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Treating Gut Feelings: A Systematic Review of Psychological Treatments for Pediatric Inflammatory Bowel Disease

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TREATING GUT FEELINGS:
A SYSTEMATIC REVIEW OF PSYCHOLOGICAL TREATMENTS FOR PEDIATRIC INFLAMMATORY BOWEL DISEASE

A clinical dissertation submitted in partial satisfaction

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by

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DEDICATION

For my fellow IBD warriors.

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ABSTRACT

Psychological comorbidities and psychosocial challenges are prevalent among children and adolescents with Inflammatory Bowel Disease (IBD). However, a comprehensive review of the availability and effectiveness of psychological treatments for pediatric IBD patients is lacking. This systematic review aimed to determine the availability and efficacy of psychological interventions for children and adolescents with IBD. The systematic review was conducted in accordance with PRISMA guidelines and performed using two electronic databases, PsycINFO and PubMed, from inception until March 2022. Databases were searched for English-language, controlled trials of psychological interventions for children and adolescents with IBD. Outcomes of interest included: depression, anxiety, health-related quality of life, physical/somatic symptoms, and disease activity/severity. Of 478 identified articles, 11 articles reporting on seven original intervention studies met inclusion criteria. All interventions were cognitive-behavioral in nature and drew from principles of cognitive-behavioral therapy (CBT). Clinical and methodological diversity was observed across trials. Majority of trials included small sample sizes and were underpowered, with four recruiting fewer than 50 participants. Some benefits were reported in improving treatment outcomes, although findings were inconsistent. Despite an established evidence-base for psychological interventions in other pediatric chronic illness populations, evidence of efficacy for children and adolescents with IBD was limited. Interventions tested in methodologically robust trials are needed to enhance the provision of psychological treatments for pediatric IBD patients.

Keywords: Inflammatory Bowel Disease, pediatric, psychological intervention

Chapter 1: Introduction

Statement of the Problem

Inflammatory bowel disease (IBD) is a lifelong illness characterized by chronic inflammation of the gastrointestinal tract. Studies have shown that children and adolescents with IBD are at increased risk for emotional and behavioral difficulties (Mackner et al., 2013). Youth with IBD were found to have higher rates of psychological comorbidities with clinical depression rates up to 25%, in addition to lower health-related quality of life and social functioning in comparison to healthy peers and youth with other chronic illnesses (Greenley et al., 2010; Loftus Jr. et al., 2011; Ross et al., 2011). As such, psychological interventions have been recommended for pediatric IBD patients that present with reported symptoms.

Evidence of the efficacy of psychological interventions has been well-studied in adults with IBD; however, research appears limited regarding the efficacy of such treatments for youth with IBD. A Cochrane review from 2011 evaluated the effectiveness of psychological treatments for IBD with a primary focus on adult studies and included only two studies with pediatric populations (Timmer et al., 2011). Although limited, the results of the review indicated that adolescents with IBD may benefit from engaging in cognitive-behavioral therapy (CBT) with improvements found in quality of life, coping skills, and psychological symptoms. The narrow scope of this previous review precludes firm conclusions regarding the availability and efficacy of psychological interventions for pediatric IBD patients. However, research has grown in this area over the past decade, with increasing numbers of psychological intervention outcome studies for pediatric IBD patients. The present systematic review aims to determine the availability and efficacy of psychological interventions for children and adolescents with IBD.

Background

Inflammatory bowel disease (IBD) comprises a group of chronic inflammatory gastrointestinal disorders characterized by gastrointestinal inflammation and unpredictable periods of disease activity and remission (Dubinsky, 2008). There are two primary subtypes of IBD, Crohn's disease (CD) and ulcerative colitis (UC), which differ in anatomical location and nature of the inflammation. CD may involve the entire gastrointestinal tract, while UC involves solely the large intestine. The diagnosis of indeterminate colitis (IC) is used in cases in which the disease presentation cannot be clearly defined as CD or UC. IBD is estimated to affect over 3 million people in the United States, 2.5 to 3 million people in Europe, with a rising incidence in Asia (Burisch et al., 2013; Dahlhamer et al., 2016; Mak et al., 2020). IBD has been found among all races and ethnic groups (Loftus Jr., 2004). Historically, Caucasians were found to have higher incident rates of IBD; however, rates have been increasing among African American/Black and Latinx populations (Barnes et al., 2017). Approximately 25% of patients with IBD present before adulthood, with peak onset in adolescence (Abramson et al., 2010). The incidence of pediatric IBD is approximately 10 per 100,000 children with a prevalence of 100 to 200 per 100,000 children in the United States (Kappelman et al., 2013).

Common symptoms of IBD include abdominal pain, diarrhea, bloody stools, rectal bleeding, fecal incontinence and/or bowel urgency, fatigue, loss of appetite/food avoidance, and weight loss. In children and adolescents, growth failure and delayed pubertal development is common (Rabizadeh & Dubinsky, 2013). IBD patients are also at a higher risk of developing colorectal cancer in comparison with the general population (Kim & Chang, 2014). In addition, IBD with pediatric onset is often more extensive at time of presentation and undergoes continued progression within the first five to seven years following diagnosis (Szigethy et al., 2010).

The cause of IBD is not yet understood, although research has attributed it to an interaction between genetic predisposition, immune system disturbance, and environmental triggers (Rosen et al., 2015). IBD has remained an incurable disease with medical treatment focused primarily on symptom management to achieve and maintain symptom remission and improve quality of life. In times of disease flares/relapses, urgent medical treatment may be required. During periods of disease remission, patients may still experience painful and distressing gastrointestinal symptoms due to the development of visceral hypersensitivity or comorbid irritable bowel syndrome (Grover et al., 2009). Management of IBD symptoms typically involve a complex, time-consuming, and potentially burdensome treatment regimen consisting of multiple medication doses per day, infusions, dietary modifications, and in severe cases, surgery (Carter et al., 2004; Mowat et al., 2011). High-dose steroids are often utilized in treatment which elicit negative side-effects such as facial swelling, weight gain, acne, hair growth, and emotional lability (Greenley et al., 2010). Moreover, invasive medical procedures can result in traumatization and reactions ranging from dissociation, anxiety, and frustration, which can impact treatment and disease progression (Szigethy et al., 2010).

IBD often has an impact on more than just the gastrointestinal tract, as patients with IBD endorse elevated levels of emotional distress and higher rates of psychological comorbidities such as depression and anxiety diagnoses (Kappelman et al., 2014; Mikocka-Walus et al., 2016). Research has found that these psychological comorbidities have been negatively associated with psychological well-being and disease-related outcomes in IBD populations including lower quality of life, increased perceived stress, IBD relapse, inflammation, pain, poor medication adherence, and increased risk of surgery (Goodhand et al., 2012; Gray et al., 2012; Greenley et al., 2010; Regueiro et al., 2017). In pediatric IBD populations, high rates of anxiety and

depression have been found and youth with IBD have a higher risk of developing clinical depression and anxiety compared to youth with other chronic illnesses and healthy peers (Greenley et al., 2010; Mikocka-Walus et al., 2016). Youth with IBD are also at risk for lower quality of life and social functioning compared to healthy peers (Greenley et al., 2010; Loftus Jr. et al., 2011; Ross et al., 2011).

Current Theory and Research

There are a multitude of psychosocial challenges that pediatric IBD patients may face as a result of their illness. Diagnosis of IBD in both childhood and adolescence can involve a sense of loss of independence, control, and privacy, as well as impact one's body image, peer relationships, self-confidence, and productivity (Szigethy et al., 2010). In childhood, the unpredictable and stigmatizing symptoms of IBD may negatively impact a child's social development (Greenley et al., 2010). Frequent bathroom visits and unexpected disease flares create difficulties for children with IBD to attend social activities which can negatively impact peer-relationships and increase social isolation. These children may fear being the target of "bathroom humor," limit their social activities, and need to unexpectedly cancel plans due to disease flares (Greenley et al., 2010). Similarly, adolescents with IBD face significant psychosocial challenges related to their illness (Stapersma et al., 2019). Adolescence is a life phase characterized by changes in biological, psychological, social, and academic domains. Having a chronic disease such as IBD and its burdensome medical treatment may severely impact psychosocial functioning and quality of life in pediatric IBD patients.

Psychological Functioning

A number of studies have found that pediatric IBD patients are at-risk for developing co-morbid depression and anxiety disorders, with high prevalence rates varying from 20-50% for

depression and anxiety (Clark et al., 2014; Kilroy et al., 2011; Reigada et al., 2015a; Szigethy et al., 2014a). In a large study involving pediatric IBD patients, Loftus Jr. and colleagues (2011) found that children with IBD were at greater risk for developing depressive and anxiety disorders in comparison to healthy peers and that the utilization of steroids was a risk factor for developing such disorders. Studies conducted by Mackner & Crandall (2005; 2006) found that adolescents with IBD have a 4.6 times increased risk of having clinically significant symptoms of depression and anxiety in comparison to healthy peers. Hommel and colleagues (2008) found that 18.5-24.5% of their sample of youth with IBD exceeded the clinical cut-off for depression on validated assessment measures. Among the studies conducted that utilized a control group, depression and anxiety were found to be considerably higher among youth with IBD than control groups of healthy peers without chronic medical conditions (Greenley et al., 2010). These rates are comparable to other pediatric chronic illness populations such as cystic fibrosis, diabetes, and cancer, although rates of lifetime depression have been higher in those with IBD in comparison to individuals with cystic fibrosis (Burke et al., 1989; Greenley et al., 2010).

