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THE MODERATING ROLE OF EMOTION REGULATION IN THE RELATIONSHIP
BETWEEN STRESS AND INFLAMMATORY BOWEL DISEASE SEVERITY
AMONG DIAGNOSED INDIVIDUALS

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ABSTRACT

This study examined whether both perceived and objectively rated chronic stress are contributing external factors to altered Inflammatory Bowel Disease (IBD) disease severity among diagnosed individuals. This study further examined whether emotion regulation (ER) acts as an ameliorative factor within this relationship. Of additional interest to this investigation was whether objectively rated stress (acquired via the UCLA Life Stress Interview) provided a unique contribution to this relationship. Recent investigations suggest that higher levels of perceived stress may result in increased IBD severity. Further, ER deficits may be associated with increased IBD disease activity in response to both chronic and perceived stress. Participants ($N=30$) completed measures of perceived and chronic stress, ER, and disease severity. Multiple moderation models were examined to determine the moderating role of ER (both adaptive and maladaptive) within relationships between both perceived and chronic stress and disease severity (measured by the Harvey Bradshaw Index). No ER moderation effect was observed in the relationship(s) between objective and perceived stress ratings and IBD disease severity. However, results do suggest that adaptive and maladaptive ER significantly influence disease severity (decreased and increased respectively) independent of both objective and perceived stress ratings. These findings suggest the utility of ER-informed psychoeducation and interventions in the treatment and maintenance of IBD.

Keywords: inflammatory bowel disease, stress, emotion regulation, disease severity

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CHAPTER I

INTRODUCTION

Inflammatory Bowel Disease (IBD) is a term used to refer to both Crohn's Disease (CD) and Ulcerative Colitis (UC). IBD is highly prevalent and affects approximately 7,000 to 47,000 individuals living in the United States and Canada each year (Crohn's and Colitis Foundation of America, 2015; Loftus, 2004). IBD symptom expression is characterized by periods of "flares" and remission(s); nearly 25-50% of individuals diagnosed with IBD "relapse", or experience active expression of disease, each year (Crohn's and Colitis Foundation of America, 2015; Riley, Mani, Goodman, & Lucas, 1990; Sewitch, et al., 2001). Individuals are typically diagnosed with IBD when they are 15 to 35 years old (Crohn's and Colitis Foundation of America, 2015; Sewitch, et al., 2001). Further, the risk of mortality as a result of complications brought on by UC and/or CD approximates 50% in the first one to two years following initial diagnosis (Carter, Lobo & Travis, 2004; Murray, 1984).

Existing medical interventions for IBD can cost an individual with IBD anywhere from \$5,066 to \$18,963 annually (Crohn's and Colitis Foundation of America, 2015). IBD's impact can be felt not only individually, but nationally as well. In fact, the IBD financial burden in the U.S. is markedly high, with the total annual economic cost for

treatment of IBD estimated at \$14.6 billion to \$31.6 billion (Crohn's and Colitis Foundation of America, 2015; Gibson, et al., 2008). For these reasons, it is important to identify factors that contribute to disease exacerbation, disrupting periods of decreased, or even remitted, disease activity.

Among the myriad of identified risk factors for IBD onset and exacerbation, stress, specifically chronic *subjective* (perceived) stress, has received much attention (Bhatia & Tandon, 2005; Danese, Sans, & Fiocchi, 2004; Felton, Revenson & Hinrichsen, 1984; Soderholm, et al., 2002). While *objective* stress has been largely absent in the literature, there is evidence suggesting it may be worth investigating. Objective stress approximation measures may in fact provide for a more impartial examination of the stress-disease severity relationship (Hammen, Kim, Eberhart & Brennan, 2009; Naliboff, et al., 2008). Thus, the investigation of both types of stress is indicated in order to gain a more comprehensive understanding of the relationship between stress and IBD.

Investigation into client-directed stress mitigation tools may provide individuals with the ability to modify the potential impact of everyday external factors, such as stress, on IBD severity. Emotion regulation (ER) strategies are one such “tool” that may play a substantial role in mitigating the effects of stress on disease course (Mattlin, Wethington & Kessler, 1990; Wang & Saudino, 2011). Maladaptive attempts to deal with disease related stressors are known to contribute to poor IBD outcomes, while the use of adaptive emotion regulation strategies could lessen such deleterious effects of stress on IBD (Danese, Sans & Fiocchi 2004; Danesh, Choramrezaei, Torkzadeh, Mirbagher, Sloku & Emami, 2015; Hall & Rubin, 2005; Iglesias-Rey, et al., 2013; Wolfe & Sirois, 2008). The present study aims to examine the relationship between perceived and objective stress,

IBD severity, and ER with the goal to determine whether ER acts as a *moderator* in this relationship.

Importantly, the proposed project is part of a larger investigation comprised of a number of emotion and trait-related measures, collected in part via Ecological Momentary Assessment (EMA). The current study will solely utilize self and interview-reports of individual stress (chronic stress specifically) and self-report emotion regulation utilization and disease severity data collected as a part of the larger endeavor.

CHAPTER II

BACKGROUND

2.1 Inflammatory Bowel Disease: Overview

“IBD” refers to autoimmune diseases that affect the gastrointestinal (GI) tract: UC and CD. While individuals with either UC or CD share many similar and/or identical symptoms, the main distinction between these two disease subtypes lies in the location of disease within the body. UC is limited to the colon while CD has the potential to affect any part of the GI tract (Carter, Lobo & Travis, 2004; Crohn’s and Colitis Foundation of America, 2015; Schwarz & Blanchard, 1990). Symptoms of active disease include: abdominal pain, fatigue, blood and mucus in stool, joint pain, ulcers in small and large intestine(s), fecal frequency, weight loss, anemia, diarrhea, nausea, “brain fog” (confusion/disorientation and/or inability to think clearly), strictures (most commonly scarring causing GI blockage), fistulas (open connections between two strictures and/or a stricture with nearby organ tissue), abscesses, and eye inflammation (uveitis) (Carter, Lobo, & Travis, 2004; Greene, Blachard & Wan, 1994; Murray, 1984; Schwarz & Blachard, 1990; Wolfe & Sirois, 2008). The course of IBD is unpredictable, pervasive, and at times debilitating.

The course of IBD is marked by recurrent periods of remissions and flares. “Flare” is a term used to refer to an active exhibition of symptoms. Further, the term “remission” is used here to indicate an absence of active disease, achieved organically, natural submission of disease, or clinically, achieved via pharmacological agents (Bitton, et al., 2008; Bitton, et al., 2003; Riley, Goodman & Lucas, 1990).

