your mood, your functioning, and your attitudes and beliefs. You will also be asked to return for two more evaluation visits, which will be held 4 weeks and 12 weeks after the first evaluation session. Each of these evaluations will take about 1 hour, and you will complete the same questionnaires as you did at the first session.

After the first evaluation session, you will be randomly assigned (like by the flip of a coin) to one of three intervention conditions. You have a 1 out of 3 chance of being assigned to the Relaxation Training condition, a 1 out of 3 chance of being assigned to the Emotional Awareness and Expression Training condition, or a 1 out of 3 chance of being assigned to a Waiting condition.

If you are assigned to Relaxation Training or Emotional Awareness and Expression Training, you will attend three 50-minute sessions, which will be held today, next week, and the week after. During these sessions, you will meet privately with a therapist, who will teach you stress management skills. If you are assigned to Relaxation Training, you will learn progressive muscle relaxation, applied relaxation, deep breathing, and guided imagery. If you are assigned to Emotional Awareness and Expression Training, you will be taught to identify, experience, and express your feelings related to stress. All sessions with the therapists will be audiorecorded for supervision purposes. You will be asked to practice the techniques at home in between the sessions. Also, at the beginning and end of each session, you will be asked to rate your mood and IBS symptoms.

If you are assigned to the Waiting condition, you will wait for one of the interventions until after your evaluation session that is held at 12 weeks. At that time, you will be given the option to participate in the stress management intervention of your choice, for three sessions with a therapist.

Benefits

By taking part in this study you might learn techniques to help you manage your stress, which might also reduce your IBS symptoms. However, we do not know whether or how much your symptoms may improve. Additionally, information from this study may benefit other people now or in the future.

Risks

By taking part in this study, you may experience the following risks. The stress management sessions may be briefly upsetting or uncomfortable, or may cause you to feel some anxiety. However, any discomfort will most likely pass quickly.

Although most information will be kept confidential, there are some instances where we are obligated to report our concerns to the authorities. The following information must be released/reported to the appropriate authorities if at any time during the study there is concern that:

- child abuse or elder abuse has possibly occurred,
- you have a reportable communicable disease (i.e., certain sexually transmitted diseases or HIV)
- you disclose illegal criminal activities, illegal substance abuse or violence

Additionally, because we are recording your name and other identifying information, there is a risk of a breach or loss of confidentiality. Finally, there may also be risks involved from taking part in this study that are not known to researchers at this time.

Alternatives

An alternative is not to participate in this study. You can also obtain stress management interventions from practitioners in the community, and we encourage you to consult with your physician about this.

Study Costs and Compensation

Other than transportation and possibly parking costs, there is no cost to you for participating in this study. The intervention sessions will be provided at no cost to you.

You will be paid for each evaluation session that you complete, at $20 for each session; thus, you can be paid up to a total of $60.

Research Related Injuries

In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Care for such will be billed in the ordinary manner to you or your insurance company. No reimbursement, compensation, or free

medical care is offered by Wayne State University. If you think that you have suffered a research related injury, contact Dr. Lumley right away at (313) 577 – 2247.

Confidentiality

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code number. Information that identifies you personally will not be released without your written permission. However, the study sponsor, the Institutional Review Board (IRB) at Wayne State University, or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.) may review your records.

When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audiorecordings of you will be used for research or educational purposes, your identity will be protected or disguised. All data and audiotapes will be kept in your study file until after 6 years or until the study is completed, whichever is longer, and then will be destroyed.

Voluntary Participation/Withdrawal

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you decide to take part in the study, you can later change your mind and withdraw from the study. You are free to only answer questions that you want to answer. You are free to withdraw from participation in this study at any time. Your decisions will not change any present or future relationship with Wayne State University or its affiliates, or other services you are entitled to receive.

The PI may stop your participation in this study without your consent. The PI will make the decision and let you know if it is not possible for you to continue. The decision that is made is to protect your health and safety, or because you did not follow the instructions to take part in the study

Questions

If you have any questions about this study now or in the future, you may contact Dr. Mark Lumley or one of his research team members at the following phone number: (313) 577–2247. If you have questions or concerns about your rights as a research participant, the Chair of the Institutional Review Board can be contacted at (313) 577-1628. In the event you suffer a research related injury, you may contact the study principal investigator, Dr. Mark Lumley, at (313) 577-2247. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call (313) 577-1628 to ask questions or voice concerns or complaints.