The unpredictable nature of the disease course, as well as the invasive and embarrassing symptoms involved, place pediatric IBD patients at increased risk for developing depressive symptoms (Greenley et al., 2010; Mackner et al., 2006; Reed-Knight et al., 2018). Furthermore, Szigethy and colleagues (2014a) found three distinct profiles of depression in their sample of youths with IBD. These three profiles included *mild depression*, categorized by low-grade depressive symptoms; *somatic depression,* characterized by severe fatigue, anhedonia, depressed mood, changes in appetite, and reduced motor activity; and *cognitive despair,* differentiated by individuals having the highest severity of self-reported depressive symptoms including suicidal

ideation (Szigethy et al., 2014a). Thus, subgroup-specific interventions may be needed to optimize depression treatment options in youth with IBD.

Given the increased risk for depressive symptoms in pediatric IBD patients, researchers have recently explored the relationship between prominent features of IBD and depressive symptoms. Studies have found that youth-perceived IBD stigma is a significant predictor of depressive symptoms and that youth who perceive greater uncertainty associated with their IBD are more likely to experience increased depressive symptoms (Baudino et al., 2019; Gamwell et al., 2018; Roberts et al., 2019). Research suggests that the unpredictability of living with IBD in addition to IBD-related stigma are associated with youth depressive symptoms (Gamwell et al., 2020).

Several studies have found that disease severity, which includes disease activity and pain, has an impact on mental health and well-being (Mackner & Crandall, 2007). In studies that found an effect, pediatric IBD patients who endorsed greater disease activity and pain reported poorer mental health and well-being in comparison to pediatric IBD patients in remission (Perrin et al., 2008). In a study conducted by Szigethy and colleagues (2014a), depressed youth with IBD reported greater disease activity than non-depressed individuals with IBD. Persoons and collaborators (2005) also found decreased remission rates in individuals with major depressive disorder. Other studies have not found such an effect, suggesting that while disease severity accounts for a small amount of variation in reports of well-being and mental health, additional factors are important to consider (Reed-Knight et al., 2016).

In addition to psychological comorbidities, short-term and long-term stress may negatively impact the course of IBD. Research regarding the gut-brain axis has been emerging, which suggests bidirectional communication between the gut and brain (Abautret-Daly et al.,

2018). Due to the bidirectionality of the gut-brain axis, psychological stress and/or psychological symptoms may, in turn, exacerbate IBD symptoms (Abautret-Daly et al., 2018). Some researchers have hypothesized that stress may be a risk factor for relapse in IBD patients. Langhorst and colleagues (2013) found that short-term stress, as opposed to long-term stress, was predictive of relapse in IBD patients with UC. However, the link between stress and IBD remains a controversial topic in the field and requires further study, due to some studies reporting no effect of stress on the development of IBD or risk of relapse (Li et al., 2004; Vidal et al., 2008). While increased risk of psychological symptoms during active IBD is generally agreed upon in the field, research is limited on the prevalence of psychological symptoms during disease remission (Abautret-Daly et al., 2018).

Health-Related Quality of Life & Coping

Health-related quality of life (HRQOL) is a concept that refers to one's perceived quality of physical, mental, emotional, and social functioning (Stapersma et al., 2019). HRQOL in children and adolescents with IBD has been found to be significantly lower in comparison to healthy peers (Knowles et al., 2018; Ross et al., 2011). Primary concerns related to HRQOL identified by pediatric IBD patients include pain, frequent school absences, lack of energy, need for medication, flare-ups, and having a lifelong condition (Mackner et al., 2004).

Additionally, other psychological factors such as illness perceptions (i.e., cognitive and emotional representations of one's disease) and coping (i.e., intentional efforts for cognitive and behavioral regulation) have been shown to be related to psychosocial outcomes, such as HRQOL, general functioning, and adjustment to IBD (Stapersma et al., 2019). Cognitive coping has been found to be a key component in the etiology and maintenance of anxiety and depression, particularly for youth with IBD (Mackner et al., 2004).

The Common Sense Model (CSM) developed by Diefenbach and Leventhal (1996) describes the relationship between disease characteristics, illness perceptions, coping, anxiety, depression, and HRQOL. This model proposes that illness characteristics lead to specific illness perceptions, which then influence the type of coping one utilizes to manage symptoms. Subsequently, these factors lead to positive or negative illness outcomes such as depression, anxiety, and lower HRQOL. Research has found several relationships between these variables in IBD patients, although most studies have been conducted in adult populations. A systematic review conducted by Brooks and colleagues (2016) that focused on pediatric IBD patients demonstrated that negative illness perceptions were associated with more psychological problems. In addition, coping was found to be a predictor of depression in youth with IBD (Van Tilburg et al., 2015). Stapersma and colleagues (2019) found that negative illness perceptions and depression were significantly associated with lower HRQOL in adolescent IBD patients.

Social & Academic Functioning

Late childhood and adolescence are significant transitional stages throughout various aspects of cognitive, emotional, and social domains, which also correspond with peak age of onset in pediatric IBD (Mackner et al., 2013). The emergence of a chronic illness such as IBD can negatively influence typical development, resulting in a range of challenges with psychosocial adjustment as well as attainment of developmental milestones and functional growth. Given the chronic, complex, unpredictable, and embarrassing nature of IBD, pediatric IBD patients are at increased risk for significant psychosocial maladjustment, particularly for children who endure more aggressive treatment options (Gray et al., 2011; Mackner & Crandall, 2007). Pediatric IBD patients' overall adjustment varies based on disease factors such as disease activity/course (e.g., chronic non-remitting versus remission) and treatment (e.g., high-dose

steroids, surgery). In addition to disease factors, individual differences in cognitive capacity, emotional self-regulation ability, and behavioral impulse control can influence a child's coping style and adjustment to illness.

Youth with IBD report social problems more frequently than healthy peers, with researchers hypothesizing that challenges with social relationships may be a significant predictor of mental health problems (Mackner & Crandall, 2007). IBD is susceptible to condition-related stigma, given that most cultures endorse a social taboo toward bowel symptoms (Saunders, 2014). As such, individuals with IBD report high levels of shame and embarrassment associated with their condition (Defenbaugh, 2013). Youth with IBD often withdraw from social interactions out of fear of experiencing abdominal pain, bowel noises, fecal incontinence and/or bowel urgency in public. Shame and embarrassment further lead individuals to attempt to conceal their illness which have been associated with reduced engagement with others, feelings of disconnection, and negative affect (Kaushansky et al., 2017; Saunders, 2014). A study conducted by Roberts and colleagues (2020) showed that difficulty communicating about one's illness to others was associated with thwarted belongingness which was linked to increased depression. Pediatric IBD patients are at increased risk of internalizing stigmatized beliefs, heightened shame, and lowered social self-efficacy, which can negatively impact mental health outcomes (Kaushansky et al., 2017).

Furthermore, a diagnosis of IBD during childhood or adolescence significantly impacts school functioning (Plevinsky et al., 2020). Pediatric IBD patients report increased school absences due to clinic visits, hospitalizations, and active disease symptoms, as well as difficulties with academic performance and social adjustment (Carreon et al., 2018). In a study conducted by Moody and colleagues (1999), researchers found that 60% of their sample of children with

moderate-to-severe IBD averaged three months of absences during the previous year and 80% felt that they had underachieved due to ill health. Additionally, children with chronic health conditions are at increased risk for peer victimization due to perceived differences from healthy peers (Storch & Masia-Warner, 2004). These differences such as frequent bathroom use, medication intake during school, school absences, changes in appearance (e.g., medication induced facial swelling, acne, weight loss/gain), short stature, pubertal delay, restricted diets, and limited ability to participate in normative social activities, may draw adverse attention from peers (Mackner et al., 2006). In addition, youth with IBD often experience lower grade point averages and poorer educational outcomes in comparison to their healthy peers (Mackner et al., 2012; Singh et al., 2015). Older adolescents experiencing severe disease hold the greatest risk for impaired academic functioning (e.g., attendance, academic performance), which may negatively impact transitions to higher education/college (Carreon et al., 2018).

Rationale and Relevance to Practice

There has been increasing support for the use of adjunctive psychological interventions to treat psychological comorbidities and disease-specific unmet clinical needs in chronically ill populations. While the efficacy of psychological interventions has been well-studied in adults with IBD, research appears limited regarding the efficacy of such treatments for youth with IBD. Due to the multitude of psychosocial challenges presented in pediatric IBD, a greater understanding of the effective psychological interventions available for this population is in critical need. Thus, the present systematic review aims to determine the availability and efficacy of psychological interventions for children and adolescents with IBD.

Research Questions

The research questions addressed in this review were: What are the available psychological interventions for pediatric IBD patients? Of the available interventions, which are the most effective in improving treatment outcomes? The primary treatment outcomes reviewed included depression, anxiety, and health-related quality of life. Secondary treatment outcomes consisted of physical/somatic symptoms, and disease activity. This review examined sample characteristics, intervention characteristics, and outcomes with the hope of furthering the literature regarding the availability and efficacy of psychological interventions for pediatric IBD patients.

Chapter 2: Methods

Systematic Review Approach

A systematic review was conducted to evaluate the current available quantitative research on psychological interventions for pediatric IBD patients. A narrative synthesis framework was utilized to report findings. Given the heterogeneity in study design and outcome assessments, results from individual studies were not able to be meaningfully pooled for group analysis; thus, precluding the use of a meta-analysis. As such, a narrative synthesis was most appropriate given the state of the field to summarize findings of included studies supported by evidence tables. This systematic review was carried out in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement guidelines (Page et al., 2021).