Medication, diet change, exercise, and surgery are currently the most readily accepted and implemented interventions for the treatment of IBD. These treatments are employed with the aim to reduce inflammation, not to eliminate the disease (Crane & Martin, 2004; Crohn’s and Colitis Foundation of America, 2015; Sajadinejad, Asgari, Molavi, Kalantari & Adibi, 2012; Wolfe & Sirois, 2008). While IBD can be managed by a multitude of interventions, it is a lifelong disease that ultimately cannot be cured, even by surgical intervention (considered as a last option for those with severe disease and/or with acute complications) (Wolfe & Sirois, 2008).

As autoimmune diseases are often co-morbid, there is a high possibility that an individual suffering from IBD may have another chronic/auto-immune condition, or even cancer (colorectal cancer in the case of IBD) (Cooper, Bynum & Somers, 2009; Somers, Thomas & Hall, 2009; Greene, Blanchard & Wan, 1994; van der Have, et al., 2015; Herszenyi, Barabas, Miheller & Tulassay, 2015). IBD also has the potential to contribute to the individual’s psychological distress and functional impairment (Dunne & Cook, 2005). The effects of IBD on an individual’s daily functioning can potentially reduce his quality of life either temporarily, during active disease expression, and/or permanently, in the case of severe IBD. Identified factors affecting IBD-specific Health Related Quality of Life (HRQOL) (disease relevant impact on daily functioning and outlook) include

disease longevity, disease severity, and internalizing factors, such as depression and anxiety, incurred and/or exacerbated as the result of the chronic illness (Graff, Walker, Clara, Lix, Miller, Rogala, Rawsthorne & Bernstein, 2009; Irvine, 2004; Sajadinejad, Asgari, Molavi, Kalantari, & Abidi, 2012).

IBD's chronic course not only impacts an individual physically, but can also substantially impact one socially, occupationally, and psychologically. Examples of IBD's potentially adverse impact on the social domain include interruption of plans due to frequent bathroom trips, embarrassment about the disease, social isolation, cancelling plans, feeling burdensome, romantic and friendship relationship strain, unease about dating, and fear of intimacy (Casati, Toner, de Rooy, Drossman & Maunder, 2000; Sajadinejad, Asgari, Molavi, Kalantari, & Abidi, 2012).

In the workplace, unfavorable consequences may arise as the result of leaving work early, not going to work, performing poorly due to IBD symptoms, and/or having to schedule around sick days, doctors' visits, hospitalizations, and/or surgeries. Further, it may be the case that those who used to work simply cannot continue as a result of their disease (Wolfe & Sirois, 2008). In fact approximately 34% of diagnosed individuals do not work due to their IBD diagnoses and 18.3% are on full disability, despite lifestyle, surgical, and pharmaceutical interventions (Graff, et al., 2006; van der Valk, et al., 2014).

IBD has the potential to impact the diagnosed individual's psychological health as well as their relationships and career. The unpredictable course of the disease may culminate into concerns about appearance (due to surgeries, medication, or weight loss), worries about the future, and fears of pain, disability, and worsening of disease (Casati, Toner, de Rooy, Drossman & Maunder, 2000; Sajadinejad, Asgari, Molavi, Kalantari, &

Abidi, 2012). Actually, compared to the general, healthy population, those diagnosed with IBD have expressed significantly higher levels of anxiety and depression as a function of their disease severity (Danesh, Cholanrezaei, Torkzadeh, Mirbagher, Sloku & Emami, 2015; Kurina, Goldacre, Yeates, & Gill, 2001; Voth & Sirois, 2009). The tangible impact of IBD is multifaceted, not solely limited to one's experience of the physical body state; IBD's widespread effect points toward the significance of identifying those factors that contribute to IBD's presence and expression within the body.

A variety of factors suspected to contribute to the onset of IBD include "ex-smoker" status, diet, mycobacterial infection, genetic predisposition, perinatal infections, and environmental triggers (Carter, Lobo & Travis, 2004; Crohn's and Colitis Foundation of America, 2015; Danese, Sans, & Fiocchi, 2004; Loftus, 2004). Despite the existence of numerous theories, there exists no single indisputable factor, or set of factors, responsible for IBD onset; the etiology, or cause, of IBD is ultimately *unknown*.

Just as there is no consensus in the field on what *causes* IBD, there is just as little certainty surrounding what *triggers* flare-ups of the disease. Despite this uncertainty, one risk factor for IBD exacerbation that has received much attention in the literature is stress (Danese, Sans, & Fiocchi, 2004; Levenstein, et al., 2000). On average, individuals with IBD do experience episodes of disease that lessen, if not remit, in severity. In order to aid those with IBD in achieving lengthened periods of decreased disease expression, it will be important to understand the relationship between prominent external risk factors, such as *stress*, and IBD severity.

2.2 The Role of Stress in IBD

Stress has historically been suspected to be, and more recently has been accepted as, a risk factor for exaggerated IBD severity (Mattlin, Wethington & Kessler, 1990; Naliboff, Mayer, Fass, Fitzgerald, Chang, Bolus & Mayer, 2004; Sajadinejad, Asgari, Molavi, Kalantari, & Abidi, 2012). In the past, the relationship between stress and IBD was considered nothing more than “anecdotal” or “psychosomatic” (Murray, 1984; Sajadinejad, Asgari, Molavi, Kalantari, & Abidi, 2012). Presently, stress has attained more credibility as a factor contributing to IBD disease activity.

Stress can be divided into two broad categories: “perceived” and “objective”. Perceived stress refers to the individual’s *subjective* experience of stressful events while objective stress pertains to the *unbiased*, “average interpretation”, perception of adverse/stressful events. Surprisingly, objective stress remains largely, if not completely, absent in the current IBD literature base. Historically, measures of perceived stress have been utilized in approximation of the impact of stress on IBD expression. However, the potential for unique and *novel* insight into the impact of stress on IBD, coupled with the topic’s absence in the literature, suggests an additional need to investigate the unique contribution that objective stress may provide to IBD research (Iglesias-Rey, Barreiro-de Acosta, Caamano-Isorna, Vazquez-Rodriguez, Gonzalez, Lindkvist & Dominguez-Munoz, 2013; Levenstein, Prantera, Varvo, Scribano, Berto, Andreoli & Luzi, 1994; Mawdsley & Rampton, 2005; Levenstein, Prantera & Varvo, 2000).

Traditionally, objective measures of stress have included such interventions as the monitoring and measurement of inflammatory marker or cortisol levels and/or psychophysiological activity, such as respiratory sinus arrhythmia, in response to

predetermined target stimuli (Gentzler, Santucci, Kovacs & Fox, 2009; Wolf, Nicholls & Chen, 2008). However, objective *ratings* of stress, derived from such interview tools as the UCLA Stress Interview, have been established as a well-validated alternative in the *approximation* of objective stress (See “Methods” section for further information on how objective stress ratings are calculated) (Hammen, Kim, Eberhart & Brennan, 2009; Wolf, Nicholls & Chen, 2008; Kim, Miklowitz, Biuckians & Mullen, 2007; Naliboff, Mayer, Fass, Fitzgerald, Chang, Bolus & Mayer, 2004). These objective ratings can allow for further insight into the objective experience underlying self-reported stress experiences.

