

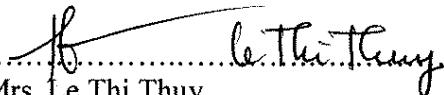
**FACTORS RELATED TO QUALITY OF LIFE AMONG
PATIENTS WITH INFLAMMATORY BOWEL DISEASE**


LE THI THUY

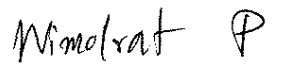
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OF THE REQUIREMENTS FOR THE DEGREE OF
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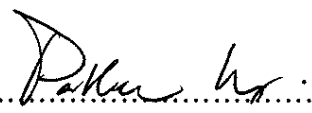
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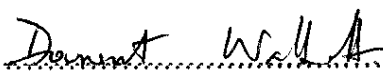
Thesis
entitled
**FACTORS RELATED TO QUALITY OF LIFE AMONG PATIENTS WITH
INFLAMMATORY BOWEL DISEASE**


.....
Mrs. Le Thi Thuy
Candidate


.....
Asst.Prof.Wallada Chanruangvanich,
D.N.S.
Major advisor


.....
Assoc. Prof.Wimolrat Puwarawuttipanit
Ph.D. (Neuroscience)
Co-advisor

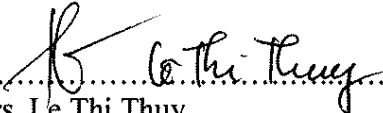

.....
Prof. Patcharee Lertrit,
M.D., Ph.D. (Biochemistry)
Dean
Faculty of Graduate Studies
Mahidol University

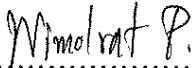

.....
Assoc. Prof.Doungrut Wattanakitkileart,
D.N.S.
Program Director
Master of Nursing Science
Program in Adult Nursing
Faculty of Nursing
Mahidol University

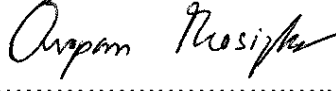
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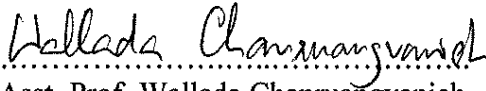
was submitted to the Faculty of Graduate Studies, Mahidol University
for the degree of Master of Nursing Science (Adult Nursing)

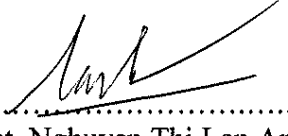
on
December 21, 2016



.....
Mrs. Le Thi Thuy
Candidate

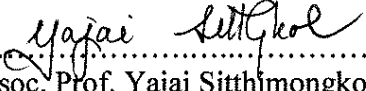

.....
Assoc. Prof. Wimolrat Puwarawuttipanit,
Ph.D. (Neuroscience)
Member


.....
Asst. Prof. Orapan Thosingha,
D.N.S.
Chair


.....
Asst. Prof. Wallada Chanruangvanich,
D.N.S.
Member


.....
Lect. Nguyen Thi Lan Anh,
Ph.D.
Member


.....
Prof. Patcharee Lertrit,
M.D., Ph.D. (Biochemistry)
Dean
Faculty of Graduate Studies
Mahidol University


.....
Assoc. Prof. Yajai Sitthimongkol,
Ph.D. (Nursing)
Dean
Faculty of Nursing
Mahidol University

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Le Thi Thuy

FACTORS RELATED TO QUALITY OF LIFE AMONG PATIENTS WITH INFLAMMATORY BOWEL DISEASE

LE THI THUY 5738766 NSAN/M

M.N.S. (ADULT NURSING)

THESIS ADVISORY COMMITTEE: WALLADA CHANRUANGVANICH, D.N.S., WIMOLRAT PUWARAWUTTIPANIT, Ph.D. (NEUROSCIENCE).

ABSTRACT

Incidences of inflammatory bowel diseases in general ASEAN was increasing in the past decade. IBDs have severe effects on the patients' health - related quality of life (HRQOL) by causing abdominal pain, diarrhea, bleeding anxiety and depression. However, the quality of life of Vietnamese patients with IBD is unknown. Therefore, this study aimed to explore the factors related to quality of life among patients with IBDs and Quality of Life Theory was used as a frame work of this study. As a descriptive correlation study, this research was conducted using 115 out-patients with IBDs in the Gastrointestinal Department of Bach Mai hospital in Hanoi, Vietnam. The study collected data using the demographic data, 36- Item Short Form Health Survey (SF-36) instrument, the Hopkins Symptom Checklist-25 (HSCL-25), the Crohn's and Colitis Knowledge Score (CCKNOW). Spearman's rho was employed to test the relationships among all variables. The results showed that patients with IBDs had low average mean of BMI (17.89 ± 2.02), poor knowledge about the disease (7.62 ± 5.03), moderate anxiety and depression (64.76 ± 10.03), and low quality of life (29.54 ± 13.91). Body mass index and knowledge about the disease had significantly positive correlation with the quality of life ($r = .345$, $r = .565$, $p < .01$). Moreover, anxiety and depression had significantly negative correlation with the quality of life among patients with IBD ($r = -.649$, $p < .01$). In conclusion, nurses should develop program to improve knowledge about disease and decrease anxiety and depression of the patients in order to promote quality of life. Further research is warranted for the developed program.

**KEY WORDS: INFLAMMATORY BOWEL DISEASE/ QUALITY OF LIFE/
ANXIETY AND DEPRESSION/ KNOWLEDGE**

114 pages

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LIST OF ABBREVIATION

| | |
|---------|--------------------------------|
| BMI | Body Mass Index |
| CCKNOW | Crohn's & Colitis Knowledge |
| CD | Crohn's Disease |
| HR_QOL | Health related quality of life |
| HSCL | Hopskin Check List |
| IBD | Inflammatory Bowel Disease |
| QOL | Quality of life |
| SD | Standard Deviation |
| SF – 36 | Short Form Health Survey - 36 |
| UC | Ulcerative Colitis |

CHAPTER I

INTRODUCTION

1.1 Background and Significance of the study

Inflammatory bowel diseases (IBD) are an unexplained type of disease arising from a deregulated immune response against host microflora found in the gastrointestinal tract. There are two significant forms of IBD which include ulcerative colitis (UC) found in the colon, as well as Crohn's disease (CD) which attacks any section of the gastrointestinal tract, involves "skip lesions", and is transmutable (Baumgart & Carding, 2007). Both of chronic diseases in the gastrointestinal system are repeatedly inflammatory with as yet undetermined pathogenesis. They are histologically unlike but have in common similar symptoms including diarrhea, rectal bleeding and abdominal pain. A genetic predisposition for IBD exists, and it is found that patients with this situation are more likely to emerge intestinal cancer. The highest incidence of both types of diseases are found in patients between 15 to 30 years in age.

IBDs are common chronic conditions in Western countries, rate of occurrence for UC and CD in Europe and the USA. The prevalence of IBD, including both CD and UC, is known to be high in some geographic areas, such as Northern Europe (Busch & Munkholm, 2014). There were 1.4 million American which was affected by IBD (Loftus, 2014). However, according to Jason and June (2015), it is becoming common for such diseases to expand around the world, as more people eat a low-fiber, high-fat Western diet (Jason & June, 2015). Moreover, there is a very clear-cut correlation between when Western civilization started using the antibiotics and the growing prevalence of a lot of these autoimmune diseases (Jason, 2015). In China, the occurrence of IBD found is lower than in Western countries, but has speeded up in the past decade (Jiang & Cui, 2002). The latest review from China announced 140,113 cases of UC and 3396 cases of CD in the previous 15 years, and a large increase in UC cases. The age-standardized proportion of UC in Japan in 2005 have been steadily increasing with time with 63.6 per 100,000 persons, and that of CD was 21.2 (Asakura

et al, 2009). In Vietnam, the UC and CD are serious issues in gastrointestinal diseases (Lingna, Qian, & Jianfeng, 2013). According to the Association of Digestive in Vietnam, there are about 20-25% of people with IBD by eating food which is not good for health and food with braided typhoid bacteria (bacillus dysentery, bacterial a- MIP) or by using too many antibiotics cause intestinal bacteria while 78% using antibiotics without prescription (Kinh, 2010). The statistics in the outpatient department of the internal digestive, Cho Ray Hospital, in 2014 shows that there are 5 % of IBD patients among patients with disease and men often are more severe disease than women (Cho Ray Hospital, 2014).

Many studies have explored the quality of life in IBD, which appears to be impaired (Graff, Walker, & Lix, 2006). IBDs are chronic inflammatory conditions that significantly reduce the quality of life of over 1.5 million Americans (Lovasz, 2013). The WHO states that the quality of life is “an individual’s perception of their position in life in the condition of the culture and value systems in which they live and relation to their goals, expectations, standards and concern” (Skevington & Lotfy, 2004). The goals of therapy are to reduce and prevent relapse, decrease the risk of complications, and improve the quality of one’s life to better reflect the subjective experience of health. The measurement of quality of life is especially appropriate in IBD, due to it being a chronic disease (Peyrin-Biroulet, Loftus, & Sandborn, 2010) which is usually expressed in young adults and therefore effects to all spheres of patients’ life, including physical, psychological and social. The relapsing cause of IBD and its early onset have major psychology, social and financial consequences (Ross, Strachan, Russel, & Wilson, 2011). Health related quality of life (HR_QOL) in IBD patients is lower compared with normal populations. The patients are suffered the fluctuating of periods of IBD with about the remission alternating and increased activity of disease. All symptoms (e.g., diarrhea, fecal incontinence, perianal symptoms, and especially abdominal pain) of this period can be particularly disruptive in their life. (Devlin & Daidone, 2014). HR_QOL studies can provide a knowledge about the effects of the IBD on patient’s ability and daily living, and the affect to their personal productivity.

HR_QOL theory is employed to use as a framework for this study. It covers concepts and variables within the study. HR_QOL is a broad, multidimensional concept applied to evaluate the effectiveness of health on physical, emotional, and social functioning (Van der Eijket et al, 2001). There are many studies in IBD patients, and prior studies have announced that the low QOL found among IBD patients, with disease activity, psychosocial factors, and some difference factors which represented some of its many potential predictors (Van der Have et al., 2014; Jaghult et al, 2011). Those studies base on components in HR_QOL theory including: symptoms, biological factors, functioning, health perception, and QOL.

The IBD patients are very vulnerable related to their chronic symptoms with anxiety and experienced other psychosocial difficulties. In addition, concomitant anxiety and depression were confirmed to affect HR_QOL (Moser, 2009). So, the high level of anxiety and depression subsequently lead to impaired QOL (Walker, Ediger, & Graff, 2008). Although, the life expectancy of IBD patients is similar to that of general population, IBD significantly worsens patients' HR_QOL (Haapamaki, 2011). Their status disease is chronicity and they will be associated hospitalizations, together with side effects of treatment and complications of disease, moreover someone need to the surgery process. Thus, the patients with severe IBD always experience a lower QOL relative than the patients with inactive disease. (Vidal, Gomez-Gil, & Sans, 2008). The poor QOL is not limited only during active periods, but the negative effects of IBD will persist even while it is not active. When they compared anxiety or depression and worsening in QOL among patients with IBD and the normal population. The results showed that healthy population had QOL that was significantly higher than IBD patients (Cuntz, Welt, Rupert, & Zillesse, 1999).

Moreover, nutritional status of IBD patients always is poor level. There are many studies shows that knowledge about nutrition is not only vital for the health care team treating IBD patients but for the patients themselves also, who have a large number of questions about how nutrition influences their quality of their lives and the disease progression (Prince, Whelan, Moosa, Lomer, & Reidlinger, 2011). There are undernourished about 20% - 85% of IBD patients, with the most common one being

low protein-energy (Lucendo & De-Rezende, 2009). Although CD is often related to malnutrition, however, CD shows the similar rates of malnutrition the same as UC patients (Nguyen, Munsell, & Harris, 2008). In addition, IBD patients with malnutrition are often associated with infection, mortality rates, the length of hospitalization, and financial costs (Ananthakrishnan & McGinley, 2013). However, there are some boundaries of BMI when used as an indicator for nutritional status (Valentini, et al., 2008). Although, there are lower BMI of CD patients than in UC patients in some studies (Teixeira, et al., 2011) and lower BMI was associated with poor health outcomes (Bryant et al, 2013) that also impact to their QOL (Kristina et al, 2006).

In addition, the knowledge about disease is important factors which help the patient with IBD can understand their disease to reduce the symptoms, prevent complications, particularly increase coping strategies and reduce anxiety (Wardle & Mayberry, 2014). Indeed, it seems that there are not noticeable enhancement in patients (Limdi & Soteriadou, 2014). In fact, poor knowledge and the lack of perception may decrease the patient's capability to participate actively in their disease control. In a tertiary care hospital, only 14% of UC patients were aware the endangering results from UC (Subasinghe, Wijekoon, Nawarathne, & Samarasekera, 2010). Although, a validated patient understanding of disease base on scores for IBD has been expanded the Crohn's and Colitis knowledge score (CCKNOW) but awareness of IBD in patients has not yet been evaluated in the patient population of the United States. The prior studies in the United Kingdom have proven that there are large gaps in patient's knowledge especially in medication selective and complications (Eaden, Abrams, & Mayberry, 1999). Beside, knowledge of IBD could impact adherence to medication or with coping skills of the patients, and thus influence HR_QOL. Furthermore, there are a few studies in the relationship between knowledge and HR_QOL. Due to this, the patients really need IBD knowledge (Wardle & Mayberry, 2014) and prove the impact of knowledge to QOL.

In conclusions, the IBD are the diseases which include the CD and UC. The symptoms of IBDs have influenced their activity. The optimal management of disease aims at achieving extenuate in IBD patients and it is essential to expect its

influence on their life. The numbers of patients who have IBDs are increasing in Vietnam. However, there is no research in Vietnam study the quality of life among patient with IBD. According to the literature review, the researcher is interested to study the relationship between BMI, anxiety & depression, illness knowledge, and quality of life (QOL) among patients with IBD in Vietnam.

1.2 Research questions

1. What is the quality of life of the patients with IBD?
2. Are anxiety & depression, BMI, knowledge about disease factors correlated with the quality of life among patients with IBD?

1.3 Purpose of the study

1. To study the level quality of life among patient with IBD
2. To study the relationship between anxiety & depression, BMI, knowledge about disease, and quality of life among patients with IBD.

1.4 Hypothesis

1. Anxiety & depression is negatively correlated with quality of life among patient with IBD
2. Knowledge about disease is positively correlated with quality of life among patient with IBD.
3. BMI is positively correlated with quality of life among patient with IBD.

1.5 Conceptual framework

Patients with IBD are suffered many symptoms which influence to activity daily living of them reduce satisfaction of them with life. The aim of this study is to examine the relationship between depression and anxiety, BMI, knowledge about disease and QOL among patients with IBD in Vietnam. There are several models explaining the relationship among health variables and QOL (Wilson, & Cleary, 1995). The conceptual models was proposed by Wilson and Cleary (2009) which is the most of conceptual famous which integrates biological, psychological and individual's characteristic aspects of health status. The Health Related Quality of Life Theory (HR_QOL) (Wilson & Cleary, 2009) is a middle-range theory. The HR_QOL is a part of Quality Of Life which represents satisfaction in areas of life that are likely to be affected by health status. HR_QOL is both subjectively multidimensional and temporal. QOL has been classified as a middle-range theory (Meleis, 1997) and it were known a philosophical and sociopolitical and phenomenon. This theory has easy to application to practice. In the context of health care, it can be constructed to concentrate on areas of life that are most affected by one's health.

This HR_QOL theory provides outcome variables which are symptom status, general health and individual's characteristic that affect the quality of life in a patient with IBD. Symptom status includes anxiety & depression; individual's characteristic includes knowledge about the disease and general health includes BMI of patients. Researcher studies the relationship between QOL and anxiety & depression, BMI, knowledge about the disease. The study was illustrated in the following conceptual framework.

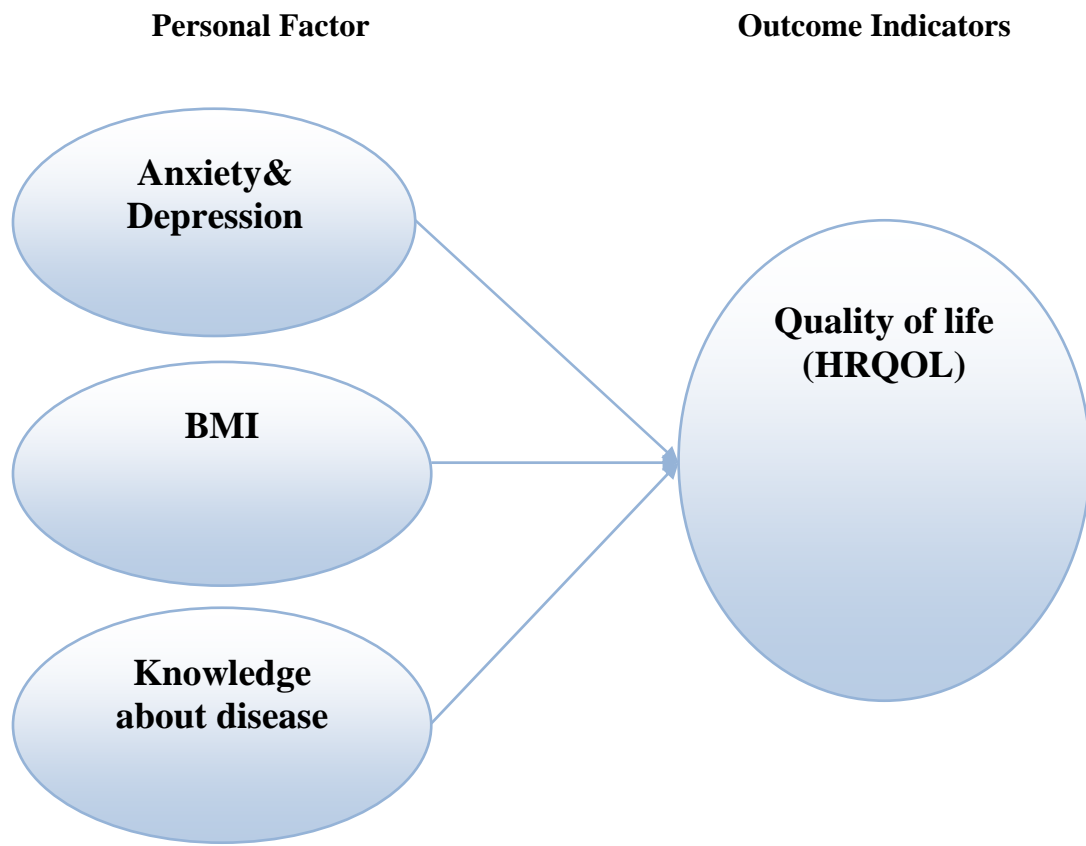


Figure 1.1 The research framework modified from Health Related Quality of Life Theory (Wilson, 2009).