Stress Management for the Treatment of Irritable Bowel Syndrome

Consent to Participate in a Research Study

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

Signature of participant / Legally authorized representative *	Date
Printed name of participant / Legally authorized representative *	Time
Signature of witness**	Date
Printed of witness**	Time
Signature of person obtaining consent	Date
Printed name of person obtaining consent	Time

**Use when participant has had this consent form read to them (i.e., illiterate, legally blind, translated into foreign language).

APPROVAL PERIOD

FEB 2 0 '14 FEB 1 9 '15

WAYNE STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD

Signature of translator	Date
Printed name of translator	Time

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ABSTRACT

THE EFFECTS OF EMOTIONAL AWARENESS AND EXPRESSION TRAINING AND RELAXATION TRAINING FOR PEOPLE WITH IRRITABLE BOWEL SYNDROME: A RANDOMIZED TRIAL

by

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Irritable bowel syndrome has historically been considered a "functional" or "medically unexplained" disorder, characterized by abdominal discomfort and altered bowel habits. However, many facets of the disorder remain unclear and symptoms are often variable, which make it difficult to find successful treatments. A history of trauma, stressful life events, and intrapsychic conflict is common among people with IBS, as is the tendency to suppress the expression of their negative emotions. Over time, such stress and emotional suppression appears to contribute to IBS or exacerbate its symptoms. Thus, an intervention that enhances emotional awareness and expression may promote better adaptation for patients with IBS; however, most interventions for IBS are aimed at symptom management (e.g., relaxation training pharmacological treatments, diet, exercise) and do not address unresolved stress and emotional suppression. To improve health outcomes for people with IBS, these stress and emotional factors need to be targeted directly in therapy. This study tested how a novel 3-session intervention, emotional awareness and expression training (EAET), compared to a protocol that teaches the

conceptually opposite approach – relaxation training (RT) – and how both of these interventions compared to a wait-list control condition.

In this study, 106 people with IBS were recruited from the community and local gastroenterological clinics. Participants completed self-report measures of IBS symptom severity, psychological functioning, and quality of life at baseline, and 4 and 12 following baseline / session 1. Then, participants were randomized to one of three conditions (emotional awareness and expression training, relaxation training, or a wait-list control). Participants in the active interventions met with a therapist weekly, for a 50-minute individual therapy session. At 4 weeks, EAET participants had greater reductions in IBS symptom severity as compared to the control condition. However, both of the active interventions reduced anxiety, hostility, and improved quality of life. At 12 weeks, participants in both of the interventions maintained their improvements; however, only quality of life remained significantly better than controls who, surprisingly, tended to improve on most other measures, eliminating the differences with the other two conditions. These findings provide preliminary evidence that emotional awareness and expression training is an efficacious treatment for IBS. Future research with greater methodological rigor is needed to confirm these findings and advance the understanding of emotional processing interventions for IBS. Research should also move towards translating best practices to front line care.

AUTOBIOGRAPHICAL STATEMENT

Elyse Thakur (Sklar) completed her undergraduate degree in Behavioral Neuroscience from Northeastern University in 2007. She is completing her PhD in Clinical Psychology, with a minor in Health Psychology, at Wayne State University. Currently, she is a Psychology Intern at Baylor College of Medicine, in the Menninger Department of Psychiatry and Behavioral Sciences, in Houston, Texas.

As a clinical researcher, Elyse has a strong interest in medically unexplained syndromes (e.g., irritable bowel syndrome, chronic pain). Identifying efficient and effective interventions for patients with these overlapping problems has been a long-standing passion of hers. Her research has focused on developing and testing novel emotional processing treatments and identifying individual differences in emotional functioning that might influence how individuals respond to these interventions. To further develop her line of research, she collaborated with investigators outside of her university on several projects examining psychosocial factors and adjustment to illness in patients with chronic pain, IBS, and related disorders.

Elyse plans to pursue a career as a clinical scientist in an academic medical setting. Next year, Elyse will begin the South Central Mental Illness Research, Education, and Clinical Center (SC MIRECC) Postdoctoral Fellowship at Michael E. DeBakey VA Medical Center/Baylor College of Medicine. During fellowship, she will spend 75% of her time conducting clinically relevant research, and 25% of her time engaging in clinical and educational activities. She plans to expand the focus of her research to adapt brief interventions for IBS patients to real-world specialty care clinics. She also plans to develop training programs for psychologists and other professionals to improve the adoption and dissemination of evidence-based psychological interventions for these patients in front-line practice settings.