Just as stress can be categorized as either perceived or objective, it can further be classified as “episodic” (discrete events spanning 1 to 3 months) or “chronic” (ongoing events spanning at least 6 months) (Lepore, Miles & Levy, 1997). Although both episodic *and* chronic stress have been shown to increase IBD severity in both human and animal subjects (Collins, McHugh, Jacobson, Khan, Riddell, Murase, & Weingarten, 1996; Soderholm, Yan, Ceponis, Vohra, Riddell, Sherman & Perdue, 2002), attention in health-related research is often placed on chronic stress as its impact is ongoing and cumulative. The cumulative nature of chronic stress allows for physiological responses (such as increased breathing and heart rate) that are meant to be adaptive to lead to maladaptive health consequences in the long run (DeSteno, Kubzansky, & Gross, 2013). As such, chronic stress is more likely than episodic stress to play a substantial role in affecting disease severity and exacerbation.

Chronic stress has the capability to affect both immune system and inflammatory functions, leading specifically to heightened immunosuppression and inflammation (Glaser & Kiecolt-Glaser, 2005; Mawdsley & Rampton, 2005; Danese, Sans, & Fiocchi,

2004) in all individuals regardless of level of health. In fact, Cohen, Tyrrell, and Smith (1993) discovered that even otherwise healthy individuals exposed to stress experienced an increased linear rate of contracting the common cold. Indeed, chronic stress been evidenced to have a profound effect on disease course in IBD patients (Danese, Sans, & Fiocchi, 2004; Levenstein, et al., 2000; Mattlin, Wethington, & Kessler, 1990).

Heightened stress has not only been shown to exacerbate IBD symptoms, such as abdominal pain and worsened immune function, but also to contribute to the increased risk for a remissive patient to relapse into active disease (Bitton, et al., 2008; Glaser & Kiecolt-Glasier, 2005; Lepore, Miles & Levy, 1997; Sajadinejad, Asgari, Molavi, Kalantari, & Abidi, 2012; Mawdsley & Rampton, 2005).

Stress is, for better or worse, a normal part of life. Individuals with IBD are regularly faced with several chronic stressors relative to both daily life experiences and disease course. As stress is a readily identifiable and salient factor with evidenced impact upon IBD disease severity, it follows that processes that can modify the degree to which varying levels of stress alter IBD expression be identified. One such modifiable process that is of particular interest to the proposed project is emotion regulation (ER).

2.3 Emotion Regulation: A Protective Factor Against Stress

When considering the role that ER may play in the relationship between IBD and stress, it is important to first make the distinction between “ER” and “coping”. “Coping” and “ER”, appearing at first to be unique terms, actually share “permeable boundaries” (Gross, 1998); both terms appear in the literature broadly as terms demarcating strategies used to ameliorate distress. “ER”, due to its large presence in related behavioral medicine literature, is to be utilized within the current proposal to maintain consistency.

“ER”, known to attenuate stress (Bitton, et al., 2008; DeSteno, Kubzansky, & Gross, 2013; Mattlin, Wethington & Kessler, 1990; Wang & Saudino, 2011), refers to the adaptive and maladaptive modifiable behavioral and/or cognitive process by which an individual can impact not only the emotions they experience, but also *how* they experience them (Folkman, Lazarus, Dunkel-Schetter, DeLongis & Gruen, 1986; Gross, 1998, 2002; Wang & Saudino, 2011). Individuals suffering from chronic, lifelong conditions/diseases, such as IBD, attempt to employ ER strategies, adaptive and/or maladaptive, to address associated challenges (Garnefski, Koopman, Kraaij & ten Cate, 2009; de Ridder, Geenen, Kuijer & van Middendorp, 2008; Kaptein, Hazes, Willems, Bergman & Rooijmans, 1997; Kiebles, Doerfler & Keefer, 2010). The ER strategies that individuals utilize in response to stress ultimately play an important role in determining their “medical outcomes” (Scharloo, Kaptein, Weinman, Hazes, Willems, Bergma & Rooijmans, 1997).

Deleterious effects on health due to stress do not happen in one instance and/or after a single utilization of a maladaptive ER strategy. It is the repeated use of maladaptive ER strategies in response to *chronic* stressful experiences that allows for unfavorable health outcomes (Danese, Sans, & Fiocchi, 2004; Glaser & Kiecolt-Glaser, 2005; Gross, 2002; Lepore, Miles & Levy, 1997). In fact, referencing the prior mentioned study conducted by Cohen, Tyrrell, and Smith (1993), those with increased negative affect *and* stress levels experienced additional increased rates of contracting the common cold. Bernstein et al (2010) found similar results indicating that diagnosed individuals experiencing high perceived stress rates, coupled with negative affect, were significantly more likely to experience a flare-up of disease activity. Chronic stress, coupled with

exacerbation of this stress through the consistent use of maladaptive ER strategies to deal with, has the potential to incite worsened IBD outcomes.

Typically, it is the case that maladaptive ER strategies are helpful in the short term, yet harmful to the individual in the long term (Felton, Revenson & Hinrichsen, 1984; Gross, 1998, 2002; Kovacs, Rottenberg, & George, 2009). It has been historically evidenced that engaging in maladaptive emotion-focused strategies, such as “distancing” and “escape avoidance”, to deal with distress leads to worsened outcomes compared to utilization of more adaptive problem-focused strategies (Folkman, Lazarus, Dunkel-Schetter, DeLongis, & Gruen, 1986). Such ER deficits are known to worsen health and functioning among those with IBD (Danesh, Gholamrezaei, Torkzadeh, Mirbagher, Soluki & Emami, 2015; Iglesias-Rey, et al., 2013). Danesh et. al. (2013), in a study on coping style utilization in the IBD population and coping style impact on disease activity, discovered, at the trend level, that the use of such maladaptive ER strategies as fatalism resulted in increased disease activity. In fact, it is well established that individuals diagnosed with IBD tend to engage significantly more in maladaptive coping than controls (Danesh, Gholamrezaei, Torkzadeh, Mirbagher, Soluki & Emami, 2015; Greene, Blanchard, & Wan, 1994; Iglesias-Rey, et al., 2013). Given that there are measurable, harmful consequences of using maladaptive ER strategies, identifying the utility of adaptive ER strategies for diagnosed individuals is readily indicated.

Adaptive ER strategies are those that successfully achieve the goal of ameliorating distress and are actually beneficial in the long term (Felton, Revenson & Hinrichsen, 1984; Gross, 1998, 2002). Trend level significance has been reported by Greene, Blanchard, and Wan (1994) and Danesh et al. (2015) regarding the impact that

adaptive ER has on maintaining or decreasing disease severity. *(It is of note that these studies utilized mediation models of ER, whereas the current project hopes to utilize a moderation model discussed later)*. Further, not all findings regarding ER and IBD severity have resulted in null or trend level findings. In fact, a recent study on ER and inflammation, conducted by Appleton, Gilman, Kubzansky, Buka, and Loucks (2013), determined that maladaptive emotion regulation heightened inflammation levels (defined as levels of plasma C-reactive protein or CRP), while the use of adaptive emotion regulation resulted in significantly lower inflammation levels. The modifiable process of ER strategy utilization can actually influence disease severity in a measurable way.