Eligibility Criteria

The inclusion and exclusion criteria for the systematic review were identified based on the research questions and the extensive literature review presented above. Eligible studies were defined as studies of interventions that are primarily psychological in nature targeting pediatric IBD patients. Studies must have been published in peer-reviewed journals and results of the intervention must have been described in the included studies. Given that the efficacy of psychological interventions for pediatric IBD has not been adequately examined, randomized controlled trials (RCTs) and nonrandomized controlled trials (NRCTs) were included in this review. Uncontrolled and qualitative studies were excluded as they are prone to subjectivity and results may not be generalizable. The full text of selected studies must have been written in English.

Participants of interest were pediatric patients (< 21 years) diagnosed with IBD (diagnosed according to clinical, radiologic, endoscopic, or histological criteria). Studies that

included mixed participant groups were included if the results were reported separately for IBD patients, or if more than 50% of the participants had IBD. Studies that included both children and adults were excluded, unless there was a separate analysis for the pediatric age group.

Included studies must have evaluated a psychological intervention. Psychological interventions were defined as any intervention based on (a) specific psychological principles, skills, or techniques, (b) a psychological theory, or (c) input from a mental health professional, delivered in isolation or in conjunction with other physical, practical, or educational components. Interventions that focused on bio-behavioral strategies (e.g., relaxation, hypnosis, biofeedback, mindfulness) were also considered for inclusion. Interventions delivered individually (with or without a parent-component), in a group-setting, or in a family context were also considered for inclusion. Studies must have gathered quantitative data utilizing outcome measures that assessed for psychological outcomes (e.g., depression, anxiety), HRQOL, physical/somatic symptoms and/or disease activity/severity. Studies that did not evaluate an intervention were excluded.

The primary goal of psychological interventions for the treatment of pediatric IBD is to reduce associated psychological symptoms (e.g., depression, anxiety), improve quality of life, decrease physical/somatic symptoms, and/or reduce disease activity/severity. Given that pediatric IBD patients are at increased risk for developing psychological comorbidities and lower quality of life, (a) depression, (b) anxiety, and (c) HRQOL were chosen as the primary outcomes as defined by scores on validated self- or caregiver-reported questionnaires and/or structured/semi-structured clinical interviews. Secondary outcomes included physical/somatic symptoms, and disease activity. Studies that did not measure primary or secondary outcomes were excluded. Additionally, studies that did not utilize validated instruments to measure outcomes were excluded.

Search Strategy

A comprehensive search was performed using two electronic databases, PsycINFO and PubMed, from inception to March 30, 2022. Searches were limited to peer-reviewed and English-language studies. Search terms used included inflammatory bowel disease, pediatric, and intervention. Synonyms for these search terms and full search strategy can be found in the List of Search Terms and Search Strategy chart (See Appendix B). The list of terms was selected based on a preliminary review of the literature, preliminary searches using various search strategies, and a brief pilot of data extraction methods. Relevant variations and combinations of search terms in the databases and MeSH terms were used. An example of these combinations included "Inflammatory bowel disease OR Crohn's disease OR ulcerative colitis" AND "pediatric OR child OR adolescent OR youth" AND "intervention OR treatment OR training OR therapy." See the Results section for details (e.g., number of records) from each database search.

Screening Process

Following database searches, each result was initially screened to determine eligibility. First, the title and abstract of each article was reviewed to determine whether the scope of the research variables was included. Unrelated articles or articles that did not focus on psychological interventions in pediatric IBD were excluded. Next, the full texts of remaining articles were read and screened for all inclusion and exclusion criteria to assess for eligibility. A spreadsheet was designed to record the results of the screening and selection process (see Appendix C for Screening and Selection Record). The PRISMA Flow Diagram (See Figure. 1) depicts the flow of sources from one phase of the systematic review to the next. It begins with a total number of records identified through database searches, then the total number of sources after duplicates were removed. Next, it states the number of articles that were screened via title and abstract for

eligibility and the number of articles that were excluded in that process. It then shows the number of sources where the full text was assessed for eligibility, and the number of studies that were excluded in that process accompanied by the reason for their exclusion. Finally, the diagram ends with the total number of studies included in the systematic review.

Data Collection and Extraction

Data from eligible studies was collected through a careful review of each selected study and stored in an excel spreadsheet (see Appendix D for Data Collection and Extraction Spreadsheet). The data collection and extraction spreadsheet was informed by various published data extraction forms. The specific variables chosen to be extracted were based on relevant information related to the research questions as well as a preliminary search of the research on psychological interventions for pediatric IBD. The data collection spreadsheet was organized by several categories: (a) General Information, (b) Design Characteristics and Methodological Features, (c) Sample Characteristics, (d) Intervention Characteristics, (e) Outcome Measures/Impact of Treatment, (f) Main Findings and Conclusions, (g) Limitations of the Study, and (h) Recommendations for Future Research. A section for additional notes was included within the categories for information that may be important but could not be obtained by the pre-identified extraction category. The data collection spreadsheet included the following columns in the presented order: Date of Extraction, Article I.D., In-text Citation, APA Citation, Study Aims, General Methodology, Study Design, Setting, Country, Sample Size, Age, Gender, Race/Ethnicity, Illness Type, Disease Severity, Age at Diagnosis, Time since Diagnosis, Theoretical Framework or Therapeutic Orientation, Intervention Format (e.g., group or individual), Caregiver/Parental Involvement, Number of Sessions, Frequency of Sessions, Duration of Treatment, Mode of Delivery, Intervention Group, Control or Comparison Group,

Intervention Components, Outcomes and Measurements: Depression, Outcomes and Measurements: Anxiety, Outcomes and Measurements: Health-related Quality of Life (HRQOL), Outcomes and Measurements: Physical/Somatic Symptoms, Outcomes and Measurements: Disease Activity/Severity, Time Points Assessed, Main Findings, Limitations, and Recommendations. Following data extraction, categories were developed based on what the authors provided and were described in the results section.

Risk of Bias and Quality Appraisal Methods

The quality of the chosen studies was assessed using a Quality Appraisal Form (see Appendix E for the Quality Appraisal Form) designed by the university's program research coordinator and modified by the researcher. The researcher evaluated each selected article with the Quality Appraisal Form to determine the overall quality of the literature used within the systematic review. The Quality Appraisal Form evaluated the following criteria: (a) Strength of literature foundation and rationale for study, (b) Clarity and specificity of research aims, (c) Quality of research design or methodological approach, (d) Sample selection and characteristics, (e) Data collection tools, (f) Data collection processes, (g) Analysis and presentation of data, (h) Discussion of study limitations, and (i) Consideration of culture and diversity. Each item was scored on a scale ranging from *weak* (1) to *strong* (3) with the option of *inapplicable* (NA). The rating for each of the above-mentioned components was used to obtain an overall rating of a study's quality. *Exemplary* quality scores were considered for studies that received a score consisting of all 3's, *Strong* quality scores consisted of mostly 3's, *Good/Adequate* quality scores consisted of mostly 2's, and *Weak* quality scores consisted of mostly 1's.

Given that the aim of this systematic review was to gather information about the availability and efficacy of psychological interventions for pediatric IBD patients, there was risk

of bias during the review and extraction process on part of the researcher. To minimize bias in the selection of studies, the quality appraisals were conducted after the data had been extracted. Following the completion of the quality appraisal process, findings were synthesized to provide a narrative conclusion on the overall caliber of the literature used in the systematic review. Furthermore, the results of this analysis helped form the basis of the recommendations and limitations of the review.

Data Management, Synthesis, and Analysis Methods

Following the completion of data collection and extraction, the collected data were organized and presented in three data tables. During the organization process, data were categorized and put into a consistent format. These tables were used as the evidence base for the research questions. Table 1. Study and Participant Characteristics presents data related to study design, sample characteristics, and demographic data from each of the included studies. Table 2. Intervention Characteristics presents information related to the availability of interventions as well as pertinent intervention components. Table 3. Treatment Outcomes and Main Findings presents information on the assessed outcomes, measuring instruments, and main findings of each included study.

Chapter 3: Results

Search Results

The final search yielded a result of 478 articles (PsycInfo: *n* = 241, PubMed: *n* = 237). Once duplicates were removed (*n* = 10), 468 articles were screened for eligibility, which included reviewing the title and abstract for relevancy. This resulted in the exclusion of 429 articles, with 39 full-text articles sought for retrieval. All full texts of the 39 articles were retrieved and assessed for eligibility based on inclusion and exclusion criteria. Of those articles, 28 were excluded due to being uncontrolled studies (*n* = 8), not assessing primary or secondary outcomes (*n* = 8), only including adult samples (*n* = 6), only including parents of children with IBD (*n* = 3), and not including separate analyses for the pediatric age group in studies that included both adolescents and young adults (*n* = 3). After full text screening for inclusion criteria, a total of 11 articles of which seven reported on original intervention studies were included in the systematic review. The remaining four articles reported on longitudinal results of the included original studies. Therefore, data from the four articles were extracted and included with the results of their respective original study. See Figure 1. PRISMA Flow Diagram for further details.

