Predictors of Health-Related Quality of Life in Younger Persons with an Ostomy and

Inflammatory Bowel Disease

by

Caitlin Werther

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ABSTRACT OF THE DISSERTATION

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Dissertation Chairperson: Dr. Jill Cox

The purpose of this study was to determine the predictors of health-related quality of life (HRQOL) in younger persons aged 18 to 40 years living with inflammatory bowel disease (IBD) and an intestinal stoma. Predictors under investigation included the symptoms of pain, fatigue, leakage of stomal appliance, peristomal skin problem, body image/sexual disturbance, and psychological distress, as well as the construct of self-rated health (SRH).

The sample was made-up of 98 individuals who completed an online survey from October 2018 through December 2018. Data was obtained from survey responses by participants. Correlational and hierarchical multiple linear regression analyses were conducted for hypotheses testing.

Significant correlations were found between the following symptoms: pain, fatigue, peristomal skin problem, psychological distress and HRQOL. SRH was also found to be significantly correlated with HRQOL. In hierarchical multiple linear regression, the variables of pain, fatigue, psychological distress, and SRH explained a significant portion of the variance in HRQOL in this sample study.

This study contributed to the body of knowledge concerning predictors of HRQOL in younger persons living with IBD and an intestinal stoma as findings from this

study suggest global disease symptoms and the manner in which individual's perceive health are more important than transient stoma symptoms in this population. However, more empirical evidence is necessary gain further insight into these predictors. Additionally, it is reasonable that individuals in this population regularly make use of online resources. In order to understand how this impacts this population, it is also essential to gain further insight into the online management of stoma and disease.

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This dissertation is dedicated to my family, my sons, Teddy and Ben and my husband Rob, who have loved and supported me in completing this dissertation. To my parents, my Mom and Dad, who have provided loved and supported me throughout my life and to my mother-in-law, Karen, who has supported me and provided lots of baby-sitting to allow me to complete this dissertation.

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Chapter 1

The Problem

Intestinal Stomas

Approximately one million individuals in the United States and Canada are currently living with an intestinal stoma, a common surgical treatment for various gastrointestinal conditions, such as Inflammatory Bowel Disease (IBD) and colorectal cancer. A stoma is defined as a surgically formed opening in the abdominal wall, created to divert intestinal contents (Martin & Vogel, 2012). A stoma can be either permanent if removal of the rectum is required, or temporary if diversion of intestinal contents is time limited for protection of a portion of the bowel (Grant et al., 2011).

IBD is a common etiology of intestinal stoma formation. IBD is a chronic, inflammatory condition of the gastrointestinal tract made-up of the two subtypes, Crohn's disease and ulcerative colitis (UC) (Katz et al., 2013). Crohn's disease can affect any part of the gastrointestinal tract and there is currently no known cure while UC is limited to the colon and rectum; therefore, removal of the colon and/or rectum is considered curative for this condition (Katz et al., 2013). IBD is a condition that initially affects younger persons as it is typically diagnosed between the ages of 18 and 35 years (Katz et al., 2013).

According to data from the National Health Interview survey in 2015, about 3.1 million or 1.3% of the adults in the United States have a diagnosis of IBD which has considerably increased from an estimated 1.8 million living with IBD in 1999 (Dahlhamer, Zammitti, Ward, Wheaton, & Croft, 2015). Around 10% of these individuals will require the formation of an intestinal stoma (Katz et al., 2013). Many of

these individuals are diagnosed with IBD before the age of 20 years making it the most significant disease of young adults (Savard & Woodgate, 2009). Additionally, the registry of ostomies from the United Ostomy Association of America showed a decline in total number of stomas in all etiologies of stoma formation due to advances in treatment after 1980, except for Crohn's disease as there has been little change in the number of stomas over time due to this diagnosis (Fleshman & Lewis, 2007).

A large financial burden is associated with IBD and surgical creation of stomas. The cost of IBD is highest during symptomatic periods which would be the time at which stoma creation may be required. Approximately, 32% of individuals are out of the workforce each year because of IBD and the total financial burden of IBD is estimated to be between $14.6-$31.6 billion per year (Katz et al., 2013). A high financial burden is also associated with surgical complications of which there are a significant, but varying rates by surgeon and hospital ranging from 10-80% of the 100,000 stoma surgeries performed each year in the United States (Kwiatt & Kawata, 2013; Sheetz et al., 2014).

Presence of an intestinal stoma has the potential to negatively affect all aspects of life (Mahjoubi et al., 2012). Immediate physiological alterations follow stoma surgery, as well as possible psychological, social, and spiritual health-related quality of life (HRQOL) consequences have been reported. (Bulkley et al., 2013; Popek et al., 2010). HRQOL is an individual's overall satisfaction with life incorporating physical, psychological, social, and spiritual well-being in relation to current health status, disease, treatments, and surgical creation of an intestinal stoma (Bulkley et al., 2013; Popek et al., 2010).

The presence of the potential for reduced HRQOL resulting from stoma formation, as well as treatments of the underlying disease processes underscore the need to understand this health indicator in persons living with IBD and a stoma. In prior studies of patients over the age of 50 with a diagnosis of colorectal cancer, the presence of a stoma was reported to be associated with poor HRQOL as a result of depression, anxiety, sexual problems, fatigue, body image deficits, peristomal skin conditions, leakage of appliance, and interference with life as a whole (Anaraki et al., 2012; Erwin-Toth et al., 2012; Grant et al., 2011; Knowles et al., 2013; Mahjoubi et al., 2012; Popek et al., 2010). Further, Abdalla et al. (2016) noted participants with an ostomy and active Crohn's disease had worse pain, fatigue, social satisfaction, and, ultimately worse HRQOL compared to persons with active Crohn's disease and no stoma. Unlike colorectal cancer and UC, surgical creation of a stoma in persons with Crohn's disease does not offer the potential of a cure which may contribute to decreased HRQOL not only from stoma formation but also as a result of disease activity, treatments, and associated side effects.

Little to no research has focused on HRQOL in younger persons with a diagnosis of IBD and living with a stoma. Younger persons often suffer from social and psychological concerns that are not present in older populations (Savard & Woodgate, 2009). Erikson (1950) described the age range of 18 to 40 years in his *Theory of Psychosocial Development* to be an essential time to interact with others outside of the family of origin to form lasting relationships and experience love and intimacy. If individuals fail to interact appropriately with others, loneliness and isolation may result (Erikson, 1950). The presence of a stoma in younger persons can exacerbate feelings of

being different, as well as diminishes self-respect and confidence that may lead to avoidance of socialization and romantic relationships, isolation, and loneliness (Erikson, 1950; Savard & Woodgate, 2009). Therefore, HRQOL is an important consideration in the care of individuals with chronic conditions, such as persons living with a stoma. This indicator provides insight into individual perceptions of health status, as well as the way their perceptions impact their health status on various aspects of life.

HRQOL is considered an essential outcome goal in healthcare that is particularly important when cure for a disease is unrealistic. HRQOL is an intricate phenomenon incorporating physical, social, psychological, and spiritual well-being that determines an individual's overall satisfaction with life because of current health status, disease, and treatments (Bulkley et al., 2013; Popek et al., 2010). An individualized and holistic assessment of patient outcomes and well-being are utilized to understand one's HRQOL (Armstrong & Caldwell, 2004).

A positive or good HRQOL is an important healthcare goal especially in persons with incurable diseases or chronic conditions (Armstrong & Caldwell, 2004). Satisfaction with life, ability to go to school or work, full engagement in physical activities, psychological stability, high self-esteem, socially active, participation in relationships/sexual/travel as desired, inner peace, resiliency, and happiness to be alive are all associated with a good HRQOL (Armstrong & Caldwell, 2004; Bulkley et al., 2013; Popek et al., 2010). However, the presence of a chronic disease can threaten overall HRQOL as health-related deficits can result from the condition itself, as well as procedures, treatments, and associated side effects. These ongoing stressful experiences associated with many chronic conditions often manifest themselves in the psychological,

social, physical, and/or spiritual domains of one's quality of life and, ultimately, affect overall satisfaction with life. An active underlying disease process, fear, worry, lack of enjoyment in activities, social isolation, inability to work or go to school, threats to mortality, and hopelessness can all potentially be present along with a chronic condition and negatively impact HRQOL (Anaraki et al., 2012; Katz et al., 2013; Knowles et al., 2013; Martin & Vogel, 2012). Healthy individuals are known to have a better HRQOL compared to those suffering from disease, therefore, when cure is unrealistic, or a condition is chronic in nature, a good HRQOL is considered the ultimate goal as it indicates one is holistically satisfied with life despite the presence of a chronic condition (Armstrong & Caldwell, 2004).

Predictors of HRQOL

Theorists postulate that indicators of health are present on a continuum from basic biologic functioning and performance to an individual's perception of the impact of one's health on life satisfaction (Wilson & Cleary, 1995). Based upon this supposition, it is predicted that symptoms and one's general health perceptions predict overall HRQOL (Wilson & Cleary, 1995). Symptoms are considered to be an individual's self-evaluation of an abnormal state (Wilson & Clearly, 1995). Additionally, theorists describe general health perceptions as an individual's interpretation of physical and mental health (Wilson & Cleary, 1995). Ultimately, Wilson and Clearly (1995) proposed that self-assessment of bodily state and an individual's evaluation of overall health would culminate in life satisfaction as a result of health.

Symptoms

Symptoms represent an individual's awareness of atypical physical, emotional, or cognitive status (Wilson & Cleary, 1995). As described above, IBD is a chronic, autoimmune disease that results in a myriad of symptoms and complications both within and outside the gastrointestinal tract. The course of IBD is typically characterized by periods of relapse and remission in which relapse indicates presence of gastrointestinal inflammation with active symptoms and remission is lack of gastrointestinal inflammation with little to no symptoms (Katz et al., 2013). Extra-intestinal symptoms may also be present during a relapse potentially affecting any and all areas outside of the gastrointestinal tract (Katz et al., 2013). Pain is a frequently reported symptom of IBD. Pain was reported by 71% of participants in a study conducted by Zeitz et al. (2016) and 87% of subjects in a study by Schirbel et al. (2010). Fatigue was also noted to be a troublesome result of IBD even during times of remission. Sleep impairment was noted in over 40% of participants in two studies with an increase to 77% prevalence with active disease (Habibi et al., 2017; Peyrin-Biroulet et al., 2012). Finally, in a study of the psychometrics of the IBD Disability Index, pain and fatigue were considered important indicators of disability in persons living with IBD (Peyrin-Biroulet et al., 2012).

IBD symptoms can also be present in the form of psychological indicators, as well as sexual disturbances. The presence of psychological manifestations in the form of anxiety, deficits in body image, and depression have been associated with IBD (Katz et al., 2013; Peyrin-Biroulet et al., 2012). As the disease course of IBD is unpredictable, psychological distress in the form of anxiety and depression has a higher prevalence in those with IBD compared to the general population even among those currently in remission (Keeton, Mikocka-Walus, Andrews, 2015; Peyrin-Biroulet et al., 2012). Also,

surgical intervention will be required in one-third of persons with UC and 70% of persons with Crohn's disease and body image deficits are commonly associated with surgical procedures even without the creation of a stoma (Katz et al., 2013; Peyrin-Biroulet et al., 2012). Along with pain and fatigue, body image and psychological distress in the form of anxiety and depression are included as measures in the IBD disability index (Peyrin-Biroulet et al. 2012). Finally, sexuality can be negatively affected in persons living with IBD, resulting in an overall decrease in life satisfaction. (El-Tawil & Nightingale, 2013).

Symptoms are not restricted to a diagnosis of IBD but can also be present in patients living with an intestinal stoma. Symptoms such as odor, gas, leakage of appliance, skin irritation around stoma, parastomal hernia, stoma prolapse, stoma retraction, and stoma ischemia/necrosis have all been reported in patients living with a stoma (Baxter et al., 2006; Kwiatt & Kawata, 2013; Martin & Vogel, 2012). Of these symptoms, leakage of the stoma appliance and peristomal skin irritation have been found to be related to HRQOL in persons with a stoma. The experience of a leaking ostomy appliance was associated with a decrease in HRQOL in multiple studies (Erwin-Toth, Thompson, & Davis, 2012; Nybaek et al., 2010). Additionally, in two of these studies, the presence of peristomal skin irritation was found to negatively affect HRQOL. Factors such as the patient's ability to recognize or self-diagnose a skin issue as well as an increased severity of the skin condition has been shown to correlate with a strong negative impact on HRQOL (Erwin-Toth et al., 2012; Nybaek et al., 2010).

As with IBD, symptoms associated with the presence of a stoma can be noted in the form of psychological deficits and body image/sexual disturbance. Psychological distress in the form of anxiety and depression are prevalent in persons living with a stoma

just like in IBD. Depression, particularly among females with stomas, and increased

anxiety has been found in the empirical literature to be related to a decrease in HRQOL

(Anaraki et al., 2013; Grant et al., 2011; Knowles et al., 2013; Rochelle & Fidler, 2012).

Also, decreases in HRQOL have been found to be associated with deficits in body images

with a greater number of females experiencing body image issues (Grant et al., 2011;

Mahjoubi et al., 2012). Sexual disturbance was additionally strongly associated with

stoma surgery and a decrease in HRQOL (Anaraki et al., 2012; Grant et al., 2011). A

supportive partner who accepted reconfigured body was essential for sexual activity

following stoma surgery with engagement in sexual activity associated with an optimal

HRQOL (Ramirez et al., 2009; Salles et al., 2014). Body image/sexual disturbance and

psychological distress in the form of anxiety and depression are thus important symptoms

to consider in the predictors of HRQOL in younger persons with IBD and a stoma.

Self-Rated Health

General health perceptions represent an individual's interpretation of physical and

mental health (Wilson & Cleary, 1995). This theoretical construct aligns with the health

indicator of self-rated health (SRH). SRH is a subjective, self-assessment of one's health

that is predictive of future health issues, use of healthcare services, and mortality (Idler &

Benyamini, 1997; Mossey & Shapiro, 1982). The focus of SRH includes the presence of

illness or medical conditions, state of current disease process if present, medical

information provided by healthcare providers, health behaviors, and disability or

functional limitations (Jylha, 2009).

An individual's SRH or a self-assessment of health has been noted to be related to

HRQOL. Gurkova and Soosova (2018) conducted a study in order to understand illness

cognitions or the manner in which one perceived disease that, in turn, affected behavior

and coping in individuals with IBD and no stoma. In this study, illness cognitions were

found to be significantly predictive of HRQOL, with the notion of helplessness about

disease the most important predictor of HRQOL. The belief that one is helpless in

relation to IBD resulted in worse HRQOL (Gurkova and Soosova, 2018). Additionally,

in persons living with a stoma and IBD, more negative beliefs about illness or belief that

the illness was serious was related to a decrease in HRQOL (Knowles et al., 2013;

Rochelle & Fidler, 2012). However, this relationship warrants further investigation as

these results were underpowered and not generalizable due to either a small sample size

(Knowles et al, 2013) and single site recruitment (Rochelle and Fidler, 2012).

The presence of a stoma has the potential to directly affect HRQOL. IBD, a health

condition that may lead to stoma formation, is an understudied diagnosis especially in the

younger population, with a limited number of studies that have examined the effects of a

stoma on HRQOL in persons living with IBD.   Thus, there is a need to understand the

physical, psychological, social, and/or spiritual challenges these persons deal with and

their associations with HRQOL. Based upon the postulation of theorists, the

aforementioned relationships merit investigation in order to explore the predictors of

HRQOL in younger persons living with IBD and a stoma.

Study Purpose

Prior research has shown that the presence of an intestinal stoma is associated

with a decrease in HRQOL resulting in deficits in physical, psychological, and social

well-being. Most studies have focused on older individuals with a stoma and a diagnosis

of colorectal cancer. The formation of an intestinal stoma presents a possible cure for

individuals with this diagnosis but the same is not true for individuals with Crohn's disease, as there is no known cure. Minimal research has focused on HRQOL in younger persons living with IBD and a stoma. Therefore, the purpose of this study is to understand the predictors of HRQOL in younger persons living with IBD and a stoma.

Research Questions

The following research questions are proposed in alignment with the relationships as postulated by theorists in the Wilson and Cleary HRQOL conceptual model. What are the interrelationships between symptoms, SRH, and HRQOL in younger persons living with IBD and a stoma?

Sub-Questions

1. Is there a relationship between symptoms (pain, fatigue, leakage of stomal appliance, peristomal skin condition, body image/sexual disturbance, and psychological distress) and HRQOL in younger persons living with IBD and an intestinal stoma?

2. Is there a relationship between SRH and HRQOL in younger persons living with IBD and an intestinal stoma?

3. Which symptoms (pain, fatigue, leakage of stomal appliance, peristomal skin condition, body image/sexual disturbance, and psychological distress) and SRH best predict HRQOL?

Significance of Study

There are approximately one million individuals currently living with a stoma in the United States and Canada with an increase of about 100,000 per year (Popek et al., 2010). IBD is a common etiology of stoma formation. Additionally, according to data

from the National Health Interview survey in 2015, about 3.1 million or 1.3% of the

adults in the United States have a diagnosis of IBD which has considerably increased

from an estimated 1.8 million living with IBD in 1999 (Dahlhamer, Zammitti, Ward,

Wheaton, & Croft, 2015). Around 10% of these individuals will require the formation of

an intestinal stoma (Katz et al., 2013). The surgical creation of a stoma, in addition to

underlying disease process and treatments, results in immediate physiological, as well as

psychological and social deficits. Younger individuals who are most likely to suffer from

IBD often experience psychological and social issues not present in an older population

(Savard & Woodgate, 2009). These physical, psychological, and social issues have the

potential to affect HRQOL. Despite the large disease and financial burden, as well as the

unique challenges present in a younger age group, little to no research is available

evaluating the predictors of HRQOL in younger persons living with IBD and a stoma.

Therefore, to provide holistic and individualized care to this population, it is essential to

understand the predictors of HRQOL in younger persons living with IBD and a stoma.

Chapter 2

This chapter focuses on the theoretical framework guiding this study, as well as the synthesis and analysis of empirical literature as it relates to the predictors of health-rated quality of life (HRQOL) in younger persons living with an ostomy and inflammatory bowel disease (IBD). An overview of the Wilson and Cleary HRQOL conceptual model, its theoretical constructs, and proposed theoretical propositions culminating in overall quality of life are presented in the theoretical discussion. A review of the empirical literature supporting the additional relationships of these theoretical concepts to be included in this study follows the discussion of the Wilson and Cleary HRQOL conceptual model. The initial section of the literature review discusses the evidence of predictors of HRQOL, followed by a description of gaps within the empirical literature, summary of theoretical rationale for research questions, hypotheses to be tested, as well as theoretical and operational definitions.

Theoretical Framework

Wilson and Cleary HRQOL Conceptual Model

HRQOL is described by Wilson and Clearly (1995) as a multi-dimensional concept including physical function, social function, mental health, and general health perceptions (pp. 60). The concept of HRQOL is derived from components of quality of life which are linked directly to health. Wilson and Cleary (1995) conceptualized different dimensions of HRQOL in five levels comprised of biological and physiological factors, symptoms, functioning, general health perceptions, and overall quality of life.

Wilson and Clearly (1995) begin their model with biological/physiological factors as these are frequently measured and applied in clinical practice. Wilson and

Cleary (1995) describe these biological/physiological factors as the evaluations of cell, organ, or organ system function, such as medical diagnoses, laboratory values, and physical examination findings. The next dimension is symptoms which are defined as an individual's awareness of atypical physical, emotional, or cognitive state (Wilson & Cleary, 1995). The subsequent level of this model involves greater interaction with society in the form of functioning. One's ability to perform a specified task in the physical, social, psychological, or role domain is the focus of functioning (Wilson & Cleary, 1995). The fourth dimension of HRQOL is termed general health perceptions and incorporates biological/physiological factors, symptoms, and functioning, as well as mental health. Wilson and Cleary (1995) define general health perceptions as an individual interpretation of physical and mental health that is also associated with biological and physiological variables, ultimately correlated to quality of life. The concept of general health perceptions as defined by Wilson and Cleary aligns with self-rated health (SRH) as SRH is subjective assessment of one's health. The aforementioned dimensions of health in the form of biological and physiological factors, symptoms, functioning, and general health perceptions are all interrelated and, ultimately, culminate in HRQOL.

A review of the empirical theoretical literature provides further insight into the Wilson and Cleary model. The biological/physiological factors of age and disease prevalence were found to be predictors of HRQOL in a study evaluating the utility of the behavioral risk factor surveillance system in randomly sampled adults living in the state of New York during the year of 2007 (Rizzo & Kintner, 2012). An association was also noted between symptoms and HRQOL with increasing severity and quantity of

symptoms yielding a negative impact upon HRQOL in multiple studies, across multiple populations including children with cleft lips/palates, adults who stutter, children with Autism, HIV-positive adults, and adults newly diagnosed with advanced cancer (Broder et al., 2014; Koedoot et al., 2011; Kuhlthau et al., 2013; Nokes et al., 2011; Rizzo & Kintner, 2012; Rodrigues et al., 2013). For example, the symptoms of pain and fatigue, were related to a decreased HRQOL in persons with newly diagnosed advanced cancers (Rodrigues et al., 2013). Figure 1 illustrates the associations to be tested in this study and include the relationships between symptoms, general health perceptions, and HRQOL.

Figure 1. Wilson and Cleary HRQOL Conceptual Model
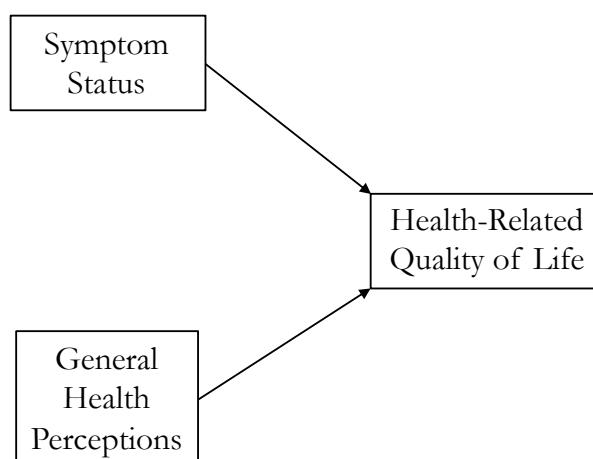
Figure 1. Redrawn Wilson and Cleary (1995) model showing relationships to be tested.

Literature Review

Predictors of HRQOL

In order to gain insight into the predictors of HRQOL in younger adults living with IBD and an ostomy, an extensive review of the empirical literature was conducted. Databases searched included Science Direct, Elseiver, Clinical Keys, Ovid, Wiley Online Library, CINHAL, Directory of Open Access Journals, and Scopus. Key terms used

included "quality of life" (QOL), "stoma", "ostomy", "HRQOL", and "IBD". After

limiting search results to English language, recent publications dating back to 2009, a

focus on IBD, and duplicate or irrelevant studies (i.e. focus other than QOL/HRQOL,

focus on life after stoma reversal, or focus on cure of colorectal cancer), 19 articles with a

focus on HRQOL remained to be reviewed. Overall, the presence of an ostomy

negatively affected all aspects of life including, but not limited to, physiological function

such as, social support, lifestyle factors, sexuality, psychological state, and coping

(Mahjoubi et al., 2012). However, HRQOL typically improved as time since stoma

creation increased (El-Tawil & Nightingale, 2013; Maydick, 2016; Popek et al., 2010;

Salles, Becker, & Faria, 2014). All studies are summarized according to authors, study

design, sample characteristics, and relevant findings in table 2.

Theorists describe a symptom as one's awareness of an atypical physical,

emotional, or cognitive state (Wilson & Cleary, 1995). A common physical

manifestation noted in persons with a stoma includes peristomal skin complications with

an incidence of 18-55% and range of severity from mild skin irritation to ulcers to

infection commonly resulting from exposure to intestinal effluent due to leakage of the

stomal appliance (Kwiatt & Kawata, 2013).

The presence of physical complications and symptoms associated with IBD can

result in an alteration in emotional or cognitive state in the form of psychological distress

and poor body image (Kwiatt & Kawata, 2013). In addition to symptoms related to

presence of a stoma, symptoms may also be attributed to the underlying disease process.

In the case of IBD, physical symptoms can take the form of gastrointestinal or extra

intestinal symptoms, such as abdominal pain, diarrhea, fatigue, weight loss, joint pain,

and mouth sores (Katz et al., 2013). Pain and fatigue due to IBD were also noted to be common physical ailments with pain reported in 71-87% of individuals with active IBD and between 40% and 77% experiencing sleep impairment (Habibi et al., 2017; Peyrin-Biroulet et al., 2013; Schirbel et al., 2010; Zeitz et al., 2016). As with the presence of a stoma, a diagnosis of IBD may result in psychological or emotional distress such as alteration in body image, depression, or anxiety (Katz et al., 2013). Finally, altered sexuality as a result of underlying disease activity, as well as physical stoma symptoms and altered body image due to stoma surgery were common in individuals with a diagnosis IBD and persons living with a stoma (El-Tawil & Nightingale, 2013; Ramirez et al., 2009; Sinclair, 2009).

Study findings in this review supported relationships between symptoms and HRQOL with symptoms including pain, fatigue, peristomal skin conditions, leakage of stomal appliance, body image/sexual disturbance, and psychological distress in the form of anxiety or depression. The self-diagnosis of physical symptoms due to stoma and/or underlying disease process was associated with a negative impact on HRQOL in five studies (Anaraki et al., 2012; El-Tawil & Nightingale, 2013; Grant et al., 2011; Nybaek et al., 2010; Popek et al., 2010). Additionally, a negative correlation between HRQOL and active symptomatology of underlying disease process, as well as recent stoma surgery was noted by the authors of four articles (Anaraki et al., 2012; El-Tawil & Nightingale, 2013; Grant et al., 2011; Popek et al., 2010). The presence of peristomal skin complications, as well as leakage from the stomal appliance were associated with an alteration in HRQOL with HRQOL inversely related to severity of the skin condition (Erwin-Toth et al., 2012; Nybaek et al., 2010). In one study, self-recognition of such a

skin condition had a strong, negative impact on HRQOL with only 38% of participants

with skin conditions having the ability to self-identify the condition (Nybaek et al., 2010).

With regard to the underlying disease process, the authors of four studies identified pain

and fatigue as having a negative impact on HRQOL with three studies focusing on the

disease course of IBD (Abdalla et al., 2016; Grant et al., 2011; Morris & Leach, 2017;

Savard & Woodgate, 2009). Prior to stoma formation, abdominal pain was noted as a

common issue in persons with UC and hindered daily activities in those suffering from

Crohn's disease (Morris & Leach, 2017; Savard & Woodgate, 2009). However, in those

with Crohn's disease, stoma formation did not completely alleviate suffering as Abdalla

et al. (2016) reported that persons living with a stoma and active disease reported greater

pain and fatigue compared to those with active disease who did not have a stoma.

Additionally, Grant et al. (2011) reported a low HRQOL was associated with sleep

difficulties in females.

Pain was not limited to physical ailments as most reported the presence of

emotional discomfort in addition to physical pain (Savard & Woodgate, 2009). The

erratic disease course of IBD, including periods of remission and exacerbations, may

potentially affect the presentation of psychological distress. Psychological distress in the

form of anxiety and depression was associated with HRQOL in four studies with higher

anxiety and depression associated with the presence of an ostomy and lower HRQOL

(Anaraki et al., 2012; Grant et al., 2011; Knowles et al., 2013; Rochelle & Fidler, 2012).

Prior to stoma formation, Morris and Leach (2017) stated that the presence of Crohn's

symptoms controlled daily activities leading to depressed mood but as there is no cure for

Crohn's disease, occurrence of symptoms even after stoma formation would also likely cause psychological distress.

Sexual disturbance is a common issue following stoma surgery that has found to be related to poor HRQOL with sexual problems such as difficulty with erection and lack of sexual activity reported in the literature (Anaraki et al., 2012; Grant et al., 2011; Popek et al., 2010). Persistence of IBD symptoms following stoma surgery also has been found to negatively affect sexuality after surgery (El-Tawil & Nightingale, 2013). In two studies, sexual challenges following surgery including erectile dysfunction and dyspareunia in persons living with a stoma were reported to increase with age. (Grant et al., 2011; Mahjoubi et al., 2012). Additionally, body image was associated with HRQOL in the literature as the authors of four studies found that a poor body image was correlated with a worse HRQOL (Aronovitch et al., 2010; Grant et al., 2011; Mahjoubi et al., 2012). Deficits in body image were noted to be associated with sexual disturbance in the literature as avoidance and loss of romantic relationships occurred as a result of negative impacts of stoma on body image, as well as embarrassment due to threats to body image and intimacies with an ostomy (Savard & Woodgate, 2009; Sinclair, 2009). Also, the presence of a supportive partner, often as a result of marriage, who accepted the reconfigured body was more likely to result in engagement in sexuality activity and therefore, a better HRQOL (Ramirez et al., 2009; Salles et al., 2014; Sinclair, 2009). Finally, in the studies in which sexual disturbance was less of a concern for the participants, at least 75% were married or partnered, mainly had a stoma as a result of colorectal cancer and had a mean age of participants in the 70s (Grant et al., 2011; Ramirez et al., 2009; Sinclair, 2009).

Stoma formation can be considered curative for UC and colorectal cancer, however in Crohn's disease this may not be the case. Therefore, the potential for symptoms related to presence of stoma, as well as underlying disease process in these persons is present for persons living with Crohn's disease and a stoma. In order to understand the manner in which stoma and IBD symptoms affect HRQOL simultaneously, it is important to include symptoms of peristomal skin condition, leakage, pain, fatigue, psychological distress in the form of anxiety and depression, body image/sexual disturbance as predictors of HRQOL.

According to the empirical literature, the manner in which one self-evaluates and interprets health or SRH was found to be related to HRQOL. A greater number of negative illness beliefs about stoma or a conviction that one's illness is serious has been found to be associated with a worse HRQOL (Knowles et al., 2013; Rochelle & Fidler, 2012). Knowles and colleagues (2013) reported that the one's own interpretation that the presence of a stoma impacted or reduced control over life was correlated with a decrease in HRQOL in an investigation focused on understanding the impact of surgery/stoma type, illness perceptions, coping style, and psychological well-being on HRQOL in persons with Crohn's disease. In a study of pre- and post-ileostomy experiences in individuals with Crohn's disease, Morris and Leach (2017) also found that the presence of symptoms due to Crohn's disease reduced control over life while stoma formation allowed for return to daily activities, however, none of the participants included in this study experienced symptoms due to Crohn's disease after a stoma was created. Savard and Woodgate (2009) found that the presence of disease and a stoma was a threat to the sense of self in a qualitative inquiry into the life experience of younger persons living

with IBD and a prior temporary stoma. Finally, in an evaluation of relationships between

illness cognitions or perceptions about disease affecting behaviors and coping and

HRQOL in adults with IBD, Gukova and Soosova (2018) reported that illness cognitions

were related to HRQOL with a belief of helplessness as an important predictor of a worse

HRQOL.

As aforementioned, Crohn's disease is not curative with stoma formation, thus the

continued presence of Crohn's disease symptoms along with stoma symptoms would

likely affect the manner in which one would self-evaluate his or her health state (Katz et

al., 2013). Additionally, even without UC symptoms, the presence of a stoma can also

impact the manner in which health is interpreted as stomal symptoms may be present

even in the absence of UC symptoms. Finally, IBD is typically diagnosed and treatment

usually begins in younger persons aged 18-35. Wong et al. (2013) found that the manner

in which a younger person evaluates health status differs from an older individual, as

older persons are more likely to suffer from numerous co-morbidities than younger

individuals. Therefore, it is important to understand SRH distinguishing between

Crohn's disease and UC as a predictor of HRQOL in younger persons living with IBD

and a stoma.

Table 1. Predictors of HRQOL: Literature Reviewed

Author/ Year	Study Design	Study Purpose	Sample Characteristics	Relevant Findings
Abdalla, M. I. et al. (2016).	Cross-sectional study.	Purpose: evaluate persons with Crohn's disease and a stoma for at least 6	N = 4,733, recruited online as part of Crohn's and Colitis Foundation cohort study.	Participants with an ostomy were older (mean age 49.3yrs.) and had longer disease

		months compared to persons with Crohn's disease and no stoma to understand impact of stoma on certain patient-reported outcomes including anxiety, depression, fatigue, pain interference, sleep disturbances, social satisfaction, and sexual interest & satisfaction.	Age: 49.3yrs. mean age of those with stoma, 43.7yrs. mean age of those without a stoma. Gender: 71.8% of those with stoma were female, 72.9% of those without stoma were female. Stoma characteristics: 402 had a stoma present for at least 6 months. Diagnoses: all had Crohn's disease.	duration (mean 26.2yrs.) compared to participants without an ostomy (mean age 43.7yrs. and mean disease duration 15.1yrs.). Overall, presence of stoma didn't impact HRQOL, but tool used not validated in persons with a stoma. Participants with an ostomy were more likely to be in remission (48.5% for those with an ostomy vs. 31.3% for those without an ostomy, p <0.001). Multivariate logistic regression & group analysis of covariance revealed statistically significant findings:

				Participants with an ostomy were more likely to use narcotics (OR 1.68, 95% CI 1.24-2.27, p=0.001). Participants with active disease and an ostomy had worse pain (OR 1.63, 95% CI 1.12-2.35), fatigue (OR 1.66, 95% CI 1.15-2.39), and social satisfaction (OR 1.42, 95% CI 1.03-1.95).
Anaraki, F. et al. (2012).	Cross-sectional study.	Purpose: evaluate quality of life of persons undergoing stoma surgery as a result of cancer and non-cancer causes using the City of Hope Quality of Life Ostomy Questionnaire.	N = 102, participants from Iranian Ostomy Society. Age: mean age 53.5yrs. Gender: 58 males. Stoma characteristics: ostomy present for at least 3 months, 80.4% had permanent stomas Diagnoses: 77.5% had	66.7% reported loss of sexual activity and 82.4% noted change in diet after stoma surgery. 40.2% of males had erectile problems following surgery. Multivariate regression analysis revealed that depression ((β = -0.70) and problem with stoma location ((β = -0.61)

			stomas due to cancer.	significantly predicted overall QOL p<0.05).
Aronovitch, S.A., Sharp, R., & Harduar-Morano, L. (2010).	Descriptive, non-experimental study.	Purpose: evaluate if contact with a wound ostomy continence nurse improved HRQOL in persons living with an ostomy.	N = 120, participants with ostomies recruited from North Florida. Age: mean age 62yrs. Gender: 60 males and 60 females. Stoma characteristics: mean of 10yrs. Living with stoma, 95% had permanent stomas, 32 with ileostomies, and 69 with colostomies. Diagnoses: not specified. 103 Caucasian. 71 retired, 67 lived with a spouse.	Majority of participants had satisfactory HRQOL despite ostomy. Wilcoxon signed rank & Kruskal-Wallis tests revealed statistically significant findings: Living with persons other than family had highest HRQOL (p = 0.01) and living with family had higher HRQOL than living alone (p = 0.02). No additional statistics were reported by the authors.
El-Tawil, A.M. & Nightingale, P. (2013).	Descriptive study.	Purpose: to understand if persons' self-perception and others perception of them is fixed or	N = 78, all participants members of United Ostomy Association of America. Age: specifics not included.	Participants were divided into two groups by age (< or > 50yrs.) & time since diagnosis (< or > 5yrs.) and were compared

		changeable overtime, as well as the influence of time on persons' impression on existence of stoma in relation to self-image and sexual/social relationships.	Gender: 33 were female. Diagnoses: 84.8% had diagnosis of UC.	through Mann-Whitney tests. Participants with longer time since diagnosis were more likely to feel better (p=0.042), have better self-perception (p=0.039), be more satisfied with sexual performance (p=0.007), and enjoy same things as before diagnosis (p=0.025). Persistence of disease after surgery affected sexuality after surgery.
Erwin-Toth, P., Thompson, S.J., & Davis, J.S. (2012).	Descriptive study.	Purpose: determine peristomal skin condition and HRQOL after wearing a double-layer adhesive stoma pouching device.	N = 673, all participants living with stoma in North America. Age: mean age of 61.4yrs. Gender: 439 females. Stoma characteristics: mean length of time since surgery of	61% had peristomal skin conditions, 38% self-identified peristomal skin conditions. Analysis of covariance reveled statistically significant findings: HRQOL improved

| | | | 10.2yrs., 658 had permanent ostomies, and 546 had planned ostomies.

Diagnoses: 263 ostomies due to cancer, 154 ostomies due to UC, and 119 ostomies due to Crohn's disease. | significantly with decreased leakage of appliance having greatest impact (p<0.0001).

Use of correct appliance increased HRQOL as frequency and severity of perceived leaks decreased significantly following use of proper appliance (p < 0.0001). |
|---|---|---|---|---|
| Grant, M. et al. (2011). | Qualitative study using content analysis of focus group data. | Purpose: understand how gender affects specific challenges, adaptation processes, and strategies for self-care in long-term colorectal cancer survivors with ostomies. | N = 33, participants living with a stoma divided into groups by gender and high or low scores on the City of Hope Quality of Life-Ostomy questionnaire.

Gender and age: mean age of men with high QOL 73yrs., mean age men with low QOL 67yrs., mean age of females with high QOL 76yrs., and mean age of | Focus group data was analyzed using directive content analysis and placed into 4 domains of HRQOL: physical, psychological, social, & spiritual well-being.

Physical domain: theme of sleep – women with low QOL noted sleep difficulty.

Psychological domain: theme of sadness & |

			females with low QOL 63yrs. Stoma characteristics: not specified. Diagnoses: 282 had stomas due to colorectal cancer. 29 Caucasian. 25 had college degrees. 25 married or partnered at time of surgery. 15 had income of $50,000 or less.	depression – women with low QOL noted depression. Theme of body image – women with low QOL noted issues with body image. Social domain: theme of sexuality – sexual challenges were noted by all with no sexual problems noted in those with a high QOL.
Gurkova, E. & Soosova, M.S. (2018).	Cross-sectional, observational study.	Purpose: evaluate the relationship between illness cognitions (manner in which person perceives and considers disease) and HRQOL in adults with IBD.	N = 118, adults with IBD for at least 6 months. Age: mean age of 33.51yrs (range 19-60 yrs.). Gender: 50.8% female. Stoma characteristics: no stomas present. Diagnosis: 51 with Crohn's	Multiple regression analysis revealed statistically significant findings: Illness cognitions are significant in influencing HRQOL with the illness cognition of helplessness as the most important predictor of

			disease and 67 with UC. All had biological therapy.	HRQOL (β = -0.593, p = 0.000, R^2 = 0.433, F = 12.18). No additional statistics reported by authors.
Knowles, S.R. et al. (2013).	Descriptive, cross-sectional study.	Purpose: to understand relationships between elective vs. emergent surgery, permanent vs. temporary stoma type, illness perceptions and coping style, anxiety, depression, and HRQOL in persons with Crohn's disease, as well as use of psychological care and psychotropic medications.	N = 31 participants recruited from 2 hospitals in Australia. Age: mean age 31yrs. Gender: 14 females and 17 males. Stoma characteristics: 55% had permanent stoma, mean age since most recent stoma surgery 32yrs., and 24% have >1 stoma-related surgery. Diagnoses: all had Crohn's disease. 11 worked full-time.	Differences between groups were analyzed through Mann-Whitney U test that revealed statistically significant findings. More negative illness beliefs about stoma or belief stoma adversely impacted or reduced control over life was associated with higher anxiety and depression and poorer quality of life (p < 0.05).
Mahjoubi, B. et al. (2012).	Cross-sectional study.	Purpose: understand quality of life in Iranian	N = 96. Age: Mean age of males 51yrs. And	Presence of a stoma negatively affected all aspects of life.

| | | persons living with a colostomy and analyze results in relation to age and gender. | mean age of females 47yrs.

Gender: 54 females and 42 males.

Stoma characteristics: all had permanent stomas, mean duration since surgery was 32 months, and 25% received pre-op stoma education.

Diagnoses: all participants had colorectal cancer.

76% were married, 54% had full-time jobs, 44% were high school graduates, and 38% were college graduates. | Sexual enjoyment and function were impaired in all.

Groups were compared using Chi-squared test, Mann-Whitney U test, Kruskal-Wallis test, Fisher's exact test, and One-Way ANOVA test:

Occupational status changed significantly after stoma surgery ($p=0.00$).

Males had better body image ($p=0.00$), increased physical ($p=0.02$) and sexual function ($p=0.00$), and handled stoma issues and side effects better.

Females had poor body image ($p=0.00$) but body image increased with age ($r = 0.355$, $p = 0.01$). |

				Age significantly related to sexual function – problems increased with increasing age (males – r = -0.406, p = 0.01; females – r = -0.419, p = 0.006). No additional statistics were reported by authors.
Maydick, D.R. (2016).	Comparative, descriptive study.	Purpose: evaluate the relationship between quality of life and preoperative stoma site marking in adults with a permanent stoma.	N = 140, all participants recruited from a United Ostomy Association of America conference. Age: mean age for females 59.06yrs. and mean age for males 65.02yrs. Gender: no specifics. Stoma characteristics: more than half had an ileostomy, 63% had one surgery, yrs. Since recent surgery ranged 0-58yrs., pre-	Logistic regression analysis and analyses of covariance revealed statistically significant findings: QOL increased with increased age (r [137] = 0.27, p=0.001), years since first surgery (r [138] = 0.25, p=0.003), and years since most recent surgery (r [137] = 0.28, p=0.001). QOL increased with pre-op site marking by a WOC nurse (M = 7.705, SE =

			op marking by a WOC nurse more likely with recent surgery. Diagnoses: > 75% had Crohn's disease or UC. Majority was Caucasian. 69.3% were married before surgery.	0.160) or surgeon (M = 8.185, SE = 0.374) compared to no pre-op site marking (F [3, 118] = 3.44, p = 0.019). No additional statistics were reported by author.
Morris, A. & Leach, B. (2017).	Qualitative study using Hermeneutical phenomenology.	Purpose: increase understanding of pre- and post-ileostomy experiences in persons living with Crohn's disease.	N = 10, all participants from West Midlands, UK. Age: mean age 52.2yrs. (range 34-83yrs.) Gender: 6 females. Stoma characteristics: all had an ileostomy for a mean duration of 18.3yrs. (range 3-36yrs.). Diagnoses: all had Crohn's disease.	The interview data was analyzed through interpretive phenomenology and reflexivity was also incorporated into interviews. Theme – Being controlled by Crohn's: Before ileostomy, all participants felt controlled by Crohn's disease as physical symptoms (i.e. abdominal pain) limited ability to perform daily activities and

| | | | | socialize which led to depressed mood.

Theme – New life: experiences of an ileostomy:

All perceived ileostomy creation as a positive change and a way to return to "normal life" where they were able to work, socialize, and perform daily activities.

Creation of ileostomy relieved symptoms. |
|---|---|---|---|---|
| Nybaek, H. et al. (2010). | Cross-sectional study. | Purpose: understand quality of life in persons with peristomal skin problems and the variables that affect it. | N = 141, participants all recruited from a single county in Denmark.

Age: specifics not described.

Gender: specifics not described.

Stoma characteristics: all participants had permanent stomas and | Two-sample Wilcoxon test and Kruskal-Wallis test revealed statistically significant findings:

Presence of peristomal skin condition negatively affected QOL (p = 0.0026 based on dermatological life quality |

			2mo-51yrs. Was range of time since surgery. Diagnoses: etiology of stoma not described, 74 had a diagnosis of peristomal skin disease.	index, p = 0.0083 based on ostomy adjustment score) and was strongly affected by awareness of skin condition (p = 0.004 based on dermatological life quality index, p = 0.046 based on ostomy adjustment score). Presence of peristomal skin condition was related to a lower ostomy adjustment score (p=0.046). QOL was inversely related to severity of peristomal skin condition (p = 0.0068). Leakage of stoma appliance was associated with a lower QOL (p = 0.0036). Presence of an ileostomy was associated with

				lower QOL (p = 0.0388).
Person, B. et al. (2012).	Descriptive study.	Purpose: determine how pre-operative site marking and education by an enterostomal therapist affected quality of life, as well as if site marking and education improved independence and rates of post-operative complications.	N = 105, all participants recruited from single hospital in Israel. Age: median age of 65yrs. Gender: 57% were males. Stoma characteristics: 57% had permanent stomas, 50% received pre-op stoma site marking. Diagnoses: etiology of stoma not described.	Person's chi-squared test revealed statistically significant findings: QOL (p < 0.05) and independence (p < 0.05) were better with pre-op stoma site marking. Stoma complications decreased with pre-op stoma site marking (p < 0.05). No additional statistics were reported by authors.
Popek, S. et al. (2010).	Mixed methodology – quantitative survey and qualitative focus group. Qualitative methodology is not clearly defined.	Purpose: understand concerns affecting HRQOL in male veterans living with an ostomy.	N = 16. Age: specifics not described. Gender: all male veterans. Stoma characteristics: all had permanent ostomies present for 2yrs. or longer. Diagnoses: rectal and	Focus group data was assessed through content analysis. Theme – mastering ostomy care: Increased QOL was associated with sense of pride/ accomplishment when learning

			colon cancer, IBD, trauma, and diverticulitis.	to manage ostomy. Decreased QOL associated with no sense of pride and lack of control in managing ostomy. Theme – positive thinking /acceptance: Increased QOL was associated with positive thinking, optimism, positive acceptance of being alive, & enjoyment of activities. Theme – coping: Increased QOL associated with psychosocial adjustment with pre-op self-efficacy. Decreased QOL associated with poor coping & lack of motivation to manage disease.

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| | | | | Theme – sexual relationships:

Increased QOL was associated with experience with sexual activity.

Decreased QOL was associated with difficulty with erection.

Theme – quality of care:

Decreased QOL associated with dissatisfaction with care.

QOL was related to perception of care. |
| Ramirez, M. et al. (2009). | Framework not clearly defined as authors state anthropological perspective, phenomenological examination, and use of grounded theory to analyze data. | Purpose: increase understanding of the experiences related to sexuality in female colorectal cancer survivors living with a permanent stoma. | N = 30.

Age: median age 74yrs.

Gender: all female.

Stoma characteristics: all had permanent stomas. | Interview data were analyzed through grounded theory methods resulting in 4 groups of sexual experience – no long-term sexual difficulties, long-term sexual difficulties, |

			Diagnoses: all had colorectal cancer. 22 were Caucasian, 22 were married, and all in a heterosexual relationship.	age-related changes in sexuality, and no partnered sexual experience post-surgery. Group I – No Long-Term Sexual Difficulties: Supportive partner who accepted reconfigured body was essential to experiencing sexual desire after stoma surgery. Group III – Lifecoure, Age-Related Changes in Sexuality: Many not bothered by lack of sexual activity if believed lack of activity was due to age-related changes.
Rochelle, T.L. & Fidler, H. (2012).	Prospective study.	Purpose: determine illness perceptions of persons with IBD in an outpatient	N = 102, all participants recruited from single London hospital.	Univariate analysis and hierarchical regression models revealed statistically

		setting and evaluate if illness perceptions are related to disease severity, QOL, and psychological adjustment in persons with IBD.	Age: mean age of 41.9yrs. Gender: 67 females. Stoma characteristics: not clearly described. Diagnoses: 56 had Crohn's disease and 46 had UC with a mean disease duration of 8.8yrs.	significant findings: Negative associations were noted between QOL and anxiety (p < 0.001), depression (p < 0.001), consequences (p < 0.001), personal control (p < 0.001), and emotional representation (p < 0.001) (hierarchical model: F = 9.38, p < 0.01).
Salles, V.J.A., Becker, C.P.P, & Faria, G.M.R. (2014).	Cross-sectional, epidemiological study.	Purpose: determine quality of life in persons living with an ostomy.	N = 30, all participants recruited from Ostomy Association in Brazil. Age: mean age of females was 48yrs. and mean age of males was 54yrs. Gender: 70% were female. Stoma characteristics: specifics not described. Diagnoses: 50% had stoma	Data was analyzed through means of answers and final assessment of QOL was determined by adding points in the questionnaire with highest scores considered best QOL. Presence of stoma for greater than 2 yrs. had better QOL than presence of a stoma for a

			due to colorectal cancer and 30% had stoma due to IBD.	shorter period of time. Adapting to stoma was associated with better QOL. Family support and personalized healthcare helped participants adapt to stoma (support of family/ friends/ spouse increased final score). Social support and engaging in sexual activity (60% were satisfied with sexual life) were associated with optimal QOL.
Savard, J. & Woodgate, R. (2009).	Hermeneutic phenomenology using Van Manen's approach.	Purpose: increase understanding of the experience of young persons living with IBD and a temporary stoma.	N = 6. Age: age ranged from 19-24yrs. Gender: 5 females. Stoma characteristics: all participants previously had a temporary stoma 1-8yrs. ago.	Interview data was analyzed through Hermeneutic phenomenology procedures as outlined by Van Manen. Essence – Concealing and revealing the self: Sense of self was considered

			Diagnosis: all participants had UC diagnosed 3-13yrs. ago. All Caucasian. No participants were married, 1 was engaged.	important and presence of disease and stoma threatened sense of self. Theme – "Uneasy Feeling" Subtheme – Embarrassment: Threats to self-esteem and body image often led to embarrassment. Presence of ostomy was embarrassing with most wanting to conceal ostomy. Many described intimacies with an ostomy present as embarrassing. Theme – "It's Hard…" Subtheme – Pain: Emotional and physical pain were

				experienced by all with physical pain rated as worse. All experienced difficulty as a result of UC.
Sinclair, L.G. (2009).	Qualitative study using narrative inquiry.	Purpose: understand the experience of young persons living with a permanent ileostomy to add to knowledge base of nurses and other healthcare providers.	N = 7, all participants had a permanent ileostomy for < 4yrs. Age: mean age 34.5yrs., age range from 24-40yrs., and only 1 in range from 24-30 yrs. Gender: 4 females, 3 males. Stoma characteristics: all had permanent stomas, 4 started as temporary stomas and were converted to permanent. Diagnosis: 4 had UC, 3 had Crohn's disease, and 1 had chronic constipation.	Participant's narratives were analyzed through Clandinin and Connelly's framework it identifies common or divergent themes. Theme – Looking Backward: Subtheme – Ostomy care: Leakage was an issue for most. Subtheme – Impact on body image: Two participants mourned loss of intestine and new body image. Stoma negatively affected body

| | | | 3 participants were married. | image and sexual life.

Married participants couldn't image dating again and most of single participants avoided dating.

Theme – Looking Inward:

Presence of temporary stoma experience helped with adjustment to permanent stoma. |
|---|---|---|---|---|
| Wong, S.K., Young, P.Y., Widder, S., & Khadaroo, R.G. (2013). | Retrospective chart review followed by descriptive study. | Purpose: evaluate how age affects QOL after stoma surgery including determining if persons 65 years or older were more likely to have lower perceived QOL and decreased self-efficacy compared to persons younger than 65 years. | N = 18, all participants recruited from single hospital in Canada.

Age: age ranged from 26-91 with 11 over 65yrs.

Gender: majority were male.

Stoma characteristics: length of time since stoma surgery ranged from 6mo-3yrs., | Participants 65yrs. and older had more co-morbidities.

Most did not require daily assistance with stoma management but participants 65yrs. or older were more likely to require assistance.

Statistical significance discussed but exact method of analysis not |

			colostomies were more common than ileostomies, and older participants were more likely to have emergent surgery. Diagnosis: cancer was the most common stoma etiology.	described by authors. QOL was increased in the participants 65yrs. or older compared to younger participants but not statistically significant (p = 0.14). Participants younger than 65yrs. were more likely to spend > $50/mo. on stoma management (p = 0.21).

Current State of Knowledge and Gaps

The presence of symptoms including pain, fatigue, peristomal skin condition, leakage of stomal appliance, body image/sexual disturbance, and psychological distress in the form of anxiety and depression was noted to strongly and negatively affect HRQOL as noted in the empirical literature. Physical pain and fatigue negatively affected HRQOL with Abdalla et al. (2016) describing greater pain and fatigue in individuals with active Crohn's disease and a stoma compared to active Crohn's disease without a stoma (Grant et al., 2011; Savard & Woodgate, 2009). Leakage of stomal appliance and presence of peristomal skin disease also resulted in worse HRQOL with more severe skin conditions and self-diagnosis of such a condition further impeding HRQOL (Erwin-Toth et al., 2013; Nybaek et al., 2010). Further, anxiety and depression,

as well as deficits in body image were negatively related to HRQOL in women, while

presence of a temporary stoma, and experience of IBD symptoms increased the presence

of anxiety, depression, and deficits in body image (Anaraki et al., 2012; Grant et al.,

2011; Knowles et al., 2013; Rochelle & Fidler, 2012; Savard & Woodgate, 2009, Morris

& Leach, 2017; Sinclair, 2009). The majority of persons living with a stoma reported

sexual challenges following stoma surgery in prior studies with the persistence of

underlying disease process, threats to body image, lack of sexual activity, and sexual

problems, such as impotence, was associated with decreased HRQOL (Anaraki et al.,

2012; El-Tawil & Nightingale, 2013; Grant et al., 2011; Popek et al., 2010; Savard &

Woodgate, 2009; Sinclair, 2009).

General health perceptions or SRH was associated with HRQOL in the empirical

literature. A greater number of negative beliefs about illness, such as the belief that

illness was serious, or sense of helplessness surrounding illness were all correlated with a

worse HRQOL (Gurkova & Soosova, 2018; Knowles et al., 2013; Rochelle & Fidler,

2012).

The majority of the studies centering on HRQOL in persons with a stoma

included participants with a mean age of 50 years or older and with a diagnosis of

colorectal cancer. The few articles that did include younger participants ranging from 19-

30s years were underpowered and not generalizable as the authors included small sample

size and recruited from one or two healthcare settings outside of the United States, and in

the study conducted by Savard and Woodgate (2009) only subjects with a previous

temporary stoma were included. Of the 11 studies featuring a sample where participants

designated a diagnosis of IBD, only three included both IBD sub-types and distinguished

between Crohn's disease and UC, but the authors did not report findings according to IBD-subtype (Gurkova & Soosova, 2018; Rochelle & Fidler, 2012; Sinclair, 2009).

The empirical literature supported the relationships as proposed by theorists and empirical theoretical literature between symptoms, SRH, and HRQOL. There is a paucity of research focusing on HRQOL in younger participants living with IBD and a stoma. Thus, this proposed study will examine the relationships between symptoms, SRH, and HRQOL in younger individuals living with IBD and a stoma.

Study Hypotheses

The following hypotheses will be examined in adults between the ages of 18 and 40 years living with IBD and an intestinal stoma:

1. The symptom of pain is inversely related to HRQOL in younger persons living with IBD and an intestinal stoma.

2. The symptom of fatigue is inversely related to HRQOL in younger persons living with IBD and an intestinal stoma.

3. The symptom of leakage of stomal appliance is inversely related to HRQOL in younger persons living with IBD and an intestinal stoma.

4. The symptom of peristomal skin problem is inversely related to HRQOL in younger persons living with IBD and an intestinal stoma.

5. The symptom of body image/sexual disturbance is inversely related to HRQOL in younger persons living with IBD and an intestinal stoma.

6. The symptom of psychological distress is inversely related to HRQOL in younger persons living with IBD and an intestinal stoma.

7. SRH is directly related to HRQOL in younger persons living with IBD and an intestinal stoma.

8. There will be significant combined effects in terms of variance accounted for of symptoms (pain, fatigue, leakage of stomal appliance, peristomal skin problem, body image/sexual disturbance, psychological distress) and SRH on HRQOL in younger persons with IBD and an intestinal stoma.

Theoretical and Operational Definitions

Symptoms

Theorists define a symptom as an individual's awareness of atypical physical, emotional, or cognitive state (Wilson & Cleary, 1995). Based upon the literature review, essential symptoms to consider in the population of interest include peristomal skin condition, leakage of stomal appliance, pain, fatigue, and psychological distress in the form of anxiety and depression, and body image/sexual disturbance. These symptoms include those specific to the IBD disease process as well as unique to the presence of a stoma. Symptoms will be operationalized through the use of the Young-Fadok Stoma Quality of Life Scale. This scale includes symptoms specific to stoma formation including sexuality/body image and stoma function subscales, as well as the additional question related to skin irritation (Baxter et al., 2006). Additionally, the *Short-Form 36* (SF-36) health survey subscales of bodily pain, general mental health, and vitality will be used to operationally define pain, fatigue, and psychological distress, respectively (Hays, Sherbourne, & Mazel, 1995). For the purpose of this study, symptom status will be based upon scores from these subscales and appropriate items on one of the two tools described above.

SRH

Theorists define general health perceptions as an individual interpretation of physical and mental health (Wilson & Cleary, 1995). SRH is a representation of the theoretical conceptualization of general health perceptions. General health perceptions will be operationalized as SRH or a self-assessment of one's health for the objective of this study (Idler & Benyamini, 1997; Mossey & Shapiro, 1982). SRH will be operationally defined in this study as a single item on the *Heathy Days Core Module* (CDC HRQOL-4) in which an individual rates health in general on a five-point Likert scale from excellent (1) to poor (4) that is included as the first question on the CDC HRQOL-4 (CDC, 1993).

HRQOL

Wilson and Cleary (1995) describe HRQOL as an individual's level of happiness or satisfaction with current life events. HRQOL is composed of four levels including biological/ physiological factors, symptoms, functioning, and general health perceptions. For the purpose of the proposed study, HRQOL will be operationalized as the total score of the CDC HRQOL-4 (CDC, 1993). This tool is a generic HRQOL tool that was designed to measure generic HRQOL in the general population, as well as SRH aligning with the four-dimensional definition of HRQOL as described by Wilson and Cleary (1995).

Conclusion

Wilson and Cleary (1995) proposed a conceptual model in which HRQOL was purported to be comprised of five dimensions including biological/physiological factors, symptoms, functioning, general health perceptions, and overall quality of life that were

related to one another in a linear relationship culminating in HRQOL. A review of the empirical theoretical literature indicated that symptoms and general health perceptions were directly related to HRQOL with limited support for an association for between functioning and HRQOL, as well as general health perceptions and HRQOL. Additionally, evidence supported relationships between symptoms (pain, fatigue, peristomal skin condition, leakage of stomal appliance, body image/sexual disturbance, and psychological distress in the form of anxiety and depression) and general health perceptions (SRH) with HRQOL in persons living with a stoma and/or IBD. The presence of a stoma was noted to negatively impact life as a whole but with time, most eventually learned to adjust to life with a stoma (El-Tawil & Nightingale, 2013; Mahjourbi et al., 2012). Additionally, UC resulted in pain and threatened sense of self while symptoms of Crohn's disease-controlled life resulting in a depressed mood whereas persons with active Crohn's disease and a stoma had more pain and fatigue resulting in worse HRQOL than individuals with active Crohn's disease without a stoma (Abdalla et al., 2012; Morris & Leach, 2017; Savard & Woodgate, 2009). The majority of studies within the empirical literature included participants with a mean age of 50 years or older with a main diagnosis of colorectal cancer. The limited studies including younger participants ranging from 19-30 years with possible diagnosis of IBD were underpowered and not generalizable as authors recruited small sample sizes from limited locations.

IBD is typically diagnosed between the ages of 18 and 35 years with many diagnosed under the age of 20, making it the most significant chronic disease of younger persons (Savard & Woodgate, 2009). One-third of persons with UC and 10% of those requiring surgery will ultimately result in the creation of a stoma (Katz et al., 2013).

Younger persons often experience psychological distress not found in an older

population, while stoma formation in an individual with Crohn's disease does not offer

potential for a cure. Individuals aged 18-40 are in a stage of life, according to Erikson

(1950), in which interaction with those outside of their family is imperative for

psychological well-being (Katz et al., 2013; Savard & Woodgate, 2009). Therefore, in

order understand the unique needs of younger person living with IBD and a stoma, it is

important to understand the predictors of HRQOL in this understudied population.

Chapter 3

Methods

This chapter describes the research design and methods for this study. A description of the research setting, sample size, sampling method, as well as inclusion and exclusion criteria are provided followed by a discussion of the instruments and procedures for data collection and analysis. A discussion of protection of human subjects conclude this chapter. In order to understand predictors of health-related quality of life (HRQOL) in younger persons living with inflammatory bowel disease (IBD) and an intestinal stoma, a descriptive, cross-sectional study design was used.

Research Setting

The research setting for this study was online discussion boards and support groups focusing on life with IBD and/or an intestinal stoma. These online discussion boards and support groups are frequented by individuals living with IBD and/or an intestinal stoma for support and/or to discuss living with IBD and/or a stoma. Additionally, individuals in the age group of interest – 18 to 40 years – commonly participate in online communities. Therefore, this research setting was chosen to reach the population of interest.

Sample and Sampling Methods

Individuals who completed the survey posted online during the time period from October 2018 to December 2019 that met the inclusion criteria were included in this sample. Inclusion criteria: (1) currently living with an intestinal stoma for at least two months, (2) have a diagnosis of IBD, (3) community-dwelling adults aged 18-40 years, and (4) the ability to read and write in English. The age range of 18 to 40 years is an

essential time to interact with persons outside the family of origin in order to maintain psychological well-being according to Erikson's *Theory of Psychosocial Development* (Erikson, 1950). As IBD is typically diagnosed by age 35 years and the presence of a stoma may threaten socialization and psychological well-being, 18 to 40-year-olds are the target population in this study. Additionally, the surgical creation of a stoma requires an estimated six to eight-week healing period before individuals undergoing surgery can return to work/school, so persons were only included in this study if his or her stoma had been present for at least two months to avoid effects on HRQOL due to immediate post-operative healing (Fazio, Aukett, Hendren, & Erwin-Toth, 2014). Exclusion criteria from study participation included: 1) age under 18 years or age over 40 years; 2) living with a non-intestinal stoma; 3) living with an intestinal stoma due to a diagnosis other than IBD.

Dillman, Christian, and Smyth (2014) proposed an estimated response rate of 50-65% with emailed surveys. According to Dillman and colleagues (2014), follow up with personalized messages and repeated contacts overtime were associated with an increased response rate when using an electronic format. The recruitment of this study did not include email but posting of electronic messages on online discussion forums. Therefore, to recruit participants, the initial post was written to personally connect with those viewing the discussion boards, and four additional posts were made to encourage supplementary responses. The additional posts followed the template outlined by Dillman and colleagues (2014) for use in electronic surveys including four contacts after initial post: (1) second post three days after initial post; (2) third post six days after second post; (3) fourth post 13 days after third post; (4) final post six days after fourth post to encourage an increased overall response rate to the survey. Initial posting on

online discussion boards did not yield enough participants. Therefore, additional private support groups for living with IBD and/or an ostomy were also used to recruit participants.

Sample Size

A power analysis for correlational and regression analysis was calculated utilizing the R statistic software package version 3.4.3 to determine the appropriate sample size to obtain necessary power (Cohen, 1988; R Core Team, [R: A Language and Environment for Statistical Computing], 2017). For correlational analysis, making use of a moderate effect size (r = 0.30) based upon the standard specified by Cohen (1988) a sample size of 84 was necessary to obtain a power of 0.80 at a 0.05 significance (Cohen, 1988). For regression analysis, making use of a moderate effect size (f^2 = 0.15) based upon the standard specified by Cohen and seven predictor variables, a minimum sample size of 97 was necessary to obtain a power of 0.80 at a significance level of 0.05 (Cohen, 1988). The total sample for this study was 98, which exceeded the minimum number of participants required to achieve statistical power for correlation and regression analyses.

Of the 167 individuals who completed the survey posted online from October 2018 to December 2018, 98 persons met the inclusion criteria and were included in the final sample for analysis. Sixty-nine individuals were eliminated from the sample as they were older than 40 years.

The age range for persons in this sample was 18 to 40 years (M = 30.56; SD 6.151). Seventy-seven percent (n=75) were female, and twenty-four percent (n=23) were male. The ethnic make-up of in this sample included Caucasian (87.8%; n=86), Black/African American (4.1%; n=4), and Hispanic/Latino (4.1%; n=4). This aligns with

the demographic make-up associated with IBD as the majority of individuals living with

IBD are Caucasian and Caucasians have more commonly have a family history of IBD

than other ethnic groups (Katz et al., 2013). For marital status, participants reported

single/never married (37.8%; n=37), divorced/separated (2%; n=2), remarried (3.1%;

n=3), living with someone (15.3%; n=15), and married (41.8%; n=41). Twenty-four

percent were unemployed (n=23), fifteen percent were working full-time (n=15), forty-

two percent were working part-time (n=41), and nineteen percent were students (n=19).

With regard to living situation, the situations reported included living alone (12%; n=12),

living with a spouse or intimate partner (58.2%; n=57), living with family (20.4%; n=20),

living with a friend (2%; n=2), and living with a roommate (7.1%; n=7).

The IBD-subtype of participants included ulcerative colitis (UC) (26.5%; n=26),

Crohn's disease (59.2%; n=58), and both (7.1%; n=7). Eight-four percent (n=82) were

living with an ileostomy and fifteen percent (n=15) were living with a colostomy. Thirty-

five percent (n=34) had a temporary stoma and sixty-four percent (n=63) had a

permanent stoma. For pre-operative stoma site marking, seventy-four percent (n=72) had

pre-operative site marking and nineteen percent (n=19) did not. Nineteen percent (n=19)

were living with a stoma for less than six months, twenty-six percent (n=25) were living

with a stoma for six months to two years, twenty-nine percent (n=28) were living with a

stoma for two years to five years, and twenty-six percent (n=25) were living with a stoma

for more than five years. The demographic characteristics for this sample are presented

in Table 2.

Table 2.

Frequency Distribution of Selected Demographic Subject Variables

Variable	n	Percentage
Gender		
Female	75	76.5%
Male	23	23.5%
Race/Ethnicity		
Caucasian	86	87.8%
Black/African American	4	4.1%
Hispanic/Latino	4	4.1%
Other	3	3.1%
Marital Status		
Single, Never Married	37	37.8%
Divorced/Separated	2	2%
Remarried	3	3.1%
Living with Someone	15	15.3%
Married	41	41.8%
Employment Status		
Unemployed	23	23.5%
Full-time	15	15.3%
Part-time	41	41.8%
Student	19	19.4%
Living Situation		
Living Alone	12	12.2%
Living with Spouse or Intimate Partner	57	58.2%
Living with Family	20	20.4%
Living with Friend	2	2%
Living with Roommate	7	7.1%
IBD-Subtype		
UC	26	26.5%
Crohn's disease	58	59.2%
Both	7	7.1%
Ostomy Type		
Ileostomy	82	83.7%
Colostomy	15	15.3%
Stoma Type		
Temporary	34	34.7%
Permanent	63	64.3%
Pre-op Site Marking		

Yes	72	73.5%
No	19	19.4%
Years Living with Stoma		
6 months or less	19	19.4%
> 6 months to 2yrs.	25	25.5%
>2yrs. to 5yrs.	28	28.6%
>5yrs.	25	25.5%

Instruments

Healthy Days Core Module (CDC HRQOL-4)

Healthy-related quality of life (HRQOL), the outcome variable, was measured using the *Heathy Days Core Module* (CDC HRQOL-4). The Centers for Disease Control and Prevention (CDC) (1993) created the CDC HRQOL-4 which is a self-report questionnaire available in the public domain that included four items to measure generic HRQOL in the general population (Appendix A). This was designed to be a surveillance tool to determine health status and function in the general population. The first item on this tool is a measure of global health in which the respondent rated health in general from excellent (1) to poor (4) with a higher score indicative of poorer health (CDC, 1993). For the remaining three items, the respondent provided a number of days for the last 30 days in which his or her physical health was not good, mental health was not good, and usual activities were limited due to poor physical or mental health (CDC, 1993). A total score for HRQOL or "unhealthy days" was calculated by subtracting total days physical and mental health was not good from 30 for possible range in score from 0 to 30 with a maximum score of 30 and higher score indicative of worse health (CDC, 1993).

In addition to measure of HRQOL as represented by "unhealthy days", the predictor of self-rated health (SRH) was represented by item one on the CDC HRQOL-4 which involved an individual rating of health in general from excellent (1) to poor (5) and is not included in the total score for HRQOL (CDC, 1993). SRH is a subjective, self-assessment of one's health that is predictive of future health issues, use of healthcare services, and mortality (Idler & Benyamini, 1997; Mossey & Shapiro, 1982). The focus of SRH is the presence of illness, state of current disease if present, medical information, health behaviors, and disability or functional limitations (Jylha, 2009). A low SRH is strongly associated with increased rates of mortality and use of healthcare services as compared to high SRH (Falconer & Quesnel-Vallee, 2017).

Psychometrics for the CDC HRQOL-4 was established through construct and convergent validity, as well as internal consistency and test-retest reliability. Convergent validity was determined through correlations between the CDC HRQOL-4 and the *Short-Form 36* (SF-36) *Healthy Survey* or a well-validated and reliable generic measure of HRQOL in numerous studies across multiple conditions (Andresen et al., 1999; Lackner et al., 2006; Mielenz et al., 2006; Toet, Raat, & Van Ameijden, 2006). "Unhealthy days" due to physical health were more strongly correlated with the physical component score of the SF-36 ($r=-0.78$, $p<0.0001$) than the mental component score of the SF-36 ($r=-0.50$, $p<0.00001$) and "unhealthy days" as a result of mental health were more strongly with the mental component score of the SF-36 ($r=-0.71$, $p<0.0001$) as compared to the physical component score of the SF-36 ($r=0.23$, $p<0.0001$) in adults osteoarthritis, rheumatoid arthritis, and fibromyalgia (Mielenz et al., 2006). Additionally, Andresen et al. (1999) found correlations between the CDC HRQOL-4 and the SF-36 and *Short-Form*

12 (SF-12) *Health Survey*, a shortened version of the SF-36, with the strongest

correlations with similar underlying constructs (p<0.05) in participants with spinal cord

injuries. Finally, overall "unhealthy days" score from the CDC HRQOL-4 was correlated

with summary scores of the SF-36 (r=-0.43 for physical component score and r=-0.59 for

mental component score, p<0.001), as well as the IBS-Quality of Life Scale (disease-

specific HRQOL measure) (-0.52 for overall "unhealthy days and -0.46 for activity

limited days) in participants living with IBS (Lackner et al., 2006). Reliability was

established through test-retest reliability in randomly-sampled adults in Massachusetts at

a 21-44 day interval (intraclass coefficient (ICC) = 0.70), randomly-sampled adults in

Missouri at a two-week interval (ICC = 0.75), and adults living with IBS at a two-week

interval (r=0.57-0.71) with highest reliability for overall "unhealthy days" in this sample

(r = 0.75) (Andresen, Catlin, Wyrwich, & Jackson-Thompson, 2003; Lackner et al.,

2006; Stein, Lederman, & Shea, 1993).

Psychometrics were also established in the Dutch version of the CDC HRQOL-4

in a study conducted by Toet et al. (2006) in a sample of randomly-sample Dutch

participants aged 16-75 years. Evidence for reliability was determined through internal

consistency for "unhealthy days" due to physical and mental health, as well as activity

limitations (α = 0.77). Convergent validity was established between CDC HRQOL-4 and

the SF-36, World Health Quality of Life Instrument (WHOQOL-Bref), and General

Health Questionnaire (GHQ-12) with strongest correlations noted between physical

domains of SF-36 and physically "unhealthy days" and mental domains of SF-36 and

mentally "unhealthy days" (r=-0.426—0.713), mentally "unhealthy days" and

WHOQOL-Bref mental health domain (r=-0.557), and mentally "unhealthy days" and

GHQ-12 (r=-0.673) (Toet et al., 2006). Finally, construct validity was determined in the Dutch version of the CDC HRQOL-4 as it could distinguish between respondents without a chronic condition and those with one or multiple chronic conditions (Toet et al., 2006).

The CDC HRQOL-4 has not been used in individuals living with inflammatory bowel disease (IBD) or a stoma. However, Lackner and colleagues (2006) conducted a study in participants suffering from irritable bowel syndrome (IBS) in order to increase understanding of symptom burden in this population. IBS is not considered a life-threatening condition, but this is a chronic illness with gastrointestinal symptoms similar to those associated with IBD, such as abdominal pain, diarrhea, psychological distress, and decreases in HRQOL (Lackner et al., 2006). The "unhealthy days" score for the CDC HRQOL-4 was significantly associated with improvement in gastrointestinal symptoms in this sample as assessed by participants (r=-0.36, p<0.01) and gastroenterologist (r=-0.28, p<0.01) as greater improvement in symptoms following treatment was associated with less impairment in HRQOL (Lackner et al., 2006). The results of this study as reported by Lackner et al. (2006) showed the CDC HRQOL-4 distinguished disease severity as participants with more severe IBS symptoms reported more unhealthy days and more activity limitations than participants with less severe IBS symptoms. The CDC HRQOL-4 was an appropriate tool to measure the outcome variable of HRQOL as it has been shown to be valid and reliable in numbers studies across multiple conditions including IBS, a chronic condition with gastrointestinal symptoms.

Short-Form 36 (SF-36) Health Survey

The SF-36 is a well-validated and reliable generic measure of well-being and functioning in relation to health status. However, unlike the aforementioned CDC HRQOL-4 which contains only four items and takes a couple minutes at most to complete, the SF-36 can be daunting to complete in its entirety as it contains 36 items. Therefore, for this study, the entire tool was not used but rather the subscales of bodily pain, general mental health, and vitality.

The SF-36 is a 36-item self-report measure of medical outcomes in relation to patient functioning and well-being that is available in the public domain (Hays, Sherbourne, & Mazel, 1995; Ware & Sherbourne, 1992) (Appendix B). This is a self-administered questionnaire that is composed of one 36-item scale measuring eight health concepts of physical functioning, role limitations due to physical health issues, bodily pain, social functioning, general mental health, role limitations due to emotional problems, vitality, and general health problems each measured on a Likert scale from excellent (1) to poor (5) with lower scores indicative of limited function or greater experience of symptoms and higher scores indicative of no issues with functioning and no symptoms present (Ware & Sherbourne, 1992). Scores are based upon a sum of ratings and culminate in two component scores inclusive of the physical component summary and the mental component summary.

The aforementioned eight health concepts are also considered eight subscales and the subscales of bodily pain, general mental health, and vitality were used as measures of the symptoms of pain, psychological distress, and fatigue, respectively in this study. The bodily pain subscale included two items and is considered a predictor of pain with low scores meaning very severe and extremely limiting pain while high scores are associated

with no pain or limits due to pain in the last four weeks (Ware & Sherbourne, 1992). Additionally, the general mental health subscale was a predictor of psychological distress through five items where a low score indicated feeling nervousness or depressed all the time and a high score represented feeling peaceful, happy, and calm at all times for the past four weeks (Ware & Sherbourne, 1992). Finally, the vitality (energy/fatigue) subscale was made-up of four items that predicted fatigue in which a low score represented feeling tired or worn out all the time and a high score represented feeling full of pep and energy all the time during the past four weeks (Ware & Sherbourne, 1992). The entire SF-36 tool is presented in Appendix B and the items included in this study are bolded.

The psychometrics presented are limited to the use of the SF-36 in samples comprised of participants with IBD. Bernklev and colleagues (2005) conducted a study using the SF-36 in 514 Norwegian-based participants with IBD (348 UC and 166 Crohn's disease) to compare HRQOL to a normal reference population (n = 2323), and to determine differences in HRQOL in symptom-free IBD persons compared to those with moderate-to-severe symptoms and evaluate the psychometrics of the SF-36 in this population. Reliability was assessed through internal consistency and test-retest reproducibility as the SF-36 was administered to this sample at initial encounter and again six months later to persons reporting no change in disease status. The SF-36 was noted to have good internal consistency for all subscales for Crohn's disease ($\alpha = 0.72$-0.90) and ulcerative colitis (UC) ($\alpha = 0.74$-0.91), as well as subscales of bodily pain ($\alpha = 0.90$ for Crohn's disease, $\alpha = 0.88$ for UC), general mental health ($\alpha = 0.84$ for Crohn's disease, $\alpha = 0.81$ for UC), and vitality ($\alpha = 0.86$ for Crohn's disease, $\alpha = 0.86$ for UC)

(Bernklev et al., 2005). These reliable subscales of bodily pain, general mental health, and vitality will be measures of the symptoms of pain, psychological distress, and fatigue in this study. Test-retest reliability was assessed six months after initial completion of SF-36 for individuals reporting no change in condition with no differences from baseline to follow-up found to be significant except for physical function and bodily pain for UC (ICC = 0.56-0.89 for Crohn's disease and 0.63-0.92 for UC) (Bernklev et al., 2005). Discriminant validity was assessed by η^2, Wilks λ, and pairwise comparison between no/mild symptoms to moderate/severe symptoms which Bernklev et al. (2005) report as significant by F statistic, however no F statistic or p value was reported. Satisfactory reliability and discriminant ability were found for all dimensions of the SF-36 in persons with Crohn's disease and UC in this Norwegian sample. Responsiveness to change in disease status was also assessed but scores were low, therefore, it is unclear if the SF-36 can be used to determine deterioration or improvement of IBD over time, and likely more research is necessary (Bernklev et al., 2005).

Yarlas et al. (2018) conducted a systematic literature review of 43 studies in order to determine the reliability, construct validity, and responsiveness of the SF-36 in persons with UC. This systematic review revealed good psychometric properties for the SF-36 in persons with UC. Internal consistency was noted for all scales ($\alpha > 0.70$) and test-retest reliability for six of eight subscales (ICC ≥ 0.70) which was all based upon a single publication by Bernklev et al. (2005) as previously described. Strong evidence for construct validity was found for the SF-36 with UC as the findings in greater than 12 studies evidenced associations between the SF-36 and other measures of key clinical constructs such as the *Inflammatory Bowel Disease Questionnaire* and Rachmilewitz's

Clinical Activity Index (UC clinical disease activity), as well as correlations between the

SF-36 and other measures of disease symptoms and functioning ($r \geq 0.40$) (Yarlas et al.,

2018). Support for convergent validity for the SF-36 in persons with UC was found as

bivariate and multivariate models showed decreased UC disease activity was predictive

of increased SF-36 scores and clinically meaningful differences were found across

severity of symptoms and SF-36 scores ($r = -0.23$—0.74) (Yarlas et al., 2018). Finally,

there was also strong evidence for responsiveness to treatment related changes as several

random control trials showed those receiving treatment showed significant improvement

in SF-36 scores compared to controls (Yarlas et al., 2018).

The SF-36 is a well-validated and reliable generic measure of well-being and

functioning in relation to health status. This tool has also been shown to be valid and

reliable in persons living with IBD. Additionally, since the SF-36 is a generic HRQOL

tool the results of this study will be more generalizable. Based upon the strong evidence

of validity and reliability and potential for greater generalizability of results, the SF-36

was utilized to measure HRQOL in this study.

Young-Fadok Stoma Quality of Life (QOL) Scale

The *Young-Fadok Stoma QOL Scale* was designed to measure HRQOL in persons

with a stoma, however testing of its psychometric properties are limited to the study of

origin, and one additional study (Baxter et al., 2006; Knowles et al., 2013). Moreover,

there is limited to no information on how the psychometrics of this tool are affected in a

sample of persons living with IBD and a stoma. For this study, this entire tool was not

used, but rather only the subscales of sexuality/body image and stoma function in

addition to the single item of skin irritation from the instrument.

The *Young-Fadok Stoma* QOL *Scale* is a 21-item scale that was designed by Baxter et al. (2006) to measure HRQOL in persons living with a stoma and is available in the public domain (Appendix C). This is a self-administered questionnaire made-up of two parts: 1) rating of overall satisfaction with life in general and in the last month and 2) five domains of QOL rated on a 5-point Likert scale from 1 or never to 5 or always (Baxter et al., 2006). The five domains of QOL in part two include three subscales of work/social function, sexuality/body image, stoma function, and two additional questions of skin irritation and financial concerns (Baxter et al., 2006). A higher score is indicative of a better HRQOL and a lower score is associated with a worse HRQOL. The subscales of stoma function and sexuality/body image, as well as the additional question related to skin irritation from the *Young-Fadok Stoma Quality of Life* (QOL) *Scale* was used to measure peristomal skin irritation, leakage of stomal appliance, and body image/sexual disturbance (Baxter et al., 2006). These subscales assessed stoma-specific symptoms scored on a 5-point Likert scale (from 1 = never to 5 = always) and included five items for sexuality/body image and six items for stoma function, plus one item for skin irritation (Baxter et al., 2006). The tool in its entirety is presented in Appendix B and individual items included on the survey to assess symptoms in this study are bolded.

Reliability for this scale was first established by Baxter and colleagues (2006) in their initial study. Reliability was assessed through internal consistency and test-retest reproducibility. Total HRQOL ($\alpha = 0.89$) and all subscales ($\alpha = 0.76\text{-}0.89$) were found to be reliable through internal consistency as test-retest reproducibility was established for the overall scale through completion of the questionnaire at baseline and repeated at a three-week interval (ICC = 0.80) (Baxter et al., 2006). Additionally, reliability was

established specifically for the subscales and items aforementioned as measures of symptoms in this study. Internal consistency was confirmed for the subscale of sexuality/body image ($\alpha = 0.79$) and stoma function ($\alpha = 0.76$) while test-retest reliability was also shown between baseline and three-week interval for sexuality/body image subscale (ICC = 0.86, 95% confidence interval 0.75-0.93), stoma function subscale (ICC = 0.94, 95% confidence interval 0.88-0.96), and skin irritation item (ICC = 0.75, 95% confidence interval 0.59-0.86) (Baxter et al., 2006). In a solitary follow-up study using this instrument, Knowles et al. (2013) also noted strong internal consistency reliability for overall scale and subscales ($\alpha > 0.76$). However, with a sample size of 31 participants, this was likely underpowered and may be non-generalizable.

Construct validity was also determined by Baxter and colleagues (2006) through hypothesis testing for which they postulated that persons with better perceived HRQOL would have a higher score and scores on this instrument would moderately to strongly correlate with the *Short Form-12* (SF-12), a shorter version of the SF-36. Construct validity was established as self-perceived good HRQOL was associated with higher scores on the *Young-Fadok Stoma QOL Scale* and self-perceived worse HRQOL was related to lower scores on the *Young-Fadok Stoma QOL Scale* for the subscales of sexuality/body image ($p = 0.0009$) and stoma function ($p = 0.009$) but not for the items of skin irritation ($p = 0.99999$) (Baxter et al., 2006). Moderate-to-strong correlations were also found between the SF-12 and stoma function subscale (0.39 for physical scale and 0.69 for mental scale of SF-12), as well as a moderate correlation was assessed between mental health scale of the SF-12 and sexuality/body image (0.49) (Baxter et al., 2006). Validity of this instrument was not assessed in additional studies.

Since a paucity of psychometric testing was found, related to the Young-Fadok

stoma QOL scale, a pilot study was conducted by this investigator in order to determine

its reliability with younger persons living with IBD and a stoma. Participants were

recruited from online discussion boards focusing on living with IBD and/or a stoma.

After Rutgers University Institutional Review Board (IRB) approval, a detailed

description of this study, as well as a link to the survey were placed on the discussion

board of the United Ostomy Association of America and the ostomy sub-reddit

discussion board on reddit.com. A final sample of 81 individuals living with a stoma due

to various diagnostic etiologies (50% had stoma due to IBD) completed the *Young-Fadok*

Stoma QOL Scale over the month the survey link was placed on discussion boards.

Reliability through internal consistency was assessed in this pilot study. The subscale of

stoma function was found to be reliable ($\alpha = 0.79$), but the sexuality/body image subscale

($\alpha = 0.64$) was below the acceptable level (0.70) so it was not considered to be reliable in

this study (DeVellis, 2012). However, numerous participants reported that they had

difficulty completing the questions within the sexuality/body image subscales as they

were not currently sexually active due to lack of a partner, thus these results are likely not

an accurate representation of reliability of this subscale in the population of interest.

Demographic Questionnaire

A demographic questionnaire was used in order to collect data that described the

sample characteristics (Appendix D). Specifically, variables that were gathered included

gender, age, marital status, race/ethnicity, living arrangements, employment status,

presence of a pre-operative stoma site marking, years living with stoma, stoma type, IBD-

subtype, and permanent vs. temporary stoma. Aronovitch, Sharp, & Harduar-Morano

(2010) found that highest HRQOL was associated with living with persons other than family (p = 0.01) and living with family was correlated with a higher HRQOL than living alone (p = 0.02) which indicated the necessity to understand with whom the participants of this study were living. Additionally, pre-op stoma site marking, and presence of a stoma for more than two years were also associated with increased HRQOL (Maydick, 2016; Salles, Becker, & Faria, 2014). Finally, return to sexual activity which was associated with a better HRQOL was noted most commonly in persons with a supportive partner by Ramirez et al. (2009), most of whom were married prior to stoma surgery. On the other hand, occupational status changed significantly after stoma surgery (p = .00), presence of an ileostomy was associated with worse HRQOL, and surgical creation of a stoma is considered curative for UC but not Crohn's disease indicating potential persistence of symptoms following stoma surgery for those with Crohn's disease (Abdalla et al., 2016; Katz et al., 2013; Mahjoubi et al., 2012; Nybaek et al., 2010). Therefore, the demographic questionnaire provided basic information that described this sample, as well as described the possible additional influencing factors of living arrangements, marital status, employment status, preoperative stoma site marking, time living with a stoma, IBD-subytpe, and ostomy type.

Procedure for Data Collection and Analysis

This study received approval from the Institutional Review Board (IRB) of Rutgers, The State University of New Jersey including approval of two modifications to include additional online sites for recruitment (Appendix E, F, and G). Additionally, approval from moderators of all online sites was obtained. Online sites included the online discussion boards of the sub-reddit discussion boards of ostomy

(reddit.com/r/ostomy/) and Crohn's disease (reddit.com/r/CrohnsDisease/) from reddit.com, as well as, private support groups on Facebook of Ostomy Land Community, The Real Ostomy Support Group, Ostomy and Jpouch Moms, Making Ostomies Cool, Ostomies – Bringing People Together, Crohn's Coliits, Stoma, & Jpout Support Group, My Crohn's Friends, Crohn's and UC Chill House, OstoMyFamily, Ulcertative Colitis Crohn's Disease SUPPORT GROUP, Ostomy Canada Society, Colostomy Urostomy~Stoma~OstomatesRus, and Fun Bags N Shitbags.

Data was obtained from survey responses completed by participants. Scores for the CDC HRQOL-4, subscales from the SF-36 of bodily pain, vitality, and general mental health, as well as, subscales from the *Young-Fadok Stoma QOL Scale* of stoma function, body image/sexuality, and skin irritation item were calculated by the PI from participant responses to survey.

Human Subjects Protection

This study was determined to cause no greater harm or discomfort than experienced in daily life. Each participant was given an ID number but remained anonymous as no personal identifying information including IP addresses were collected from participants. A computer list was made of survey ID numbers and associated responses. Data collected from this study was entered into SPSS version 25 and included survey ID numbers and associated responses but no personal information was included in the database as none was collected from participants (IBM [SPSS], 2017). All files were password protected and only available to the PI.

Data collected from this study that is either published or presented will not be reported with use of personal information as none was collected from participants. All

survey responses and computer files will be destroyed after study is completed with

compliance to mandatory six-year record retention of the IRB.

Chapter 4

Analysis of the Data

The purpose of this study was to understand the predictors of health-related

quality of life (HRQOL) in younger persons aged 18-40 years living with inflammatory

bowel disease (IBD) and a stoma. Pain, fatigue, leakage of stomal appliance, peristomal

skin problems, body image/sexual disturbance, psychological distress, and self-rated

health (SRH) are the potential predictors under investigation in this study. Data was

collected from 98 adults aged 18 to 40 years living with IBD and a stoma who completed

the survey posted on online discussion boards or private message boards focused on

support for individuals living with IBD and/or stomas. The findings from the analysis of

this data are presented in this chapter.

Statistical Description of the Variables

Outcome Variable

The outcome variable was HRQOL and was measured through a total number of

"unhealthy days" calculated from the *Healthy Days Core Module* (CDC HRQOL-4). The

mean number of "unhealthy days" or HRQOL score was 18.40 (SD = 11.44, range 0-30).

Predictor Variables

Pain.

The mean score on the bodily pain subscale of the *Short-Form 36* (SF-36)

Healthy Survey was 57.37 (SD = 26.05, range 0-100).

Fatigue.

On the vitality subscale of the SF-36, the mean score was 31.33 (SD = 22.54,

range 0-90).

Psychological distress.

On the general mental health subscale of the SF-36, the mean score was 57.51 (SD = 20.86, range 0-100).

Leakage of stomal appliance.

The mean score of the stoma function subscale on the *Young-Fadok Stoma Quality of Life* (QOL) *Scale* was 61.05 (SD = 22.36, range 0-100).

Peristomal skin problem.

For the skin irritation item on the *Young-Fadok Stoma QOL Scale*, the mean score was 51.53 (SD = 30.84, range 0-100).

Body image/sexual disturbance.

The mean score of the sexuality/body image subscale of the *Young-Fadok Stoma QOL Scale* was 60.66 (SD = 20.89, range 5-95).

SRH.

For item SRH on the CDC HRQOL-4, the mean score was 2.61 (SD = .87, range 1-4). The descriptive statistics of the study variables are presented in Table 3.

Table 3.

Descriptive Statistics of Study Variables

Dependent Variable (n=98)	Mean (SD)	Range
HRQOL	18.40 (11.44)	0-30

Independent Variables (n=98)	Mean (SD)	Range
Pain	57.37 (26.05)	0-100
Fatigue	31.33 (22.54)	0-90
Psychological Distress	57.51 (20.86)	0-100
Leakage of Stomal Appliance	61.05 (22.36)	0-100
Peristomal Skin Problem	51.53 (30.84)	0-100

Body Image/Sexual Disturbance	60.66 (20.89)	5-95
SRH	2.61 (.87)	1-4

Psychometric Properties of the Instruments

Reliability was assessed for the whole scale of the CDC HRQOL-4, as well as, the subscales of SF-36 and *Young Fadok Stoma QOL Scale* in the form of Cronbach's alpha. The subscales included in this study are the bodily pain, vitality, and general mental health for the SF-36, as well as the stoma function and body image/sexuality for the *Young-Fadok Stoma QOL Scale*. Internal consistency is an important measure of reliability as a high inter-item correlation indicates that all items in the scale or sub-scale are measuring the same thing (DeVellis, 2012). Cronbach's alpha is an appropriate measure of internal consistency as it is a widely used measure of reliability with 0.70 considered an acceptable level with a value of greater than 0.80 considered to be superior (DeVellis, 2012). Reliability statistics are presented in Table 4.

CDC HRQOL-4

The CDC HRQOL-4 scale was found to be reliable ($\alpha = .756$).

SF-36

The bodily pain and vitality subscales of the SF-36 were determined to be reliable ($\alpha = .866$ for bodily pain subscale, $\alpha = .7$ for vital subscale) in this study sample. For the general mental health subscale of the SF-36, Cronbach's alpha was equal to .018, in this study sample which is below the accepted level of reliability. However, in a significantly larger sample of 514 Norwegian-based persons with IBD, the general mental health subscale of the SF-36 was found to be reliable ($\alpha = .81$ for ulcerative colitis (UC), $\alpha = .84$ for Crohn's disease) (Bernklev et al., 2005).

Young-Fadok Stoma QOL Scale

The stoma function subscale and sexuality/body image subscale for the *Young-Fadok Stoma QOL Scale* in this study sample had Cronbach's alpha equal to .555 and .472, respectively, which is below the accepted level of reliability. However, these subscales were found to be reliable in the pilot study conducted by Baxter et al. (2006) (α = .76 for stoma function subscale, α = .79 for sexuality/body image subscale), as well as a study performed by Knowles et al. (2013) (α > .76 for overall scale). Additionally, based on the reliability assessments from a pilot study conducted by this investigator to evaluate the reliability of the *Young-Fadok Stoma QOL Scale*, the sexuality/body image subscale was also under the acceptable level of reliability (α = .64) but some participants noted difficulty completing the items on this subscale as they weren't currently sexually active due to lack of a partner. The participants in this study have similarities to the pilot study conducted by this investigator as all are living with a stoma, half the participants in the pilot study had a diagnosis of IBD, the mean age of the subjects in the pilot study was 43.8 years, and all participants were recruited from online discussion boards and groups. Therefore, there is a potential that the participants in this study also had difficulty completing the items on the sexuality/body image subscale which could have affected results of the reliability assessment.

Table 4.

Reliability Statistics

Scale	Number of Items	Coefficient Alpha
CDC HRQOL-4	4	.756
SF-36: Bodily Pain Subscale	2	.866
SF-36: Vitality Subscale	4	.7
SF-36: General Mental Health Subscale	5	.018

Young-Fadok Stoma QOL Scale: Stoma Function Subscale	5	.555
Young-Fadok Stoma QOL Scale: Body Image/Sexuality Subscale	5	.472

Hypotheses

Hypotheses 1-7 were tested using the Pearson product moment correlation coefficient. Alternatives to this method are analysis of covariance and Spearman rho. However, as the Pearson product moment correlation coefficient is a widely used bivariate analysis with ease of interpretation and shows a linear relationship between two continuous variables (-1.0 to +1.0), it is an appropriate method to analyze these hypotheses (Setlman, 2014). Hypothesis 8 was tested using hierarchical multiple regression. Results of bivariate analysis are presented in Table 5 and results of hierarchical multiple regression are presented in Table 6. In order to analyze data with this method, it is important to check if the assumptions of linear regression are met including multicollinearity, normality, linearity, outliers, homoscedasticity, and independence of residuals (Seltman, 2014). No predictor variables had a correlation of .7 or higher indicating no multicollinearity (Seltman, 2014). Additionally, the data approximated the normal distribution, no outliers were noted, and no clear patterns were noted in the residuals (Seltman, 2014). As the data approximated the normal distribution, no data transformations were attempted. SPSS version 25 was used for statistical analysis (IBM [SPSS], 2017).

Hypothesis 1

Hypothesis 1 stated that the symptom of pain would be inversely related to HRQOL in younger persons living with IBD and a stoma. The Pearson product moment

correlation for this relationship was r = -.691, p = .000. In hierarchical multiple

regression, pain was found to be a significant predictor of HRQOL in this sample of

younger adults living with IBD and a stoma (beta = -.301, p = .000). Based on these

findings, hypothesis 1 was supported.

Hypothesis 2

Hypothesis 2 stated that the symptom of fatigue would be inversely related to

HRQOL in younger persons living with IBD and a stoma. For this relationship, the

Pearson product moment correlation was r = -.695, p = .001. In hierarchical multiple

regression, fatigue was found to be a significant predictor of HRQOL in this sample of

younger adults living with IBD and a stoma (beta = -.239, p = .003). Based on these

findings, hypothesis 2 was supported.

Hypothesis 3

Hypothesis 3 stated that the symptom of leakage of stomal appliance would be

inversely related to HRQOL in younger persons living with IBD and a stoma. The

Pearson product moment correlation for this relationship was r = .033, p = .746. Based

on this finding, Hypothesis 3 was not supported.

Hypothesis 4

Hypothesis 4 stated that the symptom of peristomal skin problems would be

inversely related to HRQOL in younger persons living with IBD and a stoma. For this

relationship, the Pearson product moment correlation was r = -.247, p = .014. In

hierarchical multiple regression, peristomal skin problem was not found to be a

significant predictor of HRQOL in this sample of younger adults living with IBD and a

stoma (beta = .034, p = .571). Based on this finding, hypothesis 4 was only supported in bivariate analysis.

Hypothesis 5

Hypothesis 5 stated that the symptom of body image/sexual disturbance would be inversely related to HRQOL in younger persons living with IBD and a stoma. The Pearson product moment correlation was r = .086, p = .397. Based on this finding, hypothesis 5 was not supported.

Hypothesis 6

Hypothesis 6 stated that the symptom of psychological distress would be inversely related to HRQOL in younger persons living with IBD and a stoma. For this relationship, the Pearson product moment correlation was r = -.668, p = .000. In hierarchical multiple regression, psychological distress was found to be a significant predictor of HRQOL in this sample of younger adults living with IBD and a stoma (beta = -.321, p = .000). Based on these findings, hypothesis 6 was supported.

Hypothesis 7

Hypothesis 7 stated that SRH would be directly related to HRQOL in younger persons living with IBD and a stoma. The Pearson product moment correlation was r = .641, p = .000. In hierarchical multiple regression, SRH was found to be a significant predictor of HRQOL in this sample of younger adults living with IBD and a stoma (beta = .229, p = .002). Based on these findings, hypothesis 7 was supported.

Table 5.

Bivariate Correlations: Independent Variables and Dependent Variable (HRQOL)

Independent Variable	r
Pain	-.691**

Fatigue	-.695**
Leakage of Stomal Appliance	.033
Perisomal Skin Problem	-.247*
Body Image/Sexual Disturbance	.086
Psychological Distress	-.668**
SRH	.641**

*Correlation significant ≤0.05 level
**Correlation significant ≤0.01 level

Table 6.

Multiple Hierarchical Regression: Coefficients

Model	Beta	Sig.
1 (Constant)		.000
Marital	-.134	.149
Employment	-.420	.000
2 (Constant)		.000
Marital	-.098	.089
Employment	.011	.857
Pain	-.301	.000
Fatigue	-.239	.003
Psychological Distress	-.321	.000
Skin Condition	.034	.571
SRH	.229	.002

Hypothesis 8

Hypothesis 8 stated that there would be significant combined effects of variance

accounted for by symptoms (pain, fatigue, leakage of stomal appliance, peristomal skin

condition, body image/sexual disturbance, psychological distress) and SRH on HRQOL

in younger persons living with IBD and a stoma. The assumptions of linear regression

were met as aforementioned including multicollinearity, normality, linearity, outliers,

homoscedasticity, and independent residuals. No multicollinearity was found as no

predictor variables had a correlation of .7 or higher (Seltman, 2014). The correlational

matrix is presented in Table 7. Figure 2 and Figure 3 shows the normality and linearity

of this data.

Table 7.

Correlation Matrix for Hierarchical Multiple Regression

		HRQOL	Marital	Employment	Pain	Fatigue	Psychological distress	Skin condition	SRH
Pearson Correlation	HRQOL	1.000	-.188	-.437	-.691	-.695	-.668	-.247	.641
	Marital	-.188	1.000	.128	-.036	.043	.238	.033	-.072
	Employment	-.437	.128	1.000	.427	.468	.333	.076	-.397
	Pain	-.691	-.036	.427	1.000	.547	.417	.133	-.605
	Fatigue	-.695	.043	.468	.547	1.000	.576	.318	-.516
	Psychological distress	-.668	.238	.333	.417	.576	1.000	.400	-.340
	Skin condition	-.247	.033	.076	.133	.318	.400	1.000	-.151
	SRH	.641	-.072	-.397	-.605	-.516	-.340	-.151	1.000
Sig. (1-tailed)	HRQOL	.	.032	.000	.000	.000	.000	.007	.000
	Marital	.032	.	.104	.364	.336	.009	.374	.241
	Employment	.000	.104	.	.000	.000	.000	.229	.000
	Pain	.000	.364	.000	.	.000	.000	.097	.000
	Fatigue	.000	.336	.000	.000	.	.000	.001	.000
	Psychological distress	.000	.009	.000	.000	.000	.	.000	.000
	Skin condition	.007	.374	.229	.097	.001	.000	.	.069
	SRH	.000	.241	.000	.000	.000	.000	.069	.
N	HRQOL	98	98	98	98	98	98	98	98
	Marital	98	98	98	98	98	98	98	98
	Employment	98	98	98	98	98	98	98	98
	Pain	98	98	98	98	98	98	98	98
	Fatigue	98	98	98	98	98	98	98	98
	Psychological distress	98	98	98	98	98	98	98	98
	Skin condition	98	98	98	98	98	98	98	98
	SRH	98	98	98	98	98	98	98	98

Figure 2.
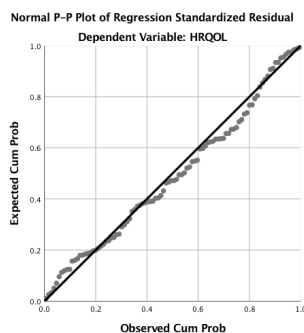
Figure 3.
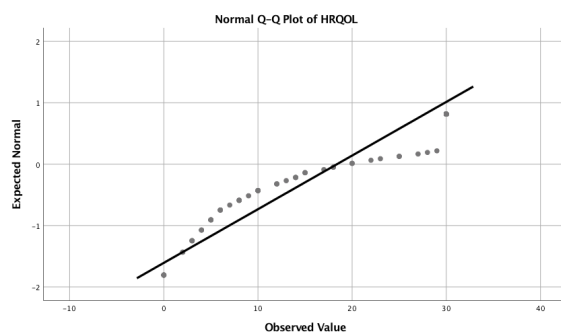
Predictor variables found to be significantly associated with the outcome variable of

HRQOL were included in the hierarchical multiple regression analysis. These variables

included pain, fatigue, peristomal skin problem, psychological distress, and SRH.

Additionally, relationships between demographic variables (marital status, employment

status, IBD-subtype, race/ethnicity, living situation, ostomy type, stoma type, time living

with a stoma, pre-operative site marking) and HRQOL were analyzed. Statistically

significant differences at the p<.05 level in HRQOL scores were noted between groups

for marital status (F (4,93) = 2.575, p = .043) and employment status (F (3,94) = 9.623, p

= .000). Therefore, hierarchical multiple regression was the appropriate analysis for this

data in order to control for the demographic variables that have an effect on the

dependent variable of HRQOL (Seltman, 2014). In this hierarchical multiple regression

analysis, marital status and employment status were entered into step one in order to

control for the effect of these variables followed by the predictors of pain, fatigue,

peristomal skin problem, psychological distress, and SRH entered into step two. The test

of the model using an ANOVA indicated that the model was significant (F (7,90) =

36.658, p = .000). Table 8 shows the ANOVA.

Table 8.

Multiple Hierarchical Regression ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	2644.575	2	1322.287	12.501	.000[b]
	Residual	10048.905	95	105.778		
	Total	12693.480	97			
2	Regression	9397.499	7	1342.500	36.658	.000[c]
	Residual	3295.981	90	36.622		
	Total	12693.480	97			

[a] Dependent Variable: HRQOL
[b] Predictors: (Constant), Employment, Marital
[c] Predictors: (Constant), Employment, Marital, Skin condition, SRH,
Psychological distress, Pain, Fatigue

According to R Square test, 20.8% of the variance in HRQOL is explained by

marital status and employment status. The R Square test also revealed that 74.0% of the

variance in HRQOL was explained by this whole model. R Square Change test showed

that after controlling for marital status and employment status, pain, fatigue,

psychological distress, peristomal skin problem, and SRH explained an addition 53.2% of

the variance in HRQOL. However, peristomal skin problem was not found to be a

significant predictor of HRQOL (p = .571). Table 8 shows the summary of this model.

Table 9 shows the analysis of the variables in this equation.

Table 9.

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.456[a]	.208	.192	10.285	.208	12.501	2	95	.000
2	.860[b]	.740	.720	6.052	.532	36.879	5	90	.000

[a] Predictors: (Constant), Employment, Marital
[b] Predictors: (Constant), Employment, Marital, Skin condition, SRH, Psychological distress, Pain, Fatigue
[c] Dependent Variable: HRQOL

Based on the findings, Hypothesis 8 was supported by the following significant independent predictors of pain, fatigue, psychological distress, and SRH in this sample of younger adults living with IBD and a stoma. In summary, Hypothesis 4 was only supported in bivariate analysis, while hypotheses 1, 2, 6, and 7 in bivariate analysis and hierarchical multiple regression. Hypotheses 3 and 5 were not supported. The demographic variables of marital status and employment status were found to be significantly related to HRQOL score and explained 20.8% of the variance in HRQOL score. Hypothesis 8 was partially supported. In hierarchical multiple regression, the variables of pain, fatigue, psychological distress, and SRH were found to be significant predictors of HRQOL. These variables explained 74.0% of the variance in HRQOL score when marital status and employment status were included and an additional 53.2% of the variance in HRQOL score when marital status and employment status were controlled.

Additional Findings

Additional analyses were conducted in order to better understand the relationships between the demographic variables, predictor variables, and outcome variable of HRQOL. The specific additional analyses performed included: 1) examination of the relationship between marital status and HRQOL score, 2) an analysis to understand the relationship between employment status and HRQOL score, 3) examination of the relationship between IBD-subtype and HRQOL score, 4) an analysis to understand the relationship between race/ethnicity and HRQOL score, 5) examination of the relationship between living situation and HRQOL score, 6) an analysis to understand the relationship between time living with a stoma and HRQOL score, 7) examination of the relationship between gender and HRQOL score, 8) an analysis to understand the relationship between ostomy type and HRQOL score, 9) examination of the relationship between stoma type and HRQOL score,10) an analysis to understand the relationship between pre-operative site marking and HRQOL score, 11) examination of the relationship between IBD-subtype and pain score, 12) examination of the relationship between IBD-subtype and fatigue score, 13) examination of the relationship between IBD-subtype and psychological distress score, and 14) examination of the relationship between IBD-subtype and SRH.

Marital Status and HRQOL

A one-way ANOVA was performed to evaluate if there was a statistically significant difference in the HRQOL score in the different groups according to marital status. A statistically significant difference at the p<.05 level in HRQOL scores was found for the marital status groups of single/never married, divorced/separated, remarried, living with someone, and married ($f\,(4,93) = 2.575$, p =.043). Significant

differences were found between groups of living with someone (M=9.187, SD 2.37) and

married (M=14.46, SD 10.94). No significant differences were found between groups of

single/never married (M=20.43, SD 11.89), divorced/separated (M=22, SD 11.31), and

remarried (M=17.33, SD 11.02). No significant differences were found between group of

living with someone or group (M=9.187, SD 2.37) or married with other three groups of

single/never married (M=20.43, SD 11.89), divorced/separated (M=22, SD 11.31), and

remarried (M=17.33, SD 11.02). Results of the ANOVA are presented in Table 10 and

results of post-hoc test are presented in Table 11.

Table 10.

Marital Status and HRQOL ANOVA

HRQOL

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	1265.803	4	316.451	2.575	.043
Within Groups	11427.676	93	122.878		
Total	12693.480	97			

Table 11.

Marital Status and HRQOL Post-Hoc Test

Marital Status (I)	Marital Status (J)	Mean Difference (I-J)	Std. Error	Sig.	95% CI Lower Bound	95% CI Upper Bound
Single, Never Married	Divorced/ Separated	-1.568	8.047	1.000	-23.96	20.82
	Remarried	3.099	6.654	.990	-15.41	21.61
	Living with Someone	-3.434	3.393	.849	-12.87	6.01
	Married	5.969	2.514	.131	-1.02	12.96
Divorced/ Separated	Single, Never Married	1.568	8.047	1.000	-20.82	23.96

	Remarried	4.667	10.119	.991	-23.49	32.82
	Living with Someone	-1.867	8.345	.999	-25.08	21.35
	Married	7.537	8.027	.881	-14.80	29.87
Remarried	Single, Never Married	-3.099	6.654	.990	-21.61	15.41
	Divorced/ Separated	-4.667	10.119	.991	-32.82	23.49
	Living with Someone	-6.533	7.011	.884	-26.04	12.97
	Married	2.870	6.630	.993	-15.57	21.31
Living with Someone	Single, Never Married	3.434	3.393	.849	-6.01	12.87
	Divorced/ Separated	1.867	8.345	.999	-21.35	25.08
	Remarried	6.533	7.011	.884	-12.97	26.04
	Married	9.403*	3.345	.046	.10	18.71
Married	Single, Never Married	-5.969	2.514	.131	-12.96	1.02
	Divorced/ Separated	-7.537	8.027	.881	-29.87	14.80
	Remarried	-2.870	6.630	.993	-21.31	15.57
	Living with Someone	-9.403*	3.345	.046	-18.71	-.10

*The mean difference is significant at the .05 level

Employment Status and HRQOL

A one-way ANOVA was conducted to determine if there was a statistically significant difference in the HRQOL score in the different groups according to employment status. A statistically significant difference at the $p<.05$ level in HRQOL score for the employment status groups of unemployed, full-time, part-time, and student $(F (3,94) = 9.623, p = .000)$. Significant differences were found between unemployed

group (M=27.35, SD 5.05) and part-time employed group (M=13.85, SD 11.39), as well

as unemployed group (M=27.35, SD 5.05) and student group (M=15.26, SD 11.59). No

significant difference was found between unemployed group (M=27.35, SD 5.05) and

full-time employed group (M=21.07, SD 10.49). No significant differences were found

between groups of full-time employed (M=21.07, SD 10.49, part-time employed

(M=13.85, SD 11.39), or student (M=15.26, SD 11.59). Results of the ANOVA are

presented in Table 12 and results of post-hoc test are presented in Table 13.

Table 12.

Employment Status and HRQOL ANOVA

HRQOL

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	2982.523	3	994.174	9.623	.000
Within Groups	9710.957	94	103.308		
Total	12693.480	97			

Table 13.

Employment Status and HRQOL Post-Hoc Test

Employment Status (I)	Employment Status (J)	Mean Difference (I-J)	Std. Error	Sig.	95% CI Lower Bound	95% CI Upper Bound
Unemployed	Full-Time	6.281	3.373	.251	-2.54	15.10
	Part-Time	13.494*	2.648	.000	6.57	20.42
	Student	12.085*	3.151	.001	3.84	20.33
Full-Time	Unemployed	-6.281	3.373	.251	-15.10	2.54
	Part-Time	7.213	3.067	.094	-.81	15.24
	Student	5.804	3.511	.354	-3.38	14.99
Part-Time	Unemployed	-13.494*	2.648	.000	-20.42	-6.57
	Full-Time	-7.213	3.067	.094	-15.24	.81
	Student	-1.409	2.821	.959	-8.79	5.97
Student	Unemployed	-12.085*	3.151	.001	-20.33	-3.84
	Full-Time	-5.804	3.511	.354	-14.99	3.38

Part-Time	1.409	2.821	.959	-5.97	8.79

*The mean difference is significant at the .05 level

IBD-Subtype and HRQOL

A one-way ANOVA was performed to evaluate if there was a statistically significant difference in the HRQOL score in the different groups according to IBD-subtype. There was no statistically significant difference at the p<.05 level in HRQOL score for the IBD-subtype groups of ulcerative colitis (UC), Crohn's disease, and both (F (2,88) = 2.285, p = .108). Results of the ANOVA are presented in Table 14.

Table 14.

IBD-Subtype and HRQOL ANOVA

HRQOL

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	580.131	2	290.065	2.285	.108
Within Groups	11169.540	88	126.927		
Total	11749.670	90			

Race/Ethnicity and HRQOL

A one-way ANOVA was conducted to determine if there was a statistically significant difference in the HRQOL score in the different groups according to race/ethnicity. There was no statistically significant difference at the p<.05 level in HRQOL score for the race/ethnicity groups of American Indian, Asian/Pacific Islander, Black/African American, Hispanic/Latino, White/Caucasian, and other (F (3,93) = .493, p = .688). Results of the ANOVA are presented in Table 15.

Table 15.

Race/Ethnicity and HRQOL ANOVA

HRQOL

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	197.870	3	65.957	.493	.688
Within Groups	12454.254	93	133.917		
Total	12652.124	96			

Living Situation and HRQOL

A one-way ANOVA was performed to evaluate if there was a statistically significant difference in the HRQOL score in the different groups according to living situation. There was no statistically significant difference at the $p<.05$ level in HRQOL score for the living situation groups of living alone, living with a spouse, living with family, living with a friend, and living with a roommate ($F_{(4,93)} = 2.296$, $p =.065$). Results of the ANOVA are presented in Table 16.

Table 16.

Living Situation and HRQOL ANOVA

HRQOL

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	1140.875	4	285.219	2.296	.065
Within Groups	11552.605	93	124.222		
Total	12693.480	97			

Stoma Time and HRQOL

A one-way ANOVA was conducted to determine if there was a statistically significant difference in the HRQOL score in the different groups according to time living with a stoma. There was no statistically significant difference at the $p<.05$ level in HRQOL score for the stoma time or time living with a stoma of 6 months or less, 6 months to 2 years, 2 years to 5 years, and greater than 5 years ($F_{(3,93)} = .773$, $p = .512$). Results of the ANOVA are presented in Table 17.

Table 17.

Stoma Time and HRQOL ANOVA

HRQOL

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	305.498	3	101.833	.773	.512
Within Groups	12251.987	93	131.742		
Total	12557.485	96			

Gender and HRQOL

An independent t-test was performed to evaluate if there was a statistically significant difference in HRQOL score according to gender. There was no statistically significant difference at the p<.05 level in HRQOL score for gender of male and female (males ($M = 15.57$, $SD = 11.87$) and females ($M = 19.27$, $SD = 11.24$; $t(96) = 1.364$, $p = .176$, 2-tailed)). Results of t-test are presented in Table 18.

Table 18.

Gender and HRQOL T-Test

	Gender	N	Mean	Std. Deviation	Std. Error Mean
HRQOL	Male	23	15.57	11.866	2.474
	Female	75	19.27	11.243	1.298

Independent Samples Test

	Levene's Test for Equality of Variances		t-test for Equality of Means					95% Confidence Interval of the Diff.	
	F	Sig.	t	df	Sig. (2-tailed)	Mean Diff.	Std. Error Diff.	Lower	Upper

		F	Sig.	t	df	Sig. (2-tailed)	Mean Diff.	Std. Error Diff.	Lower	Upper
HRQOL	Equal variances assumed	.461	.499	-1.364	96	.176	-3.701	2.715	-9.090	1.687
	Equal variances not assumed			-1.325	34.994	.194	-3.701	2.794	-9.374	1.971

Ostomy Type and HRQOL

An independent t-test was conducted to determine if there was a statistically significant difference in HRQOL score according to ostomy type – ileostomy or colostomy. There was no statistically significant difference at the p<.05 level in HRQOL score for ostomy type of ileostomy and colostomy (ileostomy (M = 18.88, SD = 11.255) and colostomy (M = 15.00, SD = 12.265; t (95) = 1.210, p = .229, 2-tailed)). Results of t-test are presented in Table 19.

Table 19.

Ostomy Type and HRQOL T-Test

	Ostomy type	N	Mean	Std. Deviation	Std. Error Mean
HRQOL	Ileostomy	82	18.88	11.255	1.243
	Colostomy	15	15.00	12.265	3.167

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means					95% Confidence Interval of the Diff.	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Diff.	Std. Error Diff.	Lower	Upper

	Equal variances assumed	.217	.643	1.210	95	.229	3.878	3.204	-2.483 10.239
HRQOL	Equal variances not assumed			1.140	18.569	.269	3.878	3.402	-3.254 11.010

Stoma Type and HRQOL

An independent t-test was performed to evaluate if there was a statistically significant difference in HRQOL score according to stoma type – temporary or permanent. There was no statistically significant difference at the p<.05 level in HRQOL score for stoma type of temporary and permanent (temporary (M = 21.06, SD = 10.657) and permanent (M = 16.78, SD = 11.64; t (95) = 1.779, p = .078, 2-tailied)). Results of t-test are presented in table 20.

Table 20.

Stoma Type and HRQOL T-Test

	Stoma type	N	Mean	Std. Deviation	Std. Error Mean
HRQOL	Temporary	34	21.06	10.657	1.828
	Permanent	63	16.78	11.643	1.467

Independent Samples Test

	Levene's Test for Equality of Variances		t-test for Equality of Means						
	F	Sig.	t	df	Sig. (2-tailed)	Mean Diff.	Std. Error Diff.	95% Confidence Interval of the Diff.	
								Lower	Upper

	Equal variances assumed	1.873	.174	1.779	95	.078	4.281	2.407	-.497	9.059
HRQOL	Equal variances not assumed			1.827	73.071	.072	4.281	2.344	-.390	8.952

Site Marking and HRQOL

An independent t-test was conducted to determine if there was a statistically significant difference in HRQOL score according to pre-operative site-marking. There was no statistically significant difference at the p<.05 level in HRQOL score for per-operative site marking of yes (yes (M = 17.56, SD = 11.518) and no (M = 21.53, SD = 10.895; t(89) = 1.351, p = .180, 2-tailied)). Results of t-test are presented in table 21.

Table 21.

Site Marking and HRQOL T-Test

	Site marking	N	Mean	Std. Deviation	Std. Error Mean
HRQOL	Yes	72	17.56	11.518	1.357
	No	19	21.53	10.895	2.500

Independent Samples Test

	Levene's Test for Equality of Variances		t-test for Equality of Means						
	F	Sig.	t	df	Sig. (2-tailed)	Mean Diff.	Std. Error Diff.	95% Confidence Interval of the Diff.	
								Lower	Upper

	Equal variances assumed	.797	.374	-1.351	89	.180	-3.971	2.939	-9.810	1.869
HRQOL	Equal variances not assumed			-1.396	29.532	.173	-3.971	2.844	-9.784	1.842

IBD-Subtype and Significant Predictors

IBD-subtype and pain.

A one-way ANOVA was conducted to determine if there was a statistically significant difference in the pain score in the different groups according to IBD-subtype. A statistically significant difference at the p<.05 level in pain score for the IBD-subtype groups of UC, Crohn's disease, and both (F (2,88) = 5.484, p = .008). A post-hoc test was also conducted as a significant difference was found between groups of IBD-subtype. In this study, a significant difference was found in pain scores between groups of IBD-subtype for Crohn's disease (M=57.198, SD 24.63) and both types of IBD (M=28.93, SD 18.25), as well as UC (M=63.17, SD 24.981) and both types of IBD (M=28.93, SD 18.25) but no significant difference was found between Crohn's disease (M=57.198, SD 24.63) and UC (M=63.17, SD 24.981). Results of the ANOVA are presented in table 22 and results of post-hoc test are presented in table 23.

Table 22.

IBD-Subtype and Pain ANOVA

Pain

	Sum of Squares	df	Mean Square	F	Sig
Between Groups	6502.499	2	3251.249	5.484	.006
Within Groups	52168.655	88	592.826		

Total	58671.154	90					

Table 23.

IBD-Subtype and Pain Post-Hoc Test

IBD-Subtype (I)	IBD-Subtype (J)	Mean Difference (I-J)	Std. Error	Sig.	95% CI Lower Bound	95% CI Upper Bound
UC	Crohn's Disease	5.9748	5.7465	.554	-7.725	19.674
	Both	34.2445*	10.3678	.004	9.528	58.961
Crohn's Disease	UC	-5.9748	5.7465	.554	-19.674	7.725
	Both	28.2697*	9.7422	.013	5.044	51.495
Both	UC	-34.2445*	10.3678	.004	-58.961	-9.528
	Crohn's Disease	-28.2697*	9.7422	.013	-51.495	-5.044

*The mean difference is significant at the .05 level

IBD-subtype and fatigue.

A one-way ANOVA was conducted to determine if there was a statistically significant difference in the fatigue score in the different groups according to IBD-subtype. There was no statistically significant difference at the p<.05 level in fatigue score for the IBD-subtype groups of UC, Crohn's disease, and both (F (2,88) = 2.746, p = .070). Results of the ANOVA are presented in table 24.

Table 24.

IBD-Subtype and Fatigue

Fatigue

	Sum of Squares	df	Mean Square	F	Sig
Between Groups	2800.407	2	1400.204	2.746	.070
Within Groups	44863.878	88	509.817		
Total	47664.286	90			

IBD-subtype and psychological distress.

A one-way ANOVA was conducted to determine if there was a statistically significant difference in the psychological distress score in the different groups according to IBD-subtype. There was no statistically significant difference at the p<.05 level in psychological distress score for the IBD-subtype groups of UC, Crohn's disease, and both (F (2,88) = 1.664, p = .195). Results of the ANOVA are presented in table 25.

Table 25.

IBD-Subtype and Psychological Distress

Psychological
Distress

	Sum of Squares	df	Mean Square	F	Sig
Between Groups	1400.946	2	700.473	2.746	.195
Within Groups	37042.659	88	420.939		
Total	38443.604	90			

IBD-subtype and SRH

A one-way ANOVA was conducted to determine if there was a statistically significant difference in the SRH score in the different groups according to IBD-subtype. There was no statistically significant difference at the p<.05 level in SRH score for the IBD-subtype groups of UC, Crohn's disease, and both (F (2,88) = 2.350, p = .101). Results of the ANOVA are presented in table 26.

Table 26.

IBD-Subtype and SRH

SRH

	Sum of Squares	df	Mean Square	F	Sig
Between Groups	3.424	2	1.712	2.350	.101
Within Groups	64.114	88	.729		
Total	67.538	90			

Chapter 5

Discussion of Findings

The purpose of this study was to understand the predictors of health-related quality of life (HRQOL) in younger persons aged 18 to 40 years old living with inflammatory bowel disease (IBD) and an intestinal stoma. Predictors derived from the empirical evidence included the symptoms of pain, fatigue, leakage of stomal appliance, peristomal skin problem, body image/ sexual disturbance, and psychological distress, as well as self-rated health (SRH). An explanation of the findings of these hypothesized relationships in relation to the empirical findings from which these hypotheses were postulated is presented in this chapter.

Hypotheses

Hypotheses 1-8 posited that symptoms and SRH predict overall HRQOL based on the Wilson and Clearly HRQOL conceptual model. Wilson and Cleary (1995) predicted that symptoms or self-evaluation of an abnormal state coupled with one's self-interpretation of health will predict overall HRQOL (Wilson & Cleary, 1995). A review of the empirical literature revealed the symptoms of pain, fatigue, leakage of stomal appliance, peristomal skin problem, body image/sexual disturbance, and psychological distress to be most significant predictors of HRQOL for individuals aged 18 to 40 years living with IBD and an intestinal stoma. Additionally, the theoretical construct of general health perceptions within the Wilson & Cleary model aligns with the health indicator of SRH that is a subjective self-assessment of health which is predictive of future health issues, use of healthcare services, and mortality (Idler & Benyamini, 1997; Mossey & Shapiro, 1982). Hypotheses 1-7 tested the relationships between each individual

symptom and SRH and HRQOL. Hypothesis 8 tested the relationship of all symptoms of

SRH and HRQOL in younger adults aged 18-40 years living with IBD and an intestinal

stoma.

Pain and HRQOL

Hypothesis 1 stated that there would be an inverse relationship between the

symptom of pain and HRQOL in younger persons living with IBD and an intestinal

stoma. In correlational analysis, this relationship was supported as a significant inverse

correlation ($r = -.691$, $p = .000$) was found between pain and HRQOL. Pain was also

found to be a significant predictor of HRQOL in hierarchical multivariate regression

analysis (Beta = .301, p= .000).

This finding was consistent with the empirical literature. Pain is a frequently

reported symptom of IBD with pain reported by 71% of participants in a study conducted

by Zeitz et al. (2016) and 87% of subjects in a study by Schirbel et al. (2010). Pain was

noted to have a negative impact on HRQOL by the authors of three studies as a result of

active disease symptomology and hindered participation in daily activities (Abdalla et al.,

2016; Morris & Leach, 2017; Savarad & Woodgate, 2009). However, the formation of

an intestinal stoma did not fully alleviate symptoms in persons living with a diagnosis of

Crohn's disease as pain was noted to be worse with active disease and an ostomy as

compared to active disease and no ostomy. This study found that the experience of pain

in persons living with a stoma and IBD was related to the overall activity of the

underlying disease even in the presence of an ostomy. (Abdalla et al., 2016).

In this study, a significant difference was found in pain scores between groups of

IBD-subtype ($F (2,88)=5.484$, p=.006) , with a significant difference found between

Crohn's disease (M=57.198, SD 24.63, p=.006) and mixed type of IBD (M=28.93, SD 18.25, p=.006), as well as UC (M=63.17, SD 24.981, p=.006) and mixed type of IBD but no significant difference was found between those subjects who either had just Crohn's disease or UC. Based upon the notion that UC should be cured following stoma formation, it was postulated that there should be a significant difference between pain scores of those with UC and Crohn's disease. However, the evidence in the literature is inconclusive, as four of the studies specific to IBD and a stoma included participants with either UC or Crohn's disease, and not both (Abdalla et al., 2016; Knowles et al., 2013; Savard & Woodgate, 2009; Sinclair, 2009). In one study that included patients with both Crohn's disease and UC, IBD subtype was not reported (Rochelle & Fidler, 2009).

On the other hand, in the aforementioned study by Zeitz et al. (2016) focusing on IBD and pain, irrespective of an intestinal stoma, 71% reported pain with no statistical difference between Crohn's disease and UC in relation to occurrence of pain (p=.057). The majority of pain reported in this study was localized to the abdomen (59.5%) but many participants also reported back pain, joint pain, and headaches. Pain locations beyond the abdomen are in line with the occurrence of extra-intestinal manifestations of IBD which has been cited to occur in greater than 40% of those with IBD, the most common manifestation being joint pain (Vavricka et al., 2015). Additionally, pain symptoms in those with IBD were found to be undertreated by healthcare professionals, with only three-quarters of participants who reported pain received pain medication in the form of acetaminophen, NSAIDS, and opioids (Zeitz et al., 2016).

Based upon the empirical IBD literature, pain was likely found to be a predictor of HRQOL in this study as a result of underlying disease process. Despite the fact that

stoma formation is considered curative for UC, there was no statistically significant

difference between pain scores in Crohn's disease compared to UC in this study.

Therefore, it is plausible that pain may be more of a global symptom experienced by

those with IBD and not localized to only the abdomen or gastrointestinal tract as would

be anticipated with diagnosis of IBD. Pain, including location, should be an essential

symptom to consider in the treatment of younger persons living with IBD and a stoma as

it is a significant predictor of HRQOL in this study and can be undertreated as

aforementioned in the empirical literature (Zeitz et al., 2016).

Fatigue and HRQOL

Hypothesis 2 stated that there would be an inverse relationship between the

symptom of fatigue and HRQOL in younger persons aged 18 to 40 years living with IBD

and an intestinal stoma. This hypothesis was supported in correlational analysis with a

significant inverse correlation between fatigue and HRQOL ($r = -.695$, $p = .001$). Fatigue

was also found to be a predictor of HRQOL in hierarchical multivariate regression

analysis (Beta = $-.239$, $p = .003$).

Evidence from the empirical literature supports this finding. In two studies, sleep

impairment was noted in over 40% of participants with an increase to 77% in those with

active IBD (Habibi et al., 2017; Peyrin-Biroulet et al., 2012). Fatigue was associated

with lower HRQOL in studies conducted by Abdalla et al. (2016) due to the presence of

active Crohn's disease and in another investigation by Grant et al. (2011) fatigue

occurred as a result of difficulty finding a comfortable sleep position because of stoma

location, and frequent awakening to assess if stomal appliance required emptying.   In

patients with IBD, notwithstanding intestinal stoma, a study by Hashash and colleagues

(2016) found that sleep disturbance, as well as, the presence of self-reported IBD symptoms, and use of psychotropic medications in the form anti-depressants and benzodiazepines were all related to fatigue. However, no association was found with the presence of acute inflammatory markers and fatigue in participants with Crohn's disease and UC in the aforementioned study (Hashash et al., 2018).

Upon analysis of the IBD subtypes in this study, no significant difference in fatigue scores across IBD-subtype groups was found (F(2,88)=2.746, p=.070). However, fatigue was found to be strongly correlated with psychological distress (r=.576; p=.000) and both fatigue and psychological distress are predictors of HRQOL in this study.

There is a paucity in the literature regarding the etiology of fatigue in individuals living with IBD and an intestinal stoma. Evidence from the empirical literature suggests fatigue could be a result of difficulty sleeping due to presence of a stoma, active IBD symptoms, and/or use of psychotropic medications to treat psychological distress that is often reported to coexist with IBD (Abdalla et al., 2016; Grant etl al., 2011; Hashash et al., 2018). It is also plausible that fatigue could be a manifestation of global symptoms resulting from the chronic course of IBD as, in this study, fatigue scores did not differ according to IBD-subtype. The results of this study suggest that sleep impairment or fatigue could be the result of the presence of a stoma that could directly interfere with sleep, as well as, the existence of a chronic disease as fatigue score did not differ according to IBD diagnosis, Additionally, it is reasonable to postulate that treatment of psychological symptoms could be a cause of fatigue since fatigue was strongly correlated with psychological distress in this study. Fatigue is, therefore, an important symptom to consider in the treatment of younger persons living with IBD and a stoma as it

significantly predicted HRQOL, regardless of IBD-subtype. It is also essential to consider the etiology of fatigue in each individual to adequately treat this symptom as empirical evidence and results from this study are inconclusive regarding the cause of sleep impairment in this population.

Leakage of Stomal Appliance and HRQOL

Hypothesis 3 stated that there would be an inverse relationship between the symptom of leakage of stomal appliance and HRQOL in younger individuals aged 18 to 40 years living with IBD and an intestinal stoma. This hypothesis was not supported in correlational analysis ($r = .033$, $p = .764$).

This finding was inconsistent with findings in the empirical literature. Leakage of stomal appliance was associated with worse HRQOL in previous studies, with leakage identified as a problem for individuals living with a stoma as a result of IBD or other gastrointestinal diagnoses (Nybaek et al., 2010; Sinclair, 2009). However, Erwin-Toth and Davis (2012) noted that decreased leakage of stomal appliance had greatest impact on improving HRQOL ($p<.0001$). In their study, the use of the correct stomal appliance to significantly decrease frequency and severity of perceived leaks significantly improved HRQOL ($p<.001$).

In this study, data with regard to stomal leakage was collected from a self-report survey where participants answers may have been more cross sectional in nature, thus limited to the moment of time in which the survey was completed. No information about type of stomal appliance or prior history of leakage of stomal appliance was obtained from participants in this study. Another factor to consider in the present study may have been the subscale score of stoma function from the *Young-Fadok Stoma Quality of Life*

(QOL) Scale which measured leakage of stomal appliance. In this study, this subscale was, not found to be reliable (α=.555) in this sample, which may have influenced this measure.

Age of this study sample may have also been a contributor to the non-significance of stomal appliance leakage. In this study, the mean age of participants in this study was 30.56 (SD 6.15) years as compared to the mean age of 61.4 years in the aforementioned study (Erwin-Toth & Davis, 2012). Eighty percent of individuals with chronic diseases have been reported to participate in online support groups with younger persons more likely to be a part of a social media network compared to older individuals according to Fox and Purcell (2010). Online networks are a resource for not only support but also information about disease, treatments, and useful products, such as appropriate stomal appliances (Fox & Purcell, 2010). Participants from this study were younger as ages ranged from 18-40 years and were recruited from online support groups and discussion boards. It is likely that participants in this sample actively seek out information from online resources regarding products that could help to reduce leakage of stomal appliance. Thus, the lack of support for leakage of the peristomal appliance as a predictor for HRQOL may potentially be attributed to the participant's perception regarding what constitutes appliance leakage, and the probability that study participants may be more adept at using the internet and online resources to proactively seek out products to control leakage. It is also highly plausible that leakage of the stomal appliance was not found to be significantly related to HRQOL as the subscale used to measure this phenomenon was not found to be reliable in this sample, suggesting that it may not fully represent leakage of stomal appliance in younger persons living with IBD

and an intestinal stoma. Thus, in future research it may be necessary to consider an alternative way to measure this construct.

Peristomal Skin Problem and HRQOL

Hypothesis 4 stated that the symptom of peristomal skin problem would be inversely related to HRQOL in younger adults aged 18 to 40 years old living with IBD and an intestinal stoma. This hypothesis was supported in correlational analysis (r = -.247, p = .014). However, peristomal skin problem was not found to be a significant predictor of HRQOL in this sample (Beta = .034, p = .571).

This finding is inconsistent with empirical evidence. Presence of a peristomal skin problem was found to negatively affect HRQOL (p = .0026) with severity of skin condition inversely related to HRQOL (p=.0068) (Nybaek et al., 2010). In previous empirical investigations, the effect of peristomal skin problems on HRQOL was strongly affected by awareness of the condition (p=.004) with only 38% having the ability to self-identify peristomal skin problem in an additional study (Erwin-Toth & Davis, 2012; Nybaek et al., 2010). Also, participants in the study by Erwin-Toth and colleagues (2012) had a mean age of 61.4 years, which is older than the mean age of 30.56 years for the individuals in this sample. As described for the variable of leakage of stomal appliance, it is plausible that these younger ages represented in this study sample could be more adept at using online resources to obtain information to prevent or manage peristomal skin problems (Fox & Purcell, 2010). Additionally, as with stomal leakage, data with regard to peristomal skin problem was collected from a self-report survey where participants answers may have been more cross sectional in nature, thus limited to the moment of time in which the survey was completed.

Despite significant correlation in bivariate analysis, there is insufficient evidence to support peristomal skin problem as a predictor of HRQOL in this sample because, similar to participants in Erwin-Toth and colleagues (2012) study, participants were unable to self-identify peristomal skin problem or perceive peristomal skin problems to be less severe. Additionally, data may have been limited to moment survey was completed which would fail to give a complete understanding of this phenomenon in this sample. This younger sample aged 18 to 40 years may also be more proficient in locating online resources to manage and treat skin problems. Finally, there is a paucity of evidence representing the participants in this sample indicating the empirical evidence may not fully characterize this problem in younger persons living with IBD and a stoma providing rational for additional research in this population.