The link between perceived stress/objective ratings of perceived stress, ER, and IBD disease severity ultimately remains unknown. The current investigation strives to highlight, and potentially reveal, this hypothesized relationship structure in order to inform both the research community and interventions to give diagnosed individuals the best chance at maintaining disease remission and/or stability even when faced with daily life stressors.

CHAPTER III

THE CURRENT STUDY

Existing studies have indeed attended to ER, perceived stress impact, ER/coping, and IBD disease severity outcomes. However, a study has not yet been conducted that assesses these areas concurrently.

Prior studies have focused primarily on the *mediating* role of ER/coping in illness-guided/related relationships (Danesh, Cholahrezaei, Torkzadeh, Mirbagher, Sloku & Emami, 2015; Scharloo, Kaptein, Weinman, Hazes, Willems, Bergman & Rooijmans, 1997; Voth & Sirois, 2009). These prior investigations operated on the assumption that external factors, such as chronic stress, directly influenced the ER strategies employed by an individual, thus further influencing the disease-related outcome of interest as a result. However, the current investigation seeks to decipher whether ER plays a *moderating* role in the present two-variable (stress and IBD severity) relationship model (See Appendix B, Figure 1). Investigating ER as a potential moderator in this proposed relationship model is a deliberate choice made with the goal to extricate any influence of variation in stress level solely on the hypothesized relationship. This allows for the relationship to be analyzed in such a way that there is something inherent to the stress experienced by those with IBD that is directly influenced by ER itself, and not any other artifact, which has a

further impact on incurred disease outcomes. Artifactual influences, perhaps variation in stress level in this case, could not so easily be ruled out via utilization of a mediation model. A moderation model is thus appropriate for the aims of the current investigation, allowing for the provision of focused analysis on the relationship between stress and IBD disease exacerbation, wherein ER may be found to act as a direct intervening factor. The current investigation aims to answer the questions, “Under what conditions are individuals diagnosed with IBD most susceptible to the impact of stress on disease severity?” and “Under what conditions are individuals diagnosed with IBD *least* susceptible to the impact of stress on disease severity?” Positioning ER as a potential moderator in the current project, directly impacting the relationship rather than mediating it, will allow for a reasonable and appropriate attempt at answering both parts of this question (Bitton, et al., 2008; MacKinnon & Luecken, 2008).

The current study aims to determine whether the objectively rated stress has a unique contribution in the relationship between chronic stress and disease severity. It is predicted that objective ratings of stress will indeed account for a unique amount of variance, above and beyond perceived stress, between stress and disease severity (Hypothesis 1). A further aim of this investigation is to explore the potential moderating role that ER serves in the relationship between stress experience and IBD severity, with the expectation that increased adaptive ER utilization will buffer the effects of stress, both perceived and objectively rated, on IBD severity and increased maladaptive ER utilization will augment the effects of stress on IBD severity (Hypothesis 2).

CHAPTER IV

METHODS

4.1 Participants

The sample consisted of 30 individuals diagnosed with either UC or CD (86.7% female, 96.7% Caucasian, $M_{age} = 43$, $SD = 13.14$ years) (Table I). Individuals were eligible for participation in the study if they were at least 18 years of age with one of the aforementioned diagnoses. Participants were recruited nationally via ResearchMatch, an online database that matches individuals with study opportunities according to specified qualifying characteristics (Harris, Scott, Lebo, Hassan, Lighter & Pulley, 2012). Participants who completed the study were compensated \$30.00 for their efforts.

4.2 Procedure

All interested and eligible participants were contacted via email and/or telephone call. Initial email contact provided eligible participants with further study information, initial survey and consent form links. Upon completion of consent and preliminary survey items, interested parties were contacted in order to schedule a date and time convenient for them to complete an approximately one-hour long stress interview (UCLA Life Stress Interview) over the phone.

4.3 Instruments

Demographic information. The demographic questionnaire utilized for this study included nine items pertaining to age, sex, education, ethnicity, occupation, and IBD diagnostic information.

Emotion regulation strategies. The Feelings and Me Scale (FAM) is a 54-item scale assessing utilization of adaptive and maladaptive coping strategies across social, cognitive, and behavioral domains in response to emotional experiences. Responses are made on a 3-point Likert scale to such items as “When I feel sad or down I: throw, kick, or hit objects.” The FAM scale is reasonably valid and reliable, with $\alpha=.80$ to $.91$ (Kovacs, Rottenberg & George, 2009). Internal consistency statistics for both maladaptive and adaptive sub-scales were $\alpha=.84$ within the current study.

Perceived stress. Cohen’s Perceived Stress Scale (PSS) is a 10-item questionnaire assessing individual perceptions of stress, specifically how “unpredictable, uncontrollable, and overloaded [participants] find their lives” (Cohen, 1988). Responses are made on a 5-point Likert scale to such items as “In the last month, how often have you felt that you were unable to control the important things in your life?” The PSS is considered to be a reliable and valid measure ($\alpha=.78$) (Cohen & Williamson, 1988). Internal consistency of this measure in the current investigation was $\alpha=.90$.

Disease severity. The Harvey Bradshaw Index (HBI) is a 5-item survey assessing IBD disease severity/activity. Item 1 is responded to on a 5-point Likert scale, items 2 and 4 on a 4-point Likert scale, item 3 is open response, and item 5 allows an individual to endorse as many options as apply. The survey includes such items as “General well-being (yesterday): very well, slightly below par, poor, very poor, terrible.” The HBI was

originally designed for use with patients with CD solely, in order to replace a more “complex measure”, the CDAI (Clinical Disease Activity Index); however, research has established this scale to have just as much utility for patients with UC (Sewitch, et al., 2001). The CDAI has an internal consistency of $\alpha = .5$ to $.7$, and the HBI was shown to correlate at $r = .93$ with this measure (Salaffi, Cimmino, Leardini, Gasparini, & Grassi, 2009; Harvey & Bradshaw, 1980). Internal consistency of this measure in the current investigation was $\alpha = .62$.

Chronic stressful life events. The UCLA Life Stress Interview is an approximately one-hour long interview that gathers information pertaining to individual experiences of chronic and episodic stress. (Chronic and episodic stress were defined as time periods of 6 months and 3 months prior to the date of interview for this investigation specifically). Participants are prompted with questions related to the following domains: Intimate Relationships, Close Friends, Social Life, Family Relationships, Relationships with Children, Occupation, Finances, and Health. Following completion, each domain is assigned a score on a scale from 1, being “no difficulty” to 5, “severe/persistent” difficulty” (Hammen, Kim, Eberhart & Brennan, 2009; Nicholls & Chen, 2008) by a trained team of raters.

A team of four objective raters, per UCLA Life Stress Interview scoring protocol, was trained to evaluate and score brief interview transcriptions for each participant. Raters met regularly with a supervisor trained in this scoring modality. Training on scoring protocol included discussion of manual procedures, scoring, and practice cases. Raters trained in this manner in order to gain a practical understanding of both the process and criterion that would qualify assignment of a particular rating (1 through 5)

for each chronic stress domain. Within the current investigation, an overall chronic stress value for each participant was determined by totaling the team's assigned ratings across domains (Hammen, Kim, Eberhart, & Brennan, 2009).

This measure has been deemed both reliable and valid, with internal consistency of $\alpha=.65$ for the scale in total, and $\alpha= .86$ to $.94$ pertaining to chronic stress alone (LeBovidge, Lavigne & Miller, 2005; Hammen & Rudolph, 1999). Internal consistency for the chronic stress measure in the current investigation surfaced as $\alpha=.76$.

4.4 General Methods of Analysis

All statistical analyses were completed utilizing IBM SPSS Version 24 software. Preliminary analyses revealed that no data were missing from target measures. Moderation analyses were conducted utilizing the PROCESS Macro Version 3 Add-On for SPSS Version 24 (analyses utilized PROCESS Model 1 specifically) (Hayes, 2018). PROCESS moderation analyses were run utilizing confidence intervals bias-corrected at 95% as well as bootstrapping estimates calculated with 50,000 samples.

H1: Hierarchical regression models were analyzed to determine the effect that objectively rated levels of stress have on disease severity in addition to the effects of perceived stress. Covariates were included in the model in order to eliminate as much variance due to individual differences as possible. The choice to place covariates into regression analyses was made deliberately with the aim to attain improved accuracy in the study of target predictor-outcome relationships. The "R-squared change" statistic was utilized to determine whether UCLA objective stress ratings indeed accounted for a significant amount of variability in disease severity outcomes compared to perceived stress alone.

H2: The PROCESS Macro was utilized to assess the moderating effects of adaptive and maladaptive ER on the relationship between perceived and chronic stress and disease severity in line with the proposed model (Appendix B, Figure 1). Prior to running moderation analyses, data were assessed for extreme values and violations of necessary assumptions (linear relationships between independent variables and outcome variable, normally distributed residuals, homoscedasticity, and lack of multicollinearity between independent variables) (Hair, Black, Babin & Anderson, 2009), revealing no significant deviations. Parallel hierarchical regression analyses were run in order to garner contextual coefficient and standard error statistics for relationships between target variables attained via PROCESS software (Tables IV-VII).

CHAPTER V

RESULTS

5.1 Descriptive Analyses

Descriptive statistics (means and standard deviations) and bivariate correlations are presented in Table II. As expected, higher levels of perceived stress correlated significantly with higher levels of objectively rated stress. Further, increased use of maladaptive emotion regulation strategies was significantly related to increased levels of perceived stress, chronic stress, and disease severity. Notably, frequent use of adaptive emotion regulation strategies was negatively related to disease severity. No other variables were correlated at significant or trend levels (see Table II).

5.2 Hypothesis 1

“Objective ratings of stress will account for a unique amount of variance, above and beyond perceived stress, between stress and disease severity.” Hierarchical regression models were fit to examine this hypothesis. The first model block included demographic characteristics, age and sex, the second perceived stress, and the third objective stress ratings. Contrary to expectation, neither perceived stress nor objective stress ratings emerged as significant predictors of disease severity (see Table III).

5.3 Hypothesis 2

“Increased adaptive ER utilization will buffer the effects of stress, both perceived and objectively rated, on IBD severity and increased maladaptive ER utilization will augment the effects of stress on IBD severity.”

This hypothesis was tested via a series of hierarchical regression analyses that included demographic characteristics in the first step, the stress measure in the second step, emotion regulation measure in the third step, and the interaction of between the stress measure and emotion regulation index in the final step. Each model tested one measure of stress and emotion regulation, which resulted in four hierarchical regression models. Across all models, neither demographic characteristics, nor the two stress indices emerged as significant predictors of disease severity. In contrast, adaptive and maladaptive ER repertoires significantly predicted lowered and elevated levels of disease severity respectively (see Tables IV-VII). Contrary to expectation, neither adaptive nor maladaptive ER indices moderated the effects of the two stress measures.

CHAPTER VI

DISCUSSION

The current research study investigated the role of ER in the relationship between chronic, objectively rated, stress and perceived stress, and Inflammatory Bowel Disease (IBD) disease severity. Inflammatory Bowel Disease is one of many autoimmune diseases in which maladaptive attempts to deal with disease-related stress can result in a protracted disease course (Kiecolt-Glaser, McGuire & Robles, 2002; Pellissier, Dantzer, Canini, Mathieu, & Bonaz, 2010). A body of work suggests that objective measures of stress diverge in their effects on biological processes from the effects of perceived stress (e.g., chromosome methylation) (Vidal, Benjamin Neelon, Liu, Tuli, Fuemmeler, Hoyo, Murtha, Huang, Schildkraut, Overcash, Kurtzberg, Jirtle, Iversen & Murphy, 2014). However, the relative contribution of such stressors to IBD severity is not known, nor is it clear whether ER responses differentially modify their effects. As ER has recently surfaced as an important psychosocial factor that affects “immune-related health outcomes”, not only for IBD, but also for such diseases as cancer and HIV (Appleton, Gilman, Kubzansky, Buka, & Loucks, 2013; Danesh, Gholamrezaei, Torkzadeh, Mirbagher, Soluki & Emami, 2015; Kiecolt-Glaser, McGuire & Robles, 2002),

elucidating the relationship between ER, chronic and perceived stress, and IBD remains an important area of study.

The first aim of this study was to investigate whether objective ratings of stress would account for a unique amount of variance in the relationship between stress and IBD disease severity. Contrary to expectation, neither perceived nor objectively rated stress arose as significant predictors of disease severity within this sample. This finding adds to a mixed body of literature with respect to the relationship between stress and IBD severity. For instance, while it has been observed that perceived stress is significantly related to symptom expression in both UC and CD (Targownik et al., 2015), and relapse into active disease states (Bernstein et al., 2010; Bitton et al., 2003), others have observed no true association between the two constructs (Keefer, Keshavarzian & Mutlu, 2008; Wahed & Rampton, 2013). For example, Wahed and Rampton (2013) investigated the impact of stress on IBD disease course and discovered that while there were certainly many studies performed on the subject, there were “limited reliable data” on the impact of stress on IBD due to employed methodology concerns and an insufficient literature base on the topic. In a similar vein, Keefer and colleagues (2008) analyzed the literature base on methodology and conclusions of studies on IBD and stress relationships and posited that the way that stress has been historically measured and defined within this area of study makes it difficult to truly pin down the impact of stress on IBD. The current study, with results suggesting no association between perceived or objective stress and IBD disease severity, adds to the body of work that largely remains undecided regarding the impact of perceived stress upon disease severity. Future investigations may attend to

contemporary validated definitions and measures of perceived stress within the field in order to gain further clarity of insight into this relationship.