1.6 Scope of the study

This study examines the relationship between anxiety & depression, BMI, knowledge about disease and QOL among 115 out-patients with IBD. The patients are 18 years old or over being treated as outpatients at the Gastrointestinal Department and Functional Examination Department of Bach Mai Hospital from August – October, 2016.

1.7 Expected outcomes and benefits

1. Patients can use this knowledge to improve quality of life for them.
2. Health care teams can use this knowledge to teach, evaluate quality of life and prevent relapse to the patients.
3. This knowledge can be used for the researchers in the other areas of inflammatory bowel disease studies.
4. This concept will apply into the curriculum for nursing students to improve role of nurses in taking care the patients.

1.8 Definition of terms

The following expressions will be used in this study and are described for clarity:

Health Related Quality of Life (HR_QOL): HR_QOL is a person's overall satisfaction with life, general sense of personal well being, and physical and psychological health (Casellas et al., 2001; Love, Irvine, & Fedorak, 1992). HR_QOL reflects a medical care focus beyond physical symptom improvement or management and specific HR_QOL dimensions include: tension, anxiety or worry, depression, adjustment, anger, helplessness, physical symptoms, and daily operating (for example: sleep patterns, energy, movability, social isolation, housework, occupation) (Kennedy et al., 2001). For this study, the researcher assessment health related quality of life using the Short Form Health Survey Instrument which was developed by Ware (1993). These instrumental assessment 8 sections of daily living which included 1) General health perceptions, 2) Physical functioning 3) Bodily pain 4) Vitality 5) Physical role functioning 6) Emotional role functioning 7) Social role functioning 8) Mental health. The score is from 36 to 149. The highest score of 149 indicates the best quality of life.

Anxiety & Depression: Anxiety is a sensation characterized by feelings of stress, concerned thoughts and physical changes like raised blood pressure. (American Psychiatric Association, 2000). Patients are able to have physical symptoms such as fatigue, fear, dizziness or a rapid heartbeat. Anxiety is characterized by a variety of symptoms including anxious thoughts, unidentified physical sensations and vulnerability about future events.

Depression indicated that depressed mood or lack of interest in most activities. Depression also includes other possible indicators such as (a) changes in weight, appetite, sleep patterns, psychomotor activity, and/or energy levels; (b) feelings of guilt or worthlessness; (c) difficulty making decisions or concentrating; and (d) recurrent plans, or attempts of suicide or obsessive thoughts about death, (American Psychiatric Association, 2000). One, whose primary problem is depression, instead of anxiety, doesn't generally show the same fear and insecurity that those with anxiety disorders do.

Anxiety & Depression were measured using the Hopkins Symptom Checklist-25 (HSCL-25). This scale was developed in 1950s by Parloff, Frank, and Kelman at Johns Hopkins University. The HSCL-25 is a symptom inventory which is used to measure symptoms of anxiety and depression. This scale consists of 25 items: Part I of the HSCL-25 included 10 items for measuring anxiety symptoms; Part II included 15 items for measuring depression symptoms. The scale for each question included four different categories of response rated 1 to 4 respectively: 1) not at all, 2) a little, 3) quite a bit, 4) extremely. Two domains are calculated: the total of all 25 items and the min score from 25 to max score 100 scores. The higher scores indicate more severe anxiety & depression.

BMI (Body Mass Index): BMI reflects nutritional status of the patients. BMI can be calculated by a person's weight (kilograms) divided by the square of height (meters). BMI can categorize between underweight, normal weight, overweight, and with obesity. BMI (kg/m^2) was divided into five categories which are based on the World Health Organization's classification in ASEAN (2013), BMI (kg/m^2): <18.5 (underweight), 18.5–22.9 (normal), 23.0–24.9 (overweight), 25.0–29.9 (obese class I) and ≥ 30.0 (obese class II+III).

Knowledge about inflammatory bowel diseases: knowledge is defined as facts, information, and skills acquired through experience or education; the theoretical or practical understanding of a subject. (Oxford Advanced Learner's Dictionary, 2009). In this study, knowledge is information about IBD which the patients were read and understand about their disease (Eaden, Abrams, & Mayberry, 1999). Knowledge about disease was evaluated by the Crohn's and Colitis Knowledge Score (CCKNOW) developed by Eaden Abrams and Mayberry (1999). This scale has 4 dimensions

include 1) General IBD knowledge, 2) IBD complication 3) Diet of IBD, 4) Medication or treatment IBD. There were 24 questions in this instrument each correct question have 1 score so total of this scale were 24 scores and higher scores mean the patient has more knowledge about disease.

CHAPTER II

LITERATURE REVIEW

This chapter provides a literature review of factors associated with quality of life among patients with inflammatory bowel disease. The contents enhance the understanding of phenomena of quality of life among patients with inflammatory bowel disease based on health related quality of life theory as following 4 issues including the conclusion part:

2.1 Problems among patients inflammatory bowel disease

2.1.1 Incidence of inflammatory bowel disease

2.1.2 Pathophysiology of inflammatory bowel disease

2.1.2.1 The difference of between Ulcerative colitis and Crohn's disease

2.1.2.2 Clinical aspects

2.1.2.3 Complications and manifestation in Ulcerative colitis and Crohn's disease

2.1.2.4 Treatment

2.1.3 Impact of inflammatory bowel disease

2.2 Integrate quality of life and health related quality of life theory among patients with inflammatory bowel disease

2.2.1 The concept of quality of life

2.2.2 Health related quality of life theory

2.2.3 Quality of life among patients with inflammatory bowel disease

2.2.4 Health relate quality of life theory and the patients with inflammatory bowel disease

2.2.5. Measuring QOL

2.3. Factors associated with quality of life among patients with inflammatory bowel disease

2.3.1 Anxiety/ depression and its relationship with quality of life among patients with inflammatory bowel disease

2.3.2 Body Mass Index level and its relationship with quality of life among patients with inflammatory bowel disease

2.3.3 Knowledge about disease and its relationship with quality of life among patients with inflammatory bowel disease

2.4. Conclusion

2.1 Problems among patients inflammatory bowel disease

2.1.1 Incidence of inflammatory bowel disease

IBD includes two major gastrointestinal disorders which are CD and UC, resulting from an integration of genetic, environmental exposure, and abnormal response to gut microbiota (Danes S, Fiocchi, 2006). The study of the cause of IBD is not well recognized. Both of diseases have an extreme impact on patient's life for all ages. It is of chronic nature and follows an unpredictable pattern with outreach and alleviations. However, patients of 25%–50% experience relapse yearly. (Ebbe, 2010)

Worldwide, the occurrence of UC and CD has increased over recent years. Although, there was a raised incidence, there still exist differences in UC and CD incidence and prevalence in different areas of the world. The highest common phenomenon of IBD is seen in the developed countries affecting approximately 0.5 per every 100,000 persons (Molodecky et al, 2014). Despite its low incidence in past, IBD has become more prevalent in Asia over the last twenty years (Nguyen, Tang, & Ching, et al, 2013) while America and Europe has experienced a leveling off, or even a decreasing rate of incidence (Molodecky et al, 2014). Today, IBD has become a global phenomenon. The incidence rate may range from 0.5 to 31.5 per every 100,000 persons annually, depending on the population that is studied (Burisch & Munkholm, 2013). For example, the prevalence varies between 5.3 to 63.6 per every 100,000 persons in Asian populations (Niriella et al., 2010) while in North America, it varies

between 37.5 to 238 per every 100,000 persons (Cosnes, Gower-Rousseau, Seksik & Cortot, 2011). There are a lot of factors can explain for the rising prevalence of IBD in Asia likely include changing environmental factors (including Westernization of lifestyle), industrialization of societies, changes in diet (which can be associated with changes in microbial exposure), improved sanitation, and, possibly, increasing use of antibiotics in childhood (Jason, Clatworthy, Robinson, & Horne, 2015). Moreover, evidence suggests the existence of an interaction between environmental and genetic factors in the etiology of IBD (Bruno, Andre, Raquel & Genoile, 2014). All of these lead to the increased incidence in several parts of the world in recent years, most notably in developing countries. The incidence of IBD, including UC and CD, has increased rapidly in Asian countries over the last twenty years (Nguyen, Tang, & Ching, 2014).

In Asia, the epidemiological data is one of the most important factors for examining the etiology of IBD. The rate of incidence differs widely with many countries in East Asia experiencing more than a double increase in the prevalence of IBD than in the past (Intes Res, 2016). More details, from the report of Japanese Ministry of Health (2014), the prevalence of CD and UC has increased significantly to 30.1 and 121.9 per 100,000 persons respectively. The study of Kim and colleagues (2012) showed the latest incidence for UC and CD were 4.2 and 3.1, respectively, per every 100,000 persons. Hong Kong's health care system reported the incidence of IBD patients has increased from 0.1 per 100,000 persons in 1985 to more than 3 per 100,000 persons in 2014. Additionally, some countries like Singapore, India, and other Asian countries are closely related with urbanization factor. There are great geographic differences in the incidence of CD and UC among countries in Asia (Nguyen, Tang, & Ching, 2013) and inside a country even different areas (Yang, Li & Wu, 2014).

Additionally, the information on IBD has not been common in Asia, and effective diagnosis and appropriate treatment is something that many IBD patients still do not receive. Such as, the prevalence of UC in Japan has risen from 7.85/ 100,000 to 63.6/ 100,000 persons across 3 different studies between 1984 and 2005. In Korea, there has also been a substantial increase in the prevalence of UC—from 7.6/ 100,000 persons in 1997 to 30.9/ 100,000 persons in 2005. In studies from Singapore, the

prevalence of UC has increased from 6/ 100,000 to 8.6/ 100,000 persons and the prevalence of CD has increased from 1.3/ 100,000 persons to 7.2/ 100,000 persons (Stephen & Hanauer, 2013).

These data implicated the power of environmental on disease occurrence. Some studies in Asia have found the association between IBD and diet, hygiene, and childhood immunological factors that all of which are the results of Western civilization (Kanai, Matsuoka Naganuma, Hayashi, & Hisamatsu, 2014). The changes of the gastrointestinal micro biota were linked with the environmental factor from the study in Asia. (Prideaux, Kang, & Wagner, 2013). The foundational characteristics of the pathogenesis of IBD related to the immune response with antigenic stimulation from the intestinal micro biota being less important than environmental influence, along with genetic susceptibility. Because of fewer IBD-susceptible genes, the low prevalence of IBD in the Asian population could become higher in comparison to Westerners. In the Western population, IBD-susceptible genes associated with CD like NOD2, interleukin (IL)-23R, and ATG16L1 showed no positive correlation with CD in Korean, Japanese, and Chinese Han patients, except for the fact that IL-23R had a slight association in Korean CD patients (Cheon, 2013). In contrast, single nucleotide polymorphisms (rs3810936, rs6478108, and rs7848647) on TNFSF15 were identified to act similar associated with CD patients who were Asian than with CD patients who were Caucasian (Cheon, 2013).

In Vietnam, the IBD seriously issue in gastrointestinal diseases (Lingna, 2013). There are about 20-25% of people with this disease caused by inflammatory bowel disease by eating food which are not good for health and food with braided typhoid bacteria (bacillus dysentery , bacterial a- MIP) (Report of the Association of Digestive in Vietnam, 2014) or by using too many antibiotics cause intestinal bacteria: 78% using antibiotics without prescription (Kinh, 2010). The statistics in the outpatient department of internal digestive, (Cho Ray Hospital, 2014) shows that there are 5 % of IBD patients in the department and men often are more severe disease than women.

2.1.2 Pathophysiology of inflammatory bowel disease

There is difference in lifestyle between countries of the southern and northern hemisphere, so there is distinct prevalence about the patient who has IBD. Although there is not a final conclusion about the role of nutrition in IBD, the using of carbohydrate and the intake of polyunsaturated fats or oleomarginine have been related. It can be explained in study's Jason (2015) that extreme sanitation could limit denouncement to environment antigens and damage the maturation of the muscosal immune system. These antigens could lead to unsuitable immune response in the future. Moreover, chronic depression, anxiety and stress may appear in patients with inactive disease. In spite of the fact that IBD is further common after the patient has gastrointestinal infection but there is no specific pathogens has so far been determined. All these confirm that the intestinal immune system of microbial antigens which deteriorated is the fundamental problem of IBD

Normally, the epithelial barrier in the intestine consisting of polarised single layers covered with mucus containing secretions of IgA and glycocalyx. a transcellular route is the path that fluxes came through the intestinal epithelium. A group of toll-like receptors controls immune regulation and antigen recognition. The stimulation of antimicrobial responses by those receptors will activate the nuclear transcription factors and induce of the Inflammatory Cytokine Cascade. This could be the reason of the increased risk of IBD when patients use Non-Steroidal Anti-Inflammatory Drugs (NSAID), but not aspirin, for a long time (Casellas, Rodrigo, Nino, Pantiga, Riestra, & Malagelada, 2007). The lamina propria which is mucosa in the gut contains lymphoid tissues which are B cells, T cells, granulocytes, mast cells, natural killer cells and natural killer T-cells. The epithelial barrier is the route for antigens and microbes to the lymphoid cells which will then encounter dendrite cells and macrophages. The whole range of toll-like receptors is the key for dendrite cells to differentiate the response between pathogens and normal intestinal cells. The improper response of common intestinal flora comes form the mucosal immune system imperfection in IBD

Based on experimental and clinical evidence, the inflammatory process is explained by the following mechanisms (Achleitner Ulrike, 2012):

(1) The clinical expression IBD usually happened after T-cell is a mediation which broke the tight junction of protein and made dysfunction of the gut neuron. This led to increase the intestine permeability. Moreover, there is a relation with a CARDIS15 3020insC mutation.

(2) There is different expression of toll as receptors in IBD patients. Patients with CD have TLR 3 is meaningfully down regulated but TLR4 is unregulated in both CD and UC.

(3) Because of the dendritic cells, there is a disruption of antigen recognition. A proinflammatory immune reaction was wrongly stimulated because those cell cannot differentiate the normal intestinal bacteria, it usually targeted to pathogens.

(4) IBD patients have irregular antigen-presenting cells which may transform potent T-cell activators. There are evidences showed the gut-epithelial cells might become functional antigen-presenting cells in patients with IBD.

(5) The inflammatory process of CD patients is developed by the removal of over-reactive T-cell population.

(6) The perpetuate inflammation occurred in CD patients is disorder the balance of regulatory and acts in response to a stimulus of cells.

(7) Whereas the colonic paracellular permeability can increased by the activation of the sympathetic system in UC because of the vagus has an important inhibitory effect and reduce of the systemic inflammatory action. The stability of the autonomic nervous system will be transformed by the psychosocial stress in IBD patients led to reactive the inflammatory cascade.

All these mechanisms have led to the migration of inflammatory cells from the capillaries to the gut mucosa. IL 1, TNF alpha are proinflammatory cytokines which make rising alignment of the appearance of adhesion particle ligands on the vascular endothelium lining the mucosal blood vessels. This process promoted leukocyte adhesion and extravasation into the tissue (Coteur, Feagan, Keininger, & Kosinski, 2009), (Cross, Wilson, & Binion, 2005). By this way, the tissue that got injury contains many positive metabolites and conciliators assemble in the mucosa

resulting in. Moreover, a huge amount of mediators stimulate the rise of fibroblast, collagen excretion and restriction the arrangement. The specific approach can finish or protect the initiation and continuing of the inflammatory cascade. the common result of UC is inflammation of mucosal of the gut tract which cause ulceration, fluid and electrolytes loss, edema, and bleeding (Thoreson & Cullen, 2007).. Some studies showed that genetic factors can affect the risk of IBD. There are several studies showed that a disorder of epithelial border integrity and shortage in autophagy influenced genetic factors which is one of factors influenced the risk of IBD (Rioux et al., 2007). It also caused deficiencies in innate form recognition receptors, and issues with lymphocyte differentiation, special in Crohn disease (Tsianos, Katsanos, & Tsianos, 2012).

A chronic inflammatory process is caused by the immune reaction disorder the intestinal (Lashner, 2009)

2.1.2.1 The difference of between Ulcerative colitis and Crohn's disease

a. Ulcerative colitis

Ulcerative colitis is located in the colon. It is usually beginning from the rectum. The process inflammation of UC occurs in all layers of the gut wall and running stretch within the colon.

b. Crohn disease

Crohn's disease can influence on any part of the GI tract which including the mouth, esophagus, stomach, small and large intestines, rectum and anus. This disease has the inflammation process happening in all layers of the gut wall and that inflammation might disperse via the gastrointestinal tract.

2.1.2.2 Clinical aspects

Both CD and UC have the symptom quite similarly including: abdominal pain, diarrhea, vomiting, nausea, weight loss, loss of appetite, fatigue, and fever. However, there are some differences in symptoms in these diseases.

a. Ulcerative colitis

People living with UC suffered bleeding from the rectum are much more common. UC patients usually have discontinuous pain concurrently with bowel movements.

b. Crohn's disease

The patients with CD rectal bleeding is less common but they suffered continuous abdominal pain. Besides, they also have perianal troubles such as anal sores, fistulas, and skin tags.

2.1.2.3 Complications and manifestations in Crohn's disease and ulcerative colitis.

The IBD complications are generally classified according to the areas included intestinal complications and extraintestinal complications. Many complications related with IBD can occur with UC or CD patients however, some patients are specific for each condition (Navaneethan & Shen, 2010).

Intestinal Complications:

Strictures (Atreja et al, 2013)

Fistulae and Abscesses more common in CD than UC (Andres, & Friedman 1999)

Perforation and Toxic Megacolon

Infectious Colitis

Malignancy

Extraintestinal Complications:

Arthritides (Salvarani, & Fries, 2009)

Ophthalmologic Complications (Manganelli, Turco, & Balestrazzi, 2009)

Dermatologic Complications

Urinary Complications

Other Complications

Aphthous ulcers

Pericholangitis and primary sclerosing cholangitis (Navaneethan, & Shen 2010)

Cholelithiasis (Danese et al, 2005)

Anemia

Hypercoagulable state (Singh et al, 2013)

Osteoporosis (van Staa, Leufkens, & Cooper, 2002)

Moreover, there is an associated between IBD and a higher risk of developing cancer, major of the colon. The risen of colorectal cancer chance could rely on the severity of disease, the level of inflammation, duration of the disease, and the onset of IBD, beside the family history have bowel cancer (Van Assche, et al, 2013)

The patients with IBD have the risk of colorectal cancer when they are at 20, 30 and 40 years after the onset of illness may be as much 3, 8 and 11% respectively (Rutter, 2006)

2.1.2.4. Treatment

There is no specific treatment for IBD. The goal of IBD treatment are maintaining remission and mainstay of medical management for inducing by using aminosalicylates (5ASAs), corticosteroids, exclusive enteral nutrition and immunomodulating drugs. Although, they alter the natural course of this disease remains is not clear but it helps to prevent the symptomatic effects (Cosnes et al, 2005). However, there are thirty percent of patients will fail to these medications or intolerances; instead, they may be using biological therapies or surgery.

There are at least a half of CD patients will undergo surgery within ten years after having diagnosis, more than 70% patients need to surgery at rest of their life (Mowat et al. 2011). Whereas the number of patients with UC may require surgery are about 20-30%. There are 50% patients who have chronic relapsing need a colectomy. These rates depend on countries and regions (Goldacre et al, 2007). In CD patients, the extraction of the diseased bowel part which is the common surgical method could make patient permanent loss of a stoma. Patients with UC need to surgery by removing of the whole colon. The patients have a stoma in the short term. Although the ileal pouch anal anastomosis (IPAA) is commonly considered the standard sugery to treatment for UC patients (Fazio, 2013). This method surgery improved the functional outcomes and quality of life for patients, however complications is still existed.

2.1.3 Impact of inflammatory bowel disease

The QOL of IBD on patients is considered to be the ductive treatment, the patients have to not only have to cope with their disease but also its impact on their mental health, families and jobs. There are very many difficulties for the patient with IBD in their life. The biggest impact of IBD shown by surveys is persistent illness, psychological pressure, and interruption of daily life. Patients with UC more clearly showed this than patients with migraine, asthma, or rheumatoid arthritis. It has been shown that many doctors tended to underestimate the effect that the disease had on the patient QOL. (Baker & Dudley-Brown, 2012)

Physical impact

IBD impacts patients by change their life with some foods they do not allow to eat. Their immune will be decrease, they can get diarrhea, lost of blood. Either pathogenic enteric or commensal microorganisms alongside increased mucosal adherence and with persistent activation, or invasion of T cells can cause inflammation. A genetic cause is found in the incidence and development of ulcerative colitis in studies carried out on identical twins. Most significant are the associated humoral and cellular immunological factors.

Psychological impact:

Ulcerative colitis and Crohn's disease are both chronic inflammatory diseases (IBD) which affect colonic mucosa and are characterized by exacerbations and remissions. There are common symptoms include recurrent episodes of abdominal pain, diarrhea, rectal bleeding, and fatigue. Thus, a patients quality of life can be seriously affected by ulcerative colitis. is used to measure The effect of a chronic illness and its therapy on the functional daily life of a patient , from the patients' own perspective, can be measured by using Health-Related Quality of Life (Irvine, et al, 2007), (Kalliopi, 2013). It is also used to measure care quality standards from the patient's point of view and is a vital outcome measure in ulcerative colitis patients clinical trials. (D'Haens, 2007).

In the last century, influences of IBD (UC and CD) to the patient's psychology were known. In the 1930s, it was proposed that a correlation exists

between emotional experiences and the exacerbation of gastrointestinal symptoms (Keefer, Keshavarzian, & Mutlu, 2008).

At that time, IBD was thought to be, and its association with was thought to be so strong that. During this time, it was believed that stress and psychological factors were thought to be the main causative factors associated with IBD and that it was, in fact, a psychosomatic disease. This belief was so strong that the researchers did not feel the need to use any control group while carrying out their research.

Economic impact:

There are many intermittent relapses and remissions with UC and CD disease so the patients need a lot of medicine to reduce symptoms which they take a lot of money and time to treatment. So, IBD has an increasingly deleterious effect on global financial resources and healthcare in both developed and developing countries. All patients who live in anywhere in the world always have been anxiety about the already strained health care now they have been another difficult is money. In Europe, currently approximately 2.5 million people suffer from IBD (Molodecky et al, 2012). A serious situation for IBD is found In North America too, as reported by the CDC of the USA (2011) that IBD is one of the five most prevalent gastrointestinal disease burdens with a cost of more than \$1.7 billion. There are no medical cure and commonly required a lifetime of care with more than 700,000 physician visits, 100,000 hospitalizations, and disability in 119,000 patients per year. Moreover, the patients with Crohn's disease and ulcerative colitis needed for surgery up to 75% and 25%, respectively. All of this places a very significant burden on financial systems.

In Vietnam, there are many people in a family so one of them with IBD must change the types of food and the meals in their family because it is difficult for patients with IBD to eat a regular food. Accordingly, the patients with IBD for a long time, some diagnosis of the IBD can influence their life. Specially, the patients who are the major source of family income. While a cure remains still unknown, IBD can be treated with medications that induce and maintain remission. People with long-term illnesses living at home and they often go to hospital to reexamine to take drugs from doctors. A lot of moving to hospital they are tired. Additional, there are a lot of

people in hospital so they take a lot of time to meet the doctor which is one of reasons workload hospital.

According digestive internal medicine Cho Ray Hospital, Ho Chi Minh City (2014), there are 70 percent of patients which have effectiveness of medical treatment. However, 50 percent of patients relapse after two years and 25 percent required surgery due to perforation of the colon, the colon aneurysm poisoning, serious bleeding or cancer does not respond to treatment. (Nguyen, 2013).

Moreover, there are many symptoms which influence lifestyle. Thus, the patients with IBD need to control the symptoms and avoid the IBD by changing their knowledge and practice about IBD.

2.2 Quality of life among patients with inflammatory bowel disease

2.2.1 The concept of quality of life

Greek Theorists showed that an individual's personal satisfaction with their life and QOL is a related one. Aristotle, from who the initial notion of QOL came from, defined happiness as reaping the fruits resulting from the leading of a virtuous life (Morgan, 1992). However, there is another understanding about the quality of life that appeared in the early 1950s. USA based researchers defined that quality of life meant 'a good life' in its consumer sense only i.e. denoted material status, and possession of goods and property such as a house, its furnishings, a car, etc. Thus, the concept quality of life is difficult issues which can exactly definition. The researcher Zalewska shows that the multi-dimensional character of human life and the uniqueness of each individual make defining 'quality of life' extremely difficult. As a result, each scientific discipline dealing with these issues introduces its own approaches, criteria and ways of measurement (Zalewska, 2003).

In its definition of health (1978), WHO indicated that everyone is entitled “to psychosocial care and adequate QOL in addition to physiological care” (Peterson, 2013) This made QOL become more widely focused on by professionals in health care. Since quality of Life reflects emotional and social well being and functional status, as well as indicating general health it is thus a many-sided concept. Additionally, there is a popular model of QOL is provided by Wilson and Cleary which conceptually links different six variables: physiological factors, functional health, disease symptoms, general health perceptions, and QOL (Wilson & Cleary, 1995).

Discussion of QOL and well-being is currently the focus within current health-care academic literature focusing on physical and mental health disabilities. Many QOL forms found in the literature were psychological in nature. A large body of research exists about the relationship between QOL and well-being. QOL is a common research area to both sociologists and psychologists as economic theories also take QOL into consideration, particularly in studies on happiness. A PubMed search for study with QOL in the title retrieved only 0 to 1 articles/year in the 1960s but this number has grown to almost 44.027 references in nearly a year from January 1 2014 to October 31 2015 (search performed on October 31st, 2015). Most of the research considers the effects of intervention in the QOL by medical means, or studied the patient’s own sense of well-being.

2.2.2 Health related quality of life theory

HRQOL theory is a middle range theory. HRQOL is subjective, multidimensional, and temporal. There are some conditions in middle range theory: 1) Narrow in scope 2) Concerned with less abstract. 3) Composed of fewer concepts and relationship among each concept. 4) Shows the reality of nursing impractically 5) Used for empirical testing more suitably. 6) Used for the guiding of practice more suitably (Peterson, 2013). Through being HRQOL is especially suited to nursing practice because it is an interdisciplinary-middle-range theory which assesses variables in a holistic approach to an individual’s actual or potential sickness. This is an important approach which is one of the foundations traditionally used in nursing care. Moreover, middle range theory models of the HRQOL, comprise three sections: Life domains, interventions, and perceived satisfactions.

Wilson and Cleary categorize the patients' outcome using a conceptual working model of HRQOL which is in accordance with underlying health status. Certain causal relationships between these health concepts are given. This model organizes the measurement of health against an increasing complexity of social, biological, and psychological factors. This model moves from descriptions of health status to models of health status where it is easier to see the causal relationships among the different components of HRQOL. Additionally, HRQOL improvement can be targeted and not just monitored in clinical trials. For simplicity, the model of Wilson and Cleary represents data as a linear progression, without any linkage or reciprocal impacts between nonadjacent concepts. There are 5 components in this theory including both physiological and biological variables, functional status, symptom status, general health perception and overall quality of life. An individual's characteristics and the environment will reciprocally influenced these components.

This theory has significance with nursing because of the long-standing interest of nursing in QOL. The famous nurse, Florence Nightingale, practiced this theory when she took care for the wounded in the British military. She showed how nurses can use methods to increase a patient's QOL. Since then, QOL has become an important field of research in nursing in order to improve the role of nurses to enhance patients' quality of life. The components the model theory is based on are influenced by both individual traits and environmental factors on a "continuum of increasing biological, social, and psychological complexity" (Wilson & Cleary, 1995). The hypothetical interdimensional links are shown by the arrows depicted in the model (Figure 2). In this model, cells, organs, and organ systems form the assessment of physiological variables unlike the evaluation of symptom status assesses the whole body (Wilson, Cleary, 1995). Functional health has been described in this model as the an individual's ability to respond to the environment, measured both objectively and subjectively during a certain time period.

Perceptions of general health represent a combination of all the previous health concepts and are a discrepancy between a person's present experience and their future aspirations. In this model, general health (HRQOL) is a determinant of overall QOL or subject well-being.

The model comprises five factors which are described on a “continuum of increasing biological, social, and psychological complexity”. These determinants of QOL are taxonomical in nature. They include biological factors, functioning, symptoms, general health perception and QOL overall. These are also influenced by individual traits and characteristics of the environment reciprocally.

Wilson & Cleary clearly detailed the model of HRQOL to give a its users a good understanding of its concepts and components. This theory focuses on the patients and discusses the role of their choices and the influence of psychological or emotional factors that are involved in HRQOL.

Health-related quality of life (HRQOL) is the most common index used to evaluation individuals’ well-being in relation to their health. HRQOL were defined by Shumaker and Naughton that “the subjective evaluation of how health status, health care and health promotion influence an individual’s capability to sustain a performance level to carry on their most important daily activities and that impact his/her general well-being”. This definition is based on the individual’s perception of their own health status and it is also a subjective and multidimensional concept (Bullinger, et al, 1993). In chronic cases, quality of life measurement offers additional information for making decisions in clinical practice and it is useful to detect situations which may go unseen with the traditional methods, thus allowing improving care and self-care or proposing alternative strategies so as to enhance knowledge about disease (Rajmil et al., 2012). So, this HRQOL Theory can provide frame work, concepts and many variables to measure quality of life of patient in this study.

2.2.3 Quality of life and health relate quality of life theory and the patients with inflammatory bowel disease

A life expectancy similar to normal is experienced by inflammatory bowel disease patients (IBD) (Ekbohm, Helmick, Zack, Holmberg, & Adami, 1992); however, Major psychological, social and financial consequences can occur due to the occurrence of relapses and the early onset of disease (Ross, Strachan, Russell, & Wilson, 2011). There is variation found in the clinical manifestation of inflammatory bowel disease which largely depends on the disease’s activeness and type. Evaluations of QOL in IBD make not only comparisons with healthy peoples’ quality of life, but

also in the relationships between QOL and other factors related to disease, with disease activity and duration, the patient's gender and age, and strategies for treatment, being studied. Love et al (2012) reported a decrease in the quality of life in inflammatory bowel disease outpatients compared with a healthy control group of matched age and gender. Ultimately, the level of QOL depends on the effective satisfaction of one's needs. According to the concept of QOL, it includes understanding physical, psychological and social well-being. All of that affects the quality of life of persons with IBD.

Health-Related Quality of Life (HRQoL) is important in the evaluation, management and follow up of patients and which is a quantitative measure of subjective perception of the state of emotional and social health (Mouzas, Pallis, 2000). Many researchers have found impairments in the HRQOL when used in IBD, (Graff, Walker, & Lix, 2006). In comparison with patients who are in remission, patients with active disease are seen to have significantly impaired HRQoL (Zhou, Ren, Irvin, & Yang, 2010) (Romberg-Camps, Bol, & Dagnelie, et al, 2010) (Mnif, Mzid, Amouri, Chtourou, & Tahri, 2010). Moreover, HRQoL seems to be affected by depression and concomitant anxiety (Moser, 2009). (Jaghult, Saboonchi, Johansson, Wredling, & Kapraali, 2011) found lower HRQoL scores in patients with short duration of disease compared to patients with longer durations. This finding, however, was not supported by others. (Mnif, Mzid, Amouri, Chtourou, & Tahri, 2010) found a lower HR-QOL in patients with IBD when compared with normal populations. Scandinavian studies show a significantly worse QOL for patients with ulcerative colitis, as measured by SF-36, than when compared to the population in general (Bernklev, Jahnsen, & Lygren, 2005b). Some other research findings also conflict on how the different kinds of IBD treatment effects HRQOL. It has been reported for instance that a negative effect can be caused by immunosuppressives (Hoivik, Moum & Solberg, et al. 2012), though their findings couldn't be supported by other subsequent studies (Romberg-Camps, Bol, & Dagnelie, 2010).

Health-related quality of life (HR-QOL) measures the functional impact on the daily life of a patient that a chronic illness has, as seen from the patient's point of view (Irvine, 2007). The surveys showed that UC and CD is significantly associated with frequent manifestation of disease, psychological stress, and an upheaval to daily

life. Moreover, non-adherence to prescribed medication in UC patients was seen by both patients and physicians to be an important problem. The problems of non-adherence and poor health-related quality of life found in UC patients need to be addressed by both an improvement in education and communication. Advanced Practice Registered Nurses may also use their influence to guide other health care workers and patients in order to improve adherence to medication and long-term disease outcomes, both of which are related to the patients health and quality of life. The nurse through working with both IBD patients and physicians is in a optimal position to play an important role in improving QOL.

In conclusion, this study is to investigate the role of demographic, knowledge of disease, anxiety and depress on HRQOL of IBD patients with Crohn's disease (CD) or ulcerative colitis (UC) in a Vietnamese reference center for IBD patients.

2.2.4. Measuring QOL

The aim of any health care system is, through maintaining a good health status, to bolster the quality of life. Quality of life (QOL) is a subjective concept that incorporates functional status, emotional and general health as well as social wellbeing. The patients' own perception of their state of wellbeing is measured. Nowadays, QOL has become a clinically relevant outcome parameter used in the evaluation of a patients' condition or in the measurement of new strategies of treatment effectiveness (Ruo et al, 2003). Since QOL is a major factor, the measurement of it ought to be integrated into a single intervention goal in cases where complete recovery from disease is not always achievable, such as in chronic disease.

Researching about QOL has rapidly grown over the past three decades, and is now actively supported worldwide to record and compare changes in QOL in communities of all sizes up to the national scale. Major studies of QOL have been conducted by UNESCO, OECD and WHO, (Delhey, & Jan et al, 2002). Many other researchers have also shown a growing interest in the evaluation of HR-QOL (Jenkinson, 1994), especially concerning incurable chronic conditions. Therefore, one of the most important aims of therapeutic intervention should be to increase patients' QOL. In order to evaluate the outcomes of such interventions, this guideline should be

the one that is used. An accurate health status assessment, at either individual level or at population level can be gained, in order to consider the outcomes of care more effectively. Some activity indexes used in chronic IBD do not match patients' perception of their own status particularly well (Buxton, Lacey & Feagan, 2007). Furthermore, author Drossman showed that (Drossman, Patrick, Mitchell, et al, 1989) QOL indexes related more significantly with reduced reliance on health care and general well-being than with clinical evaluation.

The SF-36 instrument was used to assess HR_QOL which is a widely used self-report questionnaire in patients with disease (RAND Corporation, 2005). It is a valid and reliable scale with Cronbach's alpha level of 0.9 and high readability (Mc Horney et al., 1994; Ware et al., 1995). The scale has 8 scores which are the sums of the questions from each part with scores ranging from 0 to 100 (Lower scores mean more disability, higher scores mean less disability). There are 8 Sections: vitality, physical function, bodily pain, general health perceptions, physical role function, emotional role function, social role functioning and mental health. Each SF-36 item response is given a score and summed up using a protocol for scoring which is standardized (Ware et al 1995) scoring the eight concepts of health on a 0 to 100 scale. Better self perception of health is represented by higher scores. Five of the scales; Physical Functioning, Role Physical, Bodily Pain, Social Functioning, and Role Emotional are classified as being 'unipolar' in that they call the absence of disability as being the definition of health status. In the absence of disability, the maximum score of 100 will be achieved. The SF-36 will be piloted to assess HR_QOL of 30 patients with IBD at Gastrointestinal Department in Bach Mai Hospital.