Body Image/Sexual Disturbance and HRQOL

Hypothesis 5 stated that body image/sexual disturbance would be inversely related to HRQOL in younger persons aged 18 to 40 years living with IBD and an intestinal stoma. This hypothesis was not supported in this sample (r = .086, p = .397).

There are inconsistent findings in the literature regarding the relationship between body image/sexual disturbance and IBD/presence of an intestinal stoma. In five studies, findings were consistent with sexual challenges after stoma surgery including loss of sexual activity, impaired sexual enjoyment and function, sexual challenges, and embarrassment when engaging in intimacy with an ostomy thus negatively affecting body image in those with a stoma (Anaraki et al., 2012; Grant et al., 2011; Mahjoubi et al., 2012; Savard & Woodgate, 2009; Sinclair, 2009). Sexual problems were noted to increase with age (p=.006) and age-related changes including erectile dysfunction were

found to interfere with sexual activity which were associated with a decreased HRQOL in persons living with an intestinal stoma mainly as a result of colorectal cancer (Mahjoubi et al., 2012; Popek et al., 2010; Ramirez et al., 2009).

On the other hand, empirical evidence from four studies revealed a positive association between engaging in sexual activity and HRQOL, with increased time since diagnosis associated with greater satisfaction in sexual performance and engagement in sexual activity (El-Tawil & Nightingale, 2013; Grant et al., 2011; Mahhoubi et al., 2012; Salles, Becker, & Faria, 2014). Presence of a supportive partner, often through marriage, who accepted reconfigured body was essential to experience sexual desire following stoma surgery (Ramirez et al., 2009; Sinclair, 2009). Abdalla et. al (2016) also found that the presence of an ostomy did not affect sexual interest or satisfaction even after adjusting for disease activity and age in a sample of participants all with a diagnosis of IBD. Finally, in younger individuals who are more likely to participate in online support groups and online educational mediums, the empirical evidence supports that the use of online videos aimed at decreasing the stigma associated with a stoma are important venues to enhance body image in those with a stoma. (Angott, Cornerford, & Ubel, 2012; Fox & Purcell, 2010).

In this sample, the sexuality/body image subscale of the *Young-Fadok Stoma QOL Scale* was not found to be reliable (α=.472) indicating this subscale may not fully represent body image/sexual disturbance in younger individuals living with IBD and an intestinal stoma. Additionally, in a pilot studying assessing the reliability of the *Young-Fadok Stoma QOL Scale* by this investigator, the sexuality/body image subscale was also found to not be reliable (α=.64) with participants indicating difficulty completing the

items in the subscale if they did not currently have a partner. All participants in this study were aged 18 to 40 years with a mean age of 30.56 years and over half (60.2%) reported being in a romantic relationship with 41.8% of these participants being married. Based upon the aforementioned empirical findings, it is plausible that body image/sexual disturbance was not found to be a significant predictor of HRQOL in this sample as participants were too young to experience age-related sexual changes, as well as, 61% of the sample (41.8% of which were married) reported support of a stable romantic partner, and, therefore, had increased likelihood of engaging in sexual activity. Additionally, as younger persons were more likely to use online resources for support and subjects were aged 18 to 40 years in this study, it is possible that individuals in this sample were less likely to have body image issues as a result of exposure to online resources. Finally, it is reasonable that body image/sexual disturbance was not significantly associated to HRQOL since the subscale representing this variable was not found to be reliable in this sample. In future research, it may be reasonable to consider alternative means of measuring sexuality/body image or providing instructions to participants about answering questions regardless of the presence of a sexual partner to more fully understand this construct.

Psychological Distress and HRQOL

Hypothesis 6 stated that the symptom of psychological distress would be inversely related to HRQOL in younger individuals aged 18 to 40 years old living with IBD and an intestinal stoma. This hypothesis was supported in both bivariate and multivariate analyses with a significant correlation between psychological distress and

HRQOL (r = -.668, p =.000) and psychological distress was found to be a significant predictor of HRQOL (Beta = -.321, p =.000).

This finding is consistent with findings from the empirical literature demonstrating psychological distress as a predictor for HRQOL in persons living with IBD and/or an intestinal stoma. In three previous studies in participants living with intestinal stomas, anxiety and depression were found to be associated with a decrease in HRQOL (Anaraki et al., 2012; Grant et al., 2011; Popek et al., 2010). Additionally, in three studies including only participants with IBD and a stoma, more beliefs that a stoma negatively impacted life, as well as, the presence of Crohn's symptoms were associated with increased anxiety and depression and, ultimately, worse HRQOL (Knowles et al., 2013; Morris & Leach, 2017; Rochelle & Fidler, 2012). In this study, psychological distress was moderately correlated with pain (r=.417, p=.000) and strongly correlated with fatigue (r=.576, p=.000) which aligns with the evidence that presence of physical symptoms was linked to psychological distress and subsequently influences one's HRQOL. There was also no significant difference in psychological distress by IBD-subtype (F (2,88) = 1.664, p = .195) in this sample.

Based upon the empirical evidence as well as the findings of this study in the form of correlations with pain and fatigue regardless of IBD-subtype, it is plausible that psychological distress in the form of anxiety and depression was a predictor of HRQOL in this sample as a result of negative beliefs about a stoma and the presence of IBD symptoms, regardless of IBD-subtype, that negatively impacted life. Therefore, based upon these findings and the supporting empirical evidence, it is essential to consider the

psychologic symptoms that occur in the treatment of younger persons living with IBD and a stoma.

SRH and HRQOL

Hypothesis 7 stated that SRH would be directly related to HRQOL in younger adults aged 18 to 40 years living with IBD and an intestinal stoma. A significant positive correlation was found between SRH and HRQOL (r = .641, p = .000). This hypothesis was also supported in multivariate analysis as SRH was found to be a significant predictor of HRQOL in this sample (Beta = .229, p = .002).

This finding is consistent with other studies in the IBD and intestinal stoma literature. Illness cognitions, or the manner in which one perceives and considers disease, as well as beliefs about stoma were significant predictors of HRQOL with more negative beliefs about a stoma associated with higher anxiety/depression and HRQOL (Gurkova & Soosova, 2018; Knowles et al., 2013). Gurkova & Soosova (2018) only included participants living with IBD and no stoma in which they reported that health status, maladaptive coping, a sense of helplessness about disease, and inability to accept chronic disease was associated with worse illness cognitions.

In this study, SRH was strongly negatively correlated with pain (r=-.605, p=.000) and fatigue (r=-.516, p=.000), as well as moderately negatively associated with psychological distress (r=-.340, p=.001), however, this did not differ by IBD-subtype (F (2,88) = 2.350, p = .101). Therefore, even though stoma formation is considered curative for UC, symptoms related to chronic disease persist after stoma formation, as aforementioned, and affected SRH in this sample in participants with both UC and Crohn's disease.

In this study, the presence of physical symptoms in the form of pain and fatigue and, to a lesser degree, the occurrence of psychological symptoms negatively impacted the manner in which one perceived his or her health and, ultimately, the HRQOL. Despite the presence of significantly predictive symptoms of pain, fatigue, and psychological distress in the form of anxiety and depression, the manner in which one perceives his or her health is just as significant as the occurrence of physical and/or mental health symptoms in predicting HRQOL which is supported by the IBD empirical literature as described above. This suggests that the manner in which one perceives his or her health can affect how one adjusts to the presence of disease and impacts HRQOL, regardless of the presence of symptoms. Thus, complete treatment of physical and psychological symptoms, as well as, understanding the manner in which one perceives disease is important in the care of younger individuals living with IBD and an intestinal stoma.

A Multivariate Model Explaining Predictors of HRQOL in Young Adults with IBD and an Intestinal Stoma

Hypothesis 8 stated that there would be a significant combined effect with regard to variance accounted for, of the predictors of HRQOL in younger persons aged 18 to 40 years living with IBD and an intestinal stoma. Marital status and employment status were entered into step 1 of the hierarchical multivariate regression analysis in order to control for their effect on HRQOL score and pain, fatigue, psychological distress, peristomal skin problem, and SRH were entered into step 2 of the model based upon significant bivariate correlations with HRQOL to produce a significant model ($F (7,90) =$ 36.658, p =.000). Marital status and employment status explained 20.8% of the variance in HRQOL. The symptoms of pain, fatigue, psychological distress, and SRH explained

53.2% of the variance of HRQOL, and these predictors plus marital status and employment status accounted for 74.0% of the variance in HRQOL.

Wilson and Cleary (1995) postulated a conceptual model in which symptoms and general health perceptions aligning with the clinical construct of SRH in this study culminated in HRQOL. The symptoms of pain, fatigue, and psychological distress, as well as SRH significantly predicted HRQOL in this sample. In this study, the variable peristomal skin problems was significantly correlated with HRQOL but was not found to be a significant predictor in multivariate analysis. In the empirical literature, an individual's awareness of the peristomal skin problems, as well as, the severity of the problem were significant predictors of HRQOL (Erwin-Toth & Davis, 2012; Nybaek et al., 2010). Thus, in this study, the inability of participants to self-identify peristomal skin problems or the severity of the problem may explain the lack of significance of peristomal skin problem as a predictor of HRQOL in this study.

Findings from this study revealed that there was no significant difference in reported pain levels in the IBD-subtype groups of Crohn's disease as compared to UC, as well as no significant difference among IBD-subtype groups for fatigue, psychological distress, and SRH scores. It is important to note that stoma formation for individuals living with UC is considered curative but the same is not true for persons with a diagnosis of Crohn's disease. However, as no significant differences were found between pain or fatigue scores between participants with Crohn's disease when compared to participants with UC, it is likely that the symptoms of pain and fatigue could be present regardless of status of disease activity or disease subtype. Additionally, as no significant difference was found in psychological distress scores for individuals with Crohn's disease compared

to those with UC in this sample, anxiety and depressive symptoms were likely related to the presence of IBD disease symptoms which aligns with findings from the empirical literature (Morris & Leach, 2017; Rochelle & Fidler, 2012). The same is true for SRH as, based on empirical evidence, not only current health status but also overall perception about disease and ability to cope with it, as well as all treatments and consequences predicted the manner in one perceived health status which was reflected in this study by lack of significant difference of SRH score by IBD-subtype (Gurkova & Soosova, 2018; Knowles et al., 2013). Findings from this study suggest that the manner in which one perceives his or her health can be just as important as the occurrence of chronic physical and/or psychological symptoms in predicting HRQOL in patients with IBD and an intestinal stoma. This aligns with the suppositions from the Wilson and Clearly HRQOL model that symptoms and SRH (described as general health perceptions in their model) culminated in HRQOL.

Based upon the empirical evidence and study findings, it is plausible to postulate that the treatment for younger individuals living with IBD and an intestinal stoma should focus on the symptoms associated with underlying chronic disease process. Despite the notion that creation of an intestinal stoma is curative for UC, results of this study, as well as the empirical literature, provided evidence that pain, fatigue, and psychological distress impacted HRQOL regardless of activity of underlying disease process (Hashash et al., 2018; Zeitz et al., 2016). Additionally, these aforementioned symptoms were related to the manner in which one perceived health in this study, as well as, previous empirical investigations with a more positive view about health related to improved HRQOL (Gurkova & Soosova, 2018; Knowles et al., 2013). Temporary symptoms

related to the presence of an intestinal stoma that could be more easily treated, such as leakage of stomal appliance and peristomal skin problem, were not significantly predictive of HRQOL.

In multivariate analysis, significant predictors of HRQOL were pain, fatigue, psychological distress, and SRH in younger individuals aged 18 to 40 years living with IBD and an intestinal stoma. These significant predictors of HRQOL in this study are related to the chronic physical ailments of pain and fatigue, as well as psychological symptoms inclusive of psychological distress and perceptions of one's health as opposed to acute or temporary types of conditions, such as leakage of stomal appliance and peristomal skin problem, that are only transient in nature and can be more easily remedied. It is plausible that these symptoms and individual health perceptions are more likely a result of underlying chronic disease process as results did not differ by IBD-subtype and stoma specific symptoms, such as leakage of stomal appliance and peristomal skin problem, were not found to be predictive of HRQOL in this sample. Therefore, in the care of younger individuals living with IBD and a stoma, healthcare providers need to be more aware of and routinely assess for the global symptoms associated with chronic illness regardless of underlying disease process as these symptoms were predictive of HRQOL in persons living with both Crohn's disease and UC.

Chapter 6

Summary, Limitations, Conclusions, Implications, and Recommendations

The purpose of this study was to increase understanding of predictors of health-related quality of life (HRQOL) in younger persons aged 18 to 40 years living with inflammatory bowel disease (IBD) and an intestinal stoma. Seven potential predictors of HRQOL including six symptoms (pain, fatigue, leakage of stomal appliance, peristomal skin problem, body image/sexual disturbance, and psychological distress) and self-rated health (SRH) were examined in this study.

Pain, fatigue, stomal appliance leakage, peristomal skin problems, body image/sexual disturbance, psychological distress and SRH as potential predictors of HRQOL were derived from the Wilson & Clearly (1995) HRQOL conceptual model. Wilson and Cleary (1995) postulated that symptoms or self-evaluation of an abnormal state along with one's general health perceptions or self-interpretation of health (represented by SRH in this study) would culminate in overall HRQOL. The suppositions that symptoms would have an inverse relationship with HRQOL, while general health perceptions (described as SRH in this study) would have a positive relationship with HRQOL are purported in this conceptual framework (Wilson & Cleary, 1995).

The empirically-derived symptoms postulated to have negative relationships with HRQOL included pain, fatigue, leakage of stomal appliance, peristomal skin problem, body image/sexual disturbance, and psychological distress. Additionally, the empirically-based construct of SRH was posited to have a positive relationship with HRQOL.

Based upon the theoretical postulation that abnormal state (symptoms) and general health perceptions (SRH in this study) impacted life satisfaction in relation to health, empirically-derived IBD and stoma symptoms and the construct of SRH were examined to understand the most significant predictors of HRQOL in younger persons aged 18 to 40 years living with IBD and an intestinal stoma.

The following hypotheses were tested:

1. The symptom of pain is inversely related to HRQOL in younger persons living with IBD and a stoma.

2. The symptom of fatigue is inversely related to HRQOL in younger persons living with IBD and a stoma.

3. The symptom of leakage of stomal appliance is inversely related to HRQOL in younger persons living with IBD and a stoma.

4. The symptom of peristomal skin problem is inversely related to HRQOL in younger persons living with IBD and a stoma.

5. The symptom of body image/sexual disturbance is inversely related to HRQOL in younger persons living with IBD and a stoma.

6. The symptom of psychological distress is inversely related to HRQOL in younger persons living with IBD and a stoma.

7. SRH is directly related to HRQOL in younger persons living with IBD and a stoma.

8. There will be significant combined effect in regard to variance accounted for, of the predictors of HRQOL in the form of symptoms and SRH in younger persons aged 18 to 40 years living with IBD and a stoma.

The study sample included 98 participants that completed an online survey posted on online discussion boards or private message boards focused on support for individuals living with IBD and/or an intestinal stoma. Participants were included if they met the inclusion criteria of currently living with an intestinal stoma for at least two months, having a diagnosis of IBD, aged 18 to 40 years, and having the ability to read and write in English. Participants were excluded if they were under the age of 18 or over the age of 40, were living with a non-intestinal stoma, or were living with an intestinal stoma due to a diagnosis other than IBD. The sample was made-up of 23.5% (n=23) males and 76.5% (n=75) females. Ages ranged from 18 to 40 years with a mean age of 30.56 (SD 6.151) years. Eighty-eight (n=86) percent of the sample were Caucasian, four percent (n=4) were African American, four percent (n=4) were Hispanic, and three percent (n=3) were another race/ethnicity. Marital status included 37.8% (n=37) single/never married, 2% (n=2) divorced/separated, 3.1% (n=3) remarried, 15.3% (n=15) living with someone, and 41.8% (n=41) married. Twelve percent (n=12) were living alone, fifty-eight percent (n=57) were living with spouse/intimate partner, twenty percent (n=20) were living with family, two percent (n=2) were living with a friend, and seven percent (n=7) were living with a roommate. For employment status, 23.5% (n=23) were unemployed, 15.3% (n=15) were employed full-time, 41.8% (n=41) were employed part-time, and 19.4% (n=19) were a student. IBD diagnosis included 26.5% (n=26) with UC, 59.2% (n=58) with Crohn's disease, and 7.1% (n=7) with both. In regard to ostomy type, 83.7% (n=82) had an ileostomy and 15.3% (n=15) had a colostomy, while 64.9% (n=63) had a permanent stoma and 34.7% (n=34) had a temporary stoma. Seventy-four percent (n=72) had pre-operative stoma site marking and nineteen percent (n=19) did not. Time living

with an intestinal stoma included 19.4% (n=19) for six months or less, 25.5% (n=25) for six months to two years, 28.6% (n=28) for two years to five years, and 25.5% (n=25) for greater than five years.

All data was obtained from participant responses to an online survey. The outcome variable of HRQOL was calculated from individual answers to the items of the *Healthy Days Core Module* (CDC HRQOL-4). Symptoms of pain, fatigue, leakage of stomal appliance, peristomal skin problem, body image/sexual disturbance, and psychological distress were calculated from participant responses to appropriate subscales of bodily pain (representing pain), vitality (represented fatigue), and general mental health (representing psychological distress) in the *Short-Form 36* (SF-36) *Healthy Survey*, as well as stoma function (representing leakage of stomal appliance), sexuality/body image (representing body image/sexual disturbance), and the single item of skin irritation (representing peristomal skin problem) in the *Young-Fadok Stoma Quality of Life* (QOL) *Scale*. SRH was represented by the first item of the CDC HRQOL-4 (not included in final score) as completed by the participants in the survey.

Hypothesis 1-7 were tested using Pearson's product moment correlations. Variables significantly related to HRQOL were subjected to hierarchical multiple regression and included the following: pain, fatigue, peristomal skin problem, psychological distress, and SRH. HRQOL scores were found to significantly differ according to the demographic variables of martial and employment status. These demographic variables were, therefore, entered into step one of the hierarchal multivariate analysis in order to control for their effects on the outcome variable of HRQOL. In multivariate analysis, marital status and employment status explained 20.8% of the variance in HRQOL, the

whole model accounted for 74.0% of the variance in HRQOL, and, after controlling for marital and employment status, pain, fatigue, psychological distress, peristomal skin problem, and SRH explained an additional 53.2% of the variance in HRQOL in this study sample of younger persons aged 18 to 40 years living with IBD and an intestinal stoma.

In summary, while five symptoms and SRH were found to be significantly related to HRQOL, multivariate analysis revealed that only pain, fatigue, psychological distress, and SRH were independently predictive of HRQOL in this sample.

Limitations

1. Due to the descriptive, cross-sectional design of this study with data obtained from online surveys, the following limitations are recognized:

   a. The researcher was only able to determine associations between predictor and outcome variables, but not stronger causal relationships.

   b. Survey responses were all based upon self-report by participants in which it is possible for participants to exaggerate symptoms, under-report symptoms, inaccurately remember symptoms, or misunderstand survey items. Under-reporting of symptoms may be increased with perceived embarrassing symptoms, such as stoma function or sexual disturbance, however, since all responses were anonymous, this may not have been a factor.

   c. The survey response to verify presence of intestinal stoma was based upon self-report and, as responses were anonymous, there was no way for researcher to verify this information. However, as participants were recruited from online discussion boards/groups designed to support

individuals living with IBD and/or an intestinal stoma, it is unlikely

individuals without these conditions would access this discussion boards

or groups.

    d.   Social desirability response bias in which responses are based upon

believed favorability is also possible in self-reported survey responses.

This also may have been less of an issue in this study than typically noted,

as aforementioned, all responses were anonymous.

2. Due to recruitment of participants from online discussion boards/groups designed

for support of individuals living with IBD and/or an intestinal stoma, as well as

required memberships for the Facebook groups used in this study, it is more likely

that individuals would access these discussion boards or actively seek

membership to these groups if one was currently suffering from symptoms or

recently had stoma surgery due to the supportive nature of these discussion boards

and groups. Therefore, this decreases the generalizability of these study findings.

Conclusions

Conclusions that may be drawn from this study of 98 younger persons aged 18 to

40 years living with IBD and an intestinal stoma include the following:

1. Symptoms significantly associated with HRQOL were pain, fatigue, peristomal

skin problem, and psychological distress.

2. The construct of SRH was significantly associated with HRQOL.

3. HRQOL scores significantly differed with respect to marital status and

employment status of participants.

4. The symptoms of pain, fatigue, and psychological distress, as well as SRH explained a significant portion of the variance in HRQOL.

5. Alternative means to measure leakage of stomal appliance and body image/sexual disturbance need to be considered as the scales used in this study likely do not fully represent these constructs.

Implications for Nursing Practice

When cure is unrealistic, such as in the case of IBD, HRQOL is considered an essential outcome goal in healthcare. HRQOL is an intricate phenomenon integrating physical, psychological, social, and spiritual well-being that determines an individual's overall satisfaction with life as a result of disease, treatments, and current health status (Bulkley et al., 2013; Popek et al., 2010). As healthy individuals are known to have a better HRQOL compared to those suffering from disease, a good HRQOL is the ultimate goal as it indicates one is holistically satisfied with life regardless of the presence of a chronic condition (Armstrong & Caldwell, 2004).

Wilson and Cleary (1995) postulated that atypical state (symptoms) and general health perceptions (SRH in this study) impacted life satisfaction in relation to health. Based upon this supposition, it was predicted that symptoms and general health perceptions (described as SRH in this study) would be associated with HRQOL (Wilson & Cleary, 1995). Presence of an intestinal stoma has been found to negatively affect all aspects of life as a result of the physiological changes in the immediate post-operative time following stoma surgery (Mahjoubi et al., 2012). Evidence within the empirical literature demonstrated that presence of an intestinal stoma was associated with worse HRQOL as a result of depression, anxiety, sexual problems, fatigue, body image deficits,

peristomal skin problems, leakage of stomal appliance, and interference with life as a whole (Anaraki et al., 2012; Erwin-Toth et al., 2012; Grant et al., 2011; Knowles et al., 2013; Mahjoubi et al., 2012; Popek et al., 2010).

A common etiology of stoma formation is IBD which is a chronic, inflammatory disease of the digestive tract made-up of the two subtypes of Crohn's disease and UC that may result in possible intestinal and extra-intestinal manifestations (Katz et al., 2013). The creation of an intestinal stoma is considered curative for intestinal manifestations associated with UC, but the same is not true for Crohn's disease, as Crohn's disease can affect any part of the gastrointestinal tract (Katz et al., 2013; Vavricka et al., 2015). As IBD is typically diagnosed in adolescence and early adulthood, it is important to note that the presence of a stoma in younger persons aged 18 to 40 years can exacerbate feelings of being different, as well as diminish self-respect and confidence that may lead to avoidance of socialization and romantic relationships, isolation, and loneliness (Erikson, 1950; Katz et al., 2013; Savard & Woodgate, 2009). Presence of an intestinal stoma for the management of IBD has the potential to decrease HRQOL due to changes associated with stoma formation, as well as symptoms, subsequent treatments, and psychological and social impacts unique to younger individuals. As such, HRQOL is an important consideration in the care of younger individuals aged 18 to 40 years living with IBD and a stoma, as this indicator provides insight into individual perceptions of health status, as well as the way their perceptions impact their health status on various aspects of life.

The symptoms of pain, fatigue, and psychological distress were significantly predictive of HRQOL in this study sample. On the other hand, the symptoms of leakage of stomal appliance and peristomal skin problem were not predictive of HRQOL in this

study sample. Therefore, it is reasonable to postulate that global symptoms, such as pain, fatigue, psychological distress that are related to the underlying IBD, may be more likely to impact the younger person's HRQOL rather than transient issues related to intestinal stoma which could be easily resolved with treatment. Thus, in younger patients with IBD and a stoma, the focus of care should shift to the symptoms associated with the chronic disease of IBD as opposed to concerns related to stoma management.

The assessment of pain is an integral part of the both nursing and provider practice., as well as all healthcare providers interacting with patients. Pain is also regularly reported by individuals living with IBD ranging in occurrence from 71-87% (Schirbel et al., 2010; Zeitz et al., 2016). Therefore, it was reasonable to predict that pain be would predictive of HRQOL in this sample. However, unlike previously postulated, pain did not significantly differ between individuals with Crohn's disease as compared to those with UC which was unexpected as the formation of an intestinal stoma is considered curative for UC, thus one would expect pain to abate once the diseased intestine is remove. This finding is consistent with the empirical literature as extra-intestinal manifestations are noted in individuals who have a diagnosis of IBD with joint pain (40%) the most frequently reported manifestation (Vavricka et al., 201; Zeitz et al., 2016). Despite the likely occurrence of pain in this population, regardless of location, pain is often undertreated with only three-quarters of patients receiving appropriate pain management in the form of acetaminophen, NSAIDs, or opioids (Zeitz et al., 2016). In the care of younger persons living with IBD and a stoma, it is essential to not only assess pain but also location beyond the abdomen, as well as, occurrence and adequacy of pain management. Additionally, pain that origins from extra-intestinal manifestations, such as

joint pain, must always be considered in the treatment of individuals with IBD since it likely has a major impact upon HRQOL which is supported by the findings in this study that pain score did not differ in Crohn's disease compared to UC and stoma formation should be curative for UC.

As with pain, fatigue is a common occurrence in individuals living with IBD with over 40% reporting fatigue which increased to 77% in accordance with active disease (Habibi et al., 2017; Peyrin-Biroulet et al., 2012). There is a paucity of literature about the etiology of fatigue in individuals living with IBD and an intestinal stoma. Possible causes include sleep disturbance, self-reported IBD symptoms, use of psychotropic drugs in the form of anti-depressants and benzodiazepines, frequent awakening to empty a stomal appliance, and difficulty with comfort due to stoma location (Grant et al., 2011; Hashash et al., 2018). Additionally, findings from this study suggest psychological distress associated with the disease as a possible source of fatigue. Despite the cause, fatigue was noted to be predictive of HRQOL in this sample. In the care of younger persons living with IBD and a stoma it is important to assess fatigue, as well as understand the source of that fatigue in order to more accurately treat it. Hashash and colleagues (2018) recommended a multi-dimensional approach in the treatment of fatigue in IBD that included assessment of sleep patterns, as well as psychological health status in order to make provide potential behavioral modifications that could alleviate disturbed sleep or referral to psychological health services. More research is still necessary to more fully understand the cause of fatigue and optimal treatment in this population.

In this sample, psychological distress was correlated with pain and fatigue, as well as predictive of HRQOL. This aligns with evidence in the empirical literature as the

presence of IBD symptoms was associated with depression and psychological distress in the form of anxiety and depression were predictive of HRQOL in several studies (Anaraki et al., 2012; Grant et al., 2011; Morris & Leach, 2017; Rochelle & Fidler, 2012). Based upon this, it is reasonable to not only assess and treat psychological distress but also focus on the treatment of symptoms related to the underlying disease process as physical chronic disease symptoms likely impact psychological distress. Additionally, it is important to inquire if psychological symptoms are adequately treated in this population as the main provider for the majority of these individuals is likely a gastroenterologist who may focus on physical symptom management. Consequently, in order to improve treatment outcomes overall, gastroenterologists should not only be aware of potential psychological symptoms but make appropriate referrals to mental health providers when deemed necessary.

The manner in which an individual perceives his or her health, as measured by the variable of SRH, was predictive of HRQOL in this study sample. This finding was consistent with other studies with participants living with IBD and/or a stoma (Gurkova & Soosova, 2018; Knowles et al., 2013). As with psychological distress, SRH was related to the presence of symptoms as SRH was strongly negatively correlated with pain and fatigue, as well as, moderately negatively correlated with psychological distress. Based upon this finding, it is likely that a focus on treatment of chronic disease symptoms (pain, fatigue, psychological distress) will improve SRH and, therefore, HRQOL. However, as SRH was independently predictive of HRQOL in this sample, it is reasonable to postulate that symptom management alone would not be enough to alter SRH in a way that would result in optimal HRQOL in this population. Therefore, in the

care of younger persons aged 18 to 40 years living with IBD and an intestinal stoma, how one perceives health state is as important as successful treatment of one's underlying chronic disease symptoms (pain, fatigue, psychological distress). Additionally, as SRH and HRQOL were positively related in this study, it is plausible that understanding why one perceives health in a certain way, as well as assisting him or her to view health in a more positive could improve HRQOL in younger persons with IBD and a stoma.

Findings from this study suggest that chronic physical (pain, fatigue) and psychological ailments resulting from IBD are more significant than transient conditions due to intestinal stoma (leakage of stomal appliance, peristomal skin problem) in this population. Based upon the empirical literature, care is optimized when received from a specialist provider (Nguyen, Nugent, Shaw, & Bernstein, 2011). In a sample of participants all living with Crohn's disease, care from a specialist provider within one year of IBD diagnosis was associated with lower incidence of surgery and use of more aggressive treatments, such as immunomodulators and biologics (Nguyen et al., 2011). Receiving care from a gastroenterologist with experience in IBD management was related to reduced IBD-symptoms and complications (Nguyen et al., 2011). As pain, fatigue, and psychological distress are significant symptoms which may be undertreated in this population, it is reasonable that gastroenterologists should not only treat IBD symptoms, but also make appropriate referrals to specialists including mental health, pain, and/or sleep providers (Hashash et al., 2018; Zeitz et al. (2016). Therefore, care from all relevant specialist providers would likely improve treatment outcomes in this population as chronic disease symptoms were more problematic. Additionally, individual perceptions about health are just as important in impacting HRQOL as physical and

psychological aliments. Thus, ascertaining the health perceptions of the individual is an important consideration in care of younger persons living with IBD and an intestinal stoma.

This study contributed to the body of knowledge concerning predictors of HRQOL in younger persons living with IBD and an intestinal stoma, but more empirical evidence is necessary to further understand these predictors in this population. Despite the notion that creation of an intestinal stoma is curative for UC, predictors in this study did not differ in individuals with Crohn's disease as compared to those with UC. It is likely that symptoms predictive of HRQOL in this population (pain, fatigue, psychological distress) are a result of not only active gastrointestinal inflammation but also underlying global chronic disease symptoms. A larger portion of individuals living with IBD experience not only gastrointestinal manifestations but also extra-intestinal manifestations with the most common being joint pain (Vavricka et al., 2015). Additionally, there is a lack of literature regarding the etiology of fatigue in this population. Therefore, it is vital for practitioners to understand the cause of both pain and fatigue in order to provide optimal care to this population. Psychological distress was related to physical symptoms, but also independently predictive of HRQOL in this study sample. It is essential to understand the source of psychological distress, as well as the assessment and treatment of these symptoms in this population. SRH, as with psychological distress, was additionally independently predictive of HRQOL in this study despite association with physical and psychological symptoms. Understanding the manner in which individuals perceive health, as well as, the impacts of these perceptions, are important to promote ideal HRQOL in this population. The findings of this study

suggest that care of younger persons aged 18 to 40 years with IBD and an intestinal stoma should include a strong focus on the underlying chronic condition, regardless of presence of active gastrointestinal inflammation, as well as individualized health perceptions.

Recommendations

Based on the findings of this study, the following recommendations for future research are proposed:

1. Replication of current study making use of additional recruitment sites to improve generalizability of the study findings.

2. Prospective in-depth analysis of pain in younger persons aged 18 to 40 years living with IBD and an intestinal stoma in order to more fully understand this phenomenon in this population.

3. Prospective in-depth analysis of fatigue in younger persons aged 18 to 40 years living with IBD and an intestinal stoma in order to more fully understand this phenomenon in this population.

4. Prospective study using alternative measures for leakage of stomal appliance and body image/sexual disturbance to more fully understand the impact of these predictors on HRQOL.

5. Prospective study to understand use of online resources to manage IBD and an intestinal stoma in this younger population to appreciate the manner in which this could impact HRQOL.

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Appendix A: Healthy Days Core Module (CDC HRQOL-4)
This instrument is available in the public domain.
(CDC, 1993)

1. **Self-Perceived Health**

Would you say that in general your health is:

    a. Excellent
    b. Very Good
    c. Fair, or
    d. Poor?

2. **Recent Physical Health**

Now thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good?

___ days

3. **Recent Mental Health**

Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good?

___ days

4. **Recent Activity Limitation**

During the past 30 days for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation?

___ days

Appendix B: Short-Form 36 (SF-36) Health Survey
This instrument is available in the public domain.
(Hays, Sherbourne, & Mazel, 1995)

1. In general, would you say your health is:
__ Excellent (1)
__ Very Good (2)
__ Good (3)
__ Fair (4)
__ Poor (5)

2. **Compared to one year ago**, how would you rate your health in general **now**?
__ Much better now than one year ago (1)
__ Somewhat better now than one year ago (2)
__ About the same (3)
__ Somewhat worse now than one year ago (4)
__ Much worse now than one year ago (5)

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

3. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports:
__ Yes, Limited a Lot (1)
__ Yes, Limited a Little (2)
__ No, Not Limited at All (3)

4. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf:
__ Yes, Limited a Lot (1)
__ Yes, Limited a Little (2)
__ No, Not Limited at All (3)

5. Lifting or carrying groceries:
__ Yes, Limited a Lot (1)
__ Yes, Limited a Little (2)
__ No, Not Limited at All (3)

6. Climbing **several** flights of stairs:
__ Yes, Limited a Lot (1)
__ Yes, Limited a Little (2)
__ No, Not Limited at All (3)

7. Climbing **one** flight of stairs:
__ Yes, Limited a Lot (1)
__ Yes, Limited a Little (2)

__ No, Not Limited at All (3)

8. Bending, kneeling, or stooping:
   __ Yes, Limited a Lot (1)
   __ Yes, Limited a Little (2)
   __ No, Not Limited at All (3)

9. Walking **more than a mile**:
   __ Yes, Limited a Lot (1)
   __ Yes, Limited a Little (2)
   __ No, Not Limited at All (3)

10. Walking **several blocks**:
    __ Yes, Limited a Lot (1)
    __ Yes, Limited a Little (2)
    __ No, Not Limited at All (3)

11. Walking **one block**:
    __ Yes, Limited a Lot (1)
    __ Yes, Limited a Little (2)
    __ No, Not Limited at All (3)

12. Bathing or dressing yourself:
    __ Yes, Limited a Lot (1)
    __ Yes, Limited a Little (2)
    __ No, Not Limited at All (3)

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

13. Cut down the amount of time you spent on work or other activities:
    __ Yes (1)
    __ No (2)

14. **Accomplished less** than you would like:
    __ Yes (1)
    __ No (2)

15. Were limited in the **kind** of work or other activities:
    __ Yes (1)
    __ No (2)

16. Had **difficulty** performing the work or other activities (for example, it took extra effort):
    __ Yes (1)
    __ No (2)

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

17. Cut down the **amount of time** you spent on work or other activities:
    __ Yes (1)
    __ No (2)

18. **Accomplished less** than you would like:
    __ Yes (1)
    __ No (2)

19. Didn't do work or other activities as **carefully** as usual:
    __ Yes (1)
    __ No (2)

20. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?
    __ Not at all (1)
    __ Slightly (2)
    __ Moderately (3)
    __ Quite a bit (4)
    __ Extremely (5)

21. **How much bodily pain have you had during the past 4 weeks?**
    __ **None (1)**
    __ **Very Mild (2)**
    __ **Mild (3)**
    __ **Moderate (4)**
    __ **Severe (5)**
    __ **Very Severe (6)**

22. **During the past 4 weeks, how much did pain interfere with your normal work (including work outside the home and housework)?**
    __ **Not at all (1)**
    __ **A little bit (2)**
    __ **Moderately (3)**
    __ **Quite a bit (4)**
    __ **Extremely (5)**

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that come closest to the way you have been feeling.

23. Did you feel full of pep?
__ **All of the Time (1)**
__ **Most of the Time (2)**
__ **A Good Bit of the Time (3)**
__ **Some of the Time (4)**
__ **A Little of the Time (5)**
__ **None of the Time (6)**

24. Have you been a very nervous person?
__ **All of the Time (1)**
__ **Most of the Time (2)**
__ **A Good Bit of the Time (3)**
__ **Some of the Time (4)**
__ **A Little of the Time (5)**
__ **None of the Time (6)**

25. Have you felt so down in the dumps that nothing could cheer you up?
__ **All of the Time (1)**
__ **Most of the Time (2)**
__ **A Good Bit of the Time (3)**
__ **Some of the Time (4)**
__ **A Little of the Time (5)**
__ **None of the Time (6)**

26. Have felt calm and peaceful?
__ **All of the Time (1)**
__ **Most of the Time (2)**
__ **A Good Bit of the Time (3)**
__ **Some of the Time (4)**
__ **A Little of the Time (5)**
__ **None of the Time (6)**

27. Did you have a lot of energy?
__ **All of the Time (1)**
__ **Most of the Time (2)**
__ **A Good Bit of the Time (3)**
__ **Some of the Time (4)**
__ **A Little of the Time (5)**
__ **None of the Time (6)**

28. Have you felt downhearted and blue?
__ **All of the Time (1)**
__ **Most of the Time (2)**
__ **A Good Bit of the Time (3)**
__ **Some of the Time (4)**
__ **A Little of the Time (5)**

__ **None of the Time (6)**

29. Did you feel worn out?
__ **All of the Time (1)**
__ **Most of the Time (2)**
__ **A Good Bit of the Time (3)**
__ **Some of the Time (4)**
__ **A Little of the Time (5)**
__ **None of the Time (6)**

30. Have you been a happy person?
__ **All of the Time (1)**
__ **Most of the Time (2)**
__ **A Good Bit of the Time (3)**
__ **Some of the Time (4)**
__ **A Little of the Time (5)**
__ **None of the Time (6)**

31. Did you feel tired?
__ **All of the Time (1)**
__ **Most of the Time (2)**
__ **A Good Bit of the Time (3)**
__ **Some of the Time (4)**
__ **A Little of the Time (5)**
__ **None of the Time (6)**

32. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting friends, relative, etc.)?
__ All of the Time (1)
__ Most of the Time (2)
__ Some of the Time (3)
__ A Little of the Time (4)
__ None of the Time (5)

33. I seem sick a little easier than other people:
__ Definitely True (1)
__ Mostly True (2)
__ Don't Know (3)
__ Mostly False (4)
__ Definitely False (5)

34. I am as healthy as anybody I know:
__ Definitely True (1)
__ Mostly True (2)
__ Don't Know (3)

__ Mostly False (4)
__ Definitely False (5)

35. I expect my health to get worse?
__ Definitely True (1)
__ Mostly True (2)
__ Don't Know (3)
__ Mostly False (4)
__ Definitely False (5)

36. My health is excellent:
__ Definitely True (1)
__ Mostly True (2)
__ Don't Know (3)
__ Mostly False (4)
__ Definitely False (5)

Appendix C: Young-Fadok Stoma Quality of Life (QOL) Scale
This instrument is available in the public domain.
(Baxter et al., 2006)

Part 1

1. Rate your **overall** satisfaction with *your life in general* **right now** on a scale from 0 to 100, with 0 being totally unsatisfied and 100 being totally satisfied.
2. Rate your **overall** satisfaction with *your life in general* **during the last month** on a scale from 0 to 100 with 0 being totally unsatisfied and 100 being totally satisfied.

Part 2

Never (1)
Seldom (2)
Occasionally (3)
Frequently (4)
Always (5)

For each of the following questions, please choose a number from the choices above that corresponds to your answer.

3. I am able to participate in the hobbies I enjoy __.
4. I am able to go out with friends __.
5. My stoma interferes with my ability to work or attend school __.
6. I worry about traveling because of my stoma __.
7. **I enjoy sexual activity __.**
8. **I feel attractive __.**
9. **My sexual partner is bothered by my stoma __.**
10. **It bothers me if others are aware I have a stoma __.**
11. **I worry about lack of privacy when I need to empty my pouch __.**
12. **I feel comfortable in my clothing __.**
13. **I am satisfied with the foods that I eat __.**
14. I have financial concerns regarding my ostomy supplies __.
15. **I have problems with odor __.**
16. **I am able to share my feelings and concerns about my ostomy with a family member or friend __.**
17. **I am embarrassed by gas (noises or rapid filling of bag) __.**
18. **I worry my ostomy appliance will leak __.**
19. **I am bothered by skin irritation around the stoma __.**
20. Social situation make me feel anxious __.
21. I perform the same household and family duties __.

Appendix D: Demographic Questionnaire

1. Age ___

2. Gender (check one)
   __ Female
   __ Male

3. Marital Status (check one)
   __ Single, Never Married
   __ Divorced/Separated
   __ Widowed
   __ Remarried
   __ Living with Someone

4. Race/Ethnicity (check one)
   __ American Indian
   __ Asian/Pacific Islander
   __ Black/African American
   __ Hispanic/Latino
   __ White/Caucasian
   __ Other

5. Who are you living with currently? (check one)
   __ Living Alone
   __ Living with Husband, Wife, Intimate Partner
   __ Living with Family
   __ Living with Friend
   __ Living with Roommate

6. Employment Status
   __ Unemployed
   __ Part-Time
   __ Full-Time
   __ Student

7. Pre-operative marking of your stoma site?
   __ Yes
   __ No
   __ Don't Know

8. Ostomy Type (check one)
   __ Ileostomy

__ Colostomy

9. How long have you been living with your stoma __?
____ 6 months of less
___> 6months to 2 years
___> 2years – 5 years
___> 5 years

10. Inflammatory Bowel Disease Type/Diagnosis? (check one)
__ Ulcerative Colitis
__ Crohn's Disease
__ Both

11. Stoma Type (check one)
__ Temporary (Expect Reversal Surgery)
__ Permanent (Do Not Expect Reversal Surgery)

Appendix E: Rutgers, The State University of New Jersey IRB Approval of Study

RUTGERS eIRB

Arts & Sciences **IRB** - New Brunswick	Health Sciences **IRB** - New Brunswick/Piscataway	Health Sciences **IRB** - Newark
335 George Street	335 George Street	65 Bergen Street
Suite 3100, 3rd Floor	Suite 3100, 3rd Floor	Suite 511, 5th Floor
New Brunswick, NJ 08901	New Brunswick, NJ 08901	Newark, NJ 07107
Phone: 732-235-2866	Phone: 732-235-9806	Phone: 973-972-3608

DHHS Federal Wide Assurance Identifier: FWA00003913
IRB Chair Person: Cheryl Kennedy
IRB Director: Carlotta Rodriguez
Effective Date: 10/8/2018
Approval Date: 9/24/2018
Expiration Date: 9/23/2019

eIRB Notice of Approval for Initial Submission # Pro2018001663

STUDY PROFILE

Study ID: Pro2018001663
Title: Understanding Predictors of Health-Related Quality of Life in Younger Persons Living with an Ostomy and Inflammatory Bowel Disease.

Appendix F: Rutgers, The State University of New Jersey IRB Approval of Modification 1

RUTGERS eIRB

Arts & Sciences **IRB** -	Health Sciences **IRB** -	Health Sciences **IRB** -
New Brunswick	**New Brunswick/Piscataway**	**Newark**
335 George Street	335 George Street	65 Bergen Street
Suite 3100, 3rd Floor	Suite 3100, 3rd Floor	Suite 511, 5th Floor
New Brunswick, NJ 08901	New Brunswick, NJ 08901	Newark, NJ 07107
Phone: 732-235-2866	Phone: 732-235-9806	Phone: 973-972-3608

DHHS Federal Wide Assurance Identifier: FWA00003913
IRB Chair Person: Cheryl Kennedy
IRB Director: Carlotta Rodriguez

Effective Date: 10/31/2018

eIRB Notice of Approval for Modification 1 for IRB Study #Pro2018001663

STUDY PROFILE

Study ID:	Pro2018001663
Title:	Understanding Predictors of Health-Related Quality of Life in Younger Persons Living with an Ostomy and Inflammatory Bowel Disease.

Appendix G: Rutgers, The State University of New Jersey IRB Approval of
Modification 2

Rutgers eIRB

eIRB Notice of Approval for Modification 2 for IRB Study #Pro2018001663

STUDY PROFILE

Study ID: Pro2018001663

Title: Understanding Predictors of Health-Related Quality of Life in Younger Persons Living with an Ostomy and Inflammatory Bowel Disease.