Study Population Characteristics

Majority of studies were conducted in the United States of America (*n* = 5; Levy et al., 2016; McCormick et al., 2010; Reigada et al., 2015b; Szigethy et al., 2007; Szigethy et al., 2014b). Remaining studies were conducted in the Netherlands (*n* = 2; Grootenhuis et al., 2009; Stapersma et al., 2018). Five were randomized controlled trials (RCTs; Levy et al., 2016; Reigada et al., 2015b; Stapersma et al., 2018; Szigethy et al., 2007; Szigethy et al., 2014b) and two were non-randomized controlled trials (NRCTs; Grootenhuis et al., 2009; McCormick et al.,

2010). Control conditions included treatment as usual (TAU; Stapersma et al., 2018; Szigethy et al., 2007), education support (Levy et al., 2016), supportive non-directive therapy (SNDT; Reigada et al., 2015b; Szigethy et al., 2014b), and wait-list control groups (Grootenhuis et al., 2009; McCormick et al., 2010). Sample sizes of included studies ranged from 22 to 217. Majority of trials were small, with four recruiting fewer than 50 participants (Grootenhuis et al., 2009; McCormick et al., 2010; Reigada et al., 2015b; Szigethy et al., 2007). Mean age ranged from 13.2 to 15.7 years. Majority of trials had an even gender distribution, except for two studies, one which consisted of 68.6% females (Stapersma et al., 2018) and the other which recruited females only to ensure a homogenous group (McCormick et al., 2010). All but one study (Grootenhuis et al., 2009) provided information on ethnicity/race. Of these studies, all had samples with 68% or more self-identified White/Caucasian participants (ranged from 68.2% to 94.6%).

All but one study (Reigada et al., 2015b) reported separately for IBD subtypes, in which the proportions with Crohn's disease (CD) ranged from 51.4% to 74.2%, ulcerative colitis (UC) from 22% to 37.2%, and indeterminate colitis (IC) from 7.5% to 12.5%. Of those studies, all samples had a higher rate of participants with Crohn's disease in comparison to the other two disease subtypes. Four of the studies reported on disease severity at baseline (Levy et al., 2016; McCormick et al., 2010; Stapersma et al., 2018; Szigethy et al., 2007). Severity rates ranged from 50% to 75.5% for *remission*, 24.3% to 29% for *mild*, and 8.2% to 29% for *moderate to severe*. Of those studies, majority of their samples were in remission at baseline. One trial recruited only participants who had comorbid IBD and an anxiety disorder (Reigada et al., 2015b) and two trials recruited participants with IBD who met criteria for mild to moderate depression (Szigethy et al., 2007; Szigethy et al., 2014b). One study recruited participants who

only had subclinical anxiety and/or depressive symptoms (Stapersma et al., 2018). See Table 1. Study and Participant Characteristics for details.

Intervention Availability

All of the studies evaluated interventions that were cognitive-behavioral in nature and drew from principles of cognitive-behavioral therapy (CBT), emphasizing the interrelationship between thoughts, feelings, behaviors, and physiology. Sessions ranged from three to 13 weekly sessions. All but one study included parental involvement in their interventions (Grootenhuis et al., 2009). One intervention held joint-sessions in which parents and children participated in the sessions together (Levy et al., 2016). One intervention incorporated parents intermittently throughout the session (e.g., parents were involved at the beginning and end of each session) in addition to having separate parent sessions (Reigada et al., 2015b). Three interventions held parent sessions separately from the child sessions (Stapersma et al., 2018; Szigethy et al., 2007; Szigethy et al., 2014b). Majority of interventions were delivered in-person, with one intervention being primarily virtual (e.g., one day in-person group workshop followed by six-weeks web-based skill review; Levy et al., 2016). Three interventions included a mix of in-person and telephone sessions, although primarily included face-to-face sessions (Stapersma et al., 2018; Szigethy et al., 2007; Szigethy et al., 2014b). Majority of the interventions utilized individual-based psychotherapy, while two studies utilized group interventions (Grootenhuis et al., 2009; McCormick et al., 2010).

Four studies evaluated two manualized, empirically-based, health-sensitive cognitive-behavioral interventions that were adapted specifically for IBD patients with comorbid psychological symptoms (e.g., depression, anxiety): Treatment of Anxiety and Physical Symptoms for Inflammatory Bowel Disease (TAPS + IBD; Reigada et al., 2015b) and Primary

and Secondary Control Enhancement Training for Physical Illness (PASCET-PI; Stapersma et al., 2018; Szigethy et al., 2007; Szigethy et al., 2014b). Both interventions utilized an individual psychotherapy format with parental involvement that ranged from nine to 13 weekly sessions. TAPS + IBD was developed to concurrently treat anxiety (including IBD-specific anxiety) and physical symptoms among pediatric patients with comorbid IBD and anxiety (Reigada et al., 2015b). This treatment utilizes components such as relaxation, cognitive restructuring, exposures, and homework exercises to target fears related to IBD-specific concerns and symptom management in addition to general (non-disease related) anxiety and functional physical symptoms. PASCET-PI is a disease-specific protocol developed for adolescents with IBD and depression. In addition to behavioral activation, cognitive restructuring, and problem-solving skills, disease-specific components are also included in the intervention such as physical illness narrative, disease-specific psychoeducation, techniques for pain and immune functioning, social skills training, and emphasis on IBD-related cognitions and behaviors (Szigethy et al., 2007).

Three additional skills-based cognitive-behavioral interventions were adapted for use with IBD patients to promote adaptive coping (Grootenhuis et al., 2009; Levy et al., 2016; McCormick et al., 2010), with two studies utilizing a group format (Grootenhuis et al., 2009; McCormick et al., 2010) and two studies including parental involvement (Levy et al., 2016; McCormick et al., 2010). Common components of these structured, skills-based interventions included psychoeducation regarding the CBT model and coping skills, teaching of relaxation skills, cognitive restructuring (e.g., identifying and changing maladaptive cognitions and discouraging negative self-talk), active skill practice in session, and homework assignments to reinforce the learned skills. See Table 2. Intervention Characteristics for details.

Intervention Efficacy

To examine the efficacy of the reported interventions, information regarding primary and secondary treatment outcomes and their respective measuring instruments were extracted from each of the included studies. For the purposes of this study, primary outcomes included depression, anxiety, and health-related quality of life (HRQOL). Secondary outcomes included physical/somatic symptoms and disease activity/severity. All studies included in this systematic review utilized validated assessment tools to measure treatment outcomes. All studies utilized at least one outcome assessment that included both self- and parent-report. Three studies incorporated semi-structured diagnostic clinical interviews in addition to assessment measures (Reigada et al., 2015b; Szigethy et al., 2007; Szigethy et al., 2014b). See Table 3. Treatment Outcomes and Main Findings for more details.

Depression

Five studies evaluated depression or depressive symptoms using validated symptom-based measures (Grootenhuis et al., 2009; Levy et al., 2016; Stapersma et al., 2018; Szigethy et al., 2007; Szigethy et al., 2014b). Among these studies, three showed significant findings (Stapersma et al., 2018; Szigethy et al., 2007; Szigethy et al., 2014b). In a RCT conducted by Szigethy and colleagues (2007), a disease-specific CBT intervention (i.e., PASCET-PI) was conducted for pediatric patients with comorbid IBD and subsyndromal depression. Results demonstrated that the CBT intervention was effective in reducing depressive severity but not for the number of depressive symptoms immediately post-intervention (Szigethy et al., 2007). The impact on depressive severity was not maintained at six- or 12-month follow-up (Thompson et al., 2012). In a later RCT, the same disease-specific CBT intervention was effective in reducing depressive symptoms, although outcomes were equally favorable to supportive non-directive

therapy (SNDT; Szigethy et al., 2014b). There were no significant differences between the CBT and SNDT groups in change over time and the trial did not include a treatment as usual control group (Szigethy et al., 2014b). Stapersma and colleagues (2018) conducted a RCT to evaluate the effectiveness of a disease-specific CBT protocol for IBD patients with subclinical anxiety and/or depressive symptoms compared to a treatment as usual control group. The trial utilized the same disease-specific CBT intervention that was originally developed to treat comorbid IBD and depression (i.e., PASCET-PI), although tailored the intervention for participants with anxiety. Participants in both the intervention and control groups improved in their symptoms of depression, anxiety, and HRQOL, indicating that the intervention did not perform better than standard medical care in improving depressive symptoms.

Anxiety

Four studies evaluated anxiety or anxiety-related symptoms using validated symptom-based measures (Grootenhuis et al., 2009; Levy et al., 2016; Reigada et al., 2015b; Stapersma et al., 2018). Of these studies, two trials showed significant findings (Reigada et al., 2015b; Stapersma et al., 2018). In a RCT conducted by Reigada and colleagues (2015b), a disease-specific CBT intervention (i.e., TAPS +IBD) was conducted for pediatric patients with comorbid IBD and anxiety. Results demonstrated that the CBT intervention was effective in reducing IBD-specific anxiety post-treatment and at three-month follow-up. As mentioned above, Stapersma and colleagues (2018) found that participants in both intervention and control groups improved in their symptoms of anxiety, indicating that the intervention did not perform better than standard medical care in improving anxiety symptoms.