2.3 Factors associated with quality of life among patients with inflammatory bowel disease

2.3.1 Anxiety & depression and its relationship with quality of life among patients with inflammatory bowel disease

Both anxiety and depression are symptoms commonly found in IBD patients. Feelings of unease, excessive worry, and fear that patients may be unable to control and are common to the condition of anxiety disorder and can vary in severity and duration (World Health Organization, 2014). Since IBD is a chronic disease, when compared to the general population, patients will be expected to have suffer from higher rates of anxiety (Scott, Bruffaerts, & Tsang, 2007). People with chronic illness frequently develop problems with depression and anxiety due to the pain, physical changes, loss of personal control, and uncertainty about the future (Roberts et al., 2002). Some researchers have clearly shown that both depression and anxiety are common problems for people diagnosis with IBD (Freitas, et al, 2015; Magalhães et al, 2014).

In the case of CD patients, anxiety and depression disorder occurs statistically more frequently than expected. (Scott, Bruffaerts, & Tsang, 2007) Higher rates of anxiety disorder were also found in UC patients than in either groups of patients with other kinds of chronic illnesses or in the general population (Addolorato et al, 1997). In addition, the most effective ways to measure HRQOL is through symptoms of anxiety and depression among patients with IBD (Freitas et al, 2015).

The researchers indicate that there are significance correlations between QOL among patient with IBD and depression and anxiety with proportion: depression symptoms ($r = -.56, p < .05$), anxiety symptoms ($r = -.50, p < .05$) (Faust, Halpern, Danoff-Burg, & Cross, 2012). A significant difference was found between HRQOL groups in the prevalence of anxiety and depression (anxiety, 48.1% vs. 16.3%; depression, 49.4% vs. 25.2%, $p < 0.01$) (Kim, 2013).

Psychological comorbidities are often associated with IBD causes due to serious disabling physical symptoms. IBD patients often suffer from adverse psychological effects resulting from IBD and IBD medications. Anxiety, in particular,

can adversely affect both their ability to work as well as negatively affect their family life and thus have a dramatic impact on a person's overall quality of life. Over 40% of patients with IBD showed higher than normal anxiety levels (Ayman, Bannaga, Christian, & Selinger, 2015). Anxiety symptoms are usually related to the burst of IBD and can reduce to an extended remission. If anxiety disorder is not accurately diagnosed in IBD patients, it can be difficult to improve their quality of life. So, symptoms associated with functional gastrointestinal disorders can also be found in patients with anxiety.

2.3.2 Body Mass Index level and its relationship with quality of life among patients with inflammatory bowel disease

A medical condition commonly found in chronic gastrointestinal disease patients which affects both their morbidity and mortality is malnutrition. Nutrient intake in IBD patients is affected by many factors. Malnutrition may be caused by decreased food intake to poor nutrient absorption, medications or intestinal losses. The body mass index (BMI) can be used to assess nutritional risk. According to the theory, a lower BMI means the patient has more metabolically active tissue and less adipose tissue, and is therefore leaner. Regular muscular function also helps to decrease the degree of impairment to nutritional status (Norman, 2005) and, thereby, lead to improved functional status. The nutritional status in patients with IBD is of paramount clinical importance. It is well established that nutritional deficits are closely related with the degree of activity, location, and with the extent of disease duration (John, Triantafillidis, & Apostolos, 2015). When compared with other patients, IBD patients were found to have lower BMIs. Moreover, IBD patients also had lower quality of life values than patients with liver cirrhosis in terms of quality of life. There were low in the general health, mental health and social functioning but more bodily pain (Kristina, Henriette, Herber, & Matthias, 2006).

It is clear that more than just disease severity or nutritional status can determine a subjective perception of quality of life. The research shows that in benign gastrointestinal disease cases, QOL can be impaired and that malnutrition can be a contributing factor also (Kristina, Henriette, Herber, & Matthias, 2006). So that, improving the status nutritional is the first step for successful in enhancing QOL in

these patients. To measurement BMI [weight (kg)/height (m²)], at baseline, participants were asked to report their current height and body weight, which were used in the calculation of body mass index (BMI) at baseline. We grouped subjects according to five BMI categories: (kg/m²) was divided into five categories based on the World Health Organization's classification in ASEAN (2013), BMI (kg/m²): <18.5 (thin), 18.5–22.9 (normal), 23.0–24.9 (overweight), 25.0–29.9 (obese class I) and ≥30.0 (obese class II+III).

2.3.3 Knowledge about disease and its relationship with quality of life among patients with inflammatory bowel disease

In spite of many advances in pharmacology and surgical technique, most patients' understanding and knowledge of their disease is still lacking (Wolfen & Sirois, 2008). The level of knowledge of IBD and QOL are strongly interrelated, and a lower level of disease-related knowledge leads to more severe decline of the QOL (Moskovitz, Maunder, Cohen, McLeod, & MacRae, 2000). No significant improvements in IBD patients' understanding of their disease have been seen to have occurred (Limdi & Soteriadou 2014). Insufficient knowledge and understanding about IBD will impair a patient's ability to manage and cope with their condition by themselves. For example, a study carried out at a tertiary care hospital found that only 14% of ulcerative colitis (UC) patients had any awareness that UC was associated with an increased risk of colorectal cancer (CRC) (Subasinghe, Wijekoon, Nawarathne, & Samarasekera, 2010). Additional, there is some supports that the higher the level of disease-related information, the better the HRQOL in IBD (Husain & Triadafilopoulos, 2004; Van der Eijk I, Vlachonikolis IG, Munkholm P, et al., 2004). Thus, IBD patients need to have a clear knowledge of their symptoms and management for optimal recovery (Eaden, Abrams, & Mayberry, 1999).

The Crohn's and colitis knowledge score (CCKNOW), a well-proven knowledge score for IBD patients, can be used to assess IBD patients' knowledge. Although it has not yet been widely studied in relationship to HRQOL, some studies in the UK have shown that, particularly in respect to medication and in IBD-related complications, there are large gaps in patients' disease-related knowledge (Eaden, Abrams, & Mayberry, 1999). Hou and colleges (2015) showed that patients with

higher education level were higher CCKNOW score and knowledge about diet was significantly correlated to HRQOL. However, the results from other studies had contrast with this finding (Jackson, Clatworthy, Robinson, & Horne, 2010; Selinger, 2011). Finally, suitable education could help IBD patients to use of more adaptive coping strategies (Moradkhani, 2011) and to improve a patients' disease treatment and reduction anxiety (Blumenstein et al., 2013; Moradkhani et al, 2011) which in turn, should affect to the patients' HRQOL.

2.4 Conclusion

In conclusion, it is clear that UC and CD, have a significant impact on a patient's HRQOL. On the one hand, disease symptoms can be used to predict levels of anxiety and depression found among patients. However, on the other hand, anxiety, depression, may be an accommodating risk factor in relapse. HRQOL in patient with IBD was measured by the SF-36. According to the literature review, there are a lot of factors have a negative correlation with HRQOL. In this study, the research determined the factors which can improve their QOL by the easy method. The patient can enhanced their knowledge about disease by reading such as the medicine paper, leaf information, discussion with the nurse, the doctor, their friend who have IBD. These lead to change habit about their food, exercise, life style and then they were improved their BMI and decrease anxiety/depress. All of these can improve their QOL.

Few studies on HRQOL in IBD patients have been carried out In Vietnam, particularly for CD patients and it is urgently important to try to increase patients' quality of life in Vietnam. Therefore, the systematic study of a large-sized sample group of Vietnamese UC and CD patients would help to clearly understand these phenomena and will assist the researcher to conduct research to confirm the relationship among these variables. Life quality in patients with chronic disease and could also be assessed and it would be possible to compare differences between CD and UC patients. Also beneficial would be studies on patients' ability to cope with their disease symptoms, as would studies on their personal perception of anxiety/depression and level of dependence on the health care system. The aim of this

thesis is therefore to contribute new knowledge and insights about IBD conditions in patients in view of improving their QOL. Relationships between the factors involved in living with a chronic disease are identified by using this theoretical framework.

CHAPTER III

METHODOLOGY

3.1 Research design:

The study was descriptive correlation research in order to study the relationship between anxiety, BMI, knowledge about disease and quality of life among patients with inflammatory bowel disease.

3.2 Population and sample of the study

3.2.1 The population of this study

Population of this study included the patients' age being 18 years or over and diagnosed inflammatory bowel disease. They come to receive medical treatment or follow up at the out-patient gastrointestinal department, Bach Mai Hospital, Hanoi, Vietnam.

3.2.2 The sample of the study

Sample was selected from the population according to the following criteria:

The inclusion criteria were as follow: Patients able to communicate with researcher in Vietnamese language.

The exclusion criteria

1. Inability to adequately complete the questionnaires
2. Temperature $> 39^{\circ}\text{C}$ or pain score > 5 .
3. Incomplete fill out questionnaire

Criteria to terminate the participation were:

$T > 39^{\circ}\text{C}$ or stomachache with pain score > 5 , the researcher will stop to assess the patient.

Sample size: The researcher tested the relationship between anxiety & depression, BMI, knowledge and quality of life among patient with IBD. Four parameters require including 1) the level of significance $\alpha= 0.05$, 2) the power of the statistical test (Power $1- \beta= 0.8$), 3), There are three independence variables in this study and 4) effect size for this study ($f^2=.099$). The sample size in this study will be calculated by using G*power version 3.1.9.2 program to determine the minimum number of participants needed for correlational design (Faul, Erdfelder, Buchner, & Lang, 2009). Based on G*power, sample size should be 115 patients with IBD.

3.3 Setting

The study was performed at the Gastrointestinal department at Bach Mai hospital in Hanoi city, Vietnam.

The data collection was took place in the Gastrointestinal department and Colon endoscopy department in Bach Mai hospital in Hanoi, Vietnam. Bach Mai hospital is the famous hospital in Hanoi where has doctors, nurses and medical equipment modernization. The Gastrointestinal department has 70 beds, 27 doctors, 23 nurses, and 4 assistants, though; there were 150 patients/ day. There are 2 re-examination rooms in gastrointestinal department and 6 endoscope machines in colon endoscopy. There were approximate 5% patients with IBD must hospitalizes. However, the numbers of patients with IBD go to examination and re-examination from examination rooms and center gastrointestinal are 150 patients/month (Report of the Gastrointestinal department, 20 I4). According to the Colon endoscopy department, there are more than 70 patients per month who have ulcer in their colon. Moreover, there were many the patients with IBD from other province in Vietnam (not only Hanoi city) go to Bach mai hospital for examination and treatment, that reason why the research collected the patient from Bach Mai hospital.

All of medical equipments used in the Colon endoscopy department were approved basing on the same standard from the Ministry of Health in Vietnam. The assessors from manufactures would evaluate the reliability, efficiency, and safety of medical equipment once or twice per year. Then they were calibrated by the control of

medical equipment unit from each hospital before using as a standard of laboratory instrument regularly.

Therefore, the researcher had plans to collect data from Monday to Friday, 9.00 am - 5 pm.

3.4 Instruments

In this study, researcher uses four questionnaires to collect data, including: Demographic data questionnaire, 2) Short Form Health Survey (SF-36), 3) the Hopkins Symptom Checklist-25 (HSCL-25 and 4) Cronh's & Colitis Knowledge (CCKNOW).

Part I: Demographic data, including the following: gender, ethnicity, age, body weight and height with BMI, annual income, state of residence, employment status (employed, unemployed), highest level of education completed (high school, college, graduate school), marital status, years with IBO, IBD care through a gastroenterologist (yes or no), seeing a gastroenterologist as often as recommended (yes or no), ability to keep scheduled appointments (yes/no), having attended an educational session on IBD, interest in an online educational course on IBD, number of hospitalizations due to ulcerative colitis in the past 2 years, number of surgeries for IBD, and number of ulcerative colitis relapses (i.e., flares) within the past 2 years.

Part II: The 36- Item Short Form Health Survey (SF-36) instrument was used to assess HR_QOL which is a widely used self-report questionnaire in patients with disease (RAND Corporation, 2005). It is a valid and reliable scale with Cronbach's alpha level of 0.9 and high readability (Mc Horney et al., 1994; Ware et al., 1993). There are 8 parts, 36 items, such as vitality, physical functioning, pain, general health perceptions, physical role, emotional role, social role and mental health. The scores of each item are summed into total scores with range from 36 - 149 and the higher scores indicate the better QOL. (Ware & Sherbourne, 1993).

Part III: the Hopkins Symptom Checklist-25 (HSCL-25) developed in the 1950s by Parloff, Kelman, and Frank (1950) to assess anxiety and depression symptoms. It comprises 25 items: In part I of HSCL-25 there are 10 items for measuring symptoms of anxiety; In part II there are 15 items for measuring symptoms of depression. Each question

includes categories of response assessed according to a scale of 1-4 "not at all," "a little," "quite a lot" and "Extremely". Two scores need to be calculated and the total score will be the average of all of the 25 items added together. The score for depression will be the average of all of the 15 items to measure depression. It has been shown in several different populations that there is a high correlation between the total score and the level of emotional distress. The score for depression correlates well with symptoms of depression as has been defined by the Diagnostic and Statistical Manual of the American Psychiatric Association IV Version (DSM-IV) (American Psychiatric Association, 1994).

Part IV: The Crohn's and Colitis Knowledge Score (CCKNOW) is a 30 item multiple-choice questionnaire developed by Eaden and colleges (1999) used to measure IBD-related knowledge. It is a valid and reliable measure, with a Cronbach's alpha level of 0.95. Scores range from 0 to 30, with higher scores indicating higher levels of IBD-related knowledge (Eaden, Abrams & Mayberry, 1999).

3.5 Instrument Reliability and Validity

3.5.1 Instrument Validity

In this study, the Short Form Heath Survey (SF-36), the Hopkins Symptom Checklist-25 (HSCL-25) and Cronh's & Colitis Knowledge (CCKNOW) were verified by 5 experts. Their content validity was inspected and suggestions were made. Linguistic changes were made to them before being tested on 30 samples to assure their understanding of the contents.

3.5.2 Instrument Reliability

Vietnamese versions of the Short Form Heath Survey (SF-36), the Hopkins Symptom Checklist-25 (HSCL-25) scale, and the Crohn's and Colitis Knowledge Score (CCKNOW) will be tested for internal consistency reliability before conducting the actual data collection. These questions were pilot test on 30 patients who had the qualifications like the samples, and then the scores were taken to find the reliability of each questionnaire.

Table 3.1 Reliability of scales

| Scale | n of items | Cronbach's Alpha (n=30) |
|--|------------|----------------------------|
| The 36- Item Short Form Health Survey (SF-36) instrument) | 36 | 0.92 |
| Hopkins Symptom Checklist-25 (HSCL-25 | 25 | 0.91 |
| The Crohn's and Colitis Knowledge Score (CCKNOW) | 30 | 0.73 |

3.6 Data collection process

1) Preparation research assistant

A Research assistant in this project had two years experienced nurse in the gastrointestinal at Bach Mai hospital. Researcher trained her/him about objective and details of project focusing on her/his role for approach voluntary subject, how to include and exclude by inclusion and exclusion criteria, describing to participant with simple word for understanding also process of signing consent form.

2) After research assistant introduced researcher to voluntary subjects. To collect data, researcher will meet the patient at his/her bed, introduce herself, and established a relationship with the patient also verbally explain the objective of study, data collection procedure, participant's role and rights

3) The researcher organized private room to interview the patients or do questionnaire by themselves. Then, researcher uses four questionnaires for data collection. Questionnaires are 1) demographic data questionnaire have 15 items, 2) Short Form Health Survey have 36 items, 3) the Hopkins Symptom Checklist-25 (HSCL-25 has 25 items) and 4) Cronh's & Colitis Knowledge (CCKNOW) have 30 items. Total questionnaires have 107 items and time is about 45-60 minutes.

3.7 Protection of human rights

This study was conducted based on the protection of human rights. The participants were asked to participate in the study. The researcher explained the purpose of the study, the research procedure, benefits, risks, types of questionnaire, length of time for completing questionnaire, and the right to refuse participation in the study anytime. The participants who agreed to participate were informed and assured that the data would be kept confidentially and would be reported only as a group data. Informed consent was signed by all participants.

In this research, the researcher was strictly concern on human rights and ethical issues throughout the research process by;

3.7.1 The researcher collected the data after receiving approval from Hanoi National University, Mahidol University and the Ethical Committee of Research with Human Subjects of Gastrointestinal ward.

3.7.2 The researcher introduced herself to the participants at Gastrointestinal ward, inform the patients about the research objective and all data collection process. The patients was informed that they have right to refuse to join in the research process. During anytime throughout the research process, patients have their own right to withdraw from the research project and will not influence on their treatment or caring process. If patients agreed to join in the research process, they were invited to sign their name in the consent form.

3.7.3 This research was caused any risk to the patients' physical health. The data collection process might take time about 45-60 minutes. Although the patients will not get any benefit from this research but the results will be benefit for other patients who have the same health care problem as the sample.

3.7.4 All contents were kept confidential, only the researcher and the research team were been to get access to the data. Any content related to data that will be presented in the thesis or any publication will be anonymous. In case of ones who with drawn themselves from the research, all data will be deleted from the database and will be not used as any part of the research.

3.7.5 If the participants have further questions or require more explanation in regard to the research, they will be informed to feel free to ask the researcher at anytime throughout the research process.

3.7.6 After the participants are clearly understand the research process and agree to join in the research, they will be invited to sign their name in the consent form.

3.8 Data analysis

As the data form 115 patients with IBD were collected. The researcher verified the completion of data and performed statistical analysis using SPSS 20.0 software package as follows:

1. The data with all continuous data which analyzed using statistical analysis in term of frequency, percentage, mean and standard deviation
2. The determine which nominal and ordinal data was reported with frequency and percentage.
3. The relationships between quality of life and anxiety and depression, BMI, know about disease by using Spearman Rho' product moment correlation.

Statistical analyses will be conducted using SPSS 20.0 software. Tests of significance will be two-tailed, with an alpha level of 0.05.

CHAPTER IV

RESULTS

The purpose of this research is to study the factors related to quality of life among patients with inflammatory bowel disease including BMI, knowledge about disease, anxiety and depression. The sample was 115 patients recruited from out-patient of Gastrointestinal Department and Functional Examination Department in Bach Mai hospital, Vietnam from August to October, 2016. The findings were presented in descriptive statistics as follows:

- 1) General characteristics of patients with inflammatory bowel disease.
- 2) Characteristics of illness and quality of life of patient with inflammatory bowel disease.
- 3) BMI, anxiety and depression, knowledge about disease.
- 4) The correlation between the BMI, anxiety and depression, knowledge about disease and quality of life among patients with inflammatory bowel disease.

4.1 General characteristics of patients with inflammatory bowel disease.

The sample included 115 patients with inflammatory bowel disease. The demographic data included gender, age, BMI, marital status, educational level, occupation and income. It can be seen from Table 4.1, the findings illustrated that the percentage of female (61.7%) were higher than those of male (38.3%). The age of patients with IBD ranged from 18 to 76 years. The mean age was 46.5 (SD±13.5years). The patient - age was more than 40 years old was the highest percentage of 34.8% in this sample, while the patient age of 18 – 29 years old was the least percentage of 11.3%. Most of the patients live in rural (62.5%) lived in rural areas. The major of patients (92.2%) were married. The education level at secondary made up the greatest proportion (46.1%). The common occupation of patients was

farmers and others (freelance/ they worked freely) with the percentage of 27.8% and 37.4% respectively. There were 66 patients (57.4%) who earned monthly incomes from 200 to 500 USD. The majority of IBD patients (84.3%) had to pay for treatment by themselves (table 4.1)

Table 4.1 General characteristics of patients with inflammatory bowel disease

| Characteristics | Number (n = 115) | Percentage (%) |
|--------------------------|-------------------------|-----------------------|
| Gender | | |
| Male | 44 | 38.3 |
| Female | 71 | 61.7 |
| Age (years) | | |
| 18- 29 | 13 | 11.3 |
| 30-39 | 34 | 29.6 |
| 40-49 | 28 | 24.3 |
| ≥50 | 40 | 34.8 |
| Min: 19 | | |
| Max: 76 | | |
| Mean ± SD: 46.5 ± 13.5 | | |
| Marrital status | | |
| Married | 106 | 92.2 |
| Divorced | 1 | 0.9 |
| Separated | 1 | 50.9 |
| Single | 5 | 4.3 |
| Widowed | 2 | 1.7 |
| Educational Level | | |
| Elementary school | 4 | 3.5 |
| Secondary school | 53 | 46.1 |
| High school | 23 | 20.0 |
| Two-years certificate | 11 | 9.6 |
| Bachelor degree | 22 | 19.1 |
| Post - graduated | 2 | 1.7 |

Table 4.1 General characteristics of patients with inflammatory bowel disease (cont.)

| Characteristics | Number (n = 115) | Percentage (%) |
|------------------------------------|-------------------------|-----------------------|
| Occupation | | |
| Farmer | 32 | 27.8 |
| House wife | 1 | 0.9 |
| Civil seran staff government | 17 | 14.8 |
| Retired | 22 | 19.1 |
| Other job | 43 | 37.4 |
| Location of residence | | |
| Urban | 40 | 34.8 |
| Rural | 75 | 65.2 |
| Income (USD) | | |
| No income | 5 | 4.30 |
| 1 - 100 USD | 7 | 6.10 |
| > 100 - 200 USD | 22 | 19.10 |
| >200 - 500 USD | 66 | 57.40 |
| > 500 USD | 15 | 13.00 |
| Min: 0 | | |
| Max: 869.57 USD | | |
| Mean \pm SD: 313.61 \pm 197.91 | | |
| Insurance | | |
| Company | 1 | 0.9 |
| Government | 17 | 14.8 |
| Pay by themselves | 97 | 84.3 |
| Smoking | | |
| Yes | 30 | 26.1 |
| No | 85 | 73.9 |
| Drinking alcohol | | |
| Yes | 31 | 27.0 |
| No | 84 | 73.0 |
| Doing exercise | | |
| Yes | 11 | 9.6 |
| No | 104 | 90.4 |

4.2 The information related to illness and treatment

Regarding the table 4.2, it can be clearly that patients had IBD from 1 to 5 years were the largest percentage with 62.6% and those from 6 to 10 years were the lowest one with 8.7%. The average of disease duration was 3 years (SD \pm 4.2). Most patients were treated by Western medicines with 92.2%. Moreover, there were the highest percentage of patients who were treated by two methods (traditional medicines and western medicines) with (77.4%) and only one patient who was not treated by any method (0.9%). Besides, there was no patient who was treated by combination three methods.

Table 4.2. Characteristic of illness and treatment

| Characteristics | Number (n = 115) | Percentage (%) |
|---|------------------|----------------|
| Duration of IBD (years) | | |
| < 1 | 12 | 10.4 |
| 1 – 5 | 72 | 62.6 |
| 6 – 10 | 10 | 8.7 |
| >10 | 21 | 18.3 |
| Min: 0.25 | | |
| Max: 20 years | | |
| Mean \pm SD: 3 \pm 4.2 | | |
| Treatment by traditional medicines | | |
| No | 18 | 15.7 |
| Yes | 97 | 84.3 |
| Treatment by western medicines | | |
| No | 9 | 7.8 |
| Yes | 106 | 92.2 |
| Treatment by surgery | | |
| No | 113 | 98.3 |
| Yes | 2 | 1.7 |

Table 4.2. Characteristic of illness and treatment (cont.)

| Characteristics | Number (n = 115) | Percentage (%) |
|---|-------------------------|-----------------------|
| Combination of treatment methods | | |
| No treatment | 1 | 0.90 |
| Traditional medicines and Western medicines | 89 | 77.40 |
| Traditional medicines and surgery | 2 | 1.70 |
| Western medicines and surgery | 0 | 0.00 |
| Three methods | 0 | 0.00 |

4.3 BMI, anxiety and depression, knowledge about disease and quality of life in patients with IBD

4.3.1 BMI

The table 4.3 reports level of BMI among 115 patients with IBD, the mean of BMI was 17.89 (SD = 2.02). The largest proportion of patients with abnormal BMI (thin) was 60.9% whereas the relatively small percentages of patients with overweight was 3.5%. Especially, no patients had BMI above 25 (obese).

Table 4.3 Level of BMI

| Characteristics* | Number (n = 115) | Percentage (%) |
|--------------------------------|-------------------------|-----------------------|
| BMI | | |
| < 18.5 | 70 | 60.9 |
| 18.5-22.9 | 41 | 35.7 |
| 23-24.9 | 4 | 3.5 |
| ≥ 25 | 0 | 0 |
| Min: 12.89 | | |
| Max: 24.79 | | |
| Mean ± SD: 17.89 ± 2.02 | | |

*Base on the WHO classification in ASEAN (2013)

4.3.2 Anxiety and depression

Table 4.4 showed the classification of anxiety and depression in IBD patients.

Table 4.4. Classification of anxiety and depression among patients with IBD follows scores

| Classification of anxiety & depression | n | % |
|---|----------|----------|
| No (25 - 44) | 3 | 2.6 |
| A little (45 – 64) | 52 | 45.2 |
| Quite a bit (65 – 84) | 56 | 48.7 |
| Extremely (85 – 100) | 4 | 3.5 |
| Total | 115 | 100 |

The level of anxiety and depression was calculated by the HSCL- 25 scale. There were two domains in this scale namely anxiety and depression. As shown in Table 4.5, the mean of anxiety score was 24.44 (SD= 5.26) and the mean of depression score was 36.32 (SD=5.40). Finally, the mean of anxiety and depression was 64.76 (SD=10.03).

Table 4.5 The mean of anxiety and depression scores in patients with IBD

| Domain of Anxiety & depression | Reference Range | Observed range | Mean | Std. Deviation |
|---|------------------------|-----------------------|-------------|-----------------------|
| Anxiety | 10 – 40 | 14– 38 | 28.44 | 5.26 |
| Depression | 15 – 60 | 23 – 51 | 36.31 | 5.40 |
| Total score of HSCL 25 | 25-100 | 37- 87 | 64.76 | 10.03 |

4.3.3 Knowledge about inflammatory bowel disease

The knowledge about disease in patients with IBD was calculated by the CCKNOW scale. Table 4.6 shows that the patients with IBD ranged from 0 to 18 for CCKNOW. Of these patients, 65 patients (56.5%) had poor knowledge (CCPKNOW 0–7), 11 patients (9.6%) with adequate knowledge (CCPKNOW 8–10), 20 patients

(17.4%) with good knowledge (CCPKNOW 11–13), and 19 patients (16.5%) with very good knowledge of patients-related issues in IBD (CCPKNOW ≥ 14).

Table 4.6 Levels of knowledge of the patients with IBD presented by number and percentage

| Level of knowledge* | n | % |
|--------------------------------|----|------|
| Poor (0 – 7) | 65 | 56.5 |
| Adequate (8 – 10) | 11 | 9.6 |
| Good (11 – 13) | 20 | 17.4 |
| Very good (≥ 14) | 19 | 16.5 |
| Min: 0 | | |
| Max: 18 | | |
| Mean \pm SD: 7.62 \pm 5.03 | | |

*Based on Selinger and colleges (2012)

The CCKNOW includes four domains. Follow table 4.7, the mean total CCKNOW-24 score was 7.62 (SD=5.03) while the mean general IBD knowledge score was 3.27 (SD=2.29). The mean diet of IBD score was 0.2 (SD=0.43).

Table 4.7 The mean – score of knowledge about disease in patients with IBD

| Domain of CCKNOW | Reference Range | Observed Range | Mean | SD |
|--|--------------------|-------------------|------|------|
| General IBD knowledge | 0 – 11 | 0 – 9 | 3.27 | 2.29 |
| Diet of IBD | 0 – 2 | 0 – 2 | 0.20 | 0.43 |
| Medication or Treatment IBD | 0 – 5 | 0 – 5 | 1.77 | 1.34 |
| IBD complication | 0 – 6 | 0 – 6 | 2.38 | 1.78 |
| CCKNOW-24 (knowledge about disease) | 0 – 24 | 0 – 18 | 7.62 | 5.03 |

4.3.4 Quality of life among patients with IBD

Based on quality of life score, the researcher divided it into four groups of quality of life, including poor, average, rather average and quite/well. Table 4.8 presents the majority of patients had average and rather average level of quality of life (51.30% and 41.70% respectively). Patients with quite/will level of quality of life accounted for the lowest percentage of 0.9%

Table 4.8 Classification of quality of life among patients with IBD follows scores

| Classification of QOL | n | % |
|------------------------------|----------|----------|
| Poor (0 - 25) | 48 | 41.7 |
| Average (>25 – 49) | 59 | 51.3 |
| Rather average (>49 – 75) | 7 | 6.1 |
| Quite/Well (>75 – 100) | 1 | 0.9 |
| Total | 115 | 100 |

The table 4.9 provided the means of quality of life score with all dimensions. The mean total SF-36 score was 29.54 (SD=13.91) and ranged from 2.92 to 77.08. There were eight domains of quality, base on the average, physical functioning domain had the highest mean score with 48.83 (SD=18.47), while the general health domain had the lowest mean score with 14.22 (SD=12.71), ranged from 0 to 65.

Table 4.9 The mean scores of quality of life in IBD patients

| Domain of QOL | Reference Range | Observed Range | Mean | SD |
|----------------------------|------------------------|-----------------------|-------------|-----------|
| General Health | 1 – 100 | 0 – 65 | 14.22 | 12.71 |
| Physical functioning | 1 – 100 | 0 – 90 | 48.83 | 18.47 |
| Physical health | 1 – 100 | 0 – 100 | 21.96 | 29.08 |
| Emotional problems | 1 – 100 | 0 – 100 | 15.65 | 23.50 |
| Energy- Fatigue | 1 – 100 | 0 – 70 | 21.87 | 12.94 |
| Emotional well-being | 1 – 100 | 4 – 76 | 28.52 | 12.58 |
| Social Functioning | 1 – 100 | 0 – 75 | 40.65 | 17.03 |
| Pain | 1 – 100 | 0 – 45 | 22.03 | 14.87 |
| Total scores SF-36: | 1 – 100 | 2.92 - 77.08 | 29.54 | 13.91 |
| Quality of life | | | | |

4.4 The correlation between BMI, anxiety and depression, knowledge about disease and total quality of life among patients with IBD

Before analysis the correlation between variables, the assumption was tested for their normal distribution. The results showed that only the data for QOL variable were normally distributed, whilst the data for three variables including BMI, anxiety and depression, knowledge about inflammatory bowel disease have skewed distribution. Therefore, Spearman's rho was employed to examine the correlation of BMI, anxiety & depression and knowledge about disease with QOL.

The result illustrated that BMI has positively low correlation with QOL ($r = .345$, $p = .000$). Anxiety and depression had negatively medium correlation with QOL ($r = -.649$, $p = 0.000$). Knowledge about IBD was positively medium correlation with QOL ($r = .565$, $p = 0.000$). Moreover, anxiety & depression had negatively low correlation with knowledge about IBD ($r = -.365$, $p = 0.000$).

Table 4.10 described that BMI, knowledge about disease, anxiety & depression correlated with most domains in the quality of life ($p < 0.01$). Only the general health domain was not significant correlation with BMI ($p = .142$). The item diet of IBD belonged to the CCKNOW assessed knowledge of IBD patients was not

significantly correlate with vitality (energy- fatigue) and emotional well-being domains, which were evaluated QOL among patients with IBD.

Table 4.10 Correlation between anxiety and depression, knowledge about disease, BMI and quality of life

| | Anxiety & depression | Knowledge about IBD 24 items | BMI |
|---|-------------------------------------|---|------------|
| Anxiety & depression | 1 | | |
| Knowledge about IBD (24 items) | -.365** | 1 | |
| BMI | -.058 | .314** | 1 |
| QOL | -.649** | .565** | .345** |

CHAPTER V

DISCUSSION

This descriptive correlational study was conducted to examine the relationship between BMI, anxiety and depression, knowledge about disease and quality of life among patient with inflammatory bowel disease. The chapter will provide a discussion of the sample demographic characteristics and the correlation of variables, such as BMI, anxiety and depression and knowledge about disease with quality of life. During this discussion the hypothesis of this study will be examined.

5.1. Quality of life among patient with inflammatory bowel disease

There were many studies researches examining health related in IBD patients worldwide. However, research on this topic conducted in the Asian population is limited. In addition, the development of a systematic educational resource or program management for IBD patients has remained insufficient. This study was the first attempt to determine how the quality of life of IBD patients correlated with BMI, anxiety & depression specialize knowledge about disease. Findings from this research were expected to use as baseline data for the development of knowledge for the follow-up management of IBD patients in Vietnam and further research on this topic.

The sample of 115 patients with inflammatory bowel disease at Bach Mai Hospital participated in this study. During research period, no adverse events occurred and, therefore, all of 115 patients were available for data collection.

Considering IBD, it is necessary to limit the “quality of life” (QOL) to health. HRQOL was defined as the subjective assessment of a patient’s physical, mental and social state concerning his or her own experience of health and diseases. Moreover, quality of life was an important domain for measuring the impact of chronic diseases. Specially, the treatment goal of the IBD was to provide patients with high the quality of life. Health-related quality of life (HRQOL) was more specific and

was related to the part of the QOL that is determined by health. Measurement of the QOL in this study was conducted to assess QOL among patients with the SF-36 questionnaire (Medical Outcomes Study 36 items Short-Form General Health Survey). It consists of 36 items that assess the impact on social, physical, and general daily activities that is caused by health problems such as bodily pain, general mental and physical health, and vitality (Ware, & Sherbourne, 1992).

In this study, the QOL dimension from the SF-36 questionnaire indicated that the mean scores of the HRQOL was 29.54 ($SD \pm 13.91$). There was 41% patients that had the mean of score less than 25 points and more than half of patients (51.3%) had mid-ranged level on QOL. It can be assumed that patients with IBD had a poor level of HRQOL. A possible explanation is that patients with IBD suffered troubles from the disease such as abdominal pain, fatigue, weight loss and special loss of appetite (Loftus Jr, 2004). Such troubles negatively impacted on their level of HRQOL. In other study, Norman et al carried out QOL in two hundreds patients with beginning disease of the gastrointestinal and the impact of malnutrition on QOL. The results indicated that the QOL of IBD patients was lower when compared with patients suffering from liver cirrhosis. In addition, research carried out by Love et al., explained the poor of QOL in out-patients with IBD because the old patients had lower QOL than young ones (Love et al, 1992)

Moreover, in comparison with results form other researches, Habib (2015) illustrated that the mean score of QoL (57.53 ± 23.27) was higher than this study. This issue was explained that there was a significant association between QOL and age ($r = 0.34$, $p < 0.001$) (Yoo et al., 2015). In this study, the mean score of age (46.5 ± 13.5), which was higher than that of Yoo el al's (36.4 ± 10.90). Similarly, the results in this study revealed the negative relationship between age and QOL among patients with IBD ($r = 0.448$ ($p < 0.01$), which was higher than the result of Yoo.

In addition, there were more a half of patients (62.6%) had the length of illness from one to five years in this study. It can be explained that the duration of IBD influences patients' quality of life. Finding from this study were supported by Japanese authors that revealed that the disease duration was the main factor influencing on QOL in group of 331 patients with IBD (Kuriyama et al, 2008).

Specifically, in the patient group with duration of disease < 5 years, the clinical activity index score was the most important factor affecting HRQOL.

On the other hand, the SF-36 scale had eight domains, each domain was used to assess the different problems in the life quality of patients. The result of this study was similar to results from the research of Mart et al (2014), which indicated the lowest mean score of general health and the highest one belong to physical functioning.

5.2 The relationship between BMI and quality of life

Body mass index (BMI) was an effective parameters to assess the nutritional status of the patients that could result in quality of life and outcomes with the IBD therapies (Naik & Venu, 2012). However, the majority of BMI in this study was underweight (60.9%) as same as other studies (Ghoshal et al, 2008; Mijac et al, 2010; Mohamed-Hussein et al, 2007) that could resulted to the complication, the stage of disease, medical therapy (Mijac et al, 2010). For this study, there was a significant correlation between BMI and QOL of the IBD patients ($r = .345$, $p = .000$), and domain as physical functioning ($r = .351$, $p = .000$), which was the same as research of Yoo and colleges (2015) ($r = .25$, $p = .008$). In addition, both of the findings from Capriso and colleges (1998) and Bryant colleges (2013) showed that decreased BMI was associated with negative health outcomes in patients with UC that also impact to their QOL (Kristina et al, 2006). According to the results from path analyses, explained 31 % of psychological QoL and 41 % of physical QoL, showed that BMI and symptomatology's could affect on physical and psychological QoL (Trindade, Ferreira, & Pinto-Gouveia, 2017).

5.3 The relationship between anxiety& depression and quality of life

The findings from this study showed how anxiety and depression symptoms impactes on HRQOL. As expected, anxiety and depression of the patients with IBD resulted in moderate negative correlation with emotion well being domain

scores in HRQOL ($r = -.541, p < .01$). It is also worth noting that symptoms of anxiety and depression, either independently or together contribute to moderate negative correlation with the perception of physical function ($r = -.581, p < .01$), physical health ($r = -.519, p < .01$). Specially, these symptoms had a strong negative correlation with vitality (Energy-Fatigue) domain. Despite of the differences in scale for measuring anxiety and depression, Freitas and colleagues (2012) also showed that there was significant correlation between anxiety ($r = -.191, p < .01$) and depression ($r = -.172, p < .01$) and QOL in their study.

Patients with chronic illnesses as IBD can experience emotional problems. Symptoms of IBD can emit without warning and might make such patients feel pain, discomfort, inconvenience, and oppressiveness. IBD patients might experience a wide range of different and conflicting emotions as a result of suffering from these conditions. Many previous studies (Faust et al, 2012; Freitas et al, 2015; Yoo et al, 2015; Guanwei et al, 2016) showed that anxiety and depression had correlated with QOL among patients with IBD. The researchers have described the contribution of anxiety and depression variable to its deterioration, similar this study had identified the significant impact of IBD on HRQOL of patients.

On the other hand, in the study of Bessisson and colleagues (2013) further evaluated the relationship between anxiety and depression by using various psychological assessment and disease activity. The researcher emphasized that the HRQOL correlated with anxiety ($r = .51, p < .05$). This result confirmed by the opinion of Mitchell and colleagues (1998), The authors showed that IBD had a significant psychological effect on patients on account of fluctuating symptoms and the difficulty in predicting flares or exacerbations, the stigma and embarrassment of IBD symptoms as well as fears concerning the long term effects of progression and treatment of disease which can lead to anxiety and depression and other emotional problems. This previous study was explained the result of this study. Similarly, the research of Iglesias – Rey and colleagues (2014) added that anxiety and depression were important determinants of HRQOL so that nurses should be aware of these problems in making nursing care plans for such patients.

5.4 The relationship between Knowledge about disease and quality of life

An important finding of this study is that IBD patients that have more knowledge about disease may have better quality of life ($r = .312, p < 0.01$). There has been a rapid increase in the incidence of IBD in Asia and the developing countries (Ng, 2014). However, there is little data on the level of patients' knowledge. Moreover, an effective program management for IBD patients and a systematic educational resource are still insufficiently developed. Previous studies used the Crohn's disease and Colitis Knowledge Scale (CCKNOW) to evaluate the knowledge of IBD patients based on 4 categories: general knowledge, diet, medication, and complications related to IBD. By using the CCKNOW with 24 items, the study indicated that mean of total the CCKNOW score was (7.62) range from 0 to 18. This result was lower than the result of Yoo and colleges (2015) with 10.0 for UC and 8.8 for CD. This compares well with the results from Sri-Lanka which the score of 8.0 for CD and 6.6 for UC (Subasinghe, Wijekoon, Nawarathne, & Samarasekera, 2010).

On the other hand, Hou and colleges (2015) showed that having a younger age at the time of diagnosis and having a university or post-graduate degree were higher CCKNOW score; however, there were significantly correlated between of the CCKNOW sub-domains, only diet knowledge and HRQOL. Moreover, the result of Yoo and colleges (2015) showed that information about medication, daily life were deemed significant in IBD patients, and from previous studies, suitable education could help IBD patients to use of more adaptive coping strategies (Moradkhani, 2011) and to improve a patients' disease treatment and reduction anxiety (Blumenstein et al., 2013; Moradkhani et al, 2011) that should effect to QOL. However, many patients with IBD lacked of knowledge in many aspects of their disease and better understanding of the patients' concerns should be examined to improve adherence to treatment and quality of life of IBD patients (Pittet et al, 2016). So, the development of a systematic education can help the patients with IBD manage and cope with their disease throughout their longevity. Moreover, health care teams should assess the information needs of patients with specific groups to increase their knowledge and understanding the overall effects of disease on QOL.

5.5 Conclusion

In conclusion, it could be stated that the results of this study complied with the concept of quality of life theory. When patients with IBD had normal BMI, well being psychological, and special knowledge about disease they would perceive a good QOL. The results of this study showed that BMI, anxiety and depression, knowledge about disease were correlated with QoL among patients with IBD ($r = .345, p < .01$; $r = -.649, p < .01$; $r = .312, p < 0.01$, respectively). Consequently, to improve the QOL among patients with IBD as well as self-management of their disease with diet, adherence medication and treatment, physician and nurse should provide the information about the inflammatory bowel disease. For the optimum goals of treatment, The IBD patients could be absent of symptoms, prolonged remission with better QOL.

CHAPTER VI

CONCLUSION

6.1 Conclusion of the study

This descriptive correlation study aimed to examine the relationship between BMI, anxiety and depression, knowledge about disease and quality of life among patients with inflammatory bowel disease (IBD) who aged 19 – 76 years old in Gastrointestinal Department and Functional Examination Department from August to October, 2016. Quality of life theory was utilized as a conceptual framework of this study. The sample size in this study was calculated by using G*power version 3.1.9.2 program to determine the minimum number of participants needed for co-relational design. The sample calculation yielded 115 patients. The research site was in the Gastrointestinal Department and Functional Examination Department in Bach Mai Hospital, Hanoi, Vietnam.

After obtaining the ethical approval from the Institutional Review Board of Nursing faculty, Mahidol University and Institutional of Review Board of SMP, Vietnam National University, Hanoi, Vietnam. The researcher used four instruments including; the demographic data questionnaire, the Hopkins Symptom Checklist-25 (HSCL-25), the Crohn's and Colitis Knowledge Score (CCKNOW) and the SF-36 derived from the Inflammatory Bowel Disease Questionnaire to collect data. All instruments were tested for their validity and reliability as clearly explained in chapter 3. Cronbach's alpha coefficient of the Hopkins Symptom Checklist-25 Questionnaire, the Crohn's and Colitis Knowledge Score, and the SF-36: .89, .93, and .94 respectively. The sample of 115 patients was selected according to the inclusion criteria. The researcher collected data by herself from 8.00 am to 5.30 pm every day until the sample reached the target of sample size. For each participant the researcher spent 30 to 45 minutes on interviewing and collecting some data from their patients' medical records. During data collection, there were no adverse events among the

sample. All sample recruited in the study remained throughout the study process with no attrition.

Data analysis was conducted by using SPSS computer program. The descriptive statistics were used to describe general information and study variables, including BMI, the knowledge about disease, anxiety and depression and quality of life. The assumption of Spearman's rho Product Moment Correlation was tested and it was found the distribution of data for all variables was non-parametric. Accordingly, Spearman's rho was used to examine correlation between BMI, the knowledge about disease, anxiety and depression, and quality of life among patients with IBD.

The findings are summarized as follows:

In the sample of 115 patients, there were 61.7 % of female 38.3 % of male with the ages ranged from 19 to 76 years. The mean age was 46.50 (SD = 13.50 years). The most prominent age group was more than 50 years old with 34.80%. Most of the patients lived in rural areas (65.20%), were married (92.20%) and paid treatment by themselves (84.30%).

The percentage of 62.60% patients suffered from IBD from 1 to 5 years and 8.7% had IBD from 6 to 10 years. More than half of total patients (60.9%) had BMI less than 18.5 and the mean of BMI was 17.89 (SD = 2.20), which was less than normal index of BMI. The majority of patients experienced a little and quite a bit anxiety and depression (45.20% and 48.70%, respectively). The mean scores of anxiety and depression were 64.76 (SD \pm 10.03). Most of the patients had knowledge about inflammatory disease was low with the correct question about disease less than 8 score (60%).

Regarding quality of life among patient with IBD, more than half of patients had average level of quality of life (51.30%) and there was only one patient that had quite level of quality of life (0.9%).

BMI had low positive correlation with quality of life ($r = .345$, $p = .000$), anxiety & depression had medium negative correlation with quality of life ($r = -.649$, $p = .000$). Knowledge about disease had medium positive correlation with quality of life ($r = .603$, $p = .000$). Moreover, anxiety and depression had low negative correlation with knowledge about disease ($r = -.381$, $p = .000$).

The results of this study complied with the concepts of quality of life theory, which argued that patients with IBD might have poor QOL. Internal factors, such as BMI, anxiety & depression had a relationship with poor QOL among IBD patients, while the external factor, good knowledge, positively correlated with the quality of life.

6.2 Implications of Research Findings

6.2.1 Implications for nursing practice

In order to enhance patients with IBD to optimize their quality of life, the following measures should be performed by nurses;

1) Assessment patients' quality of life by using the Short Form Health Survey (SF-36) during patients' follow up visit to monitor the patients' progress in their quality of life. Identify and manage the patients who have problems with quality of life while maintain ones who show good progress.

2) Assess patient's knowledge in order to develop education strategies, and evaluate the impact of these in the compliance of IBD management and quality of life of IBD.

3) Improve patients' knowledge about disease by providing them with knowledge about inflammatory bowel disease to enhancing the quality of life for patients due to the patients manage their disease and make decisions in the improves patients' disease treatment and coping methods. Knowledge about IBD is absolutely necessary to have advantage of daily life.

4) It is necessary to prepare more effective the training media methods, involving multidisciplinary teams and specialized nurses' training. Develop guidelines to increase the skills of disease management for patients with IBD.

5) Provide regular assessment on patients' anxiety and depression by using Hopkins Symptom Checklist -25 (HSCL -25) during patients' follow up visit to detect level of anxiety and depression. Patients whose scores show that they experience anxiety or depression have to be referred to the specialist for holistic management.

6) For patients with low BMI, nurses should improve nutritional status of the patients. Moreover, programmes that facilitate the improvement of the nutritional status for such IBD patients should be developed.

6.2.2 Implications for further study

1) Guidelines for clinical practice to reduce anxiety & depression via music, singing, and joining the IBD club should be produced based on research-based evidence from further research on this topic.

2) Clinical practice guidelines to improve quality of life among patients with IBD should be developed and tested for its effectiveness by using quasi experimental research.

3) The the Short Form Health Survey (SF-36) in the Vietnamese version should be tested in its psychometric property by using adequate numbers of patients. In addition, advanced statistic-factor analysis should be employed to test the psychometric property of SF-36 in Vietnamese context.

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APPENDICES

APPENDIX A
LIST OF EXPERT

1. Pro Dr. **Truong Viet Dung**, MD, PhD.
Dean of Faculty of Nursing, Thang Long university, Vietnam.
2. Doctor **Nguyen Thi Thu Hien**
Doctor of the Gastrointestinal Department, Bach Mai Hospital, Vietnam
3. Doctor **Ha Thi Lan Huong**
Doctor of the Functional Examination Department, Bach Mai Hospital,
Vietnam
4. Bachelor: **Nguyen Van Khanh**
Head nurse of the Gastrointestinal Department, Bach Mai Hospital,
Vietnam
5. Bachelor **Le Thi Hang**
Nurse of the Gastrointestinal Department, Bach Mai Hospital, Vietnam

APENDIX B

CERTIFICATE OF APPROVAL



MAHIDOL UNIVERSITY

Since 1888

The Institutional Review Board
Faculty of Nursing, Mahidol University
Tel 0-2441-5333 Ext 2531-32

Document No. 0517.0510/IRB-NS *462*
Date May 3, 2016
Subject Result of research project considerations after the revision
Dear Chair, Master of Nursing Science Program in Adult Nursing (for Vietnamese Nurses)

According to the student named Mrs. Le Thi Thuy has submitted the research project entitled Factors related to quality of life among patients with inflammatory bowel disease protocol no. IRB-NS2016/3 1.0703 at the Institutional Review Board, Faculty of Nursing, Mahidol University on the (date) May 2, 2016 the IRB committee have examined and found the research protocol and all the research documents are revised according to the suggestions of the IRB. The IRB committee have made the decision and the results are as follows:

Approve.

On the date May 2, 2016

Please look at the guideline for the research conduct post approval.

The document is attached together with the COA

A handwritten signature in black ink, reading "Fongcum Tilokkulchai".

(Associate Professor Dr. Fongcum Tilokkulchai)

Chair, Institutional Review Board

Copy to Assistant Professor Dr. Wallada Chanruangvanich

Mrs. Le Thi Thuy



CERTIFICATE OF APPROVAL

From

Institutional Review Board Faculty of Nursing Mahidol University

COA No.IRB-NS2016/355.0205

Title of Project: FACTORS RELATED TO QUALITY OF LIFE AMONG PATIENTS WITH INFLAMMATORY BOWEL DISEASE

Project Number: IRB-NS2016/31.0703

Principle Investigator: Mrs. Le Thi Thuy

Name of Institution: Faculty of Nursing Mahidol University

Approval includes

- 1) IRB-NS Submission form version received date 2 May 2016
- 2) Participant Information sheet version date 2 May 2016
- 3) Consent form version date 2 May 2016
- 4) Questionnaire version received date 2 May 2016

Institutional Review Board Faculty of Nursing Mahidol University is in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Approval: 02 May 2016

Date of Expiration: 01 May 2017

Signature of Chair:

(Associate Professor Dr. Fongcum Tilokskulchai)

Chair

Signature of Dean, Faculty of Nursing

(Associate Professor Dr. Yajai Sitthimongkol)

Dean, Faculty of Nursing

Office of Institutional Review Board Faculty of Nursing Mahidol University Room 503 Faculty of Nursing, Mahidol University
999 Phuttamonthon 4 Road, Salaya, Nakhon Pathom 73170, THAILAND Tel: (662)-441-5333 Ext. 2531, 2532

APPENDIX C PARTIEIPANT INFORMATION SHEET

(ENGLISH VERSION)

- 2-MAY 2016

31-0703

IRB-NS Form No. 3.1

APPENDIX2

Participant Information Sheet

In this document, there may be some statements that you do not understand. Please ask the principal investigator or his/her representative to give you explanations until they are well understood. To help your decision making in participating the research, you may bring this document home to read and consult your relatives, intimates, personal doctor or other doctor.

Title of Research Project: Factors related to quality of life among patients with inflammatory bowel disease.

Name of Researcher: Le Thi Thuy

Research Site-Office and its telephone number available for contact both in and out of the office hours:

Bach Mai hospital: 78 Giai Phong Street, Dong Da District, Hanoi City, Vietnam. Code: 100000, Mobile phone: (+ 84) 989558900 (contact Mrs. Le Thi Thuy)

Source of Fund: No research funding

This research project aims to study the level quality of life among patient with IBD and to study the relationship between anxiety, BMI, knowledge about disease, and quality of life among patients with IBD, which expects the following benefits:

- 1) Providing basic data about factors related to QOL in IBD patients.
- 2) In the future, developing program by using this data to promote QOL in IBD patients.

However, in this study, the sample don get any benefit directly but IBD patient will get benefit in the future.

You are invited to participate in this research project because you have been diagnosis in IBD participants and being age 18 years old or above

There will be 115 participants, and the research will last for 45-60 minutes for answer questionnaires.

*To participate in this research is completely VOLUNTARY.

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| Approved by Institutional Review Board |
| Faculty of Nursing Mahidol University |
| Project Number IRB-NS 2-MAY-2016 |
| Date of Approval |

IRB-NS Form No. 3.1

If you decide to participate the research project, you will go through the following procedure.

1. The researcher will organize private room to interview you or do questionnaires by yourself. Then, researcher uses four questionnaires for data collection. Questionnaires are: 1) Demographic data questionnaire have 15 items, 2) Short Form Health Survey 11 items, 3) the Hopkins Symptom Checklist-25 (HSCL-25 have 25 items) and 4) Cronh's & Colitis Knowledge (CCKNOW) have 30 items. Total questionnaire has 81 items and time is about 45-60 minutes. During you answer questionnaires, if there are any questions that are unpleasant or discomfort you have rights not reply the question.

2. During interviewing or doing questionnaire, you may feel discomfort. You can stop and rest for a while until you feel comfort to continue. If you want to stop participation to this study, you can withdraw from the study at any time.

3. During data collection, you may have unexpected conditions from stage of disease for example stomach ache, or unstable vital signs. The researcher will stop interviewing or doing questionnaire and will immediately contact with doctors who have responsibility to take care of you. The researcher will take care until you already stable.

If you do not participate in this research project, you will receive a standard assessment and treatment.

If you have any questions about this research please feel free to contact the researcher, Mrs. Le Thi Thuy) via telephone: (+84)989558900

You do not get any money or payment for participating in this research.

If relevant information arises about benefits and risks of the research project, the researcher will inform the participant immediately and without concealment.

Your information will be kept confidential, it will not be subject to an individual disclosure, but will be included in the research report as part of the overall results. Individual information may be examined by a researcher, the ethics committee, etc.

Participant Information Sheet for version 5 date 10 August 2015

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|--|
| Approved by Institutional Review Board |
| Faculty of Nursing Mahidol University |
| Project Number IRB-NS <u>216/31.0709</u> |
| Date of Approval <u>2 MAY 2016</u> |

IRB-NS Form No. 3.1

You have the right to withdraw from the project at anytime without prior notice. And the refusal to participate or the withdrawal from the research project will not at all affect the proper service or treatment that he/she will receive.

This research project is approved by The Institutional Reviews Boards, Faculty of Nursing (IRB-NS) at the office of IRB-NS room 503 5th floor, Faculty of Nursing, Mahidol University, 999 Phuttamonthon 4 Road, Salaya, NakhonPathom 73170 Thailand Tel 0066 2 441 5333 ext 2531, 2532 Fax 0066 2 441 5333 ext 2531, Email: nsirbnursing@mahidol.ac.th, ns.irbnursing@gmail.com

Then submit document and the result to SMP-IRB institutional review board of Vietnam national University, Associate Professor Le Thi Luyen, MD, PhD. Tel : +84913597423. Y1 Building, No.144 XuanThuystreet, CauGiay district, Hanoi, Vietnam.Code: 100000. Fax: +84-4-37450146. Email: smp@vnu.edu.vn

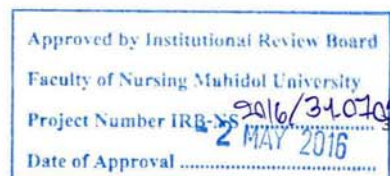
On the condition that I am not treated as indicated in the information sheet distributed to the subjects, I can contact the Chair, or the representative of the IRB-NS at the contact address presenting above.

I thoroughly read the details in this document.

Signature.....Participant

(.....)

Date.....



PARTICIPANT INFORMATION SHEET (VIETNAMESE VERSION)

Thông tin dành cho đối tượng nghiên cứu Phiên bản 02 /ngày 08 tháng 08 năm 2016

THÔNG TIN THAM GIA DÀNH CHO ĐỐI TƯỢNG NGHIÊN CỨU

Tài liệu này sẽ có một số vấn đề Ông/bà có thể không hiểu. Hãy hỏi người nghiên cứu hoặc người đại diện của cô ấy để đưa cho Ông/Bà lời giải thích cho đến khi Ông/Bà hiểu rõ ràng vấn đề. Để giúp cho việc quyết định có tham gia vào chương trình nghiên cứu hay không, Ông/Bà có thể mang tài liệu này về nhà để đọc hoặc hỏi ý kiến người thân và các bác sĩ.

Tên đề tài nghiên cứu: Các yếu tố liên quan đến chất lượng cuộc sống của người bệnh viêm ruột.

Người thực hiện nghiên cứu: Lê Thị Thuy

Địa chỉ và điện thoại liên hệ trong và ngoài giờ hành chính (Đại diện của người nghiên cứu): Bệnh viện Bạch Mai: 78 đường Giải Phóng, Quận Đống Đa, Hà Nội, Việt Nam. Mã bưu chính: 100000. Số điện thoại: (+84) 438683731 Fax: (+84). 438691607

Nguồn kinh phí: tự túc

Mục đích của nghiên cứu: nhằm khảo sát chất lượng cuộc sống của người bệnh viêm ruột và một số mối liên quan giữa sự lo lắng, BMI, kiến thức về căn bệnh và chất lượng cuộc sống ở người bệnh viêm ruột, với các lợi ích được kì vọng, bao gồm:

- 1) Nghiên cứu này cung cấp dữ liệu cơ bản về các yếu tố liên quan đến chất lượng cuộc sống ở bệnh nhân viêm ruột.
- 2) Trong tương lai, phát triển chương trình bằng cách sử dụng dữ liệu này để thúc đẩy chất lượng cuộc sống ở người bệnh viêm ruột.

Tuy nhiên, trong nghiên cứu này, người tham gia nghiên cứu có thể không thu được các lợi ích trực tiếp, nhưng những người bệnh mắc bệnh phổi tắc nghẽn mạn tính sẽ thu được các lợi ích trong tương lai.

Ông/Bà được mời tham gia chương trình nghiên cứu này bởi vì Ông/Bà đã trên 18 tuổi và được chẩn đoán viêm ruột.

Sẽ có 115 người tham gia, và các nghiên cứu sẽ kéo dài 45-60 phút cho câu hỏi câu trả lời.

Việc tham gia nghiên cứu này của Ông/Bà là hoàn toàn TỰ NGUYỆN.

Nếu Ông/Bà quyết định tham gia nghiên cứu này, Ông/Bà sẽ trải qua các bước sau:

1) Người nghiên cứu sẽ yêu cầu Ông/Bà ký tên vào bản chấp thuận tham gia nghiên cứu

2) Người nghiên cứu sẽ thu thập một số thông tin của Ông/Bà từ hồ sơ bệnh án.

3) Nghiên cứu viên sẽ chuẩn bị phòng riêng để phỏng vấn Ông/bà hoặc Ông/bà có thể tự trả lời các câu hỏi. Sau đó nghiên cứu viên sẽ sử dụng bộ câu hỏi bao gồm 4 phần: 1) thông tin chung với 15 câu hỏi. 2) Thang đánh giá chất lượng cuộc sống của bệnh nhân viêm ruột 11 câu. 3) Thang đánh giá sự lo lắng của người bệnh viêm ruột 25 câu. 4) Thang đánh giá kiến thức của người bệnh về bệnh 30 câu hỏi. Tổng số 81 câu và hoàn thành trong khoảng 45-60 phút. Trong suốt quá trình trả lời câu hỏi, nếu có câu hỏi nào Ông/ Bà không hài lòng hoặc khó trả lời Ông/ Bà có thể không trả lời.

Trong quá trình phỏng vấn, nếu Ông/bà cảm thấy khó chịu, Ông/bà có thể yêu cầu dừng lại và nghỉ ngơi cho đến khi Ông/bà cảm thấy dễ chịu trở lại và có thể tiếp tục



Thông tin dành cho đối tượng nghiên cứu Phiên bản 02 /ngày 08 tháng 08 năm 2016

phòng vấn. Nếu Ông/bà không muốn tham gia nghiên cứu nữa, Ông/bà có thể rút khỏi nghiên cứu bất kỳ lúc nào.

Trong quá trình phỏng vấn, Ông/ Bà có thể gặp phải những tình huống không mong đợi do giai đoạn bệnh của bệnh như khó thở, dấu hiệu sinh tồn không ổn định. Nghiên cứu viên sẽ dừng cuộc phỏng vấn và liên lạc với Bác sỹ điều trị cho Ông/ Bà ngay lập tức để chăm sóc Ông/ Bà. Nghiên cứu viên sẽ chăm sóc Ông/bà cho đến khi Ông/bà ổn định.

Nếu Ông/Bà không muốn tham gia vào nghiên cứu này, Ông/Bà vẫn được điều trị và chăm sóc theo đúng quy trình chuẩn của bệnh viện mà không có bất cứ trở ngại nào sau khi rút khỏi nghiên cứu.

Nếu Ông/Bà có bất cứ thắc mắc nào, vui lòng liên hệ người thực hiện nghiên cứu này là Bà Lê Thị Thủy. Số điện thoại: (+84) 989558900.

Ông/Bà không được nhận và cũng không phải trả bất cứ một khoản chi phí nào khi tham gia nghiên cứu này.

Nếu có thêm thông tin gì về các lợi ích và rủi ro của nghiên cứu, nghiên cứu viên sẽ thông báo cho Ông/Bà ngay lập tức.

Thông tin của Ông/Bà sẽ được bảo mật tuyệt đối và không được tiết lộ dưới dạng thông tin cá nhân, tuy nhiên nó sẽ được thể hiện trong báo cáo tổng thể như là kết quả của một đề tài nghiên cứu khoa học. Thông tin cá nhân của Ông/Bà sẽ được kiểm tra bởi người nghiên cứu và Hội đồng đạo đức trong nghiên cứu y sinh học.

Ông/Bà có quyền rút khỏi nghiên cứu bất cứ khi nào mà không cần thông báo trước. Việc Ông/Bà rút khỏi chương trình nghiên cứu sẽ không ảnh hưởng đến chất lượng dịch vụ y tế mà Ông/Bà thụ hưởng.

Đề tài nghiên cứu này được chấp thuận bởi Hội đồng Đạo đức trong nghiên cứu Y sinh học, Khoa Điều Dưỡng, Đại học Mahidol, tầng 5 phòng 504, số 999/4 đường Phuttamonthon 4, Salaya, Nakhon Pathom 73170 Thái Lan. Điện thoại 0066 2 441 5333 số máy lẻ 2531, 2532. Fax 0066 2 441 5333 số máy lẻ 2531, Email: nsirbnursing@mahidol.ac.th, ns.irbnursing@gmail.com.

Đề tài nghiên cứu này cũng được chấp thuận bởi Hội đồng Đạo đức trong nghiên cứu Y sinh học, Đại học Quốc gia Hà Nội, tòa nhà Y1, 144 đường Xuân Thủy, quận Cầu Giấy, thành phố Hà Nội, Việt Nam. Mã bưu chính: 100000, số điện thoại liên lạc: +84437450118, Fax: +84-4-37450146. Email: smp@vnu.edu.vn.

Nếu tôi không được hưởng sự điều trị như trong bản thông tin đưa ra, tôi có thể liên lạc với Hội đồng đạo đức, Khoa Điều dưỡng, Đại học Mahidol hoặc Hội đồng đạo đức trong nghiên cứu Y sinh học, Khoa Y dược, Đại học Quốc Gia Hà Nội với các thông tin liên lạc như đã nêu trên.

Tôi đã đọc kỹ và hiểu toàn bộ chi tiết nêu trong bản thông tin này.

Ngày.....

Họ tên, chữ ký người tham gia nghiên cứu

.....



APPENDIX D INFORM CONSENT

(ENGLISH VERSION)

= 2 MAY 2016
31.0703

IRB-NS Form No. 4

APPENDIX3

Consent Form for Informed and Voluntary Participation in Research

Date...../...../.....

My name is....., aged.....years old,
Now living at the address: No.....Road/street.....
Sub-district/tambon.....District/amphur.....
Province.....Postal code.....Tel.No.....

I give my consent to participate as a subject in the research project entitled: the relationship between anxiety, BMI, knowledge about disease and quality of life among patients with inflammatory bowel disease.

In so doing, I am informed of the background and purpose of research project; its procedural details to carry out or to be carried out; its expected benefits and risks that may occur to the subjects, including methods to prevent and handle harmful consequences; and payment/ incentives, and expense. I thoroughly read the detailed statements in the information sheet given to the research subjects, I was also given explanations and my questions were answered by the head of the research project. I was explained that researcher will collect some demographic data from my medical record form. I was explained that during interview or use questionnaire, if I feel uncomfortable. The researcher will stop the process until I feel comfort to continue or I can stop participation in the study.

I consent to participate as a subject in this research project.

On the condition that I have any questions about the research procedures, or on the condition that I suffer from an undesirable side effect from this research, I can contact Mrs. Ms. Le Thi Thuy via (+84)989558900 or email: lethithuy.91@gmail.com.

On the condition that I am not treated as indicated in the information sheet distributed to the subjects, I can contact the Chair, or the representative of the IRB-NS at the office of IRB-NS room 503 5th floor, Faculty of Nursing, Mahidol University, 999 Phuttamonthon 4 Road, Salaya, Nakhon Pathom 73170 Thailand Tel 0066 2 441 5333 ext 2531, 2532 Fax 0066 2 441 5333 ext 2531, Email: nsirbnursing@mahidol.ac.th, ns.irbnursing@gmail.com

Approved by Institutional Review Board
Faculty of Nursing Mahidol University
Project Number IRB-NS 9816/31-C703
Date of Approval 2.MAY.2016.....

IRB-NS Form No. 4

I am aware of my right to further information concerning benefits and risks from the participation in the research project and my right to withdraw or refrain from the participation anytime without any consequence on the service or health care I am to receive in the future, I consent to the researcher's use of my private information obtained in this research, but do not consent to an individual disclosure of private information. The information must be presented as part of the research results as a whole.

I thoroughly understand the statement in the information sheet for the research subjects and in this consent form. I thereby give my signature.

Signature.....Participants/Proxy/
(.....) Date.....

Signature.....Person in Charge of Informing and
Requesting a Consent/Head of (Ms. Le Thi Thuy) Research Project/Date.....

In case that the participant is not literate, the reader of all the statements for the participant is (Mr./Mrs./Ms.....), who gives his/her signature as a witness.

Signature.....Witness
(.....) Date.....

Version 5 date 10 August 2015

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| Approved by Institutional Review Board |
| Faculty of Nursing Mahidol University |
| Project Number IRB-NS 2016/37-0303 |
| Date of Approval - 2 MAY 2016 |

INFORM CONSENT (VIETNAMESE VERSION)*Bản chấp thuận tham gia nghiên cứu**Phiên bản 02 /ngày 08 tháng 08 năm 2016***BẢN CHẤP THUẬN THAM GIA NGHIÊN CỨU**

Ngày...../...../.....
 Tên tôi là, Tuổi:
 Mã ID (Người nghiên cứu ghi):.....
 Địa chỉ:
 Mã vùng: Số điện thoại:

Trước tiên, tôi xin bày tỏ sự đồng ý tham gia vào đề tài nghiên cứu có tên là **“Các yếu tố liên quan đến chất lượng cuộc sống của người bệnh viêm ruột”**.

Trước khi tham gia nghiên cứu, tôi đã được thông báo về mục đích của nghiên cứu, chi tiết quá trình thực hiện nghiên cứu, những lợi ích và rủi ro có thể xảy ra đối với người tham gia nghiên cứu, các phương pháp ngăn ngừa và giải quyết các tác dụng không mong muốn có thể xảy ra cho người tham gia nghiên cứu và cả về chi phí tham gia nghiên cứu. Tôi đã đọc kỹ toàn bộ thông tin trong bản thông tin dành cho đối tượng nghiên cứu. Bên cạnh đó các câu hỏi của tôi cũng đã được giải đáp bởi người thực hiện nghiên cứu.

Tôi đồng ý tham gia vào nghiên cứu này như một đối tượng nghiên cứu.

Trong trường hợp có bất cứ câu hỏi nào hoặc có vấn đề mới phát sinh trong quá trình nghiên cứu, tôi có thể liên hệ với chị Lê Thị Thùy qua số điện thoại (+84)989558900 hoặc email: lethithuy.91@gmail.com. (Số điện thoại liên lạc trên được kết nối 24/24 h)

Nếu tôi không được điều trị và chăm sóc như những điều khoản được đề cập trong bản thông tin dành cho đối tượng nghiên cứu, tôi có thể liên lạc với Hội đồng Đạo đức, Khoa Điều dưỡng, Đại học Mahidol, đặt văn phòng tại tầng 5 phòng 503 Đại học Mahidol, 999 Phuttamonthon 4 Road, Salaya, Nakhon Pathom 73.170 Thái Lan. Tel 00662441 5333 ext 2531, 2532 0066 Fax 24.415.333 ext 2531, Email: nsirbnursing@mahidol.ac.th, ns.irbnursing@gmail.com

Tôi cũng có thể liên lạc với Hội đồng đạo đức trong nghiên cứu Y sinh học, Khoa Y Dược, Đại học Quốc Gia Hà Nội. Địa chỉ: tòa nhà Y1, số 144 phố Xuân Thủy, quận Cầu Giấy, Hà Nội, Việt Nam; điện thoại: 04-37450188; fax: +84437450146; email: smp@vnu.edu.vn.

Tôi nhận thức được quyền của mình để tiếp tục nhận thông tin liên quan đến lợi ích và rủi ro từ việc tham gia vào các dự án nghiên cứu và tôi có quyền rút khỏi nghiên cứu hoặc từ chối không tiếp tục tham gia nghiên cứu bất cứ lúc nào mà không cần lý do, tôi bằng lòng để nghiên cứu viên sử dụng thông tin cá nhân cho việc nghiên cứu, nhưng không đồng ý việc tiết lộ thông tin cá nhân. Các thông tin phải được trình bày như là một phần của kết quả nghiên cứu.

Tôi hoàn toàn hiểu được tuyên bố trong bản thông tin dành cho đối tượng nghiên cứu và trong phiếu chấp thuận tham gia nghiên cứu này. Sau đây là chữ ký của tôi.

Chủ nhiệm đề tài
(Ký và ghi rõ họ tên)

Người tham gia nghiên cứu
(Ký và ghi rõ họ tên)

APPENDIX E INSTRUMENTS

(ENGLISH VERSION)

- 2 MAY 2016
31.0703

APPENDIX 1

INSTRUMENT

Part 1 Patient general information

General information and information related to illness of the patients Patient's general information (for researcher collect data from medication recorded)

The following questions related to patients personal information and Information related to illness. Please tick (✓) or fill in blanks in the following questions:

- Code Number: _____
1. Gender Male Female
2. Age: Month Year:
3. Weight: Height: BMI:
4. Material status
- | | | |
|----------------------------------|----------------------------------|------------------------------------|
| <input type="checkbox"/> Married | <input type="checkbox"/> Devoted | <input type="checkbox"/> Separated |
| <input type="checkbox"/> Single | <input type="checkbox"/> Widowed | |
5. Education level
- | | |
|--|--|
| <input type="checkbox"/> Elementary school | <input type="checkbox"/> Secondary school |
| <input type="checkbox"/> High school | <input type="checkbox"/> Two years certificate |
| <input type="checkbox"/> Bachelor | <input type="checkbox"/> Post graduated |
6. Occupation
- | | |
|----------------------------------|---|
| <input type="checkbox"/> Famer | <input type="checkbox"/> House wife |
| <input type="checkbox"/> Retired | <input type="checkbox"/> Staff government |
- Other:
7. Income personal/ family:
8. Payment method
- | | |
|-------------------------------------|---------------------------------------|
| <input type="checkbox"/> Government | <input type="checkbox"/> Insurance |
| <input type="checkbox"/> Self-pay | <input type="checkbox"/> Organization |
9. Length of stay in the hospital:
10. Co-morbidities
- | | |
|---|--|
| <input type="checkbox"/> Circulatory diseases | <input type="checkbox"/> Diabetes Mellitus |
| <input type="checkbox"/> Respiratory disease | <input type="checkbox"/> Gastric diseases |
| <input type="checkbox"/> Osteoporosis | <input type="checkbox"/> Other: |
11. How long you have been diagnosed with IBD? (in years)
12. How long do you take time off work due to IBD.....(days)
13. What do you have current and past treatment method?
- | | | |
|--|---|----------------------------------|
| <input type="checkbox"/> Traditional medical | <input type="checkbox"/> Pharmacy medical | <input type="checkbox"/> Surgery |
|--|---|----------------------------------|
14. Which medicines do you use in the past and now?.....
15. Do you have any habits such as: smoking? Yes No
- Drinking or exercise? Yes No

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Part 2 Short Form Health Survey (SF-36):

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. For each of the following questions, please circle the number that best describes your answer.

GENERAL HEALTH:

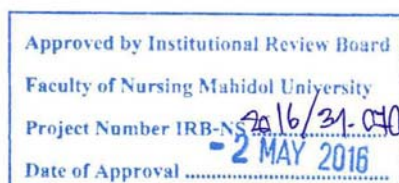
| 1. In general, would you say your health is: | |
|--|---|
| Excellent | 1 |
| Very Good | 2 |
| Good | 3 |
| Fair | 4 |
| Poor | 5 |
| 2. Compared to one year ago, how would you rate your health in general now? | |
| Much better now than one year ago | 1 |
| Somewhat better now than one year ago | 2 |
| About the same | 3 |
| Somewhat worse now than one year ago | 4 |
| Much worse than one year ago | 5 |

LIMITATIONS OF ACTIVITIES:

3. 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?

(Circle One Number on Each Line)

| | Yes, Limited a lot | Yes, Limited a Little | No, Not Limited at all |
|--|--------------------------|-----------------------------|------------------------------|
| a. Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports. | 1 | 2 | 3 |
| b. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | 1 | 2 | 3 |
| c. Lifting or carrying groceries | 1 | 2 | 3 |
| d. Climbing several flights of stairs | 1 | 2 | 3 |
| e. Climbing one flight of stairs | 1 | 2 | 3 |
| f. Bending, kneeling, or stooping | 1 | 2 | 3 |
| g. Walking more than a mile | 1 | 2 | 3 |
| h. Walking several blocks | 1 | 2 | 3 |
| i. Walking one block | 1 | 2 | 3 |
| j. Bathing or dressing yourself | 1 | 2 | 3 |



PHYSICAL HEALTH PROBLEMS:

4. 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?

(Circle One Number on Each Line)

| | Yes (1) | No (2) |
|---|------------|-----------|
| Cut down the amount of time you spent on work or other activities | 1 | 2 |
| Accomplished less than you would like | 1 | 2 |
| Were limited in the kind of work or other activities | 1 | 2 |
| Had difficulty performing the work or other activities (for example, it took extra effort) | 1 | 2 |

EMOTIONAL HEALTH PROBLEMS:

5. 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)?

(Circle One Number on Each Line)

| | Yes (1) | No (2) |
|---|------------|-----------|
| Cut down the amount of time you spent on work or other activities | 1 | 2 |
| Accomplished less than you would like | 1 | 2 |
| Didn't do work or other activities as carefully as usual | 1 | 2 |

SOCIAL ACTIVITIES:

6. 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?

(Circle One Number on Each Line)

| | |
|-------------|---|
| Not at all | 1 |
| Slightly | 2 |
| Moderately | 3 |
| Severe | 4 |
| Very Severe | 5 |

PAIN:

7. How much bodily pain have you had during the past 4 weeks?

(Circle One Number on Each Line)

| | |
|-------------|---|
| None | 1 |
| Very Mild | 2 |
| Mild | 3 |
| Moderate | 4 |
| Severe | 5 |
| Very Severe | 6 |

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

(Circle One Number on Each Line)

| | |
|--------------|---|
| Not at all | 1 |
| A little bit | 2 |
| Moderately | 3 |
| Quite a bit | 4 |
| Extremely | 5 |

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ENERGY AND EMOTIONS:

9. These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the answer that comes closest to the way you have been feeling. **(Circle One Number on Each Line)**

| | All of the time | Most of the time | A good Bit of the Time | Some of the time | A little bit of the time | None of the Time |
|--|-----------------|------------------|------------------------|------------------|--------------------------|------------------|
| a. Did you feel full of pep? | 1 | 2 | 3 | 4 | 5 | 6 |
| b. Have you been a very nervous person? | 1 | 2 | 3 | 4 | 5 | 6 |
| c. Have you felt so down in the dumps that nothing could cheer you up? | 1 | 2 | 3 | 4 | 5 | 6 |
| d. Have you felt calm and peaceful? | 1 | 2 | 3 | 4 | 5 | 6 |
| e. Did you have a lot of energy? | 1 | 2 | 3 | 4 | 5 | 6 |
| f. Have you felt downhearted and blue? | 1 | 2 | 3 | 4 | 5 | 6 |
| g. Did you feel worn out? | 1 | 2 | 3 | 4 | 5 | 6 |
| h. Have you been a happy person? | 1 | 2 | 3 | 4 | 5 | 6 |
| i. Did you feel tired? | 1 | 2 | 3 | 4 | 5 | 6 |

SOCIAL ACTIVITIES:

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? **(Circle One Number on Each Line)**

| | |
|--------------------------|---|
| All of the time | 1 |
| Most of the time | 2 |
| Some of the time | 3 |
| A little bit of the time | 4 |
| None of the Time | 5 |

GENERAL HEALTH:

11. How TRUE or FALSE is each of the following statements for you. **(Circle One Number on Each Line)**

| | Definitely true | Mostly true | Don't know | Mostly false | Definitely false |
|---|-----------------|-------------|------------|--------------|------------------|
| a. I seem to get sick a little easier than other people | 1 | 2 | 3 | 4 | 5 |
| b. I am as healthy as anybody I know | 1 | 2 | 3 | 4 | 5 |
| c. I expect my health to get worse | 1 | 2 | 3 | 4 | 5 |
| d. My health is excellent | 1 | 2 | 3 | 4 | 5 |

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Part 3: Hopkins Symptom Checklist 25 (HSCL- 25)

Listed below are symptoms or problems that people sometimes have. Please read each one carefully and describe how much the symptoms bothered you or distressed you in the last week, including today. Place a check in the appropriate column.

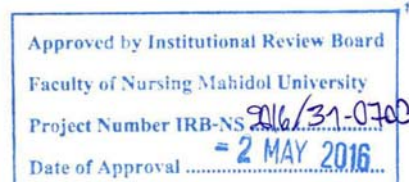
| No | ANXIETY SYMPTOMS | Not at all | A little | Quite a bit | Extremely |
|----|---|-------------------|-----------------|--------------------|------------------|
| 1 | Suddenly scared for no reason | | | | |
| 2 | Feeling fearful | | | | |
| 3 | Faintness, dizziness or weakness | | | | |
| 4 | Nervousness or shakiness inside | | | | |
| 5 | Heart pounding or racing | | | | |
| 6 | Trembling | | | | |
| 7 | Feeling tense or Keyed up | | | | |
| 8 | Headache | | | | |
| 9 | Spell of terror or panic | | | | |
| 10 | Feeling restless or can't sit still | | | | |
| | DEPRESSION SYMPTOMS | Not at all | A little | Quite a bit | Extremely |
| 11 | Feeling low in energy, slowed down | | | | |
| 12 | Blaming yourself for things | | | | |
| 13 | Crying easily | | | | |
| 14 | Loss of sexual interest or pleasure | | | | |
| 15 | Poor appetite | | | | |
| 16 | Difficulty falling asleep, staying asleep | | | | |
| 17 | Feeling hopeless about future | | | | |
| 18 | Feeling blue | | | | |
| 19 | Feeling lonely | | | | |
| 20 | Thought of ending your life | | | | |
| 21 | Feeling of being trapped or caught | | | | |
| 22 | Worry too much about things | | | | |
| 23 | Feeling no interest in things | | | | |
| 24 | Feeling everything is an effort | | | | |
| 25 | Feeling of worthlessness | | | | |

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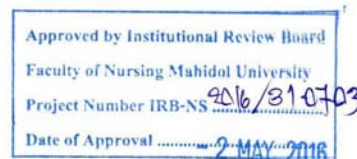
**Part 4: TESTING YOUR KNOWLEDGE OF CROHN'S AND COLITIS:
THE CCKNOW SCORE**

This questionnaire will help your doctors and nurses know on which topics you may need more information. This will help make your treatment more effective. Please tick only *one* answer for each question.

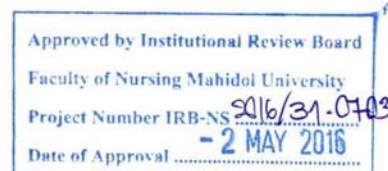
1. The intestines play an important role in the body but they only work during meal times:
 - a) True
 - b) False
 - c) Don't know
2. People with inflammatory bowel disease are never allowed to eat dairy products:
 - a) True
 - b) False
 - c) Don't know
3. Elemental feeds are sometimes used to treat Crohn's disease and ulcerative colitis. They:
 - a) Always contain a lot of fibre
 - b) Are very easy to digest
 - c) Come in the form of tablets
 - d) Don't know
4. Proctitis:
 - a) Is a form of colitis that affects the rectum or back passage only
 - b) Is a form of colitis that affects the whole of the large bowel
 - c) Don't know
5. When a patient with inflammatory bowel disease passes blood in their stool it means:
 - a) They definitely have bowel cancer
 - b) They are having a flare up of their disease
 - c) Don't know
6. Patients with inflammatory bowel disease are probably cured if they have been symptom free for 3 years:
 - a) True
 - b) False
 - c) Don't know
7. Inflammatory bowel disease runs in families:
 - a) True
 - b) False
 - c) Don't know
8. If patients with inflammatory bowel disease are not careful with their personal hygiene they can pass on their disease to friends and members of the family:
 - a) True
 - b) False
 - c) Don't know
9. Patients with inflammatory bowel disease can get inflammation in other parts of the body as well as the bowel:
 - a) True
 - b) False
 - c) Don't know



10. A fistula:
- a) Is an abnormal track between 2 pieces of bowel or between the bowel and skin
 - b) Is a narrowing of the bowel which may obstruct the passage of the contents
 - c) Don't know
11. The terminal ileum:
- a) Is a section of the bowel just before the anus
 - b) Is a section of the bowel just before the large intestine
 - c) Don't know
12. During a flare up of inflammatory bowel disease:
- a) The platelet count in the blood rises
 - b) The albumin level in the blood rises
 - c) The white cell count in the blood falls
 - d) Don't know
13. Steroids (such as prednisolone/prednisone/budesonide/ hydrocortisone):
- a) Can only be taken by mouth
 - b) Can be given in the form of an enema into the back passage
 - c) Cannot be given directly into the vein
 - d) Don't know
14. Steroids usually cause side effects:
- a) only after they have been taken for a long time and in high doses
 - b) Immediately and even after small doses
 - c) Which are not permanent and all disappear after treatment is stopped
 - d) Don't know
15. Immunosuppressive drugs are given to inflammatory bowel disease patients to:
- a) Prevent infection in the bowel by bacteria
 - b) Reduce inflammation in the bowel
 - c) Don't know
16. Sulphasalazine:
- a) Controls the level of sulphur in the bloodstream
 - b) Can be used to reduce the frequency of flare ups
 - c) Cannot be used to prevent flare ups
 - d) Don't know
17. An example of an immunosuppressive drug used in inflammatory bowel disease is:
- a) Sulphasalazine
 - b) Mesalazine
 - c) Azathioprine
 - d) Don't know
18. If a woman has Crohn's disease:
- a) She may find it more difficult to become pregnant
 - b) She should not have children
 - c) Her pregnancy will always have complications
 - d) She should stop all medication during her pregnancy
 - e) Don't know
19. Patients who smoke are more likely to have:
- a) Ulcerative colitis
 - b) Crohn's disease
 - c) Don't know



20. Which one of the following statements is false?
- a) Ulcerative colitis can occur at any age
 - b) Stress and emotional events are linked with the onset of ulcerative colitis
 - c) Ulcerative colitis is least common in Europeans and North Americans
 - d) Patients with ulcerative colitis have an increased risk of developing bowel cancer
 - e) Don't know
21. The examination of the large bowel with a flexible camera is called a:
- a) Barium enema
 - b) Biopsy
 - c) Colonoscopy
 - d) Don't know
22. Male patients who take sulphasalazine:
- a) Have reduced fertility levels that are reversible
 - b) Have reduced fertility levels that are not reversible
 - c) The drug does not have any effect on male fertility
 - d) Don't know
23. The length of the small bowel is approximately:
- a) 2 feet
 - b) 12 feet
 - c) 20 feet
 - d) Don't know
24. The function of the large bowel is to absorb:
- a) Vitamins
 - b) Minerals
 - c) Water
 - d) Don't know
25. Another name for an ileorectal anastomosis operation with formation of a reservoir is:
- a) Purse
 - b) Pouch
 - c) Stoma
 - d) Don't know
26. If a part of the bowel called the terminal ileum is removed during surgery the patient will have impaired absorption of:
- a) Vitamin C
 - b) Vitamin A
 - c) Vitamin B12
 - d) Don't know
27. Patients with IBD need to be screened for cancer of the colon. Which one of the following statements about screening is false? Screening should be offered to all patients with ulcerative colitis:
- a) Which affects only the rectum
 - b) Which has lasted for 8–10 years
 - c) Which started before the age of 50
 - d) Don't know



28. There are millions of tiny “hairs” in the small bowel to increase the absorptive surface. They are called:

- a) Villi
- b) Enzymes
- c) Bile salts
- d) Crypts
- e) Don't know

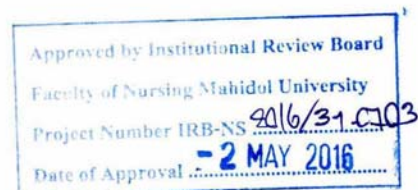
29. Which one of the following is not a common symptom of inflammatory bowel disease?

- a) Abdominal pain
- b) Change in bowel habit
- c) Headache
- d) Fever
- e) Don't know

30. If a child has inflammatory bowel disease; he/she probably will not:

- a) live beyond the age of 45
- b) be as tall as his or her friends
- c) be as intelligent as his or her friends
- d) Don't know

.....



INSTRUMENTS (VIETNAMESE VERSION)

BỘ CÂU HỎI NGHIÊN CỨU

Phần 1. Thông tin chung của người bệnh

Số thứ tự: Mã bệnh án:

Mã ID:.....

Những câu hỏi sau liên quan đến thông tin cá nhân. Xin hãy đánh dấu tích(✓) những câu hỏi sau

1. Giới tính Nam Nữ
2. Tuổi: Tháng Năm sinh:
3. Cân nặng: Chiều cao: BMI:.....
4. Tình trạng hôn nhân
- Đã lập gia đình Ly hôn Ly thân
- Độc thân Góa (chồng hoặc vợ)
5. Trình độ học vấn
- Tiểu học Trung học cơ sở
- Trung học phổ thông Trung cấp/ chuyên nghiệp
- Cao đẳng, Đại học Sau đại học
6. Nghề nghiệp
- Nông dân Nội trợ
- Nghỉ hưu Nhân viên nhà nước Khác:
7. Tổng thu nhập của bản thân/ gia đình:
8. Phương pháp chi trả viện phí
- Chính phủ Bảo hiểm
- Tự chi trả Tổ chức chi trả
9. Thời gian nằm viện được bao lâu:.....
10. Thời gian mắc bệnh (bao nhiêu năm):
11. Ông/bà được chẩn đoán là viêm loét đại tràng được bao nhiêu lâu?.....(năm)
12. Ông/bà đã phải nghỉ làm do viêm loét đại tràng là bao nhiêu ngày?(ngày)
13. Những phương pháp đã dùng trước đây?
- Đông y Tây y Phẫu thuật
14. Những thuốc đã dùng trước đây và hiện tại?
15. Ông/bà có thói quen: Hút thuốc? Có Không
- Uống rượu? Có Không
- Tập thể thao? Có Không

Phần 2. Câu hỏi khảo sát sức khỏe (SF-36):

Phần khảo sát này hỏi quan điểm của ông/bà về sức khỏe của ông/bà. Thông tin này sẽ giúp theo dõi cách ông/bà cảm nhận và khả năng thực hiện các hoạt động bình thường của ông/bà như thế nào. Cảm ơn ông/bà đã hoàn thành khảo sát này! Đối với mỗi câu hỏi sau, hãy khoanh tròn số mô tả tốt nhất câu trả lời của ông/bà.

SỨC KHỎE TỔNG QUÁT

| | |
|--|---|
| 1. Nhìn chung, sức khỏe hiện tại là | |
| Tuyệt vời | 1 |
| Rất tốt | 2 |
| Tốt | 3 |
| Bình thường | 4 |
| Kém | 5 |
| 2. So với một năm trước đây, làm thế nào ông/bà sẽ đánh giá sức khỏe của ông/bà hiện tại thế nào? | |
| Tốt hơn nhiều so với một năm trước | 1 |
| Khá tốt hơn so với một năm trước | 2 |
| Tương đương | 3 |
| Hơi kém hơn so với một năm trước | 4 |
| Tệ hơn nhiều so với một năm trước | 5 |

GIỚI HẠN CÁC HOẠT ĐỘNG:

3. Các mục sau đây là về các hoạt động ông/bà có thể làm trong một ngày điển hình. Sức khỏe của ông/bà hiện tại có giới hạn ông/bà trong các hoạt động này không? Nếu có, thì ở mức độ nào? (Khoanh tròn vào một trong số mỗi dòng)

| | Giới hạn nhiều | Một chút | Không giới hạn |
|---|----------------|----------|----------------|
| a. Hoạt động mạnh mẽ, chẳng hạn như chạy, nâng vật nặng, chơi thể thao quá sức | 1 | 2 | 3 |
| b. Hoạt động vừa phải, chẳng hạn như đi chuyên gân, đẩy máy hút bụi, chơi bowling, chơi gôn | 1 | 2 | 3 |
| c. Nâng hoặc mang túi đi chợ | 1 | 2 | 3 |
| d. Leo cầu thang nhiều tầng | 1 | 2 | 3 |
| e. Leo cầu thang 1 tầng | 1 | 2 | 3 |
| f. Uốn, quỳ, khom lưng | 1 | 2 | 3 |
| g. Đi bộ 2 km (quanh tòa nhà 2 vòng) | 1 | 2 | 3 |
| h. Đi bộ nhiều (quanh tòa nhà >2 vòng) | 1 | 2 | 3 |
| i. Đi bộ quanh 1 tòa nhà | 1 | 2 | 3 |
| j. Tự tắm hoặc mặc quần áo | 1 | 2 | 3 |

VẤN ĐỀ SỨC KHỎE THỂ CHẤT:

4. Trong suốt 4 tuần qua, ông/bà có bất kỳ vấn đề sau đây trong công việc của ông/bà hoặc các hoạt động hàng ngày thường xuyên không? **(Khoanh tròn vào mỗi lựa chọn)**

| | Có (1) | Không (2) |
|--|-----------|--------------|
| Cắt giảm số lượng giành cho hoạt động khác | 1 | 2 |
| Thực hiện ít hơn ông/bà mong muốn | 1 | 2 |
| Được giới hạn trong các loại công việc hoặc hoạt động khác | 1 | 2 |
| Gặp khó khăn khi thực hiện công việc hoặc các hoạt động khác (ví dụ, cần phải nỗ lực thêm) | 1 | 2 |

VẤN ĐỀ SỨC KHỎE CẢM XