

A Minimal Contact Cognitive-Behavioral Intervention for Abdominal Pain-Related  
Functional Gastrointestinal Disorders: Pilot-Study of "Gutstrong".

BY

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## ABSTRACT

Recurrent abdominal pain is widely known as one of the most common chronic pain conditions of children and adolescents. Functional gastrointestinal disorders make up the majority of those with abdominal pain and are a set of conditions resulting from complex interactions between physiological and psychological factors. Psychological treatments such as cognitive-behavioral therapy have been shown to be largely effective for children and adolescents with recurrent abdominal pain. However, barriers to the use of this treatment are related to accessibility, the cost and time commitment of therapy, and the ambivalence of families to pursue psychological therapy. The development of minimal contact interventions has become popular to address these barriers to treatment.

A randomized wait-list controlled pilot study was used to evaluate the preliminary efficacy of the “Gutstrong” intervention. “Gutstrong” is a CD-ROM based cognitive-behavioral intervention that was designed as part of this dissertation to treat teenagers with functional gastrointestinal disorders. Twenty adolescents aged 13-17 attending an abdominal pain specialty clinic were randomly assigned to either the treatment group (“Gutstrong” plus standard medical care) or a wait-list control group (standard medical care only). Participants completed an initial baseline phase, an intervention phase, and an immediate post-intervention follow-up phase. The primary outcome measures included indices of pain and quality of life and secondary measures of mood, stress, and coping. Consumer satisfaction was also considered to obtain feedback about the program. Data available at the time of this writing gave initial support to the “Gutstrong” program as a useful adjunctive treatment to standard medical care. The utility, appeal and cost-effectiveness of this program warrant further evaluation of its efficacy and effectiveness in the future.

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## Chapter 1: Introduction and Background

No more than a half century ago, pain was approached primarily with a biomedical model that focused on underlying pathology or bodily tissue damage. Pain was defined strictly as a symptom of disease and was directly related to the physiological malfunction within the individual. When there was an absence of underlying pathology or when an individual's pain was unable to be "cured" through medicine, psychopathology was often inferred. In these cases, the biomedical model of pain had failed because the pain experience of a large number of patients was poorly understood. A specific indication of the limitations inherent in the biomedical model occurred when Melzack and Wall (1965) first described the pain "gate control theory". This theory opened the door for research on the role of psychological variables in moderating and mediating pain and was one of the instrumental writings in the paradigm shift from the biomedical model to the biopsychosocial model for pain (Engel, 1977; Engel, 1980; Engel, 1981). The biopsychosocial model of pain deals with illness rather than disease. The concept of illness is much more comprehensive because it includes the potential components of disease, nociceptive qualities of the nervous system, emotions, cognitions, behaviors, and societal relationships. All of these components interact to define unique pain conditions for an individual.

Current definitions and understandings of pain reflect the focus on the biopsychosocial model. For instance, the International Association for the Study of Pain defines pain as "an unpleasant sensory and emotional experience associated with actual or potential damage, or described in terms of such damage" (Gerik, 2005). Pain can be caused by a disease state or an observable physical injury or trauma, a medical procedure or provider, or a behavior or habit. Perhaps the most challenging pain conditions are those that are not associated with a well-defined or specific disease state or physical injury (Gerik,

2005). In children and adolescents, one of the most common complaints belonging to this category is recurrent abdominal pain. However, patients with recurrent abdominal pain can be more specifically classified into three broad categories; those with an identifiable organic or physical cause, those with a functional gastrointestinal disorder, those with an unknown condition (Jarret, Heitkemper, Czyzewski, Shulman, 2003).

The functional gastrointestinal disorders (FGIDs) are defined as a variable combination of chronic or recurrent gastrointestinal symptoms not explained by structural or biochemical abnormalities (Rasquin, Di Lorenzo, Forbes, Guiraldes, Hyams, et al, 2006; Drossman, Thompson, Talley, Funch-Jensen, Janssens, Whitehead, 1990). Specifically, functional symptoms are caused by events that are in the repertoire of disease-free bodily symptoms; although they can result in the sensation of pain, they are not the result of nor can they cause disease (Fleisher & Feldman, 1999). The biopsychosocial model is essential for the understanding of functional gastrointestinal disorders because these conditions are the result of complex interactions between body physiology, emotions, behavior, and social relationships.

The present project focused on the development and preliminary evaluation of a CD-ROM based cognitive-behavioral intervention for teenagers with abdominal pain related to functional gastrointestinal disorders. This “Gutstrong” program was developed under the biopsychosocial model of pain. Before proceeding to the discussion of the development and initial testing of this program, this section will review the literature concerning recurrent abdominal pain in children. The majority of research regarding abdominal pain-related functional GI disorders focuses on the more general category of recurrent abdominal pain (RAP). Therefore, this review will focus primarily on the literature concerning recurrent abdominal pain in general. Wherever possible this review makes specific reference to

abdominal pain-related functional disorders as a specific category within recurrent abdominal pain. This section will also review the use of minimal contact interventions and technology for the treatment of chronic pain conditions in children.

### Diagnosis and Assessment

One of the difficulties for researchers in this area is the definition of recurrent abdominal pain itself (Blanchard & Sharff, 2002). Recurrent abdominal pain or RAP is a description of a common pattern of symptoms, not a homogenous entity (Murphy, 1993). Most of the extant literature focuses on recurrent abdominal pain, which was first operationally defined by Apley and colleagues (Apley & Naish, 1958; Apley, 1975; Apley & Hale, 1973). According to Apley's criteria, recurrent abdominal pain is characterized by three or more episodes of abdominal pain that occur over at least 3 months and are severe enough to interfere with daily activities. The pain is described as vague abdominal pain that is paroxysmal, dull or crampy, is poorly localized or periumbilical, and persists for less than 1 hour. The Apley and Naish (1958) definition of recurrent abdominal pain does not specifically exclude children with organic diagnoses. Over time, it has been consistently found that only 5%-10% of children with recurrent abdominal pain according to Apley's criteria have an underlying organic process that contributes to their pain (Apley, 1975; Apley & Hale, 1973; Liebman, 1978; Gaylord & Carson, 1983; Stickler & Murphy, 1979; Stone & Barbero, 1970; Walker, Garber, Van Slyke, Greene, 1995; Weydert, Ball, & Davis, 2003). Because Apley's criteria are ambiguous and allow for both non-organic and organic causes, there has been recognition that a reliable set of symptom-based diagnostic criteria is needed (Von Baeyer & Walker, 1999).



A classification system that focuses specifically on the functional disorders involving recurrent abdominal pain was proposed by the pediatric gastroenterology multinational Rome Working Team (Drossman, 2000; Drossman, 1994; Rasquin et al., 2006; Rasquin-Weber et al., 1999). The Rome Team reached a consensus that the term recurrent abdominal pain may be too vague to include as a childhood functional GI disorder (Hyams, 1999). Instead, they felt that five diagnostic categories of functional disorders associated with recurrent abdominal pain were more appropriate: functional dyspepsia, irritable bowel syndrome, functional abdominal pain, abdominal migraine, and aerophagia (Rome II criteria; Rasquin-Weber et al., 1999). Pediatric abdominal pain sufferers who previously met the Apley criteria would be more specifically diagnosed under the new Rome II criteria. Di Lorenzo, Colletti, Lehmann, Boyle, Gerson, et al., (2005) provided evidence that children with chronic abdominal pain have symptom patterns that can be categorized as functional dyspepsia, IBS, or abdominal migraine. Also, in a study conducted before the development of the Rome criteria, a study of 171 children with recurrent abdominal pain reported that 117 (68%) met the criteria used in adults to diagnose IBS (Hyams, Treem, Justinich, et al., 1995). Another prospective study of 257 children 5 years-of-age and older presenting with abdominal pain identified 127 children meeting Rome II criteria for dyspepsia (Hyams, Davis, Sylvester, Zeiter, Justinich, et al., 2000). With the continued development of these new diagnostic entities for abdominal pain-related functional GI disorders, it is likely the term recurrent abdominal pain will be less common because of its lack of specificity.

Since the publication of the Rome II criteria, the Rome committee members have made revisions to the criteria in light of emerging scientific research and on the basis of their own clinical experience (Rome III; Rasquin et al., 2006). The Rome III criteria (see Table 1) represent the most up to date classification of the abdominal pain-related functional GI

Table 1: Diagnostic Criteria for Abdominal Pain-Related FGIDs

H2a. <b>Functional Dyspepsia</b>	H2b. <b>Irritable Bowel Syndrome</b>	H2c. <b>Abdominal Migraine</b>	H2d. <b>Childhood Functional Abdominal Pain</b>
<p>Must include all of the following:</p> <ol style="list-style-type: none"> <li>1. Persistent or recurrent pain or discomfort centered in the upper abdomen (above the umbilicus).</li> <li>2. Not relieved by defecation or associated with the onset of a change in stool frequency or stool form (ie, not IBS).</li> <li>3. No evidence of an inflammatory, anatomic, metabolic, or neoplastic process that explains the subject's symptoms.</li> </ol> <p>*Criteria fulfilled at least once per week for at least 2 months before diagnosis.</p>	<p>Must include all of the following:</p> <ol style="list-style-type: none"> <li>1. Abdominal discomfort (an uncomfortable sensation not described as pain) or pain associated with 2 or more of the following at least 25% of the time:               <ol style="list-style-type: none"> <li>a. Improved with defecation</li> <li>b. Onset associated with a change in frequency of stool</li> <li>c. Onset associated with a change in form (appearance) of stool.</li> </ol> </li> <li>2. No evidence of an inflammatory, anatomic, metabolic, or neoplastic process that explains the subject's symptoms.</li> </ol> <p>*Criteria fulfilled at least once per week for at least 2 months before diagnosis.</p>	<p>Must include all of the following:</p> <ol style="list-style-type: none"> <li>1. Paroxysmal episodes of intense, acute periumbilical pain that lasts for 1 hour or more.</li> <li>2. Intervening periods of usual health lasting weeks to months</li> <li>3. The pain interferes with normal activities</li> <li>4. The pain is associated with 2 or more of the following:               <ol style="list-style-type: none"> <li>a. Anorexia</li> <li>b. Nausea</li> <li>c. Vomiting</li> <li>d. Headache</li> <li>e. Photophobia</li> <li>f. Pallor</li> </ol> </li> <li>5. No evidence of an inflammatory, anatomic, metabolic, or neoplastic process that explains the subject's symptoms.</li> </ol> <p>* Criteria fulfilled 2 or more times in the preceding 12 months.</p>	<p>Must include all of the following:</p> <ol style="list-style-type: none"> <li>1. Episodic or continuous abdominal pain</li> <li>2. Insufficient criteria for other FGIDs.</li> <li>3. No evidence of an inflammatory, anatomic, metabolic, or neoplastic process that explains the subject's symptoms.</li> </ol> <p>*Criteria fulfilled at least once per week for at least 2 months before diagnosis</p> <p>-----</p> <p>-</p> <p><b>H2d1. Childhood Functional Abdominal Pain Syndrome</b></p> <p>Must include childhood functional abdominal pain at least 25% of the time and 1 or more of the following:</p> <ol style="list-style-type: none"> <li>1. Some loss of daily functioning.</li> <li>2. Additional somatic symptoms such as headache, limb pain, or difficulty sleeping.</li> </ol> <p>*Criteria fulfilled at least once per week for at least 2 months before diagnosis.</p>

Note: From- Rasquin, Di Lorenzo, Forbes et al. (2006). Childhood functional gastrointestinal disorders: child/adolescent.

disorders. The categories include functional dyspepsia, irritable bowel syndrome, abdominal migraine, and childhood functional abdominal pain. The primary changes from Rome II criteria to Rome III include duration of symptoms for diagnosis (from 3 months to 2 months for all none-cyclical disorders, including abdominal migraine), the movement of aerophagia into a different diagnostic category, and the split of functional abdominal pain into functional abdominal pain and functional abdominal pain syndrome. Further research is needed to validate these diagnostic criteria, but they are the basis for continued research on abdominal pain-related functional GI disorders. It is important to emphasize that most patients previously subsumed under the general category of recurrent abdominal pain will fall into these diagnostic categories. Those that do not will likely have alarm symptoms, signs, and features that indicate organic disease.

### Epidemiology

Prevalence rates of children falling under the general descriptor of recurrent abdominal pain have been found to range between 9-25% with disparate results (Apley & Naish, 1958; Boey & Goh, 2001; Boey, Yap, Goh, 2000; Boyle, 1996; Bury, 1987; Colletti, 1998; Crushell, Rowland, Doherty et al., 2003; Faull & Nicol, 1986; Huang, Palmer, & Forbes, 2000; Mortimer, Kay, Jaron, Good, 1993; Oster, 1972; Stickler & Murphy, 1979; Stone & Barbero, 1970; Thiessen, 2002; Zuckerman, Stevenson, & Bailey, 1987). Apley and Naish (1958) were the first to study this condition and estimated that 10-15% of children and adolescents aged 4-16 had recurrent abdominal pain. For more than 90% of these children, no organic cause for their abdominal pain could be found. More recently Hyams and colleagues (1996) conducted a community-based study of recurrent abdominal pain in school children and reported that 13% (middle school) to 17% (high school) experienced

abdominal pain at least weekly. Recurrent abdominal pain is a common problem addressed by primary care providers and subspecialists, accounting for 2-4% of office visits to general pediatric practices (Starfield, Hoekelman, McCormick, et al., 1984; Starfield, Gross, Wood, et al., 1980). In addition, recurrent abdominal pain accounts for up to 25% of referrals to tertiary gastroenterology clinics (Boyle, 1997) and functional gastrointestinal disorders are among the most common reasons for consultation in pediatric gastroenterology (Hyams et al., 1996).

The relatively high variability in prevalence estimates for children and adolescents with recurrent abdominal pain is primarily due to diagnostic inconsistency and differences in the characteristics of the populations (Scharff, 1997). Specifically, it is due to the heterogeneity of functional and organic GI disorders subsumed under the label of recurrent abdominal pain. The prevalence of recurrent abdominal pain also varies with gender and age. While prevalence may be similar between boys and girls at younger ages (5-6-years old) (Faull & Nicol, 1986), most studies show that prevalence increases in girls and decreases in boys as children get older (Apley & Naish, 1958; Eminson, Benjamin, Shorell, Woods, 1996; Oster, 1972; Stickler & Murphy, 1979). Stickler and Murphy (1979) report a higher prevalence of recurrent abdominal pain in children at age 11 and 12 compared with teenagers, indicating a peak in prevalence at preadolescents, after which prevalence decreases more for boys than for girls. Conversely, Hyams et al (1996) showed that recurrent abdominal pain becomes more prevalent with increasing age into adolescents. At the present time, there appears to be no reported data on prevalence variations based on ethnicity or socioeconomic status.

More informative prevalence estimates have stemmed from the improved diagnostic specificity of recurrent abdominal pain into the abdominal pain-related functional disorders.

The prevalence of the distinct Rome criteria diagnostic groups (functional dyspepsia, irritable bowel syndrome (IBS), abdominal migraine, and functional abdominal pain) have been researched to a limited degree. Based on the Rome II criteria, the prevalence of functional dyspepsia was between 12.5% and 15.9% among children aged 4-18 years referred to tertiary clinics in North America (Caplan, Walker, & Rasquin, 2005; Walker, Lipani, Greene, Caines, Stutts, et al., 2004). Irritable bowel syndrome was diagnosed in 6% of middle school and 14% of high school students using Rome I criteria (Hyams et al., 1996). Also, IBS was found in 22%-45% of children aged 4-18 years presenting to tertiary care clinics (Caplan et al., 2005; Walker et al., 2004). Abdominal migraine was diagnosed in 2.2%-5% of children presenting to gastroenterology clinics (Caplan et al., 2005; Walker et al., 2004). Functional abdominal pain was diagnosed in 0%-7.5% of 4-18-year-old patients presenting to gastroenterology clinics (Caplan et al., 2005; Walker et al., 2004). One study conducted in Italy reported the prevalence of FGIDs (based on Rome II criteria) found in children consulting primary care pediatricians (Miele, Simeone, Marino, Greco, Auricchio, et al., 2004). In children with a mean age of 52 months, the prevalence of functional dyspepsia was 0.3% and the prevalence of irritable bowel syndrome was 0.2% (Miele et al., 2004).

#### Associated Features and Prognosis

The features of recurrent abdominal pain are often variable, as expected with the heterogeneity of conditions subsumed under this general descriptive category. In some children with recurrent abdominal pain the pain occurs daily, and in others it is more episodic (Hyams, 1999). It has also been consistently reported that children with recurrent abdominal pain are more likely than children without to have headache, joint and limb pain, anorexia, vomiting, nausea, excessive gas and altered bowel symptoms (Apley & Naish, 1958; Apley,

1975; Barr & Feuerstein, 1983; Di Lorenzo et al., 2005; Walker, Garber, & Greene, 1991).

The association with chronic headache has been one of the most consistently documented, with rates varying widely from 14% to 90% (Alfven, 1993a; Apley & Naish, 1958; Bury, 1987; Friedman, 1972; Hodges, Kline, Barbero, & Flanery, 1985; Stone & Barbero, 1970).

Further, Ernst, Routh, and Harper (1984) found that reported somatic symptoms increased as a function of duration of pain, the longer the duration of recurrent abdominal pain the more likely the patient was to complain of other functional somatic symptoms such as headache. Walker, Garber, and Greene (1993) were unable to confirm these findings in a prospective study.

Focusing on the specific abdominal pain-related functional GI disorders, children with functional dyspepsia have persistent or recurrent pain or discomfort in the upper abdomen (Rasquin et al., 2006). This pain has been described as both burning and an ache. Sometimes the pain may wake the child from sleep. In addition, the child may complain of nausea, early satiety, vomiting, and a sense of bloating or feeling full (Hyams, 1999). At times eating and gastric acid suppression can reduce the pain. Children with irritable bowel syndrome (IBS) have abdominal pain or discomfort that is often improved with defecation or associated with a change in frequency or form of stool (Rasquin et al., 2006). Sometimes this pain is described as cramping. Other associated features can include lumpy/hard or loose/watery stools, abnormal stool passage (staining, urgency), passage of mucus, or bloating or feeling distension (Hyams, 1999). Children with abdominal migraine have paroxysmal episodes of intense, acute midline abdominal pain lasting for at least one hour. These pain episodes are often separated by symptom-free intervals of weeks to months. The pain is also often associated with anorexia, nausea, vomiting, headache, photophobia, and pallor (Rasquin et al., 2006). Lastly, children with functional abdominal pain and functional

abdominal pain syndrome have episodic or continuous abdominal pain in which there is no recognizable pattern or any accompanying GI symptoms. In functional abdominal pain syndrome, additional somatic symptoms such as headache, limb pain, or difficulty sleeping are present (Rasquin et al., 2006).

Some authors have regarded recurrent abdominal pain as a short-term condition with no treatment indications other than assurance and support for the benign nature of their pain (Galler, Neustein, & Walker, 1980; Levine & Rapaport, 1984; Liebman, 1978). Croffie, Fitzgerald, and Chong (2000) approximated that 30% to 40% of children with recurrent abdominal pain do have resolution of their pain with support and empathy for the family with reassurance that no serious disease is present. However, most of the data indicates that recurrent abdominal pain is associated with a number of future health-related and other difficulties (Janicke & Finney, 1999). In short term follow-up, 90% of recurrent abdominal pain patients continued to report abdominal pain for several months (Wasserman, Whittington, & Rivera, 1988). Also, patients with recurrent abdominal pain are significantly more likely than well patients and patients with organically based abdominal pain to maintain symptoms 3 months after the initial clinic visit (Walker, Garber, & Greene, 1991).

There a large number of long-term follow-up studies of children with recurrent abdominal pain that show congruent results. Stickler and Murphy (1979) followed these patients for a minimum of 5 years after treatment and reported that 24% of 161 patients continued to suffer frequent abdominal pain. Though many children in this sample (76%) with pain no longer exhibited symptoms at follow-up, almost one-half of these children had other psychosomatic or physical complaints. In another 5-year follow-up, former recurrent abdominal pain patients reported significantly higher levels of abdominal pain and other somatic symptoms when compared to former well patients (Walker, Garber, Van Slyke, and

Greene, 1995). Further, Bury (1987) found that 66% of 78 former recurrent abdominal pain patients still suffered from pain up to 7 years after treatment. Apley & Hale (1973) found that 37% of treated and 40% of untreated patients continued to have abdominal pain 8 years after the original assessment. Ten years after standard medical treatment, up to 50% of patients with abdominal pain reported continued somatic complaints (Magni, Peirri, & Donzelli, 1987). Lastly, Christensen and Mortensen (1975) contacted 34 patients with childhood recurrent abdominal pain 28-29 years after treatment, and 53% (n=18) of these patients reported abdominal symptoms at follow-up. In the studies that report long-term follow-up for treated groups, the treatment often consists of standard medical care or support and assurance to the families that no organic disease is present.

Another consideration in the prognosis of children with recurrent abdominal pain is whether it is associated with disorders in adulthood. For example, some have suggested that recurrent abdominal pain may be a precursor to somatization disorder (Ernst, Routh, and Harper, 1984) and others have questioned whether it is an early manifestation of fibromyalgia (Burke, Elliott, Fleissner, 1999). A more common assertion is that there may be a relationship between childhood abdominal pain and adult irritable bowel syndrome (IBS) (Burke et al., 1999; Christensen & Mortensen, 1975). Continuity of the two disorders is suggested by studies which have found that a subset of children with recurrent abdominal pain have IBS when they reach early adulthood and that some IBS patients have childhood histories of abdominal pain (Burke et al., 1999; Jones & Lydeard, 1992). Further, evidence reveals striking similarities between the two disorders in the prevalence, course, medical and psychiatric comorbidity, family medical and psychiatric history, and patterns of association with life events (Burke et al., 1999). Walker, Guite, Duke, Barnard, and Greene (1998) found an increased risk of IBS in female adolescents/young adults with a history of abdominal pain,



though no such relationship was found with adolescent boys. They also found that IBS patients with a history of recurrent abdominal pain reported greater levels of disability and health service use than IBS patients without a history of pain, suggesting that recurrent abdominal pain influences symptom presentation and future coping. Some hypothesize that whether or not early recurrent abdominal pain develops into IBS may depend on a number of factors, one of which may be how well the child learns to cope with stressors that can trigger the pain (Compas, 1999; Walker, Garber, & Greene, 1994).

Recurrent abdominal pain in childhood has also been associated with an increased risk of psychiatric disorder in adulthood (Hotopf, Carr, Mayou, Wadsworth, Wesseley, 1998). Interestingly, recurrent abdominal pain was not associated with future abdominal pain or headache once psychiatric disorder was controlled for in the regression. Campo, Di Lorenzo, Chiappetta, Bridge, Colborn, et al. (2001) supported this finding by comparing adults with a history of abdominal pain with adults with a history of non-gastrointestinal pediatric illness. They found a history of childhood abdominal pain to be associated with a heightened risk of both anxiety and depressive disorders in adulthood

Finally, the personal and financial costs of childhood recurrent abdominal pain have received limited empirical attention but are hypothesized to be significant. First, childhood recurrent abdominal pain has been consistently associated with school absenteeism (Bury, 1987; Hyams et al., 1996; Garber, Zeman, Walker, 1990; Hodges, Kline, Barbero, Woodruff, 1985; Robinson, Alvarez, & Dodge, 1990; Walker, Garber, Greene, 1993; Walker et al., 1995). School absenteeism likely results in detrimental affects on the children's education and intellectual and social development. Second, children with recurrent abdominal pain are frequent users of health care resources (Finney, Riley, & Cataldo, 1991; Walker et al., 1995; Walker & Greene, 1989) and create substantial financial costs in hospital stays and diagnostic

tests (Apley & Naish, 1958; Coleman & Levine, 1986; Sheridan, Harvard, White, & Crosby, 1992). Increased use of health care resources may also be related to increased medical help seeking in adulthood (Christensen & Mortensen, 1975). The exact financial costs of recurrent abdominal pain have not been reported, but are likely substantial considering the cost of IBS in adults has been estimated between \$8-\$30 billion dollars annually (Camilleri, 2001; Drossman, Li, Andruzzi, et al., 1993; Thalley, Gabriel, Harmsen, Zinsmeister, & Evans, 1995; Martin, Barron, Zacker, 2001).

#### Potential Etiological Features of Recurrent Abdominal Pain

The etiology of recurrent abdominal pain and abdominal pain-related functional GI disorders is still fairly unclear. Conceptual models of recurrent abdominal pain have become more complex over time (Walker, 1999), moving from a dualistic view to a multivariate and interactive view. This parallels the earlier discussion about the transition from a biomedical model to a biopsychosocial model for chronic pain. The Rome Group has proposed a specific biopsychosocial conceptualization for functional gastrointestinal disorders presuming that a child's condition is a function of multiple interacting determinants, including early life factors, physiological factors, psychosocial factors, and interactions between physiological and psychological factors via the central nervous system-enteric nervous system axis. This section will review research that has looked specifically at physiological factors and psychological factors related to childhood recurrent abdominal pain. Although research often differentiates the physiological and psychological considerations of etiology, it is important to consider that all etiological factors are working together in an interactive model that defines functional GI disorders.

First, abdominal pain in general is a syndrome with many potential organic causes and these causes have been consistently found in 5-10% of all cases (Apley, 1975; Apley & Hale, 1973; Liebman, 1978; Gaylord & Carson, 1983; Stickler & Murphy, 1979; Stone & Barbero, 1970; Walker et al., 1995; Weydert, Ball, & Davis, 2003). Recurrent abdominal pain cases with a specific organic etiology usually display "red flags" on history or examination that lead to proper medical diagnosis (Frazer & Rappaport, 1999). Some potential organic causes of recurrent abdominal pain in children include obstruction of the intestinal tract, reactions to infection, severe inflammations, ulcer, spinal disease, allergic reactions, metabolic disorders, and epilepsy (Apley, 1975; Bain, 1974; Galler, Neustein, & Walker, 1980). However, organic pathology is often absent in the majority of children with recurrent abdominal pain (Rasquin-Weber et al., 1999).

### *Physiological Factors*

Despite the lack of organic disease in most children with recurrent abdominal pain, many studies have looked at potential physiological alterations within the gastrointestinal system that could be related to the etiology of the pain. The majority of research on physiological factors of recurrent abdominal pain has centered on non-pathological biological mechanisms, such as various indices of visceral sensation, autonomic nervous system functioning, altered gastrointestinal motility, and dietary factors. First, a review of potential physiological factors involved in recurrent abdominal pain must begin with a discussion of pain transmission and the brain-gut axis.

As discussed in the introduction, there has been a conceptual shift away from pain perception as discrete neural pathways or nociceptive mechanisms (biomedical model) towards an integrative, ensemble model of neural pain perception (biopsychosocial model).

In a biopsychosocial explanation of pain transmission, initiation of the nociceptive system and the brain processing of peripheral stimulation constitute the biological substrates of the experience. But pain must be looked at as a physiological and psychological phenomenon, rather than a purely physiological phenomenon (Turk & Melzack, 2001). Specifically, pain transmission represents a perceptual process associated with conscious awareness, selective abstraction, ascribed meaning, appraisal, and learning (Melzack & Casey, 1968; Price, 2000). Specifically, pain transmission begins in the peripheral receptors which transmit information via afferent fibers to the spinal cord. The spinal cord has ascending tracts that carry stimulus information to the brain for further processing. Pain transmission also involves descending tracts and endogenous pain modulation systems that allow the higher brain centers to influence the lower pain systems (pain gate control theory) (Melzack & Wall, 1965). Melzack (1993) has gone on to propose the concept of a neuromodule, which is described as a discrete program or network of interconnected neural circuits in the brain that is related to pain. The central neuromodule is said to be heavily influenced by cognitive and socio-emotional factors in the cerebral cortex and can contribute extensively to the pain experience.

Transmission of abdominal sensations and pain are carried out by the brain-gut axis, which consists of the central nervous system and the enteric nervous system. The enteric nervous system is made up of sensory neurons, interneurons, and motor neurons that are solely responsible for the gastrointestinal system. The enteric and central nervous systems have direct effects on one another through bidirectional communication pathways. Current theories suggest that recurrent abdominal pain may be the result of alterations in the nerve pathways between the GI tract and the brain (Drossman, 1994; Jarret et al., 2003; Mayer & Raybould, 1990). Alterations in central nervous system processing of sensory input involving the GI tract are possible. Therefore, cognitive processes (including emotions,

memories, learning) or various extrinsic sensations have the capacity to affect GI function through efferent neural communication. Conversely, afferent information from the gut has the capacity to affect central processes such as pain perception, emotional state, and behavior. This model of communication between the central nervous system and gut illustrates the interconnection between genetic, environmental, physiologic, and psychosocial factors that are potentially disturbed in functional GI disorders.

Research has examined specific indices of nervous system functioning as potential etiological factors involved with recurrent abdominal pain and abdominal pain-related functional GI disorders. Childhood recurrent abdominal pain may be associated with heightened sensitivity to visceral sensations or visceral hyperalgesia (Di Lorenzo, Youssef, Sigurdsson, Scharff, Griffiths, et al., 2001; Hyams & Hyman, 1998; Hyams, 1999; Van Ginkel, Voskuil, Beninga, Tamini, Boeckxstaens, 2001). Visceral hyperalgesia is a reduced threshold for pain caused by physiologic changes in the afferent neurons of the enteric and central nervous systems. Visceral hyperalgesia is a consistent physiologic finding in one half to two thirds of adult patients with IBS (Drossman, Camilleri, Mayer, Whitehead, 2002; Garnett, 1999; Quigley, 2003; Whitehead, Crowell, Davidoff, Palsson, & Schuster, 1997; Whitehead & Palsson, 1998) and it is likely that it has similar physiological activity in children with recurrent abdominal pain (Van Ginkel et al., 2001). However, further research investigating visceral sensitivity is needed in children with abdominal pain-related functional GI disorders.

There has also been a supposition that recurrent abdominal pain patients have a constitutional weakness in the functioning of the autonomic nervous system. Children are hypothesized to be sensitive to stressors, which affect the functioning of the ANS in a way that interferes with GI functioning (Scharff, 1997). Specifically, alterations in pressure pain

thresholds have been investigated as a potential physiological factor involving the autonomic NS in children with recurrent abdominal pain. Duarte and colleagues (2000) measured the pressure pain threshold in regions of the body surface in a group of children who had recurrent abdominal pain and in a group of children with chronic or recurrent disease but with no pain. The pressure pain thresholds were reduced in all body regions in children with recurrent abdominal pain. These researchers concluded that the overall reduction of pressure pain threshold on the body surface suggests a generalized alteration of pain modulation. They suggested that the recurrent pain provokes central sensitization of the nervous system, which in turn produces hyperalgesia associated with a reduced pain threshold. Alfven (1993a, 1993b, 1993c) also has studied the somatic sensitivity of children with recurrent abdominal pain using pressure pain thresholds. These studies found that children with recurrent abdominal pain have lower muscle-pressure pain thresholds compared with control children, indicating some sensitivity of the ANS to painful stimulus (Alfven 1993b, 1993c). Rubin, Barbero, and Sibinga (1967) observed that children with RAP exhibited longer pupillary response recovery time after a cold-pressor task in comparison to nonmedical controls. However, these findings have not been supported (Battistella, Carra, Zaninotto, Ruffilli, & Da Dalt, 1992). Feurstein, Barr, Franoeur, Houle, and Rafman (1982) conducted a carefully controlled physiological study comparing responses to a cold pressor in children diagnosed with recurrent abdominal pain, with hospital and nonmedical controls and found no differences in digital blood volume, heart rate, muscle tension, subjective pain reports, or behavioral responses. These studies reveal disparate findings related to autonomic functioning in children with abdominal pain and more empirical attention is needed before any conclusions can be made regarding their importance in etiology.

Insufficient findings have also been found in the few studies that have focused on motility as a potential factor in recurrent abdominal pain. Kopel, Kim, and Barbero (1967) observed that children with pain had greater rectosigmoid activity both at baseline and after parasympathetic stimulation compared with those with inflammatory bowel disease and nonmedical controls. Pineiro-Carrera, Andres, Davis, and Mathias (1988) also found higher gastroduodenal motility in a group of recurrent abdominal pain patients compared to controls. Dimson (1971) found that children with recurrent abdominal pain had prolonged transit times compared to children in a headache group. On the other hand, Christensen and Mortensen (1975) could not detect differences in an indicator of motility between children with pain and controls. The current understanding is that there is a poor correlation between recurrent abdominal pain and GI motility and it is not likely that motility is important as an etiological factor of recurrent abdominal pain (Hyams, 1999).

Inflammation has also been implicated in the generation of pain in functional GI disorders and recurrent abdominal pain (Schurman & Friesen, 2006). The three most implicated inflammatory cell types in these patients are T lymphocytes, mast cells, and eosinophils, all of which may interact with each other. Chronic gastritis is considered the most common form of inflammation in children with dyspepsia. Eosinophils may increase in the GI tract as a result of food allergies, environmental allergies, viral infections, and anxiety (Schurman & Friesen, 2006). Further, mast cells are thought to be a key mediator between stress and gastrointestinal symptoms. The interaction between inflammatory processes and the presence of inflammatory markers and psychological stress warrants further investigation, but it is relatively clear that this system is important in functional GI pain.

### *Psychological Factors*

Psychological and environmental factors have been implicated as important components in the development and maintenance of recurrent abdominal pain and abdominal pain-related functional GI disorders. To begin with, certain personality characteristics have been used to describe children with recurrent abdominal pain (Astrada, Licamele, Walsh, & Kessler, 1981; Ernst, 1984; Robinson et al., 1990). In the very first descriptions and definitions of recurrent abdominal pain, Apley and Naish (1958) described the children as "highly-strung, fussy, excitable, anxious, timid and apprehensive" (p 168). This assertion has been supported by other researchers (Bain, 1974; Leibman, Honig, & Berger, 1976; Levine & Rappaport, 1984). Children with recurrent abdominal pain were more likely than controls to withdraw from new situations and had more difficulty settling into routines (Davison, Faull, & Nicol, 1986) and showed traits of submissiveness and dependence on parents (Kaufman, Cromer, Daleiden, Zaron-Aqua, Aqua et al., 1997).

A few studies indicate that there are no differences in psychological variables between children with recurrent abdominal pain and pain-free control children (McGrath, Goodman, Firestone, Shipman, & Peters, 1983; Sawyer, Davidson, Goodwin, Crettenden, 1987). In one sample, children with recurrent abdominal pain fell within the normative range of anxiety and depression (Olafsdottir, Ellertsen, Berstad, & Fluge, 2001). However, there is substantial evidence that internalizing symptoms, specifically anxiety, are significantly elevated in children with recurrent abdominal pain. For example, Hodges, Kline, Barbero, and Woodruff (1985) compared a group of recurrent abdominal pain, nonmedical controls, and behavioral disorder children on several measures of anxiety and found children diagnosed with recurrent abdominal pain or behavior disorder scored significantly higher on measures of anxiety than controls. Wasserman, Whittington, and Rivera (1988) compared the



scores of the Social Competence, Internalizing, and Externalizing scales of the CBC-L (Achenbach, 1991) in 31 recurrent abdominal pain patients and 31 age and gender matched controls. Recurrent abdominal pain children were significantly higher in Internalizing but no different than controls in Externalizing or Social Competence scales. They also reported that 26 of 31 children with recurrent abdominal pain met criteria for an anxiety related diagnosis. More recently Benninga, Voskuil, Akkerhuis, Taminiau, and Butler (2004) found that children with recurrent abdominal pain were in the normal range for the total behavior problem score and externalizing score but elevated into the significant range of the internalizing score. Others have supported the finding that children with recurrent abdominal pain tend to score high on the Internalizing scale of the CBC-L (Garber, Zeman, & Walker, 1990; Hodges, Gordon, & Lennon, 1990).

Studies that compare anxiety levels of children with recurrent abdominal pain to children with organic abdominal pain find fewer differences between these groups, but both exhibit elevated levels of anxiety in comparison to nonmedical controls (Walker & Green, 1989; Walker, Garber, & Green, 1993). Walker & Greene (1989) compared children with recurrent abdominal pain, non-medical controls, and children with organic abdominal pain on measures of anxiety, somatization, disability, and internalizing symptoms. Both of the pain groups (RAP and organic) scored higher on measures of anxiety, somatization, disability, and Internalizing than the non-medical control group, but there were no differences between the pain groups. The only significant difference between recurrent abdominal pain patients and organic pain patients was that the non-organic group scored higher on the Internalization scale.

Also, Walker, Garber, and Greene (1991) found that recurrent abdominal pain patients and organic patients were equally likely to report enough symptoms to qualify for a

diagnosis of somatization disorder. Lastly, Walker, Garber, and Greene (1993) looked at a large group of children with recurrent abdominal pain (n=88) along with peptic ulcer (n=57), non-medical (n=56), and psychiatric control groups (n=48) on the same measures used in previous studies. Recurrent abdominal pain patients were found to score higher on Internalizing behavior and emotional distress in comparison to the non-medical controls but also scored significantly lower on these measures than the psychiatric controls. In this study there was no difference on Internalizing between children with recurrent abdominal pain and children with peptic ulcer.

Although anxiety has been shown to have some relation to recurrent abdominal pain, much less is known about symptoms of depression. Some have suggested that depressive symptoms are of little or no clinical relevance in recurrent abdominal pain patients (McGrath et al., 1983; Hodges et al., 1985; Raymer, Weininger, Hamilton, 1984; Wasserman et al., 1988; Walker & Greene, 1989). Others contend that recurrent abdominal pain is often a symptom of depression (Hughes, 1984; Livingston, Taylor, & Crawford, 1988) and that depression is associated with the onset of recurrent abdominal pain (Stone & Barbero, 1970; Hughes, 1984).

Despite the prevailing belief that psychological symptoms are of relevance in children with recurrent abdominal pain, only a few controlled studies have examined the prevalence of psychiatric diagnoses specifically (Campo, Bridge, Ehmann et al., 2004 ; Dorn, Campo, Thato et al., 2003; Garber, Zeman, Walker, 1990; Liakopoulou-Kairis, Alifieraki, Protagora, et al, 2002). In one sample, Dorn et al. (2003) found that 50% of children and adolescents with recurrent abdominal pain met the diagnostic criteria for lifetime anxiety disorder. Campo, Bridge, Ehmann et al., 2004 reported the initial results of a case-control study comparing children and adolescents who presented with abdominal pain in primary

care with pain-free control subjects who presented with minor illness or for well-child care. A current anxiety disorder was identified in 79% of the 42 recurrent abdominal pain patients, with separation anxiety disorder in 43%, generalized anxiety disorder in 31%, and social phobia in 21%. A depressive disorder was diagnosed in 43% of 42 children with abdominal pain, with major depressive disorder in 31%, dysthymic disorder in 10%, and a subthreshold depressive disorder in 7%. In total, 81% of recurrent abdominal pain patients met criteria for an anxiety or depressive disorder. This finding indicates a need for clinicians to recognize that the vast majority of recurrent abdominal pain patients may have an anxiety or a depressive disorder and that clinical management strategies and the design of clinical trials of intervention should take this reality into account.

Stressful life-events have also been investigated in children with recurrent abdominal pain. In descriptive studies of these patients, authors often note the presence of life stressors in the families, including marital problems between the parents and the recent death of a family member or friend (MacKeith & O'Neil, 1951; Liebman, 1978; Liebman et al., 1976). Empirical studies of stressful life-events in children with recurrent abdominal pain and their families have been fairly inconsistent, with some showing more stressful events when compared to controls and other showing no differences. Robinson et al. (1990) reported a higher frequency of stressful life events in recurrent abdominal pain patients compared to controls, especially in the year before the onset of their symptoms. Also, Hodges, Kline, Barbero, Flanerry (1983) indicated that children with recurrent abdominal pain had experienced significantly more life-events related to illness, hospitalization and death when compared to a group of controls. Boey & Goh (2001) expanded on these findings by showing that prevalence of recurrent abdominal pain was higher among children who had experienced hospitalization of family member, child's own hospitalization, a change in occupation in the

family, examination failure, and bullying at school. Lastly, Walker, Garber, Smith, Van Slyke, Claar, (2001) used consecutive daily telephone interviews to assess daily stressors and symptoms in 154 patients with recurrent abdominal pain and 109 well children. Patients with pain reported more frequent daily stressors than well children both at home and at school. The association between daily stressors and somatic symptoms was significantly stronger for patients with recurrent abdominal pain than for well children.

In contrast to these findings, it has been reported that children with recurrent abdominal pain do not experience more major life stressors than healthy children (McGrath, Goodman, Firestone, Shipman, & Peters, 1983; Wasserman, Whittington, & Rivara, 1988) or children with organic abdominal pain (Walker, Garber, & Greene, 1993; Walker & Greene, 1991). In a more specific description of stressful events in children with recurrent abdominal pain, Walker, Garber, and Greene (1994) reported that negative life events in these children were moderated by social competence, as measured by social skills and peer acceptance. Children low in social competence and high in negative life events reported more pain symptoms. Therefore, it appears that stressful life events by themselves may not be as important as children's resources to manage stressful situations (i.e., coping strategies).

Coping has been defined as voluntary efforts to regulate emotion, thought, behavior, physiology, and the environment in response to stressful events or circumstances (Compas et al., 2001). In this model responses to stress include both voluntary coping efforts and involuntary/automatic stress responses (Compas, Connor, Osowiecki, & Welch, 1997; Compas, Connor-Smith, Saltzman, Thomsen, & Wadsworth, 2001). Voluntary coping responses include three categories: primary control engagement coping, or efforts to directly change the stressor or one's emotions (problem-solving, emotional expression, emotional modulation); secondary control engagement coping, or attempts to adapt to the stressor by

regulating attention or cognition (cognitive restructuring, positive thinking, acceptance, distraction); and disengagement coping, or efforts to orient away from the stressor or one's emotions (wishful thinking, avoidance, denial). Involuntary stress response fall into two categories: involuntary engagement (rumination, intrusive thoughts, physiological arousal, emotional arousal, impulsive action) and involuntary disengagement (emotional numbing, cognitive interference, inaction, escape) (Connor-Smith, Compas, Wadsworth, Thomsen, & Saltzman, 2000).

In the recurrent abdominal pain literature it appears that primary engagement coping and secondary engagement are most successful for reducing pain, and those who attempt to adapt to their situation by regulating their attention and cognitions have the best outcomes (Compas & Thompson, 1999; Jarret et al., 2003). Sharrer & Ryan-Wenger (1991) compared stress management techniques of children with recurrent abdominal pain to non-medical controls. Children with recurrent abdominal pain reported a higher frequency and severity of stressors. There was no difference in the frequency of the use of stress coping strategies between the groups. However, the children with abdominal pain were more likely to report that distraction techniques (watching TV) were more effective for dealing with stress than the control group. The controls were more likely to report that physical and cognitive activity were more effective in dealing with stress. Further, Walker, Garber, and Greene (1994) found that children with recurrent abdominal pain who had the best health outcomes were those who actively attempted to manage their emotional reactions to pain, rather than isolating themselves. Passive coping was associated with increased levels of pain and somatic and depressive symptoms (Walker et al. (1997). In contrast, accommodative coping responses were generally related to decreased levels of pain. Active responses were associated with increased levels of pain and somatic complaints, but decreased depressive

symptoms. Thomsen, Compas, Colletti, Stanger, Boyer, et al. (2002) examined the relationships among coping, stress responses, pain, somatic symptoms, and anxious/depressed symptoms in a sample of children and adolescents with recurrent abdominal pain. Based on parent reports, children's primary control engagement coping (problem solving, emotional modulation) and secondary control engagement coping (acceptance, distraction, positive thinking) in response to pain were associated with fewer somatic complaints and symptoms of anxiety and depression; secondary control engagement coping was also associated with less pain. It also appears that appraisal of coping ability plays an important role in the relations between stress and recurrent abdominal pain (Walker, Smith, & Garber, 2006). Compared to healthy controls, pain patients were found to be less confident of their ability either to change or to adapt to stress and were less likely to use accommodative forms of coping.