A related aim of this study was to investigate whether adaptive ER reduced the adverse effects of stress on disease severity, and whether maladaptive ER exacerbates such effects. A body of work suggests the utility of ER in attenuating the effects of stress (Bitton et al. 2008; Wang & Saudino, 2011). In fact, there is evidence indicating that an individual's ER strategy use in response to stress is closely associated with incurred disease severity (Danese, Sans, & Fiocchi, 2004; Glaser & Kiecolt-Glaser, 2005; Scharloo et al, 1997). Increased experience of stress has indeed evidenced association with "poorer coping to IBD", thereby worsening IBD disease severity (Pellissier, Dantzer, Canini, Mathieu, & Bonaz, 2010; Sajadinejad, Asgari, Molavi, Kalantari & Abidi, 2012) and vice versa (Bernstein et al., 2010). Contrary to expectation, neither adaptive nor maladaptive ER repertoires moderated the effects of perceived and objectively rated stress within the current investigation. This observation may be due to the reality that there are many confounding variables that can contribute to observations of, or absence of, associations between perceived stress and employed coping strategies within this population. For example, Iglesias-Rey and colleagues (2013) determined that the significant association that they discovered between experienced stress and increased use of maladaptive ER strategies within their sample was at least partially due to a number of confounding factors (i.e. gender, education level, lower stress scores across the sample, clinical anxiety and depression levels). Future investigations on the relationship between stress experience, ER, and IBD disease severity may find it pertinent to acknowledge and control for these variables, as feasibly possible, in order to more

accurately explore the hypothesized relationship between stress and ER strategy utilization specifically.

While ER ultimately did not surface as a significant moderator of the relationship between stress and disease severity outcomes, both ER repertoires evidenced significant associations with IBD severity, whereby frequent use of adaptive responses was inversely linked to severity, while the use of maladaptive responses predicted worsened disease severity. These findings are in line with prior investigations on the effects of ER on IBD outcomes. Adaptive ER and maladaptive ER repertoires have indeed been shown to significantly lessen and worsen IBD disease severity respectively (Appleton, Gilman, Kubzansky, Buka, & Loucks, 2013; Goodhand & Rampton, 2008; Kuroki, Ohta & Sherriff-Tadano, 2010). For example, Appleton and colleagues (2013) studied the impact of coping strategies on inflammatory exacerbation in individuals with IBD and discovered that those who utilized more adaptive ER strategies experienced lessened disease severity, while those who utilized predominantly maladaptive ER strategies experienced worsened disease severity. Danesh et al. (2015) also observed notable associations between adaptive ER and maintained or decreased IBD disease severity. Indeed, Danesh and colleagues (2015) determined that increased use of maladaptive ER strategies was associated with increased disease severity, while use of adaptive ER strategies was associated with decreased symptom expression and increased quality of life for individuals with IBD. Results of the current study similarly suggest an association between adaptive ER strategy employment and altered IBD disease severity. ER, typically thought of as a “psychosocial mechanism” to deal with discomfort (Gross, 1998, 2002; Kiecolt-Glaser, McGuire & Robles, 2002; Wang & Saudino, 2011), is shown here

as a factor with potential to directly impact IBD, an autoimmune and fluctuating disease, outcomes independent of stress experiences.

6.1 Limitations

The results from this study should be interpreted with respect to several limitations. First, due to budgetary constraints, the study was able to recruit a relatively small sample of participants with IBD. This may have limited the statistical power of this study to detect effects of moderate or small magnitudes. It is feasible that a larger sample would have enabled this study to find the hypothesized relationships. Further, this sample was comprised of predominantly Caucasian identifying women in middle adulthood. Therefore, the findings of this study have limited generalizability as IBD affects men and women equally across ethnic and racial groups (Table I). Relatedly, IBD is most frequently diagnosed in individuals between ages 15 and 35, with a median age of approximately 31 years old (Crohn's and Colitis Foundation of America, 2015; Sewitch, Abrahamowicz, Bitton, Daly, Wild, Cohen, Katz, Szego & Dobkin, 2001). The current investigation utilized an older sample with a mean age of 43, substantially different from the national average. As the current sample is older, it is possible that these individuals may have learned to more effectively deal with disease-related stressors over time (Crohn's and Colitis Foundation of America, 2015). Another limitation of this study is the use of an objective measure of stress that relied on participants' self-report rather than a biological index. Indeed, while the approach to objectively measure stress has been well-validated, its initial reliance on participants' responses makes it susceptible to the same methodological challenges that plague self-report measures (e.g., limited self-knowledge, poor recollection, and response bias). While more objective measures of

stress exist, such as cortisol assays, such methods are not without their own limitations. For example, cortisol levels are influenced by such factors as time of day, genetics, inflammation, sleep quality, internalizing conditions (i.e. depression), posture, waking cycles, and external environmental factors (Kiecolt-Glaser, McGuire & Robles, 2002; Hennig, Friebe, Ryl, Kramer, Bottcher & Netter, 2000; Stetler & Miller, 2005). For these reasons, it can be argued that use of an objective team rated measure of stress may not be any less valuable to this field of research.

6.2 Strengths

While this study, as with other investigations, has its limitations, it also embodies notable strengths. Despite low sample size and diversity within this study, disease severity was “moderate” for 50% of participants, consistent with related investigation severity percentages (Sewitch, Abrahamowicz, Bitton, Daly, Wild, Cohen, Katz, Szego & Dobkin, 2001; Targownik, Sexton, Bernstein, Beatie, Sargent, Walker & Graff, 2015). A further strength of this study is that the sample was recruited nationally and was not regionally constrained through local hospital, clinic, and/or university recruitment as is typical for health-topic research. Another strength of this investigation was its methodological contribution to the study of stress within this field of research through use of a team-based measure of stress. Report bias is a concern largely attributed to the self-report measures of stress used frequently in this field of research, often leading to misleading or inconclusive results (Keefer, Keshavarzian & Mutlu, 2008; Wahed & Rampton, 2013); use of the UCLA Life Stress Interview (LSI) measure within the current investigation allowed for reduced likelihood of report biases given its team scoring approach.

6.3 Future Research and Implications

While it is readily apparent that future replications of the current investigation could benefit from recruitment of both a larger and more representative sample, there are other modifications and/or additions to consider. First, future investigations into the relationship between stress, ER, and IBD disease severity may endeavor to collect participant cortisol levels and inflammatory biomarkers alongside use of the LSI. The incorporation of these methods may be indicated in order to 1. garner a more comprehensive picture of this model at the biological level and 2. gain further insight into the relationship between this interview measure and a biological measure of stress. As salivary cortisol levels appear to be greatly influenced by environmental and genetic factors, discussed prior, it would be important for researchers to focus attention to potential confounding variables (such as time of collection) (Stetler & Miller, 2005).

Future investigations may also consider implementing research-informed interventions geared toward psychoeducation on ER and related disease consequences. Such interventions would allow individuals with IBD to learn, and potentially benefit from, adaptive ER strategies empirically tied to the improvement of individual life stressors and disease activity. Research on psychosocial mitigating factors, such as ER, for the harmful disease-related consequences of day-to-day life stressors can provide for accessible and inexpensive alternative treatment options to clients who are traditionally treated through expensive and invasive means. Currently recommended treatments for IBD-diagnosed individuals are largely pharmacological, with many associated side effects, and/or expensive, making these treatments harder to obtain for disadvantaged populations (Chron's and Colitis Foundation of America, 2015; Gibson, Ng,

Ozminkowski, Wang, Buron, Goetzel & Maclean, 2008; Wolfe & Sirois, 2008). This investigation brings attention to the importance of ER as a disease-maintenance intervention for individuals with IBD with diverse ability and socioeconomic levels.

Oftentimes, individuals with chronic diseases, including IBD, seek out care from a range of medical professionals, including gastroenterologists, psychologists, primary care providers, and nurse practitioners. As the field of health psychology is ever changing and evolving to embrace integrated primary care treatment models, the need to identify brief interventions geared toward patient education and disease self-management is quite salient. The incorporation of ER into healthcare provider offices as a modifiable strategy through which IBD can be contextualized and managed on an individual basis has the potential to not only empower chronically ill clients, but to change the very way IBD and other chronic diseases are treated.

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Appendix A: Tables

Table I. Frequency and percentage values of sample characteristics (sex, race, and reported disease severity; N=30).

Characteristics	Frequency	Percentage of Sample
Sex	4 (Male)	13.3%
	26 (Female)	86.7%
Race	1 (A. American)	3.3%
	29 (Caucasian)	96.7%
Disease Severity	8 (Remission)	26.7%
	4 (Mild)	13.3%
	15 (Moderate)	50%
	4 (Severe)	13.3%

Note. Frequencies are to be considered out of total N=30 and percentages out of total=100%.

Table II. Descriptive statistics and bivariate correlation of study variables (demographics, adaptive and maladaptive ER, perceived stress, and objectively rated measures of chronic stress; N=30).

Variables	M (SD)	1.	2.	3.	4.	5.	6.	7.
1. Age	43 (13.14)	--						
2. Sex	--	---	--					
3. HBI	9.17 (4.86)	-.10	.08	--				
4. PSS	29 (7.73)	-.02	.07	.27	--			
5. LSI-CS	21.97(5.64)	.16	.07	.07	.43*	--		
6. MMR	37.67(8.46)	-.26	.26	.43*	.70***	.45*	--	
7. AMR	54.47(8.25)	.02	.10	-.52**	.02	-.18	-.06	--

Note. Sex = 0 = male, 1 = female; HBI= Harvey Bradshaw Index (IBD Severity); PSS= Cohen's Perceived Stress Scale; LSI-CS= UCLA Objective Chronic Stress; MMR= Maladaptive Emotion Regulation (FAM Scale); AMR= Adaptive Emotion Regulation (FAM Scale) *** $p < .001$, ** $p \leq .01$, * $p \leq .05$

Table III. Analyses of PSS and LSI chronic stress unique contributions to disease severity.

Predictor	Step 1			Step 2			Step 3		
	B	SE	β	B	SE	β	B	SE	β
Age	-.03	.07	-.08	-.03	.07	-.08	-.03	.07	-.07
Sex	.89	2.75	.06	-.57	2.85	-.04	-.60	2.91	-.04
PSS				.20	.13	.31	.20	.14	.03
LSI							-.01	.19	-.02
R^2		.01			.09			.09	
ΔR^2		.01			.08			.00	

$\dagger p < .10$ * $p < .05$ ** $p < .001$

Table IV. Moderation analyses of adaptive ER on disease severity in relation to self-report perceived stress.

Predictor	Step 1			Step 2			Step 3		
	B	SE	β	B	SE	β	B	SE	β
Age	-.03	.07	-.08	-.03	.06	-.07	-.02	.07	-.04
Sex	.89	2.75	.06	.14	2.50	.01	.22	2.54	.02
AMR				-.30	.10	-.50**	-.29	.10	-.50**
PSS				.19	.11	.30	.18	.12	.28
PSSxAMR							-.01	.01	-.10
R^2		.01			.34			.34	
ΔR^2		.01			.33*			.01	

$\dagger p < .10$ * $p < .05$ ** $p < .001$

Table V. Moderation analyses of maladaptive ER on disease severity in relation to self-report perceived stress.

Predictor	Step 1			Step 2			Step 3		
	B	SE	β	B	SE	β	B	SE	β
Age	-.03	.07	-.08	.02	.07	.06	.02	.07	.05
Sex	.89	2.75	.06	-.84	2.70	-.06	-.50	2.75	-.03
MMR				.31	.20	.52 [†]	.35	.16	.59*
PSS				-.03	.17	-.05	-.08	.18	-.12
PSSxMMR							.01	.02	.16
R^2		.01			.22			.24	
ΔR^2		.01			.21*			.02	

[†] $p < .10$ * $p < .05$ ** $p < .001$

Table VI. Moderation analyses of adaptive ER on disease severity in relation to objectively rated chronic stress

Predictor	Step 1			Step 2			Step 3		
	B	SE	β	B	SE	β	B	SE	β
Age	-.03	.07	-.08	-.03	.07	-.08	-.03	.07	-.08
Sex	.89	2.75	.06	1.55	2.50	.11	1.54	2.55	.11
AMR				-.30	.11	-.50*	-.30	.11	-.50*
LSI				.02	.16	.02	-.02	.17	-.02
LSIxAMR							.001	.02	.01
R^2		.01			.26			.26	
ΔR^2		.01			.25*			.00	

[†] $p < .10$ * $p < .05$ ** $p < .001$

Table VII. Moderation analyses of maladaptive ER on disease severity in relation to objectively rated chronic stress.

	Step 1			Step 2			Step 3		
	B	SE	β	B	SE	β	B	SE	β
Age	-.03	.07	-.08	.04	.07	.10	.03	.08	.08
Sex	.89	2.75	.06	-1.13	2.62	-.08	-.10	2.70	-.07
MMR				.34	.13	.58*	.34	.13	.57*
LSI				-.15	.18	-.17	-.13	.19	-.15
LSI \times MMR							-.01	.02	-.07
R^2		.01			.24			.24	
ΔR^2		.01			.23*			.00	

* $p < .05$ ** $p < .001$

Appendix B: Figures

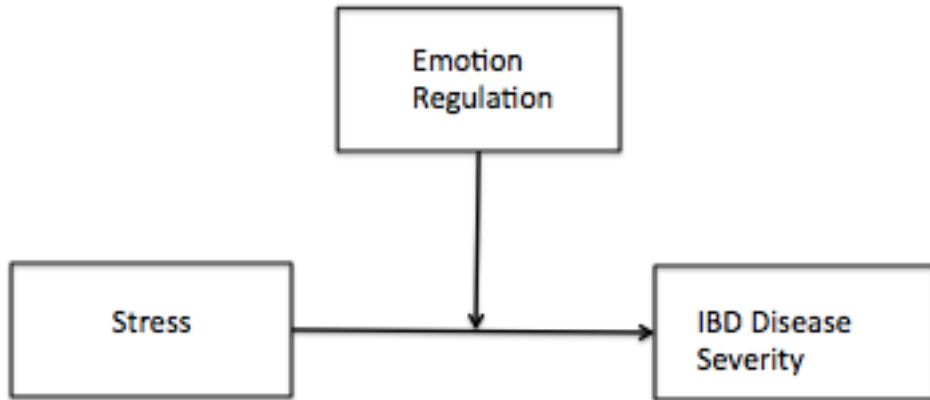


Figure 1. Conceptual moderation model of emotion regulation on stress and IBD disease severity.

Appendix C: IRB Approval Document

Feb 10, 2017

Dear Ilya Yaroslavsky,

RE: IRB-FY2017-144

Emotion Regulation and Irritable Bowel Disease Study

The IRB has reviewed and approved your application for the above named project, under the category noted below. Approval for use of human subjects in this research is for a one-year period as noted below. If your study extends beyond this approval period, *you must contact this office to initiate an annual review of this research.*

Approval Category: Expedited, Category 7

Approval Date: Feb 10, 2017

Expiration Date: Feb 9, 2018

By accepting this decision, you agree to notify the IRB of: (1) any additions to or changes in procedures for your study that modify the subjects' risk in any way; and (2) any events that affect that safety or well-being of subjects. Notify the IRB of any revisions to the protocol, including the addition of researchers, prior to implementation.

Thank you for your efforts to maintain compliance with the federal regulations for the protection of human subjects. Please let me know if you have any questions.

Sincerely,

Mary Jane Karpinski

IRB Analyst

Cleveland State University

Sponsored Programs and Research Services

(216) 687-3624

m.karpinski2@csuohio.edu

Appendix D: Informed Consent Document

Informed Consent



Project Title: Emotion Regulation and Inflammatory Bowel Disease

You are being invited to participate in a research project conducted at Cleveland State University (CSU) by Psychology Department Graduate Student Sarah Ghose, and Psychology Department Undergraduate Student Katherine Petrochic, both of whom can be contacted by phone at 216-687-4576 or by email at csuibdcollab@gmail.com.

The principal investigator of this study is CSU Psychology Department Faculty Dr. Ilya Yaroslavsky. He can be contacted with any questions or concerns at 216-687-9237 or by email at i.yaroslavsky@csuohio.edu.

Purpose of the Study:

We are interested in the role that emotion regulation plays in the relationship between emotions and Inflammatory Bowel Disease (IBD). It is our hope that findings from this project will be able to provide further insight into IBD and its treatment.

Procedures:

If you agree to participate in this study, you will be asked to:

- Read and digitally sign this consent form.
- *Privately* complete online surveys about your emotional states, stress, and IBD symptoms (45 minutes).
- Participate in an interview with a researcher about your personal experience with stress and IBD over the phone (45 minutes).
- *Privately* complete 3 minutes surveys on your cell phone 5 times a day over the next 7 days (about 15 minutes a day). This will involve you entering your telephone number and email address into the SurveySignal software in order to receive daily text messages that contain links to the online questionnaire (1 hour 25 minutes).

The study will require about 3 hours of your time, for which you will be paid up to \$30. You will also have a chance to earn an additional \$100 in a raffle at the end of the study. You will be compensated \$15 for completing the online survey and the phone interview. You will further receive \$5 for completing surveys on your phone, and an additional \$10 for completing at least 80%, or 31 out of 35, of those surveys. You will receive 5 surveys a day for 7 days, or 35 surveys in total.

To help you complete at least 80% of the surveys, we will: (1) send you text messages that contain a link to our survey only during times that you indicate that you are

available, (2) send you a reminder message if you have not completed the survey within 15 minutes of receiving the survey link, and (3) send daily updates to your email about how many surveys you completed that day.

For your safety, please refrain from attempting to answer the phone surveys while driving.

Confidentiality (Privacy):

All records of your participation in this study will be kept private. All digitally stored information will be kept on a secure drive at Cleveland State University. This means that access to your information will be limited to research personnel. Your information will be kept for at least three years. Your information will be erased through secure data disposal services. You can let us know at any time if you no longer wish to be contacted by us without penalty. In the event that you wish to no longer be contacted, please contact Dr. Yaroslavsky at the telephone number or email address provided in this document.

There are a few limits to confidentiality, or privacy, in this study that you should be made aware of. Rarely we may need to let others know who you are in order to keep you or another person safe. This includes if you tell us that you plan to hurt or kill yourself or someone else. This also includes if you tell us that a child is being neglected or abused, and/or if an older person is being neglected or abused.

Benefits/Risks:

By completing this study, you will receive a payment of up to \$30 for your time. You will also be entered into a raffle to win an additional \$100 by completing at least 80% of surveys sent to your phone. Your chances for winning the \$100 are 1 in 30 if everyone who participates completes 80% of the phone surveys.

We will ask you questions about your emotions and IBD. Some questions may make you feel discomfort (e.g. “How often has the feeling of fatigue or being tired and worn out been a problem for you during the past 2 weeks”). To help you feel more comfortable, you can skip questions at any time that make you feel uncomfortable. You can also take breaks or stop participating in the study at any time. You may also speak with Dr. Ilya Yaroslavsky, who is a licensed Clinical Psychologist and CSU Psychology faculty member. You can seek additional aid through any online/in person support groups you may be a part of. You can also reach out to another mental health professional in your area.

Voluntary Nature of the Study (Non-Participation Statement):

Your participation in this study is completely voluntary. Your refusal or withdrawal from participation will be met with no penalty to your professional or personal life. You can refuse to answer any questions. Doing so will not jeopardize our use of your data or compensation for your time.

Participation Consent:

By clicking the checkbox, you are stating that you understand the information in this form. You understand that you can contact a researcher with any questions you may have. You understand that you must be, and are, at least 18 years old with an IBD diagnosis. Further, you are stating that you understand the statement from the Institutional Review Board below.

I understand that if I have any questions about my rights as a research subject I can contact the Institutional Review Board at (216) 687-3630.