Health-Related Quality of Life (HRQOL)

Four studies evaluated health-related quality of life (HRQOL) using validated measures (Grootenhuis et al., 2009; Levy et al., 2016; Stapersma et al., 2018; Szigethy et al., 2014b). Of these studies, majority utilized the IMPACT-III questionnaire, a disease-specific HRQOL measure developed for pediatric IBD (Levy et al., 2016; Stapersma et al., 2018; Szigethy et al., 2014b). Among these studies, three found significant findings (Grootenhuis et al., 2009; Levy et al., 2016; Stapersma et al., 2018). Grootenhuis and colleagues (2009) investigated the effects of a psychoeducational group intervention for adolescents with IBD on coping and HRQOL. The study detected a positive increase in the intervention group on a subscale of HRQOL (body image), although no additional effects were found on other subscales of HRQOL (Grootenhuis et al., 2009). Levy and colleagues (2016) conducted an RCT to evaluate the efficacy of a brief CBT intervention for children with IBD and their parents. The study found a significant overall treatment effect for child-reported IBD-specific quality of life (Levy et al., 2016). As mentioned above, Stapersma and colleagues (2018) found that participants in both intervention and control groups improved in their symptoms related to HRQOL, indicating that the intervention did not perform better than standard medical care in improving HRQOL.

Physical/Somatic Symptoms

Two studies evaluated physical or somatic symptoms using validated symptom-based measures (Levy et al., 2016; McCormick et al., 2010). These studies looked at varying aspects of physical/somatic symptoms, including abdominal pain (McCormick et al., 2010), somatization (McCormick et al., 2010), functional disability (Levy et al., 2016), and pain responses (Levy et al., 2016). In a trial conducted by Levy and colleagues (2016), the intervention did not have a significant effect on reducing symptoms of functional disability. Improvements over time on

pain responses were found, although the improvements were similar between the two conditions. A small coping skills intervention conducted by McCormick and colleagues (2010) found significant improvements in adolescents' somatic symptoms following treatment, although between-group comparisons were not significant.

Disease Activity/Severity

Majority of studies included a measure for disease activity/severity (Levy et al., 2016; Reigada et al., 2015b; Stapersma et al., 2018; Szigethy et al., 2007; Szigethy et al., 2014b). Each of these studies included the Pediatric Crohn's Disease Activity Index (PCDAI) for Crohn's disease patients, and either the Pediatric Ulcerative Colitis Activity Index (PUCAI) or the Clinical Score of Kozarek (CSK) for ulcerative colitis patients. While all three validated instruments include self-report on signs and symptoms of disease activity (e.g., abdominal pain, diarrhea, well-being, functional disability), only the PCDAI includes physical/objective findings and laboratory values. Of these studies, only one showed significant findings (Szigethy et al., 2014b). The study found that participation in the disease-specific CBT intervention group was associated with a greater reduction in disease activity over time in comparison to the SNDT group (Szigethy et al., 2014b). Secondary analyses indicated that of the participants in the CBT intervention group, patients with Crohn's disease with a somatic depressive subtype and active disease showed greater improvement in disease activity (Szigethy et al., 2015).

Chapter 4: Discussion

To our knowledge, this is the first systematic review to explore the availability and efficacy of psychological interventions for children and adolescents with IBD. The review identified seven controlled trials, which were all CBT-based interventions. Primary aims and treatment outcomes varied across studies. Three skills-based CBT interventions aimed to improve HRQOL and pain/somatic symptoms as a result of learning adaptive coping skills (Grootenhuis et al., 2009; Levy et al., 2016; McCormick et al., 2010). The remaining four trials primarily focused on improving psychological functioning through the reduction of depressive and/or anxiety symptoms (Reigada et al., 2015b; Stapersma et al., 2018; Szigethy et al., 2007; Szigethy et al., 2014b). These four studies evaluated two manualized, empirically-based, health-sensitive cognitive-behavioral interventions that were adapted specifically for IBD patients with comorbid psychological symptoms (e.g., depression, anxiety): TAPS + IBD and PASCET-PI (Reigada et al., 2015b; Stapersma et al., 2018; Szigethy et al., 2007; Szigethy et al., 2014b).

Overall, evidence of the efficacy of the seven identified psychological interventions was inconsistent. Reigada and colleagues (2015b) found that the TAPS + IBD intervention was associated with significantly greater reductions in IBD-specific anxiety. Szigethy and colleagues (2007) found that the PASCET-PI intervention was associated with significantly greater improvement in depression severity post-treatment, although improvement was not maintained longitudinally. In a later study by Szigethy and colleagues (2014b), both PASCET-PI and SNDT interventions resulted in significant reductions in depressive symptoms, although the difference between the two treatments was not significant. However, findings from this study indicated that PASCET-PI was associated with a greater reduction in disease activity, particularly for Crohn's disease patients with active disease and a somatic depressive subtype. Stapersma and colleagues

(2018) found that participants in both the adapted PASCET-PI intervention group and TAU control groups improved in their symptoms of depression and/or anxiety as well as HRQOL, although no significant differences were found between groups. Levy and colleagues (2016) found significant improvements in child-reported IBD-specific quality of life and pain responses, although improvement of pain responses over time were similar between groups. It is important to consider these findings while keeping in mind that majority of the studies excluded participants with significant mental illness and active IBD. This resulted in enrollment of participants with low baseline levels of psychological parameters, which may have made it more difficult to demonstrate improvement.

The two NRCTs also found significant findings on reported treatment outcomes; however, results should be interpreted with caution given methodological limitations. Grootenhuis and colleagues (2009) found significant improvement in body image, a domain of HRQOL, although no additional effects were found for other subscales of HRQOL. McCormick and colleagues (2010) found significant improvements in somatic symptoms following treatment in the intervention group, although between group comparisons were not significant. Despite evidence of the efficacy of psychological interventions for other pediatric chronic conditions (Thompson et al., 2011), the quality of the evidence for psychological interventions within pediatric IBD was "weak" and evidence of efficacy inconsistent. Thus, intervention research is urgently needed to strengthen the evidence base and inform mental health recommendations.

Limitations

Limitations of the current review include exclusive examination of English-language trials, which may have precluded potential valuable studies published in other languages. Furthermore, methodological limitations of the included studies generally rendered the current

evidence base “weak.” Major limitations included use of small and underpowered samples and study samples consisting of predominantly White/Caucasian participants in remission or with mild disease activity. Thus, findings cannot be generalized to the larger patient population. Additionally, trials that evaluated psychological functioning only included participants with subclinical depression or anxiety, which may have led to lack of significant treatment effects and potentially restricted the range of improvement on treatment variables. Interventions had considerable diversity in terms of methods and components. Most trials used a standard care or wait-list control; those incorporating an attentional control demonstrated discrepancies in process (i.e., intervention duration, format), reducing the capacity to account for potential motivational variables or nonspecific treatment effects. Additionally, the heterogeneity of outcomes made it difficult to directly compare across trials.

Recommendations for Research and Practice

Given the multitude of psychological comorbidities and psychosocial challenges present in children and adolescents with IBD, further empirical research into effective psychological interventions is urgently needed. Future studies should be conducted that include more rigorous methods, particularly prospective RCTs of protocolled interventions. Additionally, recruiting samples with clinically significant psychological distress or active disease as well as examining efficacy based on psychological and/or biological severity would also assist in assessing differential intervention efficacy. Furthermore, searches conducted in this review did not render any controlled trials on the efficacy of other types of psychological interventions with a bio-behavioral focus (e.g., relaxation, stress management, mindfulness, hypnosis, biofeedback) for pediatric IBD patients. Future research exploring the feasibility and efficacy of additional types of psychological interventions among pediatric IBD patients is needed.

In addition to implications for future research, this review highlights implications for clinical practice. Majority of studies were conducted in medical settings, which supports the feasibility and acceptability of screening for psychological symptoms as well as providing psychosocial interventions for pediatric IBD patients in this setting. This allowed for increased participant access to psychological services and the ability for providers to support patients in times of medical crises. Integrating behavioral health strategies directly into medical settings as well as tailoring treatment to be sensitive to increased disease activity seemed to be particularly helpful when working with this specific population. Mental health providers working with pediatric IBD patients are recommended to screen for depressive/anxiety symptoms, as these symptoms can affect the disease course and quality of life. A flexible therapeutic approach appears critical when working with youth with IBD given the unpredictable and relapsing nature of the disease.

Conclusions

In sum, the evidence for the efficacy of psychological interventions for children and adolescents affected by IBD was limited. Available evidence suggests positive treatment effects of CBT-based, disease-specific psychological interventions for children and adolescents with IBD. However, significant methodological limitations preclude firm conclusions regarding the efficacy of psychological interventions for pediatric IBD. Thus, there is an urgent need for methodologically robust trials to evaluate the efficacy of psychological interventions for pediatric IBD patients.

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Tables

Table 1

Study and Participant Characteristics

Author (Year)	Country	Study Design	Sample Size Total (*n*)	Age Range; Mean Age (SD)	Gender (%)	Ethnicity (%)	Disease Type (%)	Disease Severity (%)
Grootenhuis et al. (2009)	Netherlands	NRCT	I = 22 C = 18 *n* = 40	12-18; 15.5 (1.5)	F (52.5) M (47.5)	___	CD (70) UC (22.5) IC (7.5)	___
Levy et al. (2016)	USA	RCT	I = 91 C = 94 *n* = 185	8-17; 13.5 (2.7)	F (47) M (53)	White/Caucasian (77.9)	CD (68.6) UC (31.4)	Remission (63) Mild (28.8) Moderate to Severe (8.2)
McCormick et al. (2010) & Reed-Knight et al. (2012)	USA	NRCT	I = 13 C = 11 *n* = 24	11-17; 14.5 (1.9)	F (100)	White/Caucasian (91.7) Black/African American (8.3)	CD (54) UC (33.5) IC (12.5)	Remission (50) Mild (29) Moderate (21) Severe (0)
Reigada et al. (2015b)	USA	RCT	I = 11 C = 11 *n* = 22	9-17; 13.2 (2.1)	F (59.1) M (40.9)	White/Caucasian (68.2) Multi-racial (13.6) Latino/Hispanic (9.1) Black/African American (4.5) Asian (4.5)	___	___
Stapersma et al. (2018) & Stapersma et al. (2020)	Netherlands	RCT	I = 37 C = 33 *n* = 70	10-25* 17.69 (4.82)	F (68.6) M (31.4)	Dutch/Western (78.5)	CD (51.4) UC (37.2) IC (11.4)	Remission (75.7) Mild (24.3)
Szigethy et al. (2007) & Thompson et al. (2012)	USA	RCT	I = 22 C = 19 *n* = 41	11-17; 14.99 (2.01)	F (51) M (49)	White/Caucasian (78.1) Black/African American (14.6) Latino/Hispanic (2.4) Unspecified (4.9)	CD (70.7) UC (29.3)	Moderate to Severe (29)

Author (Year)	Country	Study Design	Sample Size Total (*n*)	Age Range; Mean Age (SD)	Gender (%)	Ethnicity (%)	Disease Type (%)	Disease Severity (%)
Szigethy et al (2014b) & Szigethy et al. (2015)	USA	RCT	I = 110 C = 107 *n* = 217	9-17; 14.3 (2.5)	F (53) M (47)	White/Caucasian (89.4)	CD (74.2) UC (25.8)	___

Note: **Methodology/Study Design:** control group (C); intervention group (I); non-randomized controlled trial (NRCT); randomized controlled trial (RCT). **Disease Type:** Crohn's Disease (CD); Indeterminant Colitis (IC); Inflammatory Bowel Disease (IBD); Ulcerative Colitis (UC).

** Stapersma et al. (2018) conducted separate analyses for youth and young adult age groups (i.e.., 10-20 years, 21-25 years).*

Table 2

Intervention Characteristics

Author (Year)	Intervention Aims	Format	Number of Sessions, Frequency, & Duration	Mode of Delivery	Setting	Control or Comparison Group
Grootenhuis et al. (2009)	Psychoeducational CBT-based group intervention that aimed to strengthen coping and improve HRQOL through teaching the active use of coping skills.	Adolescent group	6 weekly sessions	In-person	Medical clinic	Wait-list
Levy et al. (2016)	Brief SLCBT intervention that aimed to reduce parent solicitousness, increase children's adaptive pain coping efficacy beliefs and use of adaptive coping strategies, improve quality of life, reduce functional disability, and decrease health care utilization and school absenteeism.	Joint parent-child sessions; Each met independently with provider for 5-mins at the end of sessions	3 weekly sessions; Mean session length of 70.68-mins (SD = 14.31)	In-person	Medical clinic or family's home	ES
McCormick et al. (2010) & Reed-Knight et al. (2012)	CBT intervention that aimed to effectively help patients cope with IBD symptoms, restructure maladaptive thoughts, use distraction techniques and communication skills.	Independent adolescent and parent groups	1-day (6-hrs) in-person intervention followed by a 6-week web-based component (30-mins online weekly chat discussion)	In-person and web-based	Medical clinic (in-person session) & home (web-based sessions)	Wait-list
Reigada et al. (2015b)	TAPS + IBD is a disease-specific CBT protocol aimed to treat youth with comorbid IBD and anxiety disorders. This intervention concurrently addresses anxiety (including IBD-specific anxiety) and disease management among children and adolescents with IBD.	Independent adolescent and parent sessions with some family involvement	13 weekly sessions (60-mins) 2 booster sessions (60-mins) 3 parent sessions (60-mins)	In-person	Medical clinic or urban college	SNDT

Author (Year)	Intervention Aims	Format	Number of Sessions, Frequency, & Duration	Mode of Delivery	Setting	Control or Comparison Group
Stapersma et al. (2018) & Stapersma et al. (2020)	Adapted the PASCET-PI intervention (a disease-specific CBT protocol) to treat youth with comorbid IBD and subclinical anxiety and/or depressive symptoms. This intervention aimed to reduce anxiety and depressive symptoms and improve HRQOL.	Independent adolescent and parent sessions	10 weekly sessions 3 booster sessions (monthly; by telephone) 3 parent sessions	In-person (6 sessions) and telephone (4 sessions)	Medical clinics (6)	TAU
Szigethy et al. (2007) & Thompson et al. (2012)	PASCET-PI is a disease-specific CBT protocol developed to treat adolescents with IBD and depression with the aim to reduce depressive symptomology.	Independent adolescent and parent sessions.	9 to 11 weekly sessions (60-mins) 3 parent sessions	In-person and telephone *(more than 1/3 of sessions via telephone)*	Medical clinic	TAU
Szigethy et al (2014b) & Szigethy et al. (2015)	PASCET-PI is a disease-specific CBT protocol developed to treat adolescents with IBD. This intervention was compared to SDNT to evaluate treatment efficacy with the aim of a comparative reduction in depressive symptom severity and improved health-related adjustment and disease activity.	Independent adolescent sessions with family involvement at the end	Up to 12 weekly sessions (45-mins) 3 parent sessions	In-person and telephone *(more than 1/2 of sessions via telephone)*	Medical clinic	SNDT

Note: **Interventions & Control/Comparison Groups:** Cognitive-Behavioral Therapy (CBT); Education Support (ES); Primary and Secondary Control Enhancement Training for Physical Illness (PASCET-PI); Social Learning Cognitive-Behavioral Therapy (SLCBT); Supportive Non-Directive Therapy (SNDT); Treatment as Usual (TAU); Treatment of Anxiety and Physical Symptoms for Inflammatory Bowel Disease (TAPS + IBD).

Table 3

Treatment Outcomes and Main Findings

Author (Year)	Time Points Assessed	Outcomes Assessed	Measuring Instruments	Main Findings
Grootenhuis et al. (2009)	Baseline Post-immediate Follow-up 6-8 mo	Depression Anxiety HRQOL	CBCL STAI-C DUX-25	Significant improvement in body image, a domain of HRQOL, although no additional effects found on other subscales of HRQOL. No intervention effects found for anxiety and behavioral-emotional outcomes.
Levy et al. (2016)	Baseline Post-immediate Follow-up 3, 6, 12 mo	Depression Anxiety HRQOL Physical/Somatic Disease Activity	CDI MASC IMPACT-III FDI; PRI PUCAI; PCDAI	Significant overall treatment effect found for child-reported IBD-specific quality of life in the SLCBT intervention group. No significant treatment effects for child- or parent-reported depression or anxiety. No significant effect on reducing symptoms of functional disability. Improvements over time on pain responses were found, although the improvements were similar between the two conditions.
McCormick et al. (2010) & Reed-Knight et al. (2012)	Baseline Post-immediate Follow-up 6 mo	Physical/Somatic	API; CSI	Significant improvements in adolescents' somatic symptoms following treatment in the intervention group, although between-group comparisons were not significant.
Reigada et al. (2015b)	Baseline Post-immediate Follow-up 3 mo	Anxiety Disease Activity	ADIS-IV-P/C; IBD-SAS PUCAI; PCDAI	TAPS + IBD intervention was associated with significantly greater reductions in IBD-specific anxiety post-treatment and at three-month follow-up.
Stapersma et al. (2018) & Stapersma et al. (2020)	Baseline Post-immediate Follow-up 6 & 12 mo	Depression Anxiety HRQOL Disease Activity	CDI SCARED IMPACT-III PUCAI; PCDAI	Participants in both the PASCET-PI intervention and TAU control groups improved in their symptoms of depression, anxiety, and HRQOL. Results showed no difference between the PASCET-PI and TAU group post treatment and at 12-month follow-up.
Szigethy et al. (2007) & Thompson et al. (2012)	Baseline Post-immediate Follow-up at 6 & 12 mo	Depression Disease Activity	CDI; K-SADS-PL CSK; PCDAI	The PASCET-PI intervention group showed significantly greater improvement in depressive severity than the comparison group. The impact on depressive severity was not maintained at six- or 12- month follow-up. No significant differences between groups for number of depressive symptoms.

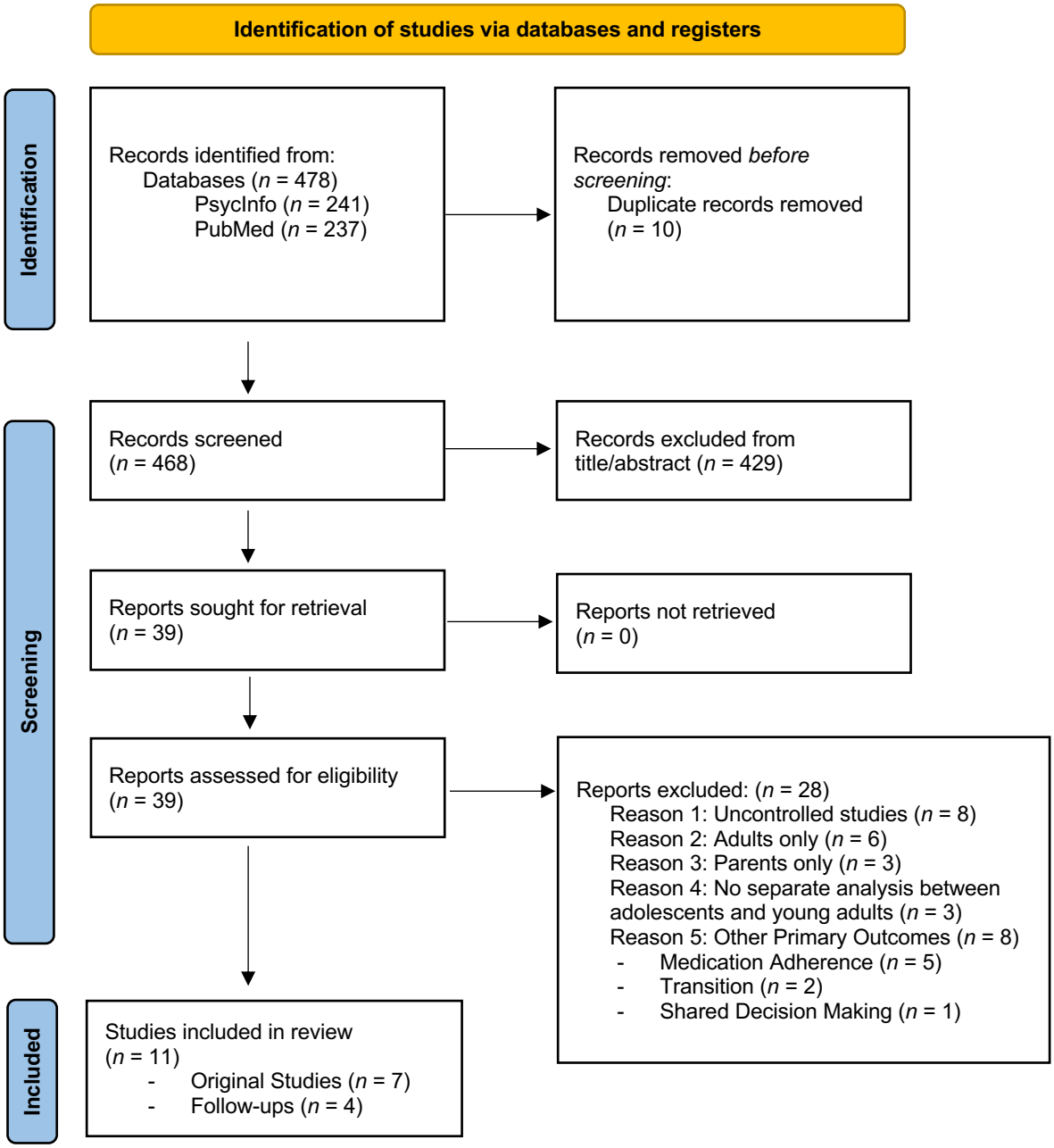
Author (Year)	Time Points Assessed	Outcomes Assessed	Measuring Instruments	Main Findings
Szigethy et al (2014b) & Szigethy et al. (2015)	Baseline Post-immediate	Depression HRQOL Disease Activity	CDI; K-SADS-PL; CDRS-R IMPACT-III PUCAI; PCDAI	Both PASCET-PI and SNDT interventions resulted in significant reductions in depressive symptoms, although the difference between the two treatments was not significant. Compared to SNDT, PASCET-PI was associated with a greater reduction in IBD activity. Secondary analyses indicated that of the participants in the CBT intervention group, patients with Crohn's disease with a somatic depressive subtype and active disease showed greater improvement in disease activity.

Note: **Measuring Instruments: Depression**: Child Behavior Check List (CBCL); Child Depression Inventory (CDI); Children's Depression Rating Scale–Revised (CDRS-R); Kiddie-Schedule for Affective Disorders and Schizophrenia – Present and Lifetime Version (K-SADS-PL). **Anxiety**: Anxiety Disorders Interview Schedule for DSM-IV: Parent and Child Versions (ADIS-IV-P/C); IBD-Specific Anxiety Scale (IBD-SAS); Multidimensional Anxiety Scale for Children (MASC); Screen for Child Anxiety- Related Emotional Disorders (SCARED); State-Trait Inventory for Children (STAI-C). **HRQOL**: Dutch Children's AZL/TNO Quality of Life Questionnaire (DUX-25); IMPACT-III Questionnaire (IMPACT-III). **Physical/Somatic Symptoms:** Abdominal Pain Index (API); Child Somatization Inventory (CSI); Functional Disability Inventory (FDI); Pain Response Inventory (PRI). **Disease Activity/Severity**: Clinical Score of Kozarek (CSK); Pediatric Crohn's Disease Activity Index (PCDAI); Pediatric Ulcerative Colitis Activity Index (PUCAI).

Figures

Figure 1

Prisma Flow Diagram



APPENDIX A

Evidence Table of Included Studies

Abbreviated Reference	APA Citation
Grootenhuis et al., 2009	Grootenhuis, M. A., Maurice-Stam, H., Derkx, B. H., & Last, B. F. (2009). Evaluation of a psychoeducational intervention for adolescents with inflammatory bowel disease. *European Journal of Gastroenterology & Hepatology*, *21*(4), 340-345.
Levy et al., 2016	Levy, R. L., Van Tilburg, M. A., Langer, S. L., Romano, J. M., Walker, L. S., Mancl, L. A., Murphy, T. B., Claar, R. L., Feld, S. I., Christie, D. L., Abdullah, B., DuPen, M. M., Swanson, K. S., Baker, M. D., Stoner, S. A., & Whitehead, W. E. (2016). Effects of a cognitive behavioral therapy intervention trial to improve disease outcomes in children with inflammatory bowel disease. *Inflammatory Bowel Diseases*, *22*(9), 2134-2148.
McCormick et al., 2010	McCormick, M., Reed-Knight, B., Lewis, J. D., Gold, B. D., & Blount, R. L. (2010). Coping skills for reducing pain and somatic symptoms in adolescents with IBD. *Inflammatory Bowel Diseases*, *16*(12), 2148-2157.
Reed-Knight et al., 2012	Reed-Knight, B., McCormick, M., Lewis, J. D., & Blount, R. L. (2012). Participation and attrition in a coping skills intervention for adolescent girls with inflammatory bowel disease. *Journal of Clinical Psychology in Medical Settings*, *19*(2), 188-196.
Reigada et al., 2015b	Reigada, L. C., Polokowski, A. R., Walder, D. J., Szigethy, E. M., Benkov, K. J., Bruzzese, J. M., & Masia Warner, C. (2015). Treatment for comorbid pediatric gastrointestinal and anxiety disorders: A pilot study of a flexible health sensitive cognitive-behavioral therapy program. *Clinical Practice in Pediatric Psychology*, *3*(4), 314-326.
Stapersma et al., 2018	Stapersma, L., van den Brink, G., van der Ende, J., Szigethy, E. M., Beukers, R., Korpershoek, T. A., Theuns-Valks, S. D., Hillegers, M. H., Escher, J. C., & Utens, E. M. (2018). Effectiveness of disease-specific cognitive behavioral therapy on anxiety, depression, and quality of life in youth with inflammatory bowel disease: A randomized controlled trial. *Journal of Pediatric Psychology*, *43*(9), 967-980.
Stapersma et al., 2020	Stapersma, L., van den Brink, G., van der Ende, J., Szigethy, E. M., Groeneweg, M., de Bruijne, F. H., Hillegers, M. H., Escher, J.C., & Utens, E. M. (2020). Psychological outcomes of a cognitive behavioral therapy for youth with inflammatory bowel disease: results of the HAPPY-IBD randomized controlled trial at 6-and 12-month follow-up. *Journal of Clinical Psychology in Medical Settings*, *27*(3), 490-506.
Szigethy et al., 2007	Szigethy, E., Kenney, E., Carpenter, J., Hardy, D. M., Fairclough, D., Bousvaros, A., Keljo, D., Weisz, J., Beardslee, W. R., Noll, R., & DeMaso, D. R. (2007). Cognitive-behavioral therapy for adolescents with inflammatory bowel disease and subsyndromal depression. *Journal of the American Academy of Child & Adolescent Psychiatry*, *46*(10), 1290-1298.
Szigethy et al., 2014b	Szigethy, E., Bujoreanu, S. I., Youk, A. O., Weisz, J., Benhayon, D., Fairclough, D., Ducharme, P., Gonzalez-Heydrich, J., Keljo, D., Srinath, A., Bousvaros, A., Kirshner, M., Newara, M., Kupfer, D., & DeMaso, D. R. (2014). Randomized efficacy trial of two psychotherapies for depression in youth with inflammatory bowel disease. *Journal of the American Academy of Child & Adolescent Psychiatry*, *53*(7), 726-735.
Szigethy et al., 2015	Szigethy, E., Youk, A. O., Gonzalez-Heydrich, J., Bujoreanu, S. I., Weisz, J., Fairclough, D., Ducharme, P., Jones, N., Lotrich, F., Keljo, D., Srinath, A., Bousvaros, A., Kupfer, D., & DeMaso, D. R. (2015). Effect of 2 psychotherapies on depression and disease activity in pediatric Crohn's disease. *Inflammatory Bowel Diseases*, *21*(6), 1321-1328.
Thompson et al., 2012	Thompson, R. D., Craig, A., Crawford, E. A., Fairclough, D., Gonzalez-Heydrich, J., Bousvaros, A., Noll, R. B., DeMaso, D. R., & Szigethy, E. (2012). Longitudinal results of cognitive behavioral treatment for youths with inflammatory bowel disease and depressive symptoms. *Journal of Clinical Psychology in Medical Settings*, *19*(3), 329-337.

APPENDIX B

List of Search Terms and Search Strategy

LIST OF SEARCH TERMS

Search Term ID#	Primary Term	Synonyms/ Alternate Forms	Notes
01	Inflammatory Bowel Disease	“IBD”, “Crohn’s disease”, “ulcerative colitis”	
02	Pediatric	"pediatric" , "child/children" , "youth" , "adolescent/adolescents/adolescence"	
03	Psychological Intervention	“therapy”, “intervention”, “treatment”, "training"	

COMPREHENSIVE SEARCH PLAN

Search Type	Databases or Sources	Search Term ID(s)	Search Syntax or Instructions	Fields to Search	Specifiers	Search Date	# of Records
Electronic Database	PsycINFO	1, 2, 3	TX (inflammatory bowel disease or ibd or ulcerative colitis of crohn’s disease) AND TX (pediatric or child or adolescent or youth) AND TX (intervention or treatment or training or therapy)	Title, Keywords, Abstract	*Language: English *Type: Peer-reviewed articles only	3/30/22	241
Electronic Database	PubMed	1, 2, 3	(("inflammatory bowel disease"[ti] OR "Crohn's disease"[ti] OR "ulcerative colitis"[ti] AND (english[Filter])) AND ("pediatric"[ti] OR "children"[ti] OR "adolescents"[ti] OR "youth"[ti] AND (english[Filter]))) AND ("intervention"[ti] OR "therapy"[ti] OR "program"[ti] OR "training"[ti] AND (english[Filter]))	Title, Keywords, Abstract	*Language: English *Type: Peer-reviewed articles only	3/30/22	237

APPENDIX C

Screening and Selection Record

Decision Codes:
Include/Continue to Abstract/Continue to Full Text/Undecided/Exclude (**IN/CFT/CAB/UN/EX**)

Criteria Codes:
(Is the Criteria Met?) Yes/Unclear/No (**Y/UC/NO**)

PHASE 1 (Red): Title/Keywords/Abstract (Screening)
PHASE 2 (Blue): Full-Text Review (Eligibility)
PHASE 3 (Green): Final Decision (Selection)

SCREENING AND SELECTION RECORD

PHASE 1: Title/Keywords/Abstract (Screening) PHASE 2: Full-Text Review (Eligibility) PHASE 3: Final Decision (Selection)

DECISION CODES: INCLUDE/CONTINUE TO ABSTRACT/CONTINUE TO FULL TEXT/UNDECIDED/EXCLUDE (IN/CAB/CFT/UN/EX)
CRITERIA CODES: (IS THE CRITERIA MET?) YES/UNCLEAR/NO (Y/UC/N)

AUTHOR(S)	YEAR	ABBREVIATED TITLE	DATABASES/ SOURCES	TITLE AND/OR KEYWORD SCREEN: DECISION - DATE	ABSTRACT SCREEN: DECISION - DATE	FULL-TEXT SCREEN?	INCL (SO): *Published & Peer-Reviewed Study*	INCL (SO): *Written in English*	INCL (RV): Psychological *Intervention*	INCL(RV): Targets *Depression, Anxiety, HRQOL, Physical/Somatic Symptoms, or Disease Activity/Severity*

INCL(PAR): Age *(under 21)*	INCL(PAR): *Illness (IBD)*	INCL (M): *Quantitative*	EXCL: *Qualitative*	EXCL: *No separate analysis for pediatric age group*	EXCL: *Did not evaluate intervention*	EXCL: *Did not utilize validated measures for outcomes*	EXCL: *Did not target primary or secondary outcomes*	REVIEWER DECISION - DATE	SECONDARY/ CONFIMATORY DECISION	FINAL DECISION	FINAL DECISION DATE	DECISION NOTES

APPENDIX D

Data Collection and Extraction Spreadsheet

Date of Extraction	Article I.D. In-text Citation	APA Citation	Study Aims	General Methodology	Study Design	Sample: Setting	Sample: Country	Sample: Size	Sample: Age	Sample: Gender	Sample: Race/Ethnicity	Sample: Illness Type	Sample: Disease Severity	Sample: Age at Diagnosis	Sample: Time since Diagnosis

Intervention: Theoretical Framework/ Therapeutic Orientation	Intervention: Format	Intervention: Caregiver/Parental Involvement	Intervention: Number of Sessions	Intervention: Frequency	Intervention: Duration	Intervention: Mode of Delivery	Intervention Group	Control / Comparison Group	Intervention Components

Outcomes & Measures: Depression	Outcomes & Measures: Anxiety	Outcomes & Measures: HRQOL	Outcomes & Measures: Physical/Somatic symptoms	Outcomes & Measures: Disease activity/ Severity	Time Points Assessed	Main Findings	Limitations	Recommendations

APPENDIX E

Quality Appraisal Form

INDIVIDUAL STUDY QUALITY APPRAISAL FORM FOR SYSTEMATIC REVIEWS

Developed by Shelly P. Harrell, Ph.D., Pepperdine University

Author(s) and Year: _____ **Study ID#**_____

Methodology: Quantitative Mixed Methods

Specific Design/Inquiry Approach: _____

RATING SCALE: Strong=3 Good/Adequate=2 Weak=1 N/A

1. **Strength of Literature Foundation and Rationale for Study:** _____
   (POSSIBLE CONSIDERATIONS: current and relevant references, background literature sufficiently comprehensive, Need/Rationale for study clearly stated, etc.)

2. **Clarity and specificity of Research Aims/Objectives/Questions/Hypotheses:** _____

3. **Quality of research design or methodological approach:** _____
   GENERAL CONSIDERATIONS: provides rationale for design chosen, appropriateness for research questions, clear description of design and methodological approach, strength of design characteristics utilized, internal and external validity considered in design; potential confounds identified and addressed in some way, specific design-based "risk of bias" criteria considered such as randomization, blinding

4. **Sample Selection and Characteristics:** _____
   GENERAL CONSIDERATIONS: detailed description of sample characteristics, adequacy of sample characteristics in the context of research aims, detailed description of recruitment/selection of participants; rationale provided for sample size; inclusion and exclusion criteria indicated as relevant, representativeness of sample, adequacy of sample size in context of design, extent of selection or sample bias

5. **Data Collection Tools (Scales, Observation, Interviews, etc.):** _____
   GENERAL CONSIDERATIONS: rationale for selection, appropriateness for assessing variables, development of study-specific tool or process clearly described, piloting, pretesting, psychometric properties (reliability, validity, utility) reported, adequacy of psychometric properties, normative or standardization data described

6. **Data Collection Processes:** _____
   POSSIBLE CONSIDERATIONS: data collection procedures clearly described in sufficient detail, intervention strategies and implementation described in detail, quality of data collected, design-specific considerations such as attrition in RCTs, saturation in grounded theory

7. **Analysis and Presentation of Data:** _____
   GENERAL CONSIDERATIONS: appropriateness of analysis for research questions and type of data; results presented clearly and comprehensively; usefulness and clarity of any tables, graphs, and charts, power and effect size reported; relevant statistics reported clearly; effective use of tables

8. **Discussion of Study Limitations:** _____
   GENERAL CONSIDERATIONS: identifies and discusses limitations in the context of design/strategy utilized, addresses various forms of bias, internal validity, external validity (generalizability), ecological validity

9. **Consideration of culture and diversity:** _____
   POSSIBLE CONSIDERATIONS: attention to diversity within sample, includes culturally appropriate methods and tools, avoids biased language, uses appropriate terminology

OVERALL RATING:	**EXEMPLARY** (e.g., all "3"s)	**STRONG** (e.g., mostly "3"s)	**GOOD/ADEQUATE** (e.g., mostly "2"s).	**WEAK** (e.g., mostly "1"s)

APPENDIX F

GPS IRB Non-Human Subjects Determination Notice

PEPPERDINE UNIVERSITY

Graduate & Professional Schools Institutional Review Board

March 29, 2022

Protocol #: **32922**

Project Title: Treating Gut Feelings: Psychological Treatment for Pediatric Inflammatory Bowel Disease.

Dear Venus:

Thank you for submitting a "GPS IRB Non-Human Subjects Notification Form" for *Treating Gut Feelings: Psychological Treatment for Pediatric Inflammatory Bowel Disease* project to Pepperdine University's Institutional Review Board (IRB) for review. The IRB has reviewed your submitted form and all ancillary materials. Upon review, the IRB has determined that the above titled project meets the requirements for *non-human subject research* under the federal regulations 45 CFR 46.101 that govern the protection of human subjects.

Your research must be conducted according to the form that was submitted to the IRB. If changes to the approved project occur, you will be required to submit *either* a new "GPS IRB Non-Human Subjects Notification Form" or an IRB application via the eProtocol system (httpw://irb.pepperdine.edu) to the Institutional Review Board.

A goal of the IRB is to prevent negative occurrences during any research study. However, despite our best intent, unforeseen circumstances or events may arise during the research. If an unexpected situation or adverse event happens during your investigation, please notify the IRB as soon as possible. We will ask for a complete explanation of the event and your response. Other actions also may be required depending on the nature of the event. Details regarding the timeframe in which adverse events must be reported to the IRB and documenting the adverse event can be found in the *Pepperdine University Protection of Human Participants in Research: Policies and Procedures Manual* at https://community.pepperdine.edu/irb/policies/.

Please refer to the protocol number denoted above in all further communication or correspondence related to this approval.

On behalf of the IRB, we wish you success in this scholarly pursuit.

Sincerely,

Institutional Review Board (IRB)
Pepperdine University

cc: Mrs. Katy Carr, Assistant Provost for Research
Dr. Judy Ho, Graduate School of Education and Psychology IRB Chair