Behavioral factors, such as operant principles and family modeling, have been cited as a possible factors involved in the etiology recurrent abdominal pain by encouraging maladaptive coping strategies. Children often experience positive consequences as a result of pain complaints (McGrath & Feldman, 1986; Walker et al., 1993). Adults encourage "illness behavior" by excusing children from school or household chores, allowing them to avoid difficult situations, or providing increased attention upon expression of pain symptoms (Fordyce, 1989; Jannicke & Finney, 1999). Walker et al. (1994) found that the parents of children with recurrent abdominal pain were more likely than parents of children without it to provide various kinds of encouragement for their children's abdominal complaints. Likewise, Walker and Zeman (1992) found that parents of children with recurrent abdominal pain encourage pain behavior through direct or indirect encouragement of pain behavior (operant conditioning) and help the child to adopt the sick role for gastrointestinal symptoms more

often than for other symptoms. Walker, Garber, Van Slyke, and Greene (1995) examined parents' reactions to somatic complaints associated with unexplained illness and demonstrated that parents tend to provide secondary gains in the presence of illness behavior. Specifically, parents responded with less anger, disappointment, and punishment to children who exhibited undesirable behavior associated with unexplained illness complaints than did parents who responded to their children who exhibited undesirable behavior not associated with illness complaints.

Some studies have reported a relationship between childhood recurrent abdominal pain and a family history of chronic pain (Oster, 1972; Robinson et al., 1990; Stone & Barbero, 1970). Specifically, children with recurrent abdominal pain often have at least one parent who also suffers from functional abdominal pain (Hughes & Zimin, 1978; MacKeith & O'Neil, 1951; Joyce & Walshe, 1980). These findings make modeling of sickness behavior a potentially important factor in the development of this condition. In modeling theories, the child observes the pain complaints and corresponding contingencies experienced by another individual (family member) and then adopts this strategy to deal with his or her own personal stressors (Janicke & Finney, 1999). Jamison and Walker (1992) found that children of patients with chronic pain reported more frequent abdominal pain and used more medication than children of parents without pain. They also reported that perceived somatic complaints in children were associated with higher levels of parent disability, pain behavior, and emotional distress. Robinson et al. (1990) found that parents of children with recurrent abdominal pain report a variety of somatic symptoms to a greater extent than parents of children without recurrent abdominal pain. Conversely, others have found little relationship between recurrent abdominal pain and parental or sibling reports of pain and put less

emphasis on modeling of pain behaviors as a factor in recurrent abdominal pain (McGrath et al., 1983; Sanders et al., 1990).

Parental psychopathology or psychological symptoms may be another important factor in this population. Parents of children with recurrent abdominal pain report higher levels of anxiety, depression, and somatic symptoms than those of unaffected controls (Mortimer et al., 1992; Zuckerman, Stevenson, Bailey, 1987; Garber, Zeman, Walker, 1990; Hodges, Kline, Barbero, Flanery, 1985; Hodges, Kline, Barbero, Woodruff, 1985) In fact, levels of anxiety and depression are indistinguishable from mothers of psychiatrically referred children (Garber, Zeman, Walker, 1990; Hodges, Kline, Barbero, Flanery, 1985). Children of parents with anxiety disorders report more somatic complaints than children of non-anxious parents (Turner, Beidel, Costello, 1987). This association between parental psychological symptoms and childhood recurrent abdominal pain could be related to a genetic disposition of anxiety and other psychological symptoms that make children vulnerable to this pain condition. Alternatively, it could be an environmental factor that adds chronic stress to the child and results in the development of recurrent abdominal pain.

The family environment of children with recurrent abdominal pain has been studied to a limited degree as a potential etiological factor. It appears that there are no differences between families of children with recurrent abdominal pain and control families on measures of marital satisfaction and cohesion (McGrath et al., 1983; Walker, Garber, Greene, 1993). Also, Walker et al. (1993) compared recurrent abdominal pain, peptic ulcer, and control families on three subscales of the Family Environment Scale along with the Family Relationship Index (Holahan & Moos, 1983) and found no significant differences between these groups in regards to family environment. Wasserman et al. (1988) and Sanders et al. (1990) also used the Family Environment Scale with recurrent abdominal pain families and



matched control groups and once again found no differences on this measure. Sanders, Rebgetz, Morrison, Bar, Gordon et al. (1989) used videotapes of child and parent behavior, and found no differences between a group of recurrent abdominal pain families and matched controls on maternal aversive behavior and child deviant behavior.

### Treatment of Recurrent Abdominal Pain in Children

The treatment of recurrent abdominal pain and abdominal pain-related functional GI disorders has received limited empirical attention (see Janicke & Finney, 1999; Scharff, 1997; and Weydert, Ball, and Davis, 2003 for reviews). Treatments can be split up into pharmacological treatment, dietary treatment, and psychological treatment. Traditional or standard treatment for recurrent abdominal pain has consisted of support and reassurance about the absence of disease processes in the recurrent pain (Edwards, Mullins, Johnson, & Bernard, 1994; Scharff, 1997). However, assurance and support as a treatment appears to provide little benefit in comparison to spontaneous remission rates, and the symptoms of functional abdominal pain can persist into adulthood in patients treated in this manner (Sharff, 1997).

#### *Pharmacological treatment*

The treatment of recurrent abdominal pain or abdominal pain-related functional GI disorders with pharmacology is very limited. Medications such as antidepressants and anticholinergics are increasingly used without good evidence for efficacy (Dorn et al., 2003; Huertas-Ceballos, Macarthur, Logan, 2002; Hyams & Hyman, 1998). Only three studies have formally evaluated the use of pharmaceuticals for these conditions. Famotidine, an H<sub>2</sub>-receptor antagonist, was tested on 25 children in a double-blind, placebo controlled, crossover

trial (See, Birnbaum, Schechter, Goldenberg, & Benkov, 2001). Famotidine may be effective in treating children with recurrent abdominal pain, especially when dyspeptic symptoms dominate the clinical presentation. Pizotifen, a serotonin antagonist, was tested on 14 children in a randomized, double-blind, crossover trial (Symon and Russell, 1995). They found that Pizotifen might be an effective treatment when used prophylactically in children specifically with abdominal migraine. However, Pizotifen is not approved for use in the United States. Lastly, Campo, Perel, Lucas, Bridge, Ehman (2004) evaluated the use of citalopram (Celexa), a selective serotonin reuptake inhibitor, for the treatment of functional pediatric recurrent abdominal pain in an open-labeled trial with twenty-five clinical patients. They found that citalopram was successful in treating pain and it also had significant decreases in anxiety, depression, somatization, and functional impairment.

#### *Dietary treatment*

Treatment of recurrent abdominal pain with dietary changes is limited to fiber treatments and lactose avoidance (Weydert et al., 2003). Janicke and Finney (1999) concluded that fiber is a promising intervention for treatment of recurrent abdominal pain associated with constipation; but the data do not support such a designation for recurrent abdominal pain without constipation. Feldman, McGrath, Hodgson, Ritter, and Shipman (1985) found that fiber was effective in reducing the frequency of pain. Conversely, Christensen (1986) found no difference in the number of pain episodes between treatment and control groups. Edwards and colleagues (1991) investigated the efficacy of fiber versus relaxation treatment and found that children with symptoms of constipation responded positively to fiber treatments, while only minimal support was provided for the use of relaxation training for children without the presenting symptoms of constipation. In

conclusion, evidence supporting the use of fiber in recurrent abdominal pain is weak at best, and at worst inconclusive (Weydert et al., 2003). Lactose avoidance has been tested as a treatment for recurrent abdominal pain as well (Dearlove, Dearlove, Pearl, & Primavesi, 1983; Lebenthal, Rossi, Nord, & Branski, 1981) and there seems to be no association between recurrent abdominal pain in children and lactose intolerance.

### *Psychological treatment*

From what we know about the biopsychosocial nature of recurrent abdominal pain and abdominal pain-related functional GI disorders, it is not surprising that the most promising treatments for this condition reported in the literature are psychological. A review of treatments for recurrent abdominal pain concluded that the psychological therapies, specifically cognitive-behavioral therapies, met criteria for a probably efficacious intervention (Janicke & Finney, 1999), only needing more independent research studies to be considered an efficacious treatment. Multiple investigations have now supported cognitive-behavioral therapies as successful in treating recurrent abdominal pain by reducing pain and related disability (Ball, Shapiro, Monheim, Weydert, 2003; Humphreys & Gevirtz, 2000; Robins, Smith, Glutting, Bishop, 2005; Sanders et al., 1989; Sanders, Shepard, Cleghorn, Woolford, 1994; Youseff, Rosh, Laughran, Schuckalo, Cotter et al., 2004). Cognitive-behavioral therapies have been found to be beneficial in children with other chronic disorders, such as migraine, pain associated with medical procedures, chronic pain syndromes, and cystic fibrosis (Chen, Joseph, & Zeltzer, 2000; Olness, 1989; Zeltzer, Fanurik, LeBaron, 1989; Belsky & Khanna, 1994). In recurrent abdominal pain, cognitive-behavioral therapies specifically address some of the most important features of the condition, such as anxiety, coping, and pain modulation.

Research and development of psychological therapy for recurrent abdominal pain began with more basic approaches to treatment. The earliest investigations of psychological treatments for recurrent abdominal pain investigated the efficacy of behavioral interventions based on operant procedures in controlled case studies (Miller & Kratochwill, 1979; Sank & Biglan, 1974). Operant procedures are based on the supposition that secondary gain (attention, school avoidance) developed and reinforced the child's pain behaviors. Miller & Kratochwill (1979) used a time-out technique in controlled case study with a 10-year-old girl presenting with severe stomach pains. In this particular case it was hypothesized that parental attention was maintaining the pain behaviors; thus a time-out procedure that removed adult attention and social activities following pain complaints was implemented. The intervention resulted in decreased reports of pain at home and school. Similarly, Sank & Biglan (1974) used a token system with a 10-year-old boy to reinforce school attendance and to encourage behaviors not related to pain. The token system rewarded non-pain behaviors while attention was removed for pain complaints. The result was a decrease in the frequency of abdominal pain attacks and subsequent pain ratings and an increase in school attendance. Lastly, Wasserman (1978) used a simple positive reinforcement intervention for behaviors other than stomach pain complaints in a 12-year-old with treatment success reported.

Current understanding of recurrent abdominal pain and functional disorders as a condition with multiple etiological factors does not support the treatment of symptoms by operant procedures in isolation (Janicke & Finney, 1999). The three studies summarized above were successful in reducing verbal reports of pain, but the reduction of verbal pain reports may not be in the child's best interest if he or she is still suffering from pain. These treatments may work for those children that are reporting pain primarily for secondary gain, but it is likely that they do not address the psychological or psychosocial components to and

abdominal pain-related functional disorders. However, these studies served as a foundation for the establishment of alternative interventions, which include operant procedures as one fundamental element of a treatment program (eg. Cognitive-behavioral interventions) (Janicke & Finney, 1999).

Cognitive-behavioral interventions address the multi-factorial nature of recurrent abdominal pain and functional disorders. Common techniques that are part of a treatment package include relaxation (deep-breathing, muscle relaxation, guided imagery), cognitive change (coping, problem solving, thought-changing, stress-management), and behavioral change (staying active, avoiding the sick role, contingency management). Linton (1986) used a case study to describe the use of relaxation, coping skills, and social skills training to treat a 17-year-old young woman presenting with a two-year history of recurrent abdominal pain. Gradual improvements were noted on measures of pain intensity, mood, nausea, activity level, and general health and the patient presented as nearly pain free at 9 month follow-up. Humphreys & Gevirtz (2000) sought to test the effects of 4 different treatment modalities on symptoms of recurrent abdominal pain. They randomized children with abdominal pain into 1 of 4 experimental groups: 1) fiber only-10g/d-control group, 2) fiber plus biofeedback, 3) fiber, biofeedback, and cognitive-behavioral intervention, and 4) fiber, biofeedback, CBT, and parental support. In this study the CBT condition included relaxation training, self-management techniques, coping skills, and parental support included distraction techniques and care giving strategies. Outcomes included self-reported pain, parent observation, medication use, health care utilization, and school attendance. Main effects were reported for self-reported pain, parent's observation of the child asking for help, child's report of pain to parents, reduced medication use, and school absences, indicating improvements in all groups. The combined groups showed more improvement than the fiber-only group on self-reported

pain. Results indicate that combination of self-regulation and cognitive-behavioral therapies along with fiber intervention may be more effective for treating recurrent abdominal pain than using fiber alone.

Finney, Lemanek, Cataldo, Katz, & Fuqua (1989) used a multi-component behavioral treatment in 16 children with recurrent abdominal pain. Treatment was individually tailored to each based on symptoms identified in assessment. Elements of treatment consisted of monitoring of symptoms, limited parent attention or reinforcement of non-illness behavior, relaxation training, increased dietary fiber, and required school attendance. Results showed that 81% of the parents rated their children's pain symptoms as improved or resolved and that both medical use and school absenteeism declined after treatment. It is important to note that not all children received all 5 treatment components and it is difficult to determine what treatment entailed for the different research participants. Also, although a group of 16 matched controls was used as a comparison group to assess changes in health care use, a wait-list control or placebo group was not included in the study design to compare ongoing treatment effects and reductions in pain symptoms.

The most comprehensive evaluation of CBT treatments in recurrent abdominal pain have been carried out by Sanders and colleagues (1989, 1994). Sanders, Rebetz, Morrison, Bor, Gordon et al. (1989) evaluated an 8 week long multi-component treatment program by comparing it to a wait-list control condition. The treatment program was divided into parent training and stress management phases and consisted primarily of self-monitoring, differential reinforcement of competing activities, relaxation and imagery, and cognitive self-control strategies including self-efficacy statements, self-administration of rewards. Parents trained to prompt and reinforce appropriate coping behaviors. The program also included generalization enhancement and relapse prevention components. Children used a visual

analog scale to record estimates of pain intensity, with parents and teachers also providing systematic observations of the child's pain behavior. Both the treatment and wait-list groups showed improvements, the treatment group improved more quickly and to a greater extent than the wait-list control group in child and parent measures of pain over the course of the study. Specifically, 87.5% of the treatment group (seven of eight children), were pain-free at 3-month follow-up versus 37.5% (3 of eight) of the control group. One explanation for the improvement of the control subjects is that recurrent abdominal pain spontaneously remits in some children (Davison et al., 1986). The authors suggest that cognitive interventions that train children to attend to their cognitive construction of pain and to develop self-control strategies may increase their sense of personal control of pain. They suggest further research on factor analysis of active treatment components as well as improvements in cost effectiveness of this method of therapy and ways to streamline the approach in routine pediatric practice.

In a later study, Sanders, Shepherd, Cleghorn, and Woolford (1994) used the same treatment as described in the earlier study but compared it to assurance from a physician. The cognitive-behavioral family intervention consisted of three components delivered in six 50-minute sessions; an explanation for recurrent abdominal pain and rationale for pain management procedures, contingency management training for parents, and self-management training for children. Standard pediatric care controlled for professional contact and treatment expectancy by providing reassurance, support, and insistence that the child must learn to cope with the pain but did not provide training in specific coping skills. This study found that both groups improved in pain intensity and frequency, while children in the CBT group were more likely to be pain-free at post-treatment and follow-up.

More recently, Youseff, Rosh, Loughran, Schuckalo, Cotter et al., (2004) evaluated the efficacy of guided imagery and progressive relaxation in reducing both the abdominal pain and the negative social effects of childhood functional gastrointestinal disorders (FGIDs). Treatment sessions were weekly for 1 hour and consisted of stress reduction therapy (progressive muscle relaxation and deep breathing exercises) and cognitive behavioral therapy (guided imagery). Treatment also took place at home (self-guided) between sessions using recorded audiotapes from the first session. Children were instructed to listen to tapes nightly as they went to bed. Sessions continued weekly at the discretion of the treating therapist, patient, and family until adequate relief of symptoms was reported by the patient. All patients were re-evaluated a mean of  $10.6 \pm 2.3$  months from the time of the last session. The mean number of sessions per patient until adequate relief of symptoms was  $4.3 \pm 3.4$  (range, 3–9 sessions). Abdominal pain improved in 16 of 18 (89%) patients. There were fewer abdominal pain episodes per week, decreased intensity of pain, fewer missed school days per month, fewer physician office contacts per year, and improved quality of life. This studies limitation includes a small sample size and the lack of control for the intervention.

Ball, Shapiro, Monheim, and Weydert (2003) investigated whether relaxation with guided imagery would regulate gastrointestinal motility and raise visceral pain threshold in children with functional abdominal pain. Children with recurrent abdominal pain were classified into IBS, functional dyspepsia, or functional abdominal pain based on Rome II criteria and then assigned to either the treatment group or a wait-list control group. Children attended four 50 minute sessions starting with rationale, deep breathing, and progressive muscle relaxation. Once relaxed, the child was asked to "let her mind do some imagining" and guided imagery was started. Children were given a cassette tape of the session and practiced twice daily. Later sessions included demonstration of the technique with



appropriate guidance. The primary finding from this study was that children with long-standing recurrent abdominal pain that was refractory to conventional therapy had a decrease in their complaints of abdominal pain during and following training in relaxation and guided imagery. The study did not end up making a comparison to the wait-list control group because all families assigned to the wait-list group immediately withdrew their children. Also, the study has very low power and a small subject number (n= 10).

In a more recent study by Weydert and colleagues (Weydert, Shapiro, Acra, Monheim, Chambers, et al., 2006), the efficacy of guided imagery with progressive muscle relaxation was supported. This study investigated 22 children who were randomly assigned to learn either breathing exercises alone or guided imagery with progressive muscle relaxation. Both groups attended 4-weekly sessions with a therapist. Children who learned guided imagery with progressive muscle relaxation had significantly greater decreases in the number of days with pain than those learning breathing alone (67% versus 21%) and they also had significantly greater decreased days with missed activities (85% versus 15%).

Anbar (2001) evaluated a treatment of self-hypnosis for the treatment of functional abdominal pain. This study also had a very small subject number with only 5 patients enrolled. Functional abdominal pain in 4 of 5 patients resolved within 3 weeks after a single session of instruction in self-hypnosis. In this study, imagery used for hypnosis was developed with input from each patient. (1) imagination of what might be perceived by all 5 senses in a relaxing place of the patients' choice; (2) progressive relaxation from head to feet; (3) choosing a sign as a reminder of how to relax when the patient is not in a state of hypnosis; (4) an opportunity to control the abdominal pain by its hypnotic induction and resolution; and (5) complimenting the patients on their hypnotic abilities. In the examples

given, the patient with motivation and positive expectancy was helped by hypnosis while the patient with skepticism and lack of motivation for hypnosis was not helped.

Robins, Smith, Glutting, Bishop (2005) investigated whether the combination of standard medical care and short-term CBT family treatment in the treatment of recurrent abdominal pain was more effective than standard medical care alone. Children recently diagnosed with recurrent abdominal pain were randomized into standard medical care (n= 29) and standard medical care plus CBT (n= 40). Outcomes included child pain reported by child and parent, somatization, and functional disability, and school absences and physician contacts. The group who received standard medical care plus CBT reported significantly less child and parent reported child pain than children in the standard medical care alone group immediately following the intervention and up to 1 year after study entry. Patients in the CBT group also had fewer school absences. However, there were no differences in functional disability and somatization.

To summarize current research on psychological treatment of recurrent abdominal pain, there is evidence that cognitive-behavioral therapy techniques are efficacious in the treatment of pain and some associated symptoms in children with recurrent abdominal pain. However, there are some important issues that need to be addressed in future research on the treatment of abdominal pain-related functional GI disorders. First, there needs to be diagnostic specificity among patients under the general description of recurrent abdominal pain. Heterogeneity of recurrent abdominal pain could lead to inconsistent outcomes in treatment studies and make results difficult to interpret. Future research should consistently use Rome III criteria for abdominal pain-related functional GI disorders to accurately and completely distinguish between patient groups. This information will allow treatment components to be matched to each individual's problem presentation. Second, intervention

studies need to be repeatedly replicated in different samples and when possible further supported with long-term follow-up. Third, there is often a problem of selection bias in intervention studies due to the long-term nature of the study and the increased burden on the participants. Those that choose to participate and remain in studies are often highly motivated to change and have the organizational skills necessary to complete the protocol. However, these characteristics may not generalize to the majority of individuals and families who deal with abdominal pain-related function disorders. Researchers need to be cognizant of this fact and develop research protocols that are less demanding on participants; this may include shorter durations of data collection and more positive incentive for participation. Another specific problem with methodology was apparent in the study done by Ball et al., (2003). In this study the participants assigned to the wait-list control condition immediately withdrew from the study, indicating that families with recurrent abdominal pain may not be willing to delay treatment. When a wait-list condition is used in future research, the time-frame for the condition will need to be minimized as much as possible. This will make treatment available after a short period of time. However, this will make it difficult to do group comparisons in long-term follow-up.

#### Minimal Contact Interventions and Technology for Pediatric Chronic Pain Conditions

The further development of abbreviated intervention programs or minimal contact (MC) interventions has been a growing trend in the literature. This movement has been driven by goals to address concerns about costs of treatment to families and to make treatment more streamlined and available within pediatric practice. A survey of practicing pediatricians found that pediatricians rarely consulted mental health professionals in the management of recurrent abdominal pain (Edwards, Mulline, Johnson, Bernard, 1994). The

primary reasons cited for the lack of referrals were concerns about cost, family resistance, and personal beliefs about the natural course of the disorder. Unfortunately, these barriers could potentially impede the process of finding appropriate and cost-effective therapy for children with recurrent abdominal pain.

There are numerous advantages to minimal contact interventions: (a) they can take place in a setting where the problem most frequently occurs, (b) they can provide an opportunity for the application of preventive rather than only curative strategies, (c) they can reduce the amount of school missed for clinic appointments, (d) they can increase accessibility to those living far away from a clinic, and (e) they can increase cost-effectiveness.

There have been only a few studies on minimal contact (MC) treatments for chronic or recurrent pediatric pain, with most of these focusing on pediatric headache. Studies comparing MC behavioral interventions versus clinic-based approaches have found that both treatment groups had lower pain intensity compared to control groups (Hicks, von Bayer, & McGrath, 2006; McGrath, Waters, Moon, 1992). These different MC protocols often range significantly on their definition of minimal contact. Some of the interventions are single clinic sessions while others are several clinic sessions. Research looking at minimal contact interventions for functional abdominal pain is limited. Ball et al. (2003) administered relaxation strategies over a period of four 50-minute sessions. They found that children with long-standing functional abdominal pain that was refractory to conventional therapy had a decrease in their complaints of abdominal pain following training in relaxation and guided imagery. Anbar (2001) found that 4 of 5 patients with functional abdominal pain resolved within 3 weeks after a single session of instruction in self-hypnosis. Also, Sanders et al. (1994) and Robins et al. (2005) showed improved abdominal pain in children after relatively

short CBT interventions (6 sessions and 5 sessions respectively). More recently, Hicks, von Baeyer, & McGrath (2006) used a randomized wait-list control design with an internet-based CBT program for children with recurrent headaches and recurrent abdominal pain. This study found that the treatment group showed a higher percentage of clinically significant improvement (defined as 50% or greater reduction in pain intensity) than the wait-list control group.

Another trend in the pediatric pain literature has been the increased use of technology for the assessment and treatment of chronic pain conditions (McGrath, Watters, & Moon, 2006). Technology uses in pediatric pain have included videoconferencing, telephone-enabled interventions, web-enabled interventions, private computer networks, computer kiosks, and personal digital assistants. In general, the use of computer technology in health care treatment has increased over the past several years as can be seen in the implementation of what has been labeled “telemedicine” or “telehealth” (Farmer & Muhlenbruck, 2001; Maheu, 2001; Maheu, Whitten, & Allen, 2001; Nickelson, 1996, 1998). Most of the research on telehealth or computer based interventions has focused primarily on education and improving knowledge (Homer, Susskind, Alpert, Owusu, Schneider, et al., 2000; Rubin, Leventhal, Sadock, Letovsky, Schottland, et al., 1986). A review article of computer-based approaches to patient education found that 16-21 research-based studies had medium to high effect sizes, suggesting that computer-based education is an effective strategy for improving knowledge in individuals from medical populations (Lewis, 1999). More recent applications of computer-based technologies have focused more on intervention. For example, Ritterband and colleagues (2003) reported findings from a web-based family intervention for pediatric encopresis. Another recent study reported on the initial testing of a CD-ROM program for children and adolescents with cystic fibrosis (Davis, Quittner, Stack, & Yang, 2004). The use

of multimedia or computer-based programs for psychological treatments has received attention because of the potential for a positive impact on the cost and/or availability of mental health services; combining research on the use of technology with minimal contact interventions (Greist, 1989; Colby, Gould, Aronson, 1989; Selmi, Klein, Greist, et al., 1990; Wright, Salmon, Wright, et al., 1995).

The use of an interactive CD-ROM program as a minimal contact intervention for pediatric populations with chronic or recurrent pain conditions was initially introduced by Connelly and colleagues (2006) in the development and investigation of the “Headstrong” program. This study utilized a CD-ROM based cognitive-behavioral program for the treatment of recurrent pediatric headache. Thirty-seven children aged 7-12 were randomly assigned to either the treatment group or wait-list control group. Children in the treatment group worked through the “Headstrong” program on their home computer for a period of 4 weeks. Children who completed the program showed significant decreases in headache activity.

The “Headstrong” program provided a model for an effective and engaging program for treating chronic pain conditions in children; one that can be easily adapted to multiple types of pain. The advantages of a CD-ROM program for the adjunct treatment of functional abdominal pain include all those associated with minimal contact interventions mentioned previously. In addition, computer-based interventions can be developmentally tailored, individualized, updated, easily disseminated, family-oriented, and delivered in a format that has become commonplace and readily accessible in American culture.

### Program Development and The Present Study

The primary goals of this project were to develop a minimal contact intervention titled “Gutstrong” for teenagers with recurrent abdominal pain and to conduct a pilot study to give preliminary investigation to the utility of the program. The “Gutstrong” program is an interactive program that aims to address some of the difficulties with psychological treatment of teenagers with this type of chronic pain. If successful, the “Gutstrong” program could provide an alternative option as a cost-effective and efficacious treatment for abdominal pain. Future studies would test the feasibility and effectiveness of having clinics disseminate the program, and the efficacy of using such an approach for other chronic pain conditions in children.

The CD-ROM developed for the present study contains both an education component and a treatment component that is based on empirically supported cognitive-behavioral techniques and the biopsychosocial model of pain (see Table 2). The theoretical foundation on which the Gutstrong program is based is the “pain-puzzle” model (Rapoff & Lindsley, 2000). The model specifies that there are multiple dimensions of pain (nociception, thoughts, feelings, and behavior), with each dimension contributing in interactive ways to the overall experience of pain. This model also incorporates the basic ideas of the “pain-gate control theory” initially proposed by Melzack & Wall (1965). The education component of “Gutstrong” presents developmentally appropriate information on the diagnosis and assessment, prevalence, possible etiologies, and experience of functional abdominal pain symptoms. The treatment component of the CD-ROM intervention is set up to be completed in three weeks. The content includes lessons that focus on teaching various psychological treatments for the self-management of stress and pain. Incorporated within the lessons are exercises and other opportunities to use the new skills that the program is teaching. One

Table 2: Outline of the "Gutstrong" CD-ROM.

Lesson	Introduction	Module #1 Education	Module #2 Relaxation	Module #3 Coping	Module #4 Behavior
1	How to use the program	What is a functional GI disorder.	Introduction to Relaxation.	Coping with stress and pain.	Why are stress and pain behaviors important?
2	Goals of the program	How do doctors diagnose functional GI disorders?	Deep-breathing	Positive Thinking	Stress and pain behavior management.
3		Who gets functional GI disorders?	Imagery	Problem-solving	Staying active and creating a pain plan.
4		How are functional GI disorders treated?	Muscle Relaxation	Other coping strategies.	Review of Gutstrong.
5		Learning about pain: the pain puzzle and pain gate?			
6		What might be affecting my gut pain?			
HW		Why is Pain so Puzzling?	Practice relaxation using CD.	Thought-changing exercises.  Problem-solving exercises.  Continue practicing relaxation.	Stress and pain behaviors worksheet.  Your Pain Plan



week of lessons on the treatment component focuses on relaxation training and the use of deep-breathing, guided imagery, and progressive muscle relaxation. Another week of lessons focuses on cognitive aspects of stress and pain management and includes training in positive-thinking, systematic problem-solving, and other coping strategies such as mental rehearsal. The third week of the treatment component focuses on pain and stress behavior management and discusses the need to stay active and have a plan for the management of pain. At the end of the program all the lessons are briefly reviewed. The “Gutstrong” program is accompanied by a workbook containing all the supplementary materials required for the intervention (review exercises, summary sheets, password records). Parents are also given a manual containing information about the program, their role in the intervention, and technical assistance information.

#### Research hypotheses for this Pilot Study

The goal of this study was an initial investigation of the utility of the “Gutstrong” program in teenagers with abdominal pain-related functional gastrointestinal disorders.

Primary hypotheses evaluated included the following:

1) Teenagers 13-17 years of age with abdominal pain-related functional GI disorders who received the "Gutstrong" program in combination with standard medical care will self-report improvement in abdominal pain indices of frequency, severity, and duration from the baseline period to the immediate post-treatment period. In addition, teenagers who completed the "Gutstrong" program will report greater improvements in these abdominal pain indices than teenagers in a standard medical-care only/ wait-list control group at immediate post-treatment.

2) Teenagers who completed the “Gutstrong” program in combination with standard medical care will self-report higher levels of quality of life during the immediate post-treatment relative to their baseline indices. In addition, teenagers who completed the "Gutstrong" group will self-report higher levels of quality of life relative to teenagers in the standard medical-care only/ wait-list control group at immediate post-treatment.

Secondary hypotheses evaluated included the following:

1) Teenagers who completed the “Gutstrong” program in combination with standard medical care will self-report increased levels of positive daily mood and decreased numbers of daily stressors in the immediate post-treatment period when compared to their baseline indices. In addition, teenagers who completed the “Gutstrong” program will self-report more positive daily mood and less daily stressors during the immediate post-treatment period relative to teenagers in the standard medical care only/wait-list control group.

2) Teenagers who completed the "Gutstrong" program in combination with standard medical care will self-report increases in active and accommodative coping and decreases in passive coping from the baseline period to the immediate post-treatment period. In addition, teenagers who completed the “Gutstrong” program will self-report greater increases in active and accommodative coping and greater decreases in passive coping during the immediate post-treatment period relative to teenagers in the standard medical care only/wait-list control group.

## Chapter 2: Method

### Participants

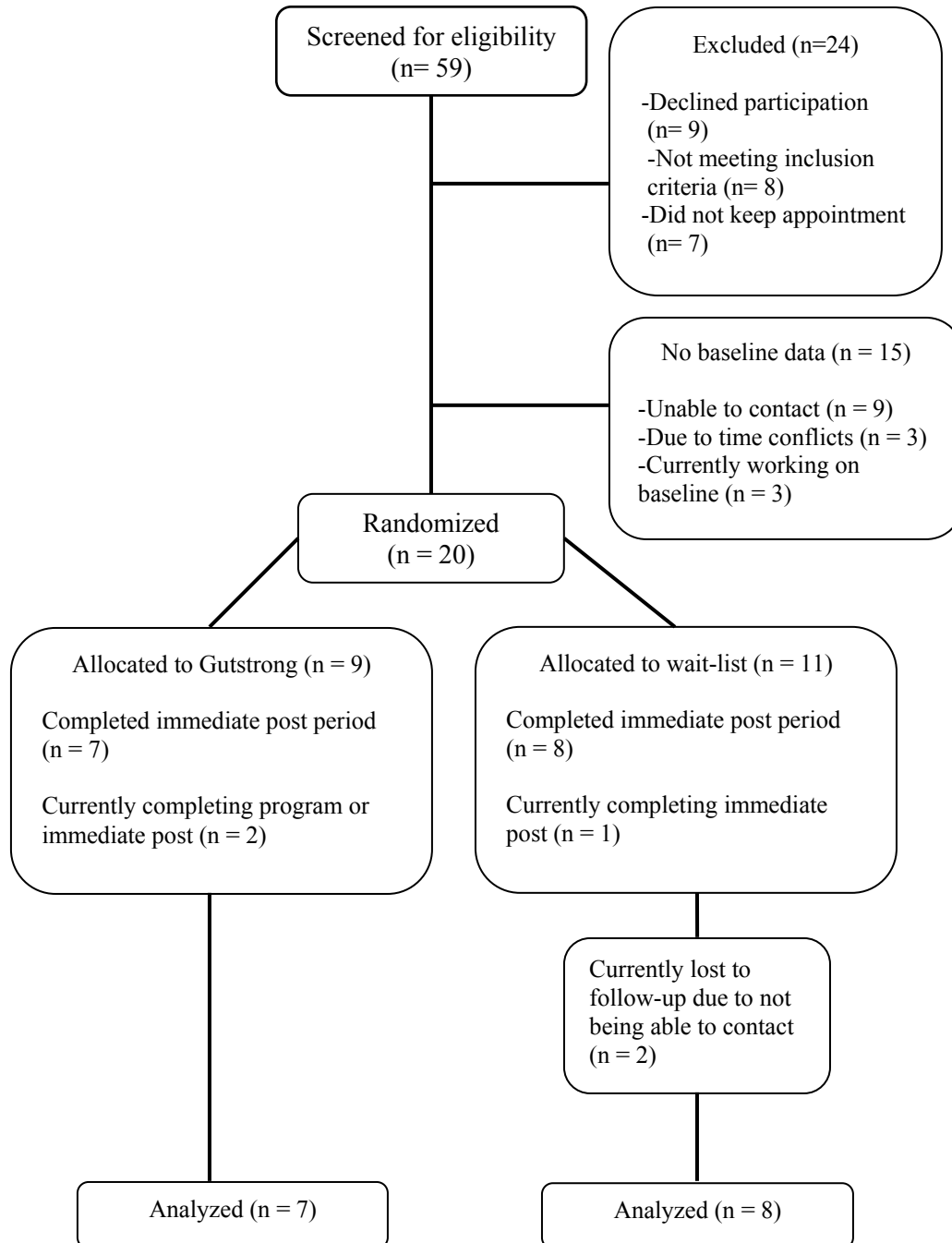
The study sample included teenagers aged 13-17 years recruited to the study during their clinical appointments in the Abdominal Pain Clinic at Children's Mercy Hospital and Clinics in Kansas City, Missouri.

Inclusion criteria. Teenagers were included in this study sample if they were (a) 13-17 years of age; (b) they were diagnosed with an abdominal pain-related functional GI disorder by a pediatric gastroenterologist based on the Rome III criteria (Rasquin et al., 2006) including functional dyspepsia, irritable bowel syndrome, functional abdominal pain or functional abdominal pain syndrome, or some combination of these diagnoses; and (c) they reported pain episodes on average of at least once per week by self-report. The age range of 13-17 was used because it is reported in the literature that 13% of middle school and 17% of high school students experience functional abdominal pain at least weekly (Hyams, Burke, Davis, Rzepski, & Andrulonis, 1996). In addition, this version of the "Gutstrong" program was designed to be developmentally appropriate for young teenagers. The diagnostic categories of functional dyspepsia, irritable bowel syndrome, and functional abdominal pain syndrome are the most prevalent in the population. In addition, the "Gutstrong" program was specifically designed to target these symptom presentations. Access to a computer with a CD-ROM drive was a necessary requirement for participation in this study. For teenagers that did not have home access to a computer, arrangements would have been made with their school to allow for the occasional use of a computer over the course of the intervention. However, no such arrangements had to be made given that all participants enrolled in the study had either home access to a computer or access to a computer at a nearby relative's house.

Exclusion criteria. Participants were not eligible for participation in this study if (a) their medical history or exam suggested that their abdominal pain was secondary to another physical or developmental condition; (b) they were currently receiving psychotherapy or other counseling services or were planning to begin such services during the study period; (c) they did not speak English; or (d) if their baseline pain diaries indicated an average pain frequency of less than once per week. Teenagers with another physical or developmental condition were excluded to ensure that the "Gutstrong" program is treating abdominal pain-related functional GI disorders. If potential subjects were currently receiving psychotherapy or counseling in another setting, it was important to exclude them to ensure that the "Gutstrong" program was the variable responsible for change in these patients. Lastly, the "Gutstrong" program was designed in English and is not available in different languages at this time. Future development of this program could include the translation to other languages.

Figure 1 shows the number of teenagers assessed for eligibility, not meeting inclusion/exclusion criteria, enrolled in the study, allocated to conditions, and analyzed in the current write-up. Fifty-nine teenagers attending the Abdominal Pain Clinic at Children's Mercy Hospital and Clinics in Kansas City for an initial abdominal pain evaluation were identified prior to their appointment as potential candidates by the clinic's nursing staff. Of these, 7 teenagers did not keep their appointment or were rescheduled and therefore could not be recruited. In those that did keep their appointment, 8 teenagers were not eligible due to inclusion/exclusion criteria, 6 were currently receiving some form of psychological services, 1 did not meet abdominal pain diagnostic criteria, and 1 reported having an average of fewer than one pain episode per week. Nine teenagers declined participation in the study due to the

Figure 1: Number of participants screened, enrolled, randomized or allocated to groups, and analyzed at the time of this writing.



time commitment or a lack of interest. Thirty-five teenagers initially agreed to participate and were enrolled into the study. However, fifteen of these participants have not completed the baseline period of the study and therefore not randomized to treatment conditions. Of the fifteen participants that have not completed baseline, nine never began submitting the baseline measures and could not be contacted by phone or email during the baseline period and three participants asked to discontinue the study because of the time-commitment. At the time of this writing, three participants had requested to start baseline at a later date or were currently working on baseline. This left a sample of 20 teenagers (16 females, 4 males) for whom complete baseline measures were obtained.

The demographic information for all enrolled participants (n=35) revealed that the sample was predominately Caucasian (n= 30, 86%). The remainder of the self-identified ethnic breakdown was 1 African American, 1 Hispanic, and 3 who identified as multiple ethnicity. Gender distribution was 9 males (26%) and 26 females (74%). All participants had either a diagnosis of functional dyspepsia or irritable bowel syndrome, with 9 participants having both diagnoses (26%). Nineteen participants had a diagnosis of functional dyspepsia only (54%) and 7 participants had a diagnosis of irritable bowel syndrome only (20%). The median symptom duration for the enrolled participants was 12 months (M = 19 months, SD = 25.4 months). Every participant in the sample was either prescribed or taking over-the-counter medication for their abdominal symptoms at the time of enrollment. Fifteen participants (43%) were taking more than one type of medication for their symptoms. Singulair® (43%), Zantac® (37%) and other acid suppression medications (31%) (such as Nexium®, Prilosec®, Aciphex®) were the most commonly reported medications. Other medications were reported in 23% of the participants and included amytriptyline,

anticholinergics, anti-inflammatories, and laxatives. The majority of participant families reported parents that were married (74%), while 17% reported parents that were divorced and 9% reported single parents. The majority of the sample (57%) reported annual family income of at least middle class (which was defined as above \$50,000 per/year).

Analyses were done to evaluate potential differences between those participants that completed baseline and those that either dropped out of the study or never began the baseline period. There were no significant differences on the variables of age,  $t(30) = 1.66, p = .10$ , sex,  $\chi^2(1, 32) = 1.74, p = .24$ , age at diagnosis,  $t(30.96) = 1.80, p = .08$ , age at initial symptoms,  $t(14) = .77, p = .45$ , symptom duration,  $t(11.8) = 1.85, p = .08$ , age at initial treatment,  $t(14.42) = .18, p = .85$ , type of diagnosis,  $\chi^2(2, 32) = 4.33, p = .11$ , family income (coded as high versus low),  $\chi^2(1, 32) = 1.10, p = .31$ , behavior assessment system for children-2<sup>nd</sup> edition (BASC-2) internalizing symptoms,  $t(18.3) = .41, p = .68$ , BASC-2 emotional symptoms index,  $t(15) = 1.17, p = .26$ , BASC-2 inattentive/hyperactive symptoms,  $t(19.74) = .83, p = .83$ , BASC-2 personal adjustment symptoms,  $t(17.37) = 1.41, p = .17$ . There was a significant difference between those that completed baseline and those that didn't on the BASC-2 school problems scale,  $t(16.5) = .245, p = .02$ . Participants who did not complete the baseline phase scored significantly higher on this scale than those that completed baseline (completed  $M=46.35, SD=9.13$ ; not completed  $M=61.25, SD=14.25$ ) indicating more problems with attitudes related to school and teachers. This finding may be important for understanding why those participants were not able to complete the study. They may have more difficulty with task demands that are present in the school setting and in this research study.

## Measures

*Demographics Form:* Demographic data was obtained at the initial meeting with participants and their families in the Abdominal Pain Clinic. Demographic information included participant's age and birthdate, gender, grade in school, diagnosis, date of initial symptoms, date of initial diagnosis, date of initial treatment, prescribed medications, whether or not they are receiving on-going psychological services, parental age, marital status, education, occupation, and family income.

### Behavior Assessment System for Children-2<sup>nd</sup> Edition (BASC-2) (Adolescent Self-Report)

(Reynolds & Kamphaus, 2004). The BASC-2 Adolescent self-report measure was completed by the teenager at the initial meeting in the clinic. The BASC-2 is a standardized assessment system designed to evaluate the behavior and self-perceptions of children and adolescents.

The measure is considered multidimensional in that it measures numerous aspects of behavior and personality, including positive or adaptive as well as negative or clinical dimensions.

The structure of scales and composites was based on factor analyses of items and scales. The composite scales of the BASC-2 Adolescent Report include the Emotional Symptoms Index, the Inattention/Hyperactivity Index, Internalizing Problems, Personal Adjustment, and School Problems. Individual scales include anxiety, attention problems, attitude to school, attitude to teachers, atypicality, depression, hyperactivity, interpersonal relations, locus of control, relations with parents, self-esteem, self-reliance, sensation-seeking, sense of inadequacy, social stress, and somatization. The items on the self-report BASC-2 are descriptions of positive and negative personality traits, thoughts, attitudes, feelings, and behaviors. The scale has items in two different forms; a True or False format and a Likert scale format consisting of never, sometimes, often, or almost always. Raw scores are standardized as T-scores



(M=50; SD=10) based on a normative sample of children aged 12-18 for the adolescent self-report measure. Reliability coefficients for the composites and scales of the BASC-2 were evaluated in the normative sample of 3,400 children and adolescents (Reynolds & Kamphaus, 2004). The measure was found to have well supported internal consistency for the BASC-2 Composites ( $\alpha = 0.90$  for ages 12-14; 0.89 for ages 15-18) and individual scales ( $\alpha = 0.82$  for ages 12-14; 0.79 for ages 15-18). The test-retest reliabilities have also been well supported for the Composites ( $\alpha = 0.82$ ) and individual scales ( $\alpha = 0.75$ ). Thus, the BASC-2 appears to be a reliable measure of a wide-range of psychological variables in adolescents.

The BASC-2 is commonly used in clinical and educational settings to facilitate diagnosis for a variety of emotional and behavioral disorders of children and to aid in intervention planning. This measure has not been used regularly in prior research with recurrent abdominal pain. However, previous research on children and adolescents with recurrent abdominal pain has shown that consideration of psychological and personality factors is important. In the current study, this measure was used primarily to evaluate potential differences on psychological variables between-subjects. Based on previous research on psychological factors in this population, it is expected that the sample will elevate scales related to internalizing symptoms (combined anxiety, depression, and somatization scales). This measure has an advantage over other broad-band scales of psychological functioning because items from the depression and anxiety scales do not overlap, leading to better specificity for these two important variables.

Daily Pain Diary: (see Appendix A). The primary outcome variables of pain frequency of episodes, pain duration, and pain severity were obtained from pain diaries filled out by the adolescent. The pain diary format used in the current study is adapted from previous research

on chronic pain in children, primarily headache (Connelly et al., 2006). It was formatted to an electronic-form and included on a website dedicated to this study, titled [www.gutstrong.com](http://www.gutstrong.com). One of the strengths of this data collection format was the ability to monitor for missing data points. If a daily diary was submitted with missing information, a brief contact was made to request the missing information. Each participant was asked to complete the diary at the end of the day during the appropriate study phases. Participants were asked to record the presence of pain episodes each day using Yes/No radio buttons. For each episode of pain, they were asked about the duration and severity. Duration included options of clicking “constant” for the day and the ability to type in time periods during the day that they had pain. Pain severity was rated using a scale from 1 (no pain) to 10 (severe pain) using 10 different radio buttons. This measure also incorporated “pain face” anchors to provide additional support for rating pain severity. The diary format employed in the current study has been successfully used in previous studies of children with chronic pain (Connelly et al., 2006; Engel & Rapoff, 1990a, 1990b; Engel, Rapoff, & Pressman, 1992, 1994).

A daily mood rating was also included as part of the daily pain diary using the Facial Affective Scale (FAS) (McGrath, 1991). The FAS is a measure that uses 9 faces that vary in their expression of distress. The adolescent was asked to pick the face that best captured how he or she felt overall that day “deep down inside”. Numerical values have been scaled experimentally and transformed to a 0 to 1 scale for this measure. The FAS has been used as a measure of daily mood in chronic pain patients across a wide age-range (including teenagers) and has been shown to be reliable and valid (McGrath, 1991). Lastly, a measure of daily stress was obtained by asking the participants to select the occurrence of any one or more of 17 common potentially stressful events from a daily events inventory (Schanberg, Sandstrom, Starr, Gil, Lefebvre, et al., 2000).

Pediatric Quality of Life Inventory 4.0 (PedsQL) (Varni, Seid, & Rode, 1999): (See Appendix B). Pain measures such as frequency, duration, and intensity may fail to capture the important outcomes of treatment related to functioning and quality of life. Therefore, quality of life measures should be considered as a means of assessing treatment response in chronic pain populations. The present study used the fourth edition of the Pediatric Quality of Life Inventory, Generic Core Scales (PedsQL 4.0) on the studies web-site. The PedsQL 4<sup>th</sup> edition uses a modular approach to measuring health-related quality of life in children. The Generic Core Scales have children report on various aspects of physical functioning (8 items), emotional functioning (5 items), social functioning (5 items), and school functioning (5 items). Participants report the extent to which they are having problems in each of the above areas using a 5-point Lickert type scale with options of 0 (never a problem), 1 (almost never), 2 (sometimes), 3 (often), and 4 (always a problem) (see Appendix C). Items are then reverse-scored and linearly transformed to a 0-100 scale such that higher scores indicate better health-related quality of life. The minimum and maximum values for the PedsQL 4.0 scales are 0 (poorest quality of life) to 100 (excellent quality of life). In the PedsQL 4.0 Generic Core Scales field trial, 1,677 families completed the instrument and internal consistency reliabilities for all scales were satisfactory for group comparisons (Total  $\alpha= 0.88$  child; Physical Health  $\alpha= 0.80$ , Psychosocial Health  $\alpha= 0.83$ ). The PedsQL 4.0 Generic Core Scales also was shown to distinguish between healthy children and children with acute or chronic health conditions, was related to indicators of morbidity and illness burden, and displayed a factor-derived solution largely consistent with a priori conceptually derived scales. Therefore, the PedsQL 4.0 appears to be a reliable and valid measure of quality of life in children.

Pain Response Inventory (PRI) (Walker, Smith, Garber, & Van Slyke, 1997). (See Appendix C). The Pain Response Inventory was developed as a multidimensional instrument to assess children's coping responses to recurrent pain. The PRI assesses 3 broad coping factors- Active, Passive, and Accommodative. Each of these factors includes subscales representing specific strategies for coping with pain, with a total of 13 subscales and 60 items (see Appendix C). The Active coping factor includes subscales of problem-solving, seeking social support, rest, massage/guard, condition-specific; the Passive coping factor includes behavioral disengagement, self-isolation, and catastrophizing; the Accommodative coping factor includes acceptance, minimizing pain, self-encouragement, distract/ignore, and stoicism. The PRI's factors and subscales were developed with confirmatory factor analysis to derive and cross-validate the structure using three different samples; school children (N= 688), abdominal pain clinic patients (N= 158), and former abdominal pain clinic patients (N= 175) (Walker et al., 1997). The subscales were found to be internally consistent across the different samples (range of  $\alpha$ = 0.69 to 0.89 for clinic patient sample). Validity of the subscales was assessed by examining the relations of particular coping strategies to various outcome indicators, including functional disability, somatization symptoms, and depressive symptoms. Results indicated that different types of health outcome were predicted by different patterns of PRI coping strategies, supporting the utility of this multidimensional approach to the assessment of coping (Walker et al., 1997). In the current study, the PRI will be used to evaluate if the "Gutstrong" program is successful in changing the participants coping strategies.

Satisfaction Questionnaires. (See Appendix D). In order to obtain user feedback about the "Gutstrong" CD-ROM for future development and improvement, a short satisfaction questionnaire inquiring about the ease of use, perceived effectiveness, and strengths and weaknesses of the program was completed by teenagers after completing the program (see Appendix D). One of the primary objectives of this project was the development of an effective, interesting and engaging program. Feedback from teenagers will be analyzed descriptively by looking at ratings on Likert scales. In addition, teenagers had the opportunity to type in written feedback concerning the program and their responses will be evaluated for common themes.

#### Procedures

The experimental design was a randomized 2 (group) x 4 (phase) design cross-over design with both a between-subject and a repeated-measures component. The two experimental groups are the treatment group (who received the "Gutstrong" program and standard medical care) and the wait-list control group (who received standard medical care only). The 4 phases of the study were baseline (2 weeks), intervention (4 weeks), immediate-post intervention follow-up (2 weeks), and 3-month post-intervention follow-up (2 weeks). Because of the cross-over nature of this design to ensure that the participants in the wait-list control group received the program as soon as possible, group comparisons were only made for the immediate-post follow-up period. The 3-month follow-up included a within-subjects repeated measures component to evaluate stability of treatment outcomes. However, at the time of this writing limited data was available for the 3-month phase and therefore no results are reported at this time.

Participants were recruited for this study during their routine clinic visits at the Abdominal Pain Clinic at Children's Mercy Hospital in Kansas City, Missouri. Teenagers who met criteria for age (13-17) were identified on the clinic schedule and a member of the research noted their potential eligibility. For the first four months of recruitment, potential participants were seen in the Abdominal Pain Clinic by both a pediatric gastroenterologist and a pediatric psychologist as part of the routine multidisciplinary approach to treatment. The next five months of recruitment, potential participants were only seen by the pediatric gastroenterologist. After the gastroenterologist or the treatment team finished with the potential participants, they briefly introduced the purpose of the research study to assess for interest in participation. The researcher briefly discussed the patient with the treatment team to confirm the diagnosis and to make sure there were no obvious disqualifying organic causes of the abdominal pain. If the teenager and family were interested in the study, they were approached by a member of the research team. After a brief screening interview to ensure that all inclusion criteria were met, the study was discussed with the teenager and their parent/guardian. Teenagers and their families were told that they were being asked to participate in a study on teenagers with functional gastrointestinal disorders and that participation involved completing daily pain diaries, brief questionnaires, and a CD-ROM program designed to give teenagers additional strategies to help manage their abdominal pain. Families were informed that their participation was strictly voluntary and their medical care at Children's Mercy Hospital would not be affected by whether or not they chose to participate in the study. It was made clear that standard medical care would continue for all participants in the study. It was also explained that some randomly selected families would receive the CD-ROM program earlier than others based on the design of the study, but that all families would receive the program if they remained in the study. Potential participants were

also informed that they would be compensated at the rate of \$30 for completing all phases of the study. If families agreed to participate, parental/guardian permission and adolescent assent were obtained by signatures on a form approved by the Institutional Review Board of Children's Mercy Hospitals and Clinics.

After obtaining informed parental permission and teenager assent, the participating teenagers parent/guardian completed a demographics form and the teenager completed the Behavior Assessment System for Children- Second Edition (Adolescent self-report form) if they had not already completed it as part of their routine clinical care. In addition, the participants were instructed on how to use the web-site dedicated to this research study to complete the additional dependent measures. Each participant was given a subject number which was subsequently used when they were completing the on-line measures. This ensured that all information entered on the web-site and sent to the research team was confidential and had no personal identifying information. The participants were informed that they would be contacted once per week during the different phases of the study to see if they had questions regarding completing the diaries or questionnaires.

Participating teenagers completed daily pain diaries on [www.gutstrong.com](http://www.gutstrong.com) for 14 days during the first baseline phase of the study. Near the end of these 14 days the participants were also asked to also complete the PedsQL 4.0 and the Pain Response Inventory on the web-site. No attempt was made to alter pain or other symptoms during this period beyond their standard medical care recommendations provided by the gastroenterologist. Contact with participant families was limited to once a week emails and/or follow-up calls to ensure consistent record-keeping and measure completion. If the research personnel were unable to contact the participant families, a brief message was left with the family. Brief contacts were also made in the event that submitted data was

incomplete to encourage as little missing data points as possible. Any questions not directly related to the study were deferred to the personnel at the Abdominal Pain Clinic.

After completing the baseline phase, teenagers were randomly assigned to either the wait-list control group or the "Gutstrong" group using a Uniform Random Numbers table. Participants were informed of their group assignment. Teenagers randomly assigned to the treatment group were sent the "Gutstrong" program and the accompanying workbooks after submitting all 14 days of daily diaries and the two questionnaires. Teenagers worked through the lessons in the program over the course of the next four weeks. During this time, they were not asked to complete daily diaries or questionnaires, but they did keep track of passwords that were given after completion of lessons on the program. Participants sent in these passwords over the web-site and this was used as a simple measure of adherence to the program. Once per week contact continued to be attempted during this treatment phase to address questions regarding the "Gutstrong" program. Participants randomly assigned to the wait-list control group had no study related activities during this phase of the study. Once per week contact continued for this group as well to ensure there was no bias in the level of contact for the two groups. Standard medical care continued for both groups.

At the completion of the four week treatment/wait-list phase, participants who had just completed the program were asked to complete an on-line satisfaction questionnaire about the program. All participants again completed 14 days of daily diaries and the two questionnaires during the immediate-post phase. After these 14 days, participants randomly assigned to the wait-list control group were sent the "Gutstrong" program and the accompanying workbooks and were encouraged to work on the program over the next four weeks. At the end of this time, they were asked to provide 14 more days of daily diaries and the two questionnaires. The decision was made to start the wait-list controls after the



immediate-post phase in order to minimize the amount of time that they went without receiving the program. A follow-up period was then attempted for all participants at 3-months after finishing their work on the “Gutstrong” program. See Table 3 for an outline of study phases and dependent measures completed during each phase for the two experimental groups.

#### Data Reduction Procedures

For the measurement phases of the study all outcome measures were totaled and averaged when appropriate to provide a single data variable for each participant. The number of pain episodes as recorded in the daily pain diaries was summated for the phase and represents the pain frequency. Pain duration and pain severity measures were averaged by summating them for the phase and then dividing by the total number of pain episodes for the phase. The percentage of pain-free days was computed for each phase by dividing the number of days without pain by the number of total days and multiplying by 100. Scores on the PedsQL 4.0 were reverse-scored and linearly transformed to a 0-100 scale, with higher scores representing higher quality of life. The subscale scores for the PedsQL are computed by summating the transformed scores on the different items and then dividing by the number of items on each scale. The secondary measures of daily mood and daily stress were averaged for the phase. Lastly, scores on the PRI were averaged for each composite factor and each individual subscale.

#### Data Analysis

Missing data on the primary pain and quality of life variables and the secondary mood, daily stress, and coping variables were limited in the current reported sample (3 data

Table 3: Outline of Study Phases and Dependent Measures Completed

Phase:	Baseline		Intervention				Immediate post		3 month post	
	1	2	3	4	5	6	7	8	15	16
Study week:	1	2	3	4	5	6	7	8	15	16
Demographics	*									
BASC-2 questionnaire	*									
Daily Pain Diary	*	*					*	*	*	*
Peds QL 4.0		*						*		*
PRI		*						*		*
Satisfaction Questionnaire						*				

points total on primary pain indices during baseline). Missing data was usually detected immediately because of the on-line daily data submission; allowing for the participant to be contacted by research personnel to request the missing data. All pain indices were computed on a per-phase average basis and therefore the three data points that were missing during baseline were simply ignored in the data reduction because of their small number. During immediate-post follow-up, one participant in the treatment group and one participant in the wait-list control group had missing data on the daily pain measures for complete days (4 days for the participant in the treatment group and 5 days for the participant in the wait-list control group). For these cases, mean and frequency data imputation was used using the average value of the individual for who there were missing data. No categorical data was missing in the reported sample.

Data was analyzed using SPSS 15.0 (SPSS, Chicago, IL). Data was generally screened for outliers and was tested for satisfaction of distributional and variance assumptions where required for the analysis. Evaluation of normality and homogeneity of variance was done by examining the distributions using measures of skewness and median and mean values. In this study, many of the continuous variables were mildly skewed away from the normal distribution due to the small sample size. However, it is believed that statistical tests such as independent t-test and analysis of variance are fairly robust to violations in the assumptions of normality (Glass & Hopkins, 1996) and only substantial violations of statistical assumptions were treated with non-parametric procedures.

Descriptive statistics were used to analyze the characteristics of the total sample and the experimental groups. In order to check for randomization between groups, independent samples t-tests were used to evaluate continuous variables from demographics and baseline data. When appropriate equal variances were not assumed (based on Levene's test of

equality of variances). Note that the Mann-Whitney U test was used to compare the mean values on the daily stressor rating because this variable did not meet the assumption of normality. Chi square analyses were used to compare categorical variables; the Fishers Exact Test was used when appropriate. For the comparative analyses at baseline,  $\alpha= 0.20$  was used as the significance level in order to consider potential confounders. Any significant differences in the two experimental groups were treated as covariates in subsequent analyses.

Analyses of changes over multiple time points by the two groups were done using separate univariate analysis of covariance for repeated measures (RM ANCOVA) for each of the dependent measures. Due to the small N in this pilot study (N=7 for treatment group and N=8 for the control group) the decision was made to not use multivariate analysis because of a lack of statistical power to detect differences. Any further investigation of within-group changes in continuous variables across the two phases will be tested by t-test or Wilcoxon test for any violations of parametric assumptions. Percentage of change in means over the two phases (baseline to immediate post-intervention) was also reported for the pain, quality of life, mood, and daily stress variables.

No inferential statistics were used on the satisfaction questionnaire data. Descriptive statistics were used to summarize the data. Qualitative data (comments about the program on the questionnaire) were recorded in the database and apparent themes of feedback are reported.

## Chapter 3: Results

### Baseline Analyses

Participant characteristics and values on the dependent variables of the baseline phase for the total sample, as well as for the participants for whom at least two phases of data are currently available are presented in Table 4 and Table 5. All subsequent analyses are based only on those individuals for whom at least baseline and immediate post-intervention follow-up data are available (N= 15). At the time of this writing, complete baseline and immediate-post follow-up data were not available for a total of 5 participants that were randomized. Two participants in the treatment condition were completing either the intervention phase or the immediate post-intervention phase. One participant in the wait-list control condition was completing the wait-list phase and two participants in this group were lost to follow-up due to inability to contact.

Independent samples t-tests and chi square analyses revealed no significant group differences on the variables of age,  $t(13) = 0.94$ ,  $p = 0.36$ , gender,  $\chi^2(1,15) = 1.76$ ,  $p = 0.28$ , diagnosis type,  $\chi^2(2,15) = 0.13$ ,  $p = 0.94$ , symptom duration,  $t(13) = 0.83$ ,  $p = 0.42$ , BASC-2 school problems index,  $t(13) = 0.75$ ,  $p = 0.47$ , BASC-2 internalizing index,  $t(13) = 1.29$ ,  $p = 0.22$ , BASC-2 inattentive/hyperactive index,  $t(13) = 0.42$ ,  $p = 0.68$ . At baseline, there were significant group differences on the BASC-2 emotional symptoms index,  $t(13) = 0.2.25$ ,  $p = 0.04$  and BASC-2 personal adjustment index,  $t(13) = 1.35$ ,  $p = 0.20$ . Therefore, these variables were considered potential confounders and included as covariates in subsequent analyses on group differences. Further baseline group equivalency analyses revealed no significant differences on the variables of pain episode frequency,  $t(13) = 0.55$ ,  $p = 0.59$ , pain duration,  $t(7.2) = 0.38$ ,  $p = 0.71$ , pain severity,  $t(6.83) = 0.60$ ,  $p = 0.59$ , percentage of pain free days,  $t(13) = 1.01$ ,

Table 4: Demographic Characteristics of the Study Sample.

	Total Baseline Sample	Available Baseline Data	
		Treatment Group	Wait-List Group
N	20	7	8
Average age in years	14.96 (1.80)	14.69 (1.33)	15.31 (1.23)
Female/Male	16/4	4/3	7/1
Diagnosis Type (FD/IBS/Both)	11/2/7	4/1/2	4/1/3
Mean symptom duration (months)	11.44 (8.98)	15.23 (12.65)	11.01 (6.52)
BASC-2 Emotional Symptoms Index	47.20 (6.12)	43.86 (4.10)	50.13 (6.29)
BASC-2 School Problems Index	46.65 (9.13)	45.29 (8.67)	48.38 (7.39)
BASC-2 Internalizing Index	52.05 (7.95)	49.00 (8.12)	53.75 (6.13)
BASC-2 Inattentive/Hyperactive Index	52.05 (10.37)	54.57 (8.10)	52.50 (10.50)
BASC-2 Personal Adjustment Index	54.75 (5.48)	50.13 (6.29)	53.00 (6.07)
Notes: Diagnosis type : FD= functional dyspepsia, IBS= irritable bowel syndrome, Both= having both diagnoses. Values within () represent standard deviations. BASC-2 = Behavior Assessment System for Children-2 <sup>nd</sup> Edition. BASC-2 has a standardized mean of 50 and standard deviation of 10.			

Table 5: Participant Baseline Values for Dependent Variables.

	Total Baseline Sample	Available Baseline Data	
		Treatment Group	Wait-List Group
N	20	7	8
Mean pain episode frequency	9.40 (3.48)	10.00 (3.69)	8.88 (4.19)
Mean duration per episode [1-7]	4.02 (1.85)	4.22 (2.64)	3.85 (0.89)
Mean severity per episode [1-10]	5.42 (0.99)	5.26 (1.44)	5.57 (0.40)
Mean % pain free days	39.53 (24.85)	32.57 (24.99)	45.62 (24.68)
Mean daily mood rating [0-1]	0.46 (0.18)	0.45 (0.21)	0.47 (0.16)
Mean daily stress rating [0-17]	1.05 (0.71)	0.84 (0.46)	1.25 (0.86)
PedsQL 4.0 Total Scale Score (0-100)	64.27 (9.12)	63.66 (10.01)	64.80 (8.94)
PedsQL 4.0 Physical Scale	58.95 (10.08)	58.93 (13.31)	58.98 (7.17)
PedsQL 4.0 Emotional Scale	61.00 (14.17)	59.28 (16.18)	62.50 (13.09)
PedsQL 4.0 Social Scale	86.67 (14.47)	87.14 (12.86)	86.25 (16.63)
PedsQL 4.0 School Scale	53.67 (9.53)	52.14 (11.12)	55.00 (8.45)
PRI Active Coping (0-4)	1.63 (0.38)	1.67 (0.29)	1.59 (0.47)
PRI Passive Coping (0-4)	1.22 (0.39)	1.24 (0.37)	1.21 (0.43)
PRI Accommodative Coping (0-4)	1.85 (0.39)	1.84 (0.30)	1.86 (0.48)
Notes: Duration episode was measured on a 1-7 scale, with 1 representing 0-60 minutes and 7 representing 360 minutes to constant. Severity measured on a 1-10 scale; 1 = no pain and 10 = severe pain. Daily mood rating ranges from 0-1; 0 = positive mood and 1 = negative mood. Values within parentheses are standard deviations; values within brackets are possible ranges. PedsQL 4.0= Pediatric Quality of Life Inventory, PRI= Pain Response Inventory.			

p= 0.33, daily mood rating,  $t(13) = 0.16$ ,  $p = 0.87$ , and daily stressor rating,  $z = 0.94$ ,  $p = 0.35$ .

There were also no significant group differences at baseline on the PedsQL 4.0 Total Generic Core Scale,  $t(13) = 0.23$ ,  $p = 0.82$ , PedsQL 4.0 physical scale,  $t(13) = 0.01$ ,  $p = 0.99$ , PedsQL 4.0 emotional scale,  $t(13) = 0.43$ ,  $p = 0.68$ , PedsQL 4.0 social scale,  $t(13) = 0.11$ ,  $p = 0.91$  and the PedsQL 4.0 school scale,  $t(13) = 0.56$ ,  $p = 0.58$ . Finally, there were no significant group differences on the Pain Response Inventory (PRI) active coping scale,  $t(13) = 0.33$ ,  $p = 0.75$ , PRI passive coping scale,  $t(13) = 0.14$ ,  $p = 0.89$ , and PRI accommodative coping scale,  $t(13) = 0.12$ ,  $p = 0.90$ . Therefore, the variables of BASC-2 emotional symptoms and BASC-2 personal adjustment represented the only group differences at baseline and randomization appeared to be fairly successful.

#### Analyses of Primary Outcome Measures (Pain and Quality of Life)

Values for the pain variables and quality of life variables by group and phase are presented in Table 6. Group x phase repeated measures ANCOVAs (with BASC-2 emotional symptoms and personal adjustment indexes entered as covariates) were conducted to analyze changes over the two phases between the two groups on each dependent variable. There was a significant group by phase interaction effect on the pain episode frequency variable, Wilks'  $\lambda = 0.678$ ,  $F(1,11) = 5.22$ ,  $p = 0.04$ , multivariate partial  $\eta^2 = 0.32$ . Pain frequency average tended to decrease from baseline to immediate-post for those that received the "Gutstrong" program,  $t(6) = 2.33$ ,  $p = 0.06$ , whereas it stayed at a constant level for those in the wait--control group,  $t(7) = 0.33$ ,  $p = 0.75$ . Pain duration/episode was significantly reduced for both groups between baseline and immediate-post intervention, Wilks'  $\lambda = 0.647$ ,  $F(1,11) = 5.99$ ,



Table 6: Means and standard deviations for the participant pain variables and quality of life variables by group and phase.

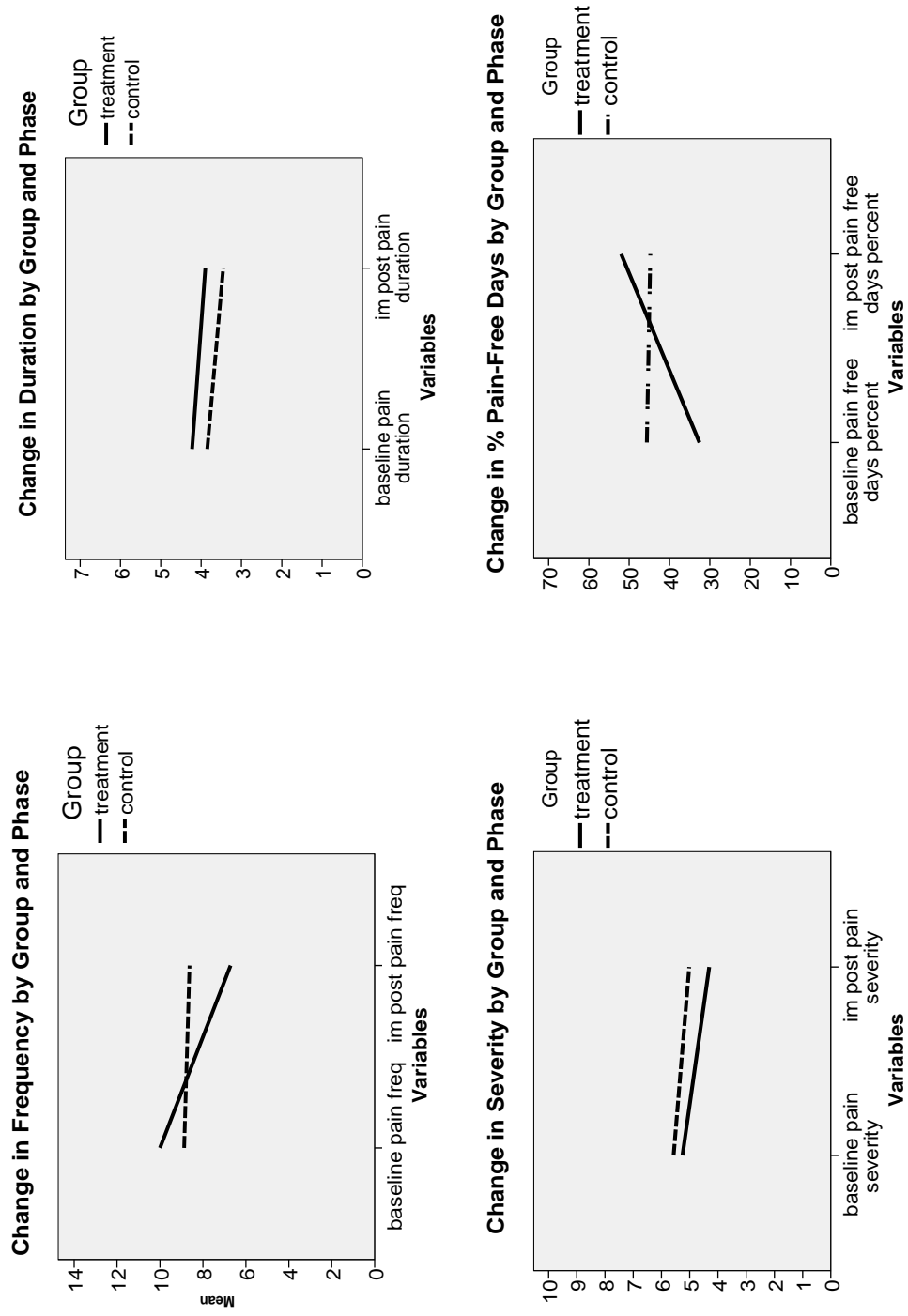
Measure [possible range]	Treatment Group (n=7)		Wait-list Control Group		Significant effects	
	Baseline	Immediate-post	Baseline	Immediate-post	Phase	Group x Phase
Pain episode frequency [0-14]	10.00 (3.70)	6.71 (4.92)	8.88 (4.19)	8.63 (2.93)	*	**
Pain duration/episode [1-7]	4.22 (2.64)	3.89 (2.55)	3.84 (0.90)	3.45 (1.58)	**	
Pain severity/episode [1-10]	5.25 (1.44)	4.31 (1.02)	5.57 (0.40)	5.01 (0.36)		
% Pain free days [0-100%]	32.57 (24.99)	52.00 (35.24)	45.62 (24.68)	44.75 (20.56)	*	**
PedsQL 4.0 Total Score [0-100]	63.66 (10.01)	73.44 (13.02)	64.80 (8.94)	65.62 (7.16)	**	**
PedsQL 4.0 Physical [0-100]	58.92 (13.31)	70.08 (14.30)	58.98 (7.17)	59.38 (8.18)	**	**
PedsQL 4.0 Emotional [0-100]	59.29 (16.18)	70.71 (18.13)	62.50 (13.09)	64.38 (13.47)	*	*
PedsQL 4.0 Social [0-100]	87.14 (12.86)	90.00 (11.18)	86.25 (16.6)	87.50 (16.26)		
PedsQL 4.0 School [0-100]	52.14 (11.12)	65.00 (16.07)	55.00 (8.45)	55.00 (8.45)	*	**

Notes: Values in parentheses () represent standard deviation; values with brackets [ ] are possible ranges. The analyses reported were univariate ANCOVAs. \*\* = significant at p<.05; \* = trend (p<.20).

$p = 0.03$ , multivariate partial  $\eta^2 = 0.35$ . There was no groups by phases interaction on pain duration, Wilks'  $\lambda = 0.879$ ,  $F(1,11) = 1.52$ ,  $p = 0.24$ , multivariate partial  $\eta^2 = 0.12$ , which suggests that both groups duration/episode changed in similar ways. Pain severity/episode did not show any significant changes from the baseline phase to the immediate-post phase, Wilks'  $\lambda = 0.95$ ,  $F(1,11) = 0.53$ ,  $p = 0.48$ , multivariate partial  $\eta^2 = 0.04$ . For percentage of pain-free days there was a significant group by phase interaction, Wilks'  $\lambda = 0.625$ ,  $F(1,11) = 6.59$ ,  $p = 0.03$ , multivariate partial  $\eta^2 = 0.38$ . Participants in the treatment group had a 19.43% increase in the percentage of pain-free days, going from a baseline average of 32.57% without pain to an immediate-post treatment average of 52.00% days without pain  $((52.0-32.57)/32.57 = 19.43\%$  change). Those in the wait-list control group had a 2% decrease in the percentage of pain-free days, going from a baseline average of 45.62% pain-free days to an immediate-post phase average of 44.75% pain-free days  $((44.75-45.62)/45.62 = 2\%$  change). Figure 2 gives a graphical display of the group by phase interaction effects on the pain variables.

There was a significant group by phase interaction effect on the PedsQL total score variable, Wilks'  $\lambda = 0.606$ ,  $F(1,11) = 7.15$ ,  $p = 0.02$ , multivariate partial  $\eta^2 = 0.39$ . The PedsQL total score remained at a fairly constant level for those in the wait-list control group, whereas the score increased from baseline to immediate-post (indicating improvements in quality of life) for participants in the treatment group. There was a significant group by phase effect on the PedsQL physical subscale, Wilks'  $\lambda = 0.493$ ,  $F(1,11) = 11.33$ ,  $p = 0.006$ , multivariate partial  $\eta^2 = 0.51$ . Participants in the treatment group showed a significant increase in their quality of life score, while participants in the wait-list control group showed scores that remained constant from baseline to immediate-post. On the PedsQL emotional score, there was a trend suggesting that scores increased from baseline to immediate-post,

Figure 2: Changes in pain frequency, pain duration, pain severity, and % pain-free days by phase and group



Wilks'  $\lambda = 0.827$ ,  $F(1,11) = 2.29$ ,  $p = 0.16$ , multivariate partial  $\eta^2 = 0.17$ . There was also a trend suggesting that these scores increased more for the treatment group, Wilks'  $\lambda = 0.747$ ,  $F(1,11) = 3.74$ ,  $p = 0.08$ , multivariate partial  $\eta^2 = 0.25$ . Scores on the PedsQL social subscale showed no significant changes between the baseline phase and the immediate-post phase, Wilks'  $\lambda = .910$ ,  $F(1,11) = 1.08$ ,  $p = 0.32$ , multivariate partial  $\eta^2 = 0.09$ . There was a significant group by phase effect on the PedsQL school scores, Wilks'  $\lambda = 0.641$ ,  $F(1,11) = 6.16$ ,  $p = 0.03$ , multivariate partial  $\eta^2 = 0.36$ . The PedsQL score remained constant for those in the wait-list control group and increased between the two phases for those that received the Gutstrong program. Figure 3 gives a graphical display of the group by phase interaction effects for the different PedsQL score variables. Figure 4 provides a graphical display of the percent improvement values from baseline to immediate-post for all the primary outcome variables.

#### Analyses of Secondary Outcome Measures (Mood, Daily Stress, and Coping)

Values for the daily mood, daily stress, and pain response inventory (coping scales) variables by group and phase are presented in Table 7. Just as with the primary outcome measures, group x phase repeated measures ANCOVAs (with BASC-2 emotional symptoms and personal adjustment indexes entered as covariates) were conducted to analyze changes over the two phases between the two groups on the daily mood variable and the different coping variables. The daily stress variable was found to be significantly skewed in preliminary analysis and was therefore analyzed using a Wilcoxon signed ranks test to look at within-group changes across the two phases. There was no significant change in daily stress ratings for the sample between the two phases,  $z = .284$ ,  $p = 0.77$ . Looking at the groups

Figure 3: Changes in the PedsQL 4.0 Subscales by phase and group

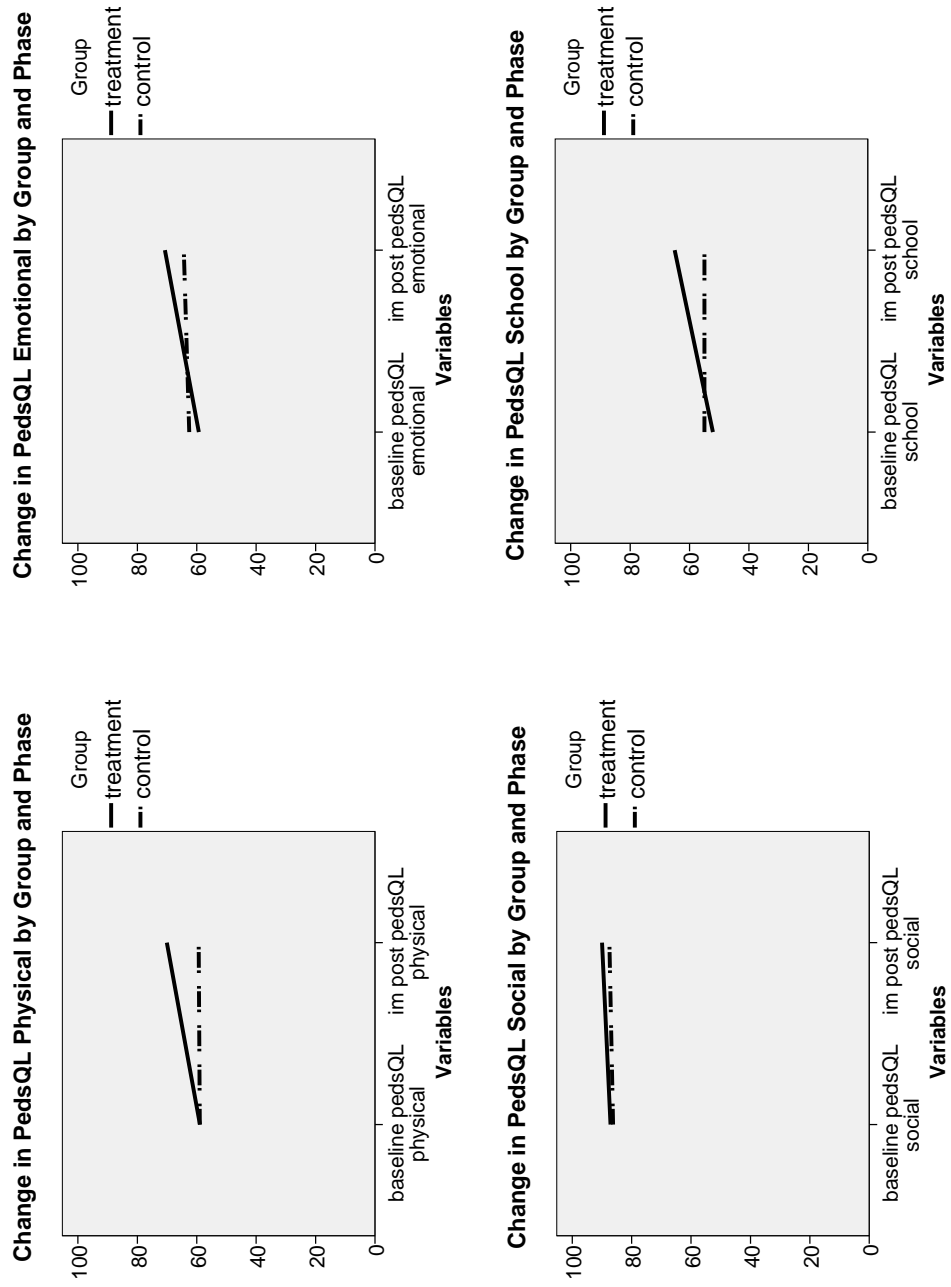


Figure 4: Percent improvement on the primary outcome measures of pain and quality of life

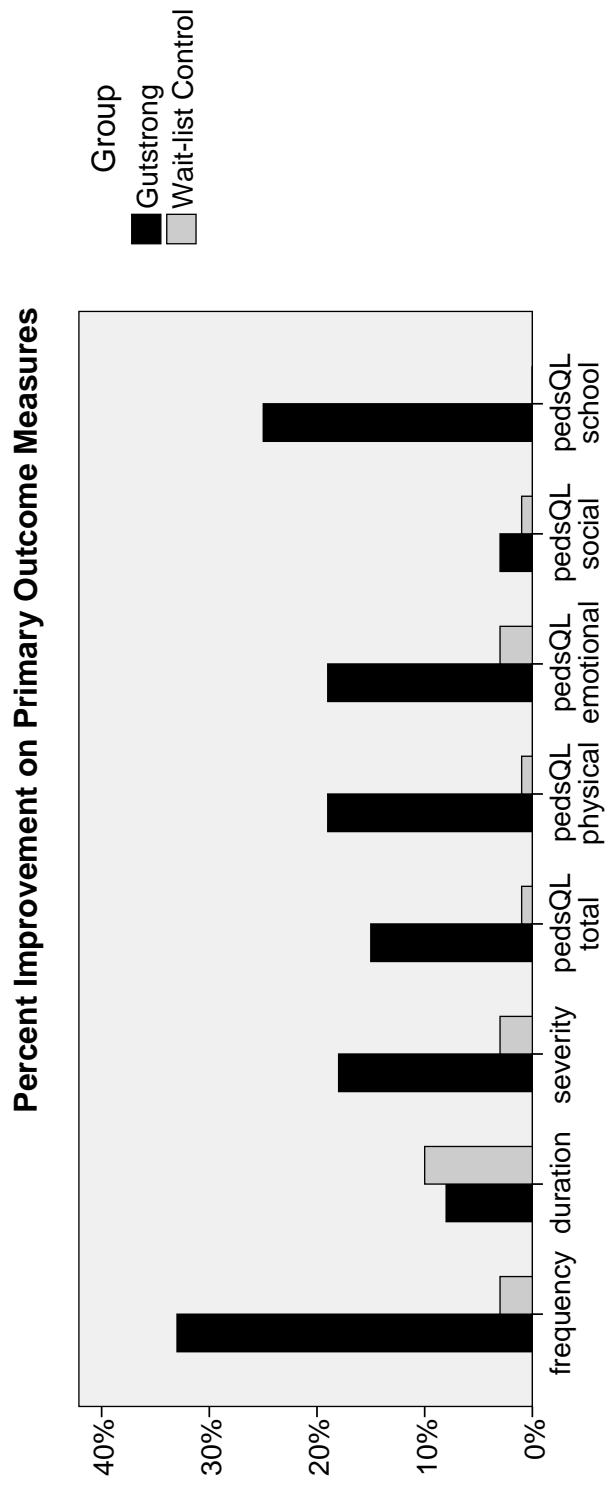


Table 7: Means and standard deviations for the participant daily mood, daily stress, and coping variables by group and phase.

Measure [possible range]	Treatment Group (n=7)		Wait-list Control Group		Significant effects	
	Baseline	Immediate- post	Baseline	Immediate- post	Phase	Group x Phase
Daily mood rating [0-1]	0.45 (0.21)	0.33 (0.13)	0.47 (0.16)	0.44 (0.15)		*
Daily stress rating [0-17]	0.84 (0.46)	0.95 (1.47)	1.25 (0.86)	1.63 (0.62)	N/A	N/A
PRI- Active coping [0-4]	1.67 (0.29)	1.92 (0.22)	1.59 (0.47)	1.64 (0.37)		*
PRI- Passive coping [0-4]	1.24 (0.37)	0.55 (0.45)	1.21 (0.43)	1.25 (0.37)	*	**
PRI- Accommodative coping [0-4]	1.84 (0.30)	1.93 (0.33)	1.86 (0.48)	1.80 (0.40)		*

Notes: Values in parentheses () represent standard deviation; values with brackets [] are possible ranges. The analyses reported were univariate ANCOVAs. \*\* = significant at  $p < .05$ ; \* = trend ( $p < .20$ ). The daily stress rating was analyzed with Wilcoxon test for within-group changes only.

separately, there was no significant group change in daily stress between phases (treatment,  $z = 1.18$ ,  $p = .24$ ; control,  $z = 1.26$ ,  $p = .21$ ). For the daily mood rating, there was a mild trend suggesting a group by phase interaction effect, Wilks'  $\lambda = 0.849$ ,  $F(1,11) = 1.95$ ,  $p = 0.19$ , multivariate partial  $\eta^2 = 0.15$ . The daily mood rating average decreased in the treatment group and remained relatively constant for those in the wait-list control group.

On the Pain Response Inventory, there was a trend suggesting a group by phase interaction effect on the PRI Active coping subscale, Wilks'  $\lambda = 0.716$ ,  $F(1,11) = 4.36$ ,  $p = 0.06$ , multivariate partial  $\eta^2 = 0.28$ . Participants who completed the Gutstrong program showed an increase on ratings within this scale, which represents an increase in more active forms of coping. Participants in the wait-list control group remained constant between the two phases. There was a significant group by phase interaction effect on the PRI Passive coping subscale, Wilks'  $\lambda = 0.453$ ,  $F(1,11) = 13.30$ ,  $p = 0.004$ , multivariate partial  $\eta^2 = 0.55$ . The PRI Passive coping average remained constant for participants in the wait-list control group, while the PRI Passive score decreased from baseline to immediate-post (indicating less passive coping). There was a trend suggesting a group by phase interaction effect for the PRI Accommodative coping subscale, Wilks'  $\lambda = 0.777$ ,  $F(1,11) = 3.15$ ,  $p = 0.10$ , multivariate partial  $\eta^2 = 0.22$ .

### Consumer Satisfaction

The currently available responses to the consumer satisfaction questionnaires are presented in Table 8. Feedback from teenagers indicated that the Gutstrong program was useful for teaching them more about functional abdominal pain; two of the participants specifically commented that they liked learning more about pain and what may influence their pain. Teenagers generally liked and enjoyed the program; with 4 participants reporting



Table 8: Satisfaction Questionnaire Responses for Teenagers Completing Gutstrong

Questions	Number of Responses and Percentage			
1) How much did you learn about functional GI disorders from the Gutstrong program?	A lot	A little	I didn't learn anything	
	5 (71%)	2 (29%)	0	
2) How much did you like the Gutstrong program?	A lot	A little	I did not like it	
	4 (57%)	3 (43%)	0	
3) How often did you use the Gutstrong program?	Every day	Almost every day	Once a week	Hardly ever
	0	2 (29%)	5 (71%)	0
4) Was the program easy to use and follow-along with?	Yes	Somewhat	No	
	6 (86%)	1 (14%)	0	
5) Would you recommend this program to others?	Yes	Maybe	No	
	4 (57%)	3 (43%)	0	
6) How much has your pain changed since starting the pogram?	A lot	A little	I has not improved	
	3 (43%)	4 (57%)	0	

Note: The above totals are based on an N of 7 participants who had completed Gutstrong at the time of this writing.

they liked it “a lot” and 3 participants reporting they liked it “a little”. The program was judged to be easy to follow-along with and use and no major complaints were given on the overall functioning of the program. Four participants reported that they would recommend the Gutstrong program to other teenagers with recurrent abdominal pain; with 3 participants reporting that they might recommend it to other teenagers. Some of the feedback of the program included comments that the content was too long at times and that the program ran too slow.

A couple of the participants specifically said that they did not like the built in quizzes. One of the younger participants (age 13) noted that some of the words on the program were hard to understand. Positive feedback included comments about the graphics and animations of the program. Most of the participants commented that the built in animations and pictures helped make the program interesting. Three of the participants commented that the information was easy to follow-along with and that learning about pain was very interesting and useful. Two participants commented that the relaxation exercises and thinking exercises were really useful for dealing with their pain and staying calm.

## Chapter 4: Discussion

The present study intended to provide an initial evaluation of the utility of the “Gutstrong” program- a minimal contact or self-management intervention for teenagers with abdominal-pain related functional gastrointestinal disorders. Previous research on the treatment of recurrent abdominal pain has shown that techniques commonly included in cognitive-behavioral therapy are effective in decreasing pain and improving quality of life in children and adolescents with this pain condition. In addition, previous minimal contact interventions for pediatric chronic pain conditions have shown effectiveness in reducing pain and improving quality of life. Connelly and colleagues (2006) recently developed and supported the efficacy of a CD-ROM minimal therapist contact intervention titled “Headstrong” for children with recurrent headache. The current study expanded on the use of this type of program by developing a similar developmentally tailored self-management CD-ROM program for functional GI disorders in teenagers aged 13-17 and evaluating the program as an adjunct to standard medical care. The primary hypotheses tested in the current study were that the “Gutstrong” program could improve primary outcome measures of pain indices (frequency, duration, and severity) from baseline to immediate post-intervention follow-up and these improvements would be greater than those made by a control group receiving standard medical care only (wait-list control group). Further, it was hypothesized that completion of “Gutstrong” could improve quality of life from baseline to immediate-follow-up and to a greater extent than for those in the standard medical care only group. The secondary hypotheses of the current study were that the “Gutstrong” program could improve daily affect and reduce daily stress from baseline to immediate follow-up and to a greater extent than the control group. Lastly, it was hypothesized that completion of the program would result in increases in more adaptive forms of coping (active and accommodative) and

decreases in passive coping from baseline to immediate follow-up. Support for both the primary and secondary hypotheses was found to some extent.

### Characteristics of the Sample

Preliminary analyses showed that the current sample of teenagers with functional gastrointestinal disorders mirrors the population of these patients in some meaningful ways. It has been reported that the prevalence of recurrent abdominal pain increases in girls and decreases in boys as children get older and move into adolescents (Apley & Naish, 1958; Eminson et al., 1996; Oster, 1972; Stickler & Murphy, 1979). The current sample was predominately female (16/4). Previous research has indicated that irritable bowel syndrome may be the most common functional GI diagnosis given tertiary care clinics (Walker et al., 2004) while other studies have reported that functional dyspepsia may be the most common (Caplan et al., 2005). It was previously reported that functional dyspepsia was the most common diagnosis at Children's Mercy Hospital (Schurman & Friesen, 2005). The current sample mirrors these findings; a functional dyspepsia diagnosis was given the most while the second most common diagnosis was a combination of functional dyspepsia and irritable bowel syndrome. Another area of research that has been well-studied in children with recurrent abdominal pain is psychological symptoms. Previous research has reported that internalizing psychological symptoms are common in children and adolescents with recurrent abdominal pain. The current total-sample scored around the normative average on a self-report measure of internalizing symptoms (BASC-2 score of 52.05) and did not score outside of the average range on any of the psychological symptoms scores from the BASC-2. Evaluating the individual BASC-2 scores revealed that very few participants scored in the at-risk range on any of the BASC-2 subscales or composites. Thus, in general the current

sample does not appear to be showing significant psychological symptoms based on adolescent self-report. Lastly, the experimental groups were judged to be generally equivalent and randomization was relatively successful. There were significant differences on the BASC-2 emotional symptoms and personal adjustment scores and these were entered as covariates on all analyses that compared the two groups.

### Changes in Pain Variables

In the current sample, the “Gutstrong” CD-ROM program was found to have significant effects on the primary pain variable of frequency of pain episodes. An analysis of the daily pain diaries sent in by participants on the studies website showed that participants in the wait-list control group who received standard medical care only during the intervention phase showed relatively no change on the amount of pain episodes they were having from baseline to immediate post follow-up. Participants who completed “Gutstrong” had an average of approximately 4-episodes of pain less during the 2-week immediate post-intervention phase when compared to their baseline. The average duration for each pain episode was significantly reduced for participants in both groups from baseline to immediate-post. However, there was no differential change in duration of pain episodes between the two groups. The ratings of pain severity for each episode did not change significantly from baseline to immediate-follow up for the sample as a whole. However, the scores on severity did decrease slightly on average for both groups.

The percentage of pain-free days was computed for all participants during the baseline and immediate-follow-up period. Percentage of pain-free days is commonly reported in research on chronic pain and is meaningful as a clinical measure. There was a significant group by phase interaction effect for change in the percentage of pain-free days.

Participants who completed “Gutstrong” had a 19.43% increase in their percentage of pain-free days from baseline (32.57%) to the post-intervention follow-up (52%); while those in the control group had a 2% decrease in percentage of pain-free days from baseline (45.62) to immediate follow-up (44.75). The finding related to % pain-free days and pain frequency changes (in which the Gutstrong group improved significantly more than the control group) is worth further discussion. While initial statistical analyses conducted to look at differences in these variables for the two groups at baseline were insignificant, it was revealed that the Gutstrong group averaged more pain episodes and more pain-days than the control group at baseline. It is important to bear this in mind when interpreting these results because of the small sample size and the potential for a Type-II error on the finding of baseline equivalency.

Despite this potential caveat, there is preliminary evidence that participants who completed the “Gutstrong” program had greater reduction in pain episode frequency and greater increases in pain-free days than participants who received standard care only. Participants in Gutstrong group also showed a decrease in pain duration/episode from baseline to immediate post-intervention follow-up, but this was a similar change to what was experienced by teenagers in the standard medical care only group.

This study was the first to evaluate a CD-ROM based psychological intervention for recurrent abdominal pain patients, but the results can be compared to previous research on treatment of recurrent abdominal pain and to previous research on other minimal contact interventions within chronic pain. Connelly and colleagues (2006) initial investigation of a similar program for children with recurrent headache showed that those children who completed the CD-ROM intervention had significant decreases in pain duration and intensity, but there were no group differences in changes in frequency. However, the sample as a whole showed improvement on headache frequency and percentage of pain-free days. The

current results are congruent with those reported by Connelly et al. (2006) as far as significant improvements for the treatment group on some primary measure of pain.

A review of treatments for recurrent abdominal pain concluded that cognitive-behavioral therapies met criteria for a probably efficacious intervention (Janicke & Finney, 1999) and numerous studies have documented improvements in pain variables after implementing CBT interventions. Sanders and colleagues (1989, 1994) have reported that both the treatment group and the wait-list control group showed improvements on pain indices, with the treatment group improving more quickly and to a greater extent. The current studies findings showed that only pain duration decreased for those in standard medical care only, which is discrepant from the findings of previous research.

#### Changes in Quality of Life

Pain measures such as frequency, duration, and severity may fail to capture the important outcomes of treatment related to functioning and quality of life. Therefore, it is important to consider quality of life measures as a primary outcome measure when investigating treatments for pain in children and adolescents. On the PedsQL General Core Scale Total Score, there was a significant group by phase interaction. For participants in the wait-list control group this score remained relatively constant, but it increased significantly from baseline to immediate post-intervention for those that completed “Gutstrong”. This increase represents an improvement in overall quality of life. There was also a significant group by phase interaction for the PedsQL physical subscale; with the “Gutstrong” group showing increases in physical quality of life while the participants receiving standard medical care alone remained constant. On the PedsQL emotional subscale, there was a trend suggesting that scores increased to a greater extent for those participants that completed

“Gutstrong”, but both groups showed an increase on this score at immediate post-intervention. Scores on the PedsQL social subscale did not change significantly for this sample from baseline to immediate post. The scores on this scale were high for both groups at baseline and remained high at follow-up, indicating that social quality of life was reported as positive for the sample. There was a significant group by phase effect on the PedsQL school subscale; with the “Gutstrong” group showing an increase in school quality of life while the control group stayed constant.

Findings based on the current study indicate that those teenagers who completed the “Gutstrong” program in addition to standard medical care had general positive changes in health-related quality of life and these changes were significantly greater than teenagers receiving standard medical care only. The largest change in quality of life occurred on the physical subscale and the school subscale. Items on the PedsQL physical subscale relate to activities such as walking, running, playing sports, and doing things around the house. It is important to consider that one of the major components of the “Gutstrong” program focuses on staying physically active and continuing to do things you usually do during pain and discomfort. This component of the program may have positively influenced the teenagers’ ability to remain active during pain. On the PedsQL school subscale, items are related to paying attention in class, forgetting things, keeping up with schoolwork, and missing school. The Gutstrong groups’ significant improvement on this score is important because of previous research that indicates school absenteeism as a consistent problem for children and adolescents with recurrent abdominal pain (Bury, 1987; Hyams et al., 1996; Garber et al., 1990; Hodges et al., 1985; Robinson et al., 1990; Walker et al., 1993, 1995). Again, a major component to the “Gutstrong” program is a discussion about the importance of continuing to do what you usually do despite having pain. There is specific focus in the program on



strategies they can use to manage pain and still function well at school. Previous research is very limited on reporting any specific changes in quality of life after psychological intervention. Robins et al. (2005) reported improvements in school attendance after a self-CBT family treatment. Other treatment outcome studies have reported significant decreases in the number of school days missed after CBT-related interventions (Finney et al., 1989; Humphreys & Gevirtz, 2000). Minimal contact intervention studies have rarely reported on quality of life as a primary outcome measure. Future studies on interventions for recurrent abdominal pain (and chronic pain in general) should continue to include quality of life and disability measures. These outcomes and areas of functioning can often be as important to patients and their families as changes in overall pain rating or pain free days.

#### Changes in Mood and Stress, and Coping

Daily mood, daily stressors, and responses on the Pain Response Inventory (PRI) were considered secondary outcome measures in this study. Previous research has implicated that psychological and environmental factors are important components in the development and maintenance of recurrent abdominal pain. Anxiety and internalizing psychological symptoms in general are prominent in many children and adolescents with recurrent abdominal pain. There has also been research indicating that stressful life events and how children cope with these events are important. The Facial Affective Scale (FAS) was used to get a cursory measure of how mood changed after using the Gutstrong program. For the FAS daily mood rating, there was a mild trend suggesting a group by phase interaction. The daily mood rating decreased in the treatment group and remained relatively constant in the control group. A measure of daily stress was also included investigate whether using the Gutstrong program decreased the identified number of stressors over time. There was no significant

change in daily stress ratings for the sample from baseline to immediate post-intervention follow-up. The scores on this daily stress rating had a possible range of 0-17. However, the vast majority of participants in both groups either did not select any of these stressors or only selected one or two. It was also noticed that many of the participants began each phase selecting a few daily stressors each day, but as the phase progressed they stopped endorsing these items. Consideration needs to be given to the validity of the data for daily stress because of this response trend and order of administration of items may have impacted responses. One possibility is that because this was the last set of items on the daily pain diary, it often was skipped over fairly quickly.

Coping has been the topic of a number of investigations in the literature on recurrent abdominal pain (Compas et al., 1997, 2001; Jarret et al., 2003; Sharrer & Ryan-Wenger, 1991; Walker et al., 1994, 1997, 2006). The general consensus is that those children and adolescents who use the more accommodative or active forms of coping have better outcomes than those that use more passive forms of coping. Passive coping has been associated with increased levels of pain and somatic and depressive symptoms (Walker et al., 1997). Accommodative coping has been found to decrease pain while Active coping has been found to decrease depressive symptoms. The Pain Response Inventory was developed to measure the variables of active, accommodative, and passive coping in children with recurrent abdominal pain and was used in this study to evaluate whether the “Gutstrong” program changed coping strategies employed. ON the PRI Active coping scale there was a trend suggesting a group by phase interaction. Participants who completed the Gutstrong program showed an increase in active coping while the participants in the wait-list control group kept this coping level relatively constant. There was a significant group by phase interaction for changes on the PRI Passive coping scale. Teenagers in the Gutstrong group showed a

significant decrease in the use of this coping strategy from baseline to immediate post-intervention. Teenagers in the wait-list control group remained constant on the use of this coping strategy. There was also a trend suggesting a group by phase interaction effect on the PRI Accommodative scale. The use of this scale increased to a mild degree for the Gutstrong group and decreased to a mild degree for those in the control group.

Changes in coping strategies are an important outcome to consider in this investigation. The basic goals of the “Gutstrong” program center on teaching teenagers with recurrent abdominal pain more adaptive ways of managing both their stress and their pain. So, it focuses on improving their coping. The theoretical foundations of cognitive-behavioral therapy in general and with the “Gutstrong” program specifically are related to changing maladaptive ways of thinking and behaving into more adaptive ways of thinking and behaving in order to positively impact the complex system responsible for pain experiences. Using scales such as the PRI to evaluate children and adolescents self-perception of how they cope with distress or pain should be considered for interventions that claim to be teaching new skills.

Much of the emphasis of “Gutstrong” falls in line with increasing skills that would fall in either the Active coping scale or the Accommodative scale of the PRI. For example, one of the modules of the 3<sup>rd</sup> week of the “Gutstrong” program is “Problem-solving”. The Active coping subscale of the PRI has a scale titled problem-solving and includes statements about trying to figure out what to do about having pain. Another major component of the “Gutstrong” program is positive-thinking or cognitive-restructuring. The Accommodative subscale of the PRI has a scale titled self-encouragement and includes items like “tell yourself you can deal with the pain”. Conversely, the “Gutstrong” program teaches skills that will hopefully decrease maladaptive functioning such as avoidance and disengagement. This

falls in line with scales and items on the Passive scale of the PRI. Findings from this initial data analysis indicate that the “Gutstrong” program does seem to be teaching more adaptive ways of coping with stress and pain. Teenagers who completed the program showed a significant decrease in Passive Coping and at least a moderate increase in Active coping; while teenagers who did not receive the program continued to use passive coping at immediate follow-up.

#### Consumer Satisfaction Discussion and Further Program Development

Teenagers who completed the “Gutstrong” program generally reported positive feedback about the program. Ratings on the satisfaction questionnaire indicated that the teenagers felt the program informed them about their functional GI disorder. A couple of the participants specifically noted how learning about the nature of their pain helped them. Participants also noted that the “Gutstrong” program was easy to use and follow. For the most part, the content of the program was thought to be appropriate to their developmental level. Although one younger participant (age 13) reported that some of the terminology on the program was too advanced. Two participants noted that some of the graphics were too young for their age. All participants had positive comments about the amount of graphics and the use of animations and moving sections to make the program more interesting. There was also a general consensus that the participants enjoyed this format for treatment because it was something they could work on whenever they had time and they could do it at home rather than going to a doctor’s office. Therefore, it appears as if the CD-ROM delivery method is desirable as adjunctive form of treatment for teenagers with recurrent abdominal pain.

Consistent “negative” feedback had to do with the amount of content on the program and the pace with which the program runs. A number of the participants commented that it was boring at times because there was too much to read on the screen and the audio narration wasn’t fast enough. In designing this version of “Gutstrong” the decision was made to control the pace of the program by not allowing children to jump ahead to the next screen until the audio for the current screen completed. This was done to ensure that the participants actually spent time reading and thinking about the lessons. There were some comments about not liking the quizzes and the review screens because they were overly repetitive. Based on the feedback on “Gutstrong” thus far, it may be necessary to improve the pacing of the program and the amount of content and how it is presented in future versions of the program. Having too many “static” screens may lead to teenagers disengaging from the program. Also, making the program even more interactive with feedback on responses to exercises and opportunities to play games and use what they learn will add to the desirability of the program. Lastly, it will be necessary to design multiple programs to more specifically target different age ranges.

#### Mechanisms of Change in the “Gutstrong” Program

As mentioned earlier, the theoretical foundation on which the “Gutstrong” program is based is the “pain puzzle” model developed by Rapoff & Lindsley (2000). In this model, the biopsychosocial or multidimensional approach to pain is conceptualized as a puzzle with different pieces that fit together to form the unique experience of pain for an individual. The model specifies four parts to this puzzle- nociception, thoughts, feelings, behaviors. Each of these pieces of the puzzle are addressed within the program through interventions that research has found to be “probably efficacious” (Janicke & Finney, 1999) for the treatment of

recurrent abdominal pain in children. The “Gutstrong” program also teaches teenagers about the “pain gate” theory that was initially described by Melzack & Wall (1965) within the framework of the “pain puzzle” model. Specifically they are taught that the three pain puzzle pieces of “thoughts”, “feelings”, and “behaviors” can alter the “nociception” piece by using the psychological interventions taught in the program.

The theoretical assumption is that the Gutstrong program influences all four pieces of the pain puzzle and therefore reduces abdominal pain. For example, teaching more adaptive forms of coping with stress and pain (as discussed above when considering changes seen on the PRI) is a form of psychological intervention to address the psychosocial pieces of the pain puzzle. Using skills such as thought-changing, problem-solving, mental rehearsal, relaxation, and staying active and following a pain plan are all coping skills that make it more likely that the “thoughts”, “feelings”, and “behaviors” pieces of the pain puzzle are interacting with physiological aspects of pain in a positive way. A specific example of how a supported psychological intervention alters pieces of the pain puzzle is relaxation training. Relaxation training is thought to be influential in altering the perception of pain (thoughts) and inducing physiological changes incompatible with the nociceptive mechanisms underlying pain. It has received good support as an efficacious treatment in recurrent abdominal pain independent of the other common psychological techniques (Anbar, 2001; Ball et al., 2003; Linton, 1986; Youseff et al., 2004). Through repeated practice, relaxation exercises may be able to significantly alter different physiological systems in the body that are responsible for pain. For example, stress is thought to affect the gastrointestinal tract by releasing corticotrophin releasing hormone with secondary release of inflammatory cells such as mucosal mast cells. Also, stress can activate the sympathetic nervous system and shift the balance in this system and its counterpart, the parasympathetic nervous system (Schurman &

Friesen, 2006). Both of these physiological changes may be significant factors in the development and maintenance of abdominal pain. It is hypothesized that relaxation training can help the body calm the stress responses and therefore these physiological mechanisms thought to be responsible for pain. Further investigation of this type theoretical assumption is warranted with studies integrating psychological interventions with physiological measurement.

The design of the current study does not allow a direct investigation into the exact mechanisms responsible for the improvements in primary outcome measures observed by the teenagers who completed “Gutstrong”. Therefore, it is emphasized that the above discussion is primarily theoretical. Although adherence to the program was monitored through the weekly submission of passwords that were embedded into the program, which techniques the children actually used and how often or when they used them was not determined. It may be important in future research to have a more detailed assessment of the use of the techniques taught in the program. For example, parents and teenagers could be asked to keep a daily record of which skills were used for what situations.

Another important consideration in any outcome research with psychological therapy techniques is the presence and influence of “non-specific” factors (therapist variables such as empathy, warmth, understanding and patient variables such as expectancies, self-efficacy). During the movement towards “empirically supported treatments”, the continued importance of non-specific factors within the supported therapy techniques has been emphasized (Chambless & Ollendick, 2001). The use of a CD-ROM as a minimal contact self-management approach at least partially reduces the impact of nonspecific factors by removing the therapist variable from the equation. In this study the only therapist-patient interaction related to the techniques taught in the program occurred at the initial meeting in

the clinic (which only last about 20 minutes and did not introduce any psychological techniques). Also, attention from treatment personnel was controlled. Both the treatment and wait-list groups received an identical amount of attention (in the form of attempted once per week contacts by email or phone). Therefore, therapist variables commonly implemented in therapy and therapist attention are not thought to be involved in change for participants who completed “Gustrong”. One factor that will be discussed in more detail later in this section is the importance of potential patient variables and selection bias in those that completed “Gutstrong”.

#### Study Limitations and Future Directions

The present study offers at least initial support for the utility of a CD-ROM based adjunctive psychological intervention for teenagers with functional gastrointestinal disorders. However, several limitations of this study need to be mentioned. This preliminary analysis is based on a small sample size and there is need for further analysis with a larger study sample. The issue of small sample size in intervention outcome research is generally related to the power to detect significant and to obtaining representative samples of a larger population. In regards to statistical power to detect differences between groups, the effect sizes on many of the analyses were large enough that the small sample size was not an issue for power to detect Type II errors. The other issue related to sample size is the assumptions that are made about normal distributions and the central limit theorem. The assumption of normal distributions is required for analyses conducted in this study and there is the possibility that violations to these statistical assumptions were made even though checks for normality were done. However, tests such as the independent t-test and the ANOVA are believed to be fairly robust to violations in the assumption of normal distributions (Glass & Hopkins, 1996). Due to the



relatively small sample size in this analysis it is important to consider the results carefully and to replicate these findings before making definitive conclusions.

Another important limitation to this study that warrants caution in interpreting the results is that teenagers in the study were not blinded to the treatment conditions and to receiving the intervention. The inability to blind participants to the intervention is a common issue in psychological intervention studies. The potential consequence of participants not being blinded to the treatment condition is the possibility that demand characteristics and favorable reporting may play an influential role in the results. It is always possible that participants who are receiving an intervention as part of a research study report what they believe the researcher wants. In the current study, teenagers in the treatment group may have reported improvements in pain, quality of life, and coping because of this. One potential solution to this problem is incorporating a control CD-ROM program that allows for blinding of research participants in future studies. Another more immediate strategy to at least partially control for the problem of demand characteristics is to use convergent sources of information on primary outcome measures (i.e. parent proxy reports on pain and quality of life).

The ability to generalize results of a research study to the general population is the issue of external generalizability. A discussion of external generalizability is important for this study because of the goal to use this program as an adjunctive to medical care for children and adolescents with functional GI disorders. Because this study was primarily an efficacy study, the generalizability and feasibility of this program was not fully evaluated as it would be in an effectiveness study. However, the use of passwords in the present study did give some indication that teenagers completed all of the lessons and used the program. It is not clear, however, whether participants actually used the skills or worked on the various

practice and review exercises that are incorporated into the program. It can also not be determined whether teenagers completed the program because they were part of a research study or because they were motivated and interested in learning techniques to help manage their pain. If the successful use of this program was primarily due to being enrolled in a research study, then teenagers in the general population may not use the program to effectively manage their pain. There is some indication that teenagers enjoyed and were motivated to use the program and this lends support to its use in the general population. Consumer satisfaction feedback indicated that the teenagers liked the program to some degree. However, satisfaction data also showed that almost half of the participants in this study would “maybe” recommend this program to other teenagers and almost half of the participants only reporting liking the program “a little”. Some of the feedback for improving the program (such as reducing content, speeding up the presentation of information, and not using quizzes) would make it more likely that this program would be used by teenagers outside of a research setting.

Another important issue to consider in this study that relates to external generalizability and feasibility of the “Gutstrong” program is the potential for selection bias. The results for the current study are based only on teenagers who were interested enough in the program to complete baseline, intervention phase, and immediate post follow-up. There was no data available for those that dropped from the study. The relatively high attrition rate (34%) indicated that many enrolled participants may not have been motivated or interested in using the “Gutstrong” program. In addition, the data collected by this study was likely biased towards teenagers that were truly interested in self-management of their pain and may be a relatively unrepresentative sample of teenagers with functional abdominal pain in the population. However, use of the “Gutstrong” program itself may have been motivating to

those teenagers that dropped out of the study, but the completion of daily diaries and other questionnaires was too much of a burden for participation. In primary efficacy studies, researchers need to be cognizant of the potential for participants to not complete the study if there are a lot of expectations for participation. Designing studies that are less demanding on participants (using shorter durations of data collection and fewer dependent measures) and provide positive incentives will help limit levels of attrition and prevent major problems with selection bias.

The current study recruited participants from a multidisciplinary tertiary specialty clinic for abdominal pain, which likely has both benefits and disadvantages. It is possible that teenagers seen in the tertiary care clinic are not representative of a large percentage of the population of teenagers with functional GI disorders and recurrent abdominal pain. Many teenagers with recurrent abdominal pain may be managed adequately in a primary care setting and may never need referral to the specialty clinic. One of the advantages to recruiting in the specialty tertiary care setting is that participants are more likely to be significantly debilitated by their pain and they may be the portion of the population that would benefit from the program the most. It is important to consider the efficacy of this program across different types of care settings. Therefore, future research might recruit from primary care settings and secondary and tertiary settings to make comparisons of the utility of the program across the broad population of teenagers with functional GI disorders. It is likely that these patients were significantly debilitated by their pain. Not representative to the majority of these patients because many are only seen and managed in the primary care setting. Future studies to look at both primary care and secondary or tertiary care.

Another issue for future studies is whether all components that make up the “Gutstrong” program are necessary for the program’s efficacy. The issue of which treatment

components are critical to positive outcomes can be addressed by doing a component analysis or a “dismantling” study in which each different type of psychological treatment is tested separately (Connelly et al., 2006). The format of the “Gutstrong” program lends itself to this type of investigation because different components could easily be included or not included. For example, future studies with this program may separate children into groups in which one group receives only the education component while the other group receives the entire program. Further, the different psychological techniques could also be looked at separately to see which are the most important for inclusion in later versions of the program.

The use of technologies such as computer-based CD-ROM programs or web-based programs for minimal contact psychological interventions will likely continue to be an exciting and useful area of research. One could argue that almost any intervention that pediatric psychologists currently deliver to chronically ill children and their families can be adapted and delivered using computer technologies (Wade, 2004). The development of these types of programs has the advantage of increasing accessibility to interventions, reducing costs to families and healthcare, and reducing the stigma and ambivalence with receiving psychological interventions. Further, it is also possible that advances in the use of computer-based technologies for minimal contact intervention could result in more individualized design for better specificity to each patient. One of the important issues with MC interventions is with more debilitated patients who require intensive individualized therapy. A potential use of these types of programs in these individuals is to coordinate them with face-to-face therapy in the clinical setting. Individuals could come to the clinic for complete diagnostic evaluation and treatment planning. The use of minimal contact programs like “Gutstrong” could be used between fairly infrequent follow-up appointments.

### Continuation of this Study

Continuation of this pilot study is planned in order to increase sample size and to give further analyses to follow-up data, feedback about the program, and analyses about predictors for program success. At the time of this writing, three participants were completing the baseline phase and three more were completing either the intervention phase or the immediate post-intervention phase. In addition, a number of the participants that were analyzed for this writing had not reached the planned 3-month follow-up phase or had failed to return complete information. The goal for continued data collection is to obtain complete follow-up data for approximately 15 participants. In addition, it is planned to follow participants who are assigned to the wait-list control group after they cross over and completed the “Gutstrong” program for further within-subject analysis. However, at this time individuals that have crossed over from the wait-list group to complete the program have failed to return follow-up data after completion. Consideration of the feasibility in obtaining follow-up data from participants who are assigned to the wait-list condition is important and special measures may need to be implemented to ensure this follow-up data is returned (i.e., incentives).

Another important issue for continuation of this preliminary investigation and for research related to minimal contact interventions in general is the problem of study attrition. In the current study, 12 of the 35 participants who enrolled in the study at the time of their clinical appointment did not complete baseline and either directly informed of withdrawal from the study or were unable to contact. This results in an attrition rate of 34%. In addition, there are a few participants who were included in this analysis that have not been able to be contacted since completing the immediate-post phase. One of the difficulties inherent in research on minimal contact interventions is the difficult balance and decision making that goes into keeping the minimal contact nature of the study with frequent check-in of

participant families to ensure study participant retention. In this study, the decision was made to limit attempts at contact to once per week for a couple of reasons. First, the nature of this program as a minimal contact intervention requires that research attend to this format by not intervening to a great extent. Second, it was important to make a decision about the degree that researchers would attempt to contact the different participant families to control for the amount of interaction from the researchers that the different families received. Steps that were taken to try to reduce attrition included gathering solid tracking information at baseline, maintaining good relationships with families when possible, making weekly email or phone contact with families, and paying incentives. Further consideration will be given to controlling attrition as this study moves forward. One consideration is to plan a specific time each week that the researcher can check in with the family rather than checking in with them randomly throughout the week. It may also be necessary to make twice weekly contacts during active phases of the study. Incentives should be used to manage attrition, but consideration needs to be given to when they are provided to families. In the current study the decision was made to provide incentives once at the end of the study. This strategy may not be as successful as providing incentives for the completion of phases.

### Summary and Conclusions

With consideration of the above mentioned limitations, the present study found initial support for the utility of using a CD-ROM program as a minimal contact adjunctive psychological intervention for teenagers with functional gastrointestinal disorders. Completion of the “Gustrong” program appeared to decrease the frequency of pain episodes and increase the percentage of pain-free days beyond what was obtained by standard medical care alone. Further, the “Gustrong” program was found to increase health-related quality of

life, especially in the physical and school areas of functioning. Improvements in quality of life should be considered as primary outcome measures in studies with chronic or recurrent pain because of the importance of improvement in functioning for these patients and their families. The “Gutstrong” program also seemed to be effective in reducing what are considered maladaptive coping strategies and slightly increasing more adaptive coping strategies. It is likely that these changes are related to gains made on the pain and quality of life variables, but the true mechanism of change in the “Gutstrong” program will need further investigation. Feedback from participants indicated that the “Gutstrong” program was fairly well-received and may be successful in engaging teenagers in self-management of their recurrent abdominal pain. Lastly, the “Gutstrong” program has the potential to be a cost- and time-effective program that addresses some of the common barriers to multidisciplinary treatment that is necessary for functional GI disorders. “Gutstrong” can be administered within the child or adolescents life and where problems generally occur, it can limit missed school days for clinic appointments, and increase accessibility to those living far way from a clinic or for those that do not have immediate access to a comprehensive treatment team.

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**GUTSTRONG Daily Pain Diary**

**Subject Number :** \* required

**Please fill this diary out each evening. Be as complete as possible and if you have questions email us or give us a call!**

1. Did you have any abdominal pain today? Click on Yes or No.

YES

NO

**If you answered Yes, go to question #2. If you answered No, go to question #6.**

2. Was your abdominal pain constant today. Click on Yes or NO.

YES

NO

**If you answered Yes, go to question #3. If you answered No, go to question #4.**

3. If your abdominal pain was constant today, click on the range below to show us how severe it was.



**NO PAIN**

**SEVERE  
PAIN**

**If your pain was constant today, go to question #6.**

Appendix A: Daily Pain Diary from gutstrong.com continued

4. If your pain was NOT constant today, tell us what time you had an episode of pain.



What time did your abdominal pain START?

AM/PM (type the time and click on AM or PM)

What time did it STOP?

AM/PM (type the time and click on AM or PM)

Click on the range below to show how bad your abdominal pain was during this time.

              
**NO PAIN** **SEVERE PAIN**

5. If you had a second period of abdominal pain today, tell us what time you had it. **If you didn't have a second period of abdominal pain, go to question #6.**


What time did your second period of abdominal pain START?

AM/PM (type the time and click on AM or PM)

What time did it STOP?

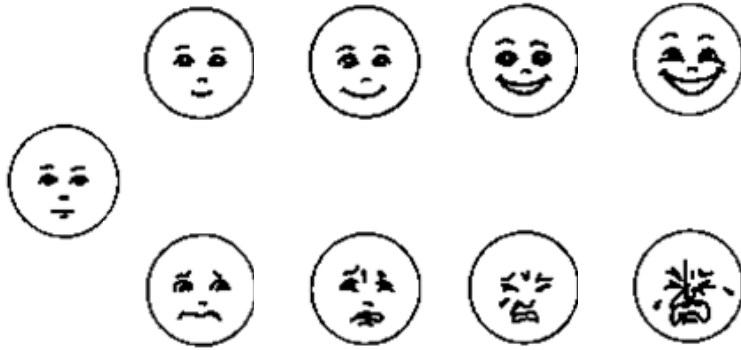
AM/PM (type the time and click on AM or PM)

Click on the range below to show how bad your second period of abdominal pain was during this time.

              
**NO PAIN** **SEVERE PAIN**

Appendix A: Daily Pain Diary from gutstrong.com continued

6. Click on the face below that best shows how you felt deep down inside *today*:



7. Click next to any of these things that happened to you today, you can click as many as you want:

- |   |   |
|---|---|
| <input type="checkbox"/> Had too much homework                  | <input type="checkbox"/> Didn't get along with others               |
| <input type="checkbox"/> Was unable to do things my friends did | <input type="checkbox"/> Didn't have money to buy things            |
| <input type="checkbox"/> Nothing fun to do                      | <input type="checkbox"/> Got in trouble                             |
| <input type="checkbox"/> Parent was away from home              | <input type="checkbox"/> Too many people told me what to do         |
| <input type="checkbox"/> Didn't like the way I looked           | <input type="checkbox"/> Didn't have anyone to hang out with        |
| <input type="checkbox"/> Was made fun of                        | <input type="checkbox"/> Argued with parents or brothers or sisters |
| <input type="checkbox"/> Had too much to do around the house    | <input type="checkbox"/> Other people at home didn't get along      |
| <input type="checkbox"/> Got a bad grade at school              | <input type="checkbox"/> Felt pressured or bossed by my friends     |
| <input type="checkbox"/> Not allowed to do things               |   |

Submit Form	Clear Form
-------------	------------



ID#	_____
Date:	_____
	_____

**PedsQL**<sup>TM</sup>  
Pediatric Quality of Life  
Inventory  
Acute Version

Version 4.0

**TEEN REPORT (ages 13-18)**

**DIRECTIONS**

On the following page is a list of things that might be a problem for you. Please tell us **how much of a problem** each one has been for you during the **past 7 days** by circling:

- 0** if it is **never** a problem
- 1** if it is **almost never** a problem
- 2** if it is **sometimes** a problem
- 3** if it is **often** a problem
- 4** if it is **almost always** a problem

There are no right or wrong answers.  
If you do not understand a question, please ask for help.

Appendix B: Pediatric Quality of Life Inventory (PedsQL 4.0) Continued

*Over the past 7 days, how much of a **problem** has this been for you ...*

<b>ABOUT MY HEALTH AND ACTIVITIES (problems with...)</b>	<b>Never</b>	<b>Almost Never</b>	<b>Some-times</b>	<b>Often</b>	<b>Almost Always</b>
1. It is hard for me to walk more than one block	0	1	2	3	4
2. It is hard for me to run	0	1	2	3	4
3. It is hard for me to do sports activity or exercise	0	1	2	3	4
4. It is hard for me to lift something heavy	0	1	2	3	4
5. It is hard for me to take a bath or shower by myself	0	1	2	3	4
3. It is hard for me to do chores around the house	0	1	2	3	4
7. I hurt or ache	0	1	2	3	4
3. I have low energy	0	1	2	3	4

<b>ABOUT MY FEELINGS (problems with...)</b>	<b>Never</b>	<b>Almost Never</b>	<b>Some-times</b>	<b>Often</b>	<b>Almost Always</b>
1. I feel afraid or scared	0	1	2	3	4
2. I feel sad or blue	0	1	2	3	4
3. I feel angry	0	1	2	3	4
4. I have trouble sleeping	0	1	2	3	4
5. I worry about what will happen to me	0	1	2	3	4

<b>HOW I GET ALONG WITH OTHERS (problems with...)</b>	<b>Never</b>	<b>Almost Never</b>	<b>Some-times</b>	<b>Often</b>	<b>Almost Always</b>
1. I have trouble getting along with other teens	0	1	2	3	4
2. Other teens do not want to be my friend	0	1	2	3	4
3. Other teens tease me	0	1	2	3	4
4. I cannot do things that other teens my age can do	0	1	2	3	4
5. It is hard to keep up with my peers	0	1	2	3	4

<b>ABOUT SCHOOL (problems with...)</b>	<b>Never</b>	<b>Almost Never</b>	<b>Some-times</b>	<b>Often</b>	<b>Almost Always</b>
1. It is hard to pay attention in class	0	1	2	3	4
2. I forget things	0	1	2	3	4
3. I have trouble keeping up with my schoolwork	0	1	2	3	4
4. I miss school because of not feeling well	0	1	2	3	4
5. I miss school to go to the doctor or hospital	0	1	2	3	4

## Appendix C: Pain Response Inventory

### **Pain Response Inventory**

(Walker, Smith, Garber, & Van Slyke, 1997)

When you have a bad stomachache, how often do you:

	Never	Once in a while	Sometimes	Often	Always
1. try to do something about it?	1	2	3	4	5
2. keep your feelings to yourself?	1	2	3	4	5
3. tell yourself that you can't deal with it and quit trying?	1	2	3	4	5
4. try to get used to it?	1	2	3	4	5
5. get as far away from other people as you can?	1	2	3	4	5
6. lie down to try to feel better?	1	2	3	4	5
7. eat something?	1	2	3	4	5
8. try to do something to make it go away?	1	2	3	4	5
9. tell yourself that it doesn't matter that much to you?	1	2	3	4	5
10. do something you enjoy so you won't think about it?	1	2	3	4	5
11. think to yourself that it is never going to stop?	1	2	3	4	5
12. not let other people see what you're going through?	1	2	3	4	5
13. give up trying to feel better?	1	2	3	4	5
14. try to accept it?	1	2	3	4	5
15. go off by yourself?	1	2	3	4	5
16. try not to move around too much?	1	2	3	4	5
17. drink something?	1	2	3	4	5
18. feel like you can't stand it anymore?	1	2	3	4	5
19. try to think of a way that you could make it better?	1	2	3	4	5
20. tell yourself that it isn't a big deal?	1	2	3	4	5
21. rub your stomach to make it better?	1	2	3	4	5
22. not tell anyone how you're feeling?	1	2	3	4	5
23. think to yourself that there's nothing you can do, so you won't even try?	1	2	3	4	5
24. try to learn to live with it?	1	2	3	4	5
25. stay away from people?	1	2	3	4	5
26. try to rest?	1	2	3	4	5
27. try to go to the bathroom?	1	2	3	4	5
28. talk to someone to find out what to do?	1	2	3	4	5
29. bend over or curl up to try to feel better?	1	2	3	4	5
30. think to yourself that it's going to get worse?	1	2	3	4	5
31. tell yourself that you can get over the pain?	1	2	3	4	5
32. try to figure out what to do about it?	1	2	3	4	5
33. tell yourself that it's not that bad?	1	2	3	4	5
34. try to think of something pleasant to take your mind off the pain?	1	2	3	4	5
35. be careful about what you eat?	1	2	3	4	5
36. give up since nothing helps?	1	2	3	4	5
37. tell yourself that's just the way it goes?	1	2	3	4	5
38. try to be alone?	1	2	3	4	5
39. try to keep still?	1	2	3	4	5
40. keep others from knowing how much it hurts?	1	2	3	4	5
41. hold your stomach to try to make it better?	1	2	3	4	5
42. think to yourself that you might be really sick?	1	2	3	4	5
43. tell yourself to keep going even though it hurts?	1	2	3	4	5
44. try not to think about it?	1	2	3	4	5
45. ask someone for help?	1	2	3	4	5

### Appendix C: Pain Response Inventory Continued

	Never	Once in a while	Sometimes	Often	Always
46. talk to someone who will understand how you feel?	1	2	3	4	5
47. think hard about what to do?	1	2	3	4	5
48. think of things to keep your mind off the pain?	1	2	3	4	5
49. stay close to someone who cares about you?	1	2	3	4	5
50. keep quiet about it?	1	2	3	4	5
51. ask someone for ideas about what you can do?	1	2	3	4	5
52. not even try to do anything because it won't help?	1	2	3	4	5
53. tell yourself, "that's life"?	1	2	3	4	5
54. try to get away from everyone?	1	2	3	4	5
55. stop what you're doing to see if it will help?	1	2	3	4	5
56. take some medicine?	1	2	3	4	5
57. think to yourself that something might be really wrong with you?	1	2	3	4	5
58. talk to someone so that you'll feel better?	1	2	3	4	5
59. tell yourself that you can deal with your pain?	1	2	3	4	5
60. try to forget about it?	1	2	3	4	5

Appendix D: Gutstrong Program Satisfaction Questionnaire

**GUTSTRONG**  
Satisfaction Questionnaire

**Subject Number :** \* required

**DIRECTIONS:** Answer the following questions about the Gutstrong program.

(1) How much did you learn about functional abdominal pain from the *Gutstrong* program?

I learned a lot	I learned a little	I did not learn anything new.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(2) How much did you like the *Gutstrong* program?

I liked it a lot	I liked it a little	I did not like it at all
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(a) What did you like about the *Gutstrong* program?

(Type your answer below)

(b) What did you NOT like about the *Gutstrong* program?

(Type your answer below)

Appendix D: Gutstrong Program Satisfaction Questionnaire Continued

(3) How often did you use the *Gutstrong* program?

Every day	Almost every day	Once a week	Hardly ever
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(4) Was the program easy to use and follow along with?

Yes	Somewhat	No
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(5) Would you recommend this program to other teenagers who have functional abdominal pain like you do?

Yes	No	Maybe
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(6) How much has your abdominal pain changed since beginning the *Gutstrong* program?

It improved a lot	It improved a little	It did not improve at all
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(7) Is there anything else you would like to say about the *Gutstrong* program? Include ways you think we could improve the program.

(Type your answer below)

<input type="button" value="Submit Form"/>	<input type="button" value="Clear Form"/>
--	---

Appendix E: Table of Contents for the Teenager Workbook

# Table of Contents

Topic	Page	When do I use this?
How to use this workbook!	3	The first day of the program.
How to use the Gutstrong CD	3	The first day of the program.
<u>WEEK 1 Lesson Reviews</u> 1. What is a functional GI disorder? 2. How do doctors diagnose functional GI disorders? 3. Who gets functional GI disorders? 4. How are functional GI disorders treated? 5. Learning about Pain: the pain puzzle and pain gate. 6. What might be affecting my gut pain?	4-6	Week ONE of the program.
Practice Exercise- Why is pain so puzzling?	7	Week ONE of the program.
Checklist for WEEK 1	8	Week ONE of the program.
<u>WEEK 2 Lesson Reviews</u> 1. Introduction to relaxation. 2. Deep-breathing. 3. Imagery. 4. Muscle Relaxation.	9-10	WEEK TWO of the program.
Practice Exercise- Deep-breathing	11	WEEK TWO of the program.
Practice Exercise- Imagery	11	WEEK TWO of the program.
Practice Exercise- Muscle Relaxation	11	WEEK TWO of the program.
Checklist for WEEK 2	12	WEEK TWO of the program.
<u>WEEK 3 Lesson Reviews</u> 1. Coping with stress and pain. 2. Changing how you think- Positive-thinking. 3. Problem-solving. 4. More coping strategies.	13-14	WEEK THREE of the program.
Practice Exercise- Thought changing	15	WEEK THREE of the program.
Practice Exercise- Positive-thinking	16-17	WEEK THREE of the program.
Practice Exercise- Problem-solving	18-20	WEEK THREE of the program.
Checklist for WEEK 3	21	WEEK THREE of the program.
<u>WEEK 4 Lesson Reviews</u> 1. Why are stress and pain behaviors important? 2. Stress and pain behavior management. 3. Staying active and creating a pain plan. 4. Review of Gutstrong.	22-23	WEEK FOUR of the program.
Practice Exercise- Stress and pain behaviors	24-25	WEEK FOUR of the program.
Practice Exercise- YOUR PAIN PLAN	26	WEEK FOUR of the program.
Checklist for WEEK 4	27	WEEK FOUR of the program.
QUESTIONS page	28	ANYTIME you have a question!

Appendix F: Table of Contents for Parent Workbook

**Table of Contents**

<b>Topic</b>	<b>Page Number</b>
Introduction to <i>Gutstrong</i>	2
Using the <i>Gutstrong</i> CD-ROM and relaxation audio CD	2
How can you help your teen with the program?	3
Week 1 summary	4-5
Week 1 exercise checklist	6
Week 2 summary	7-8
Week 2 exercise checklist	9
Week 3 summary	10-11
Week 3 exercise checklist	12
Week 4 summary	13-14
Week 4 exercise checklist	15
How to contact us	16
Troubleshooting the <i>Gutstrong</i> CD-ROM	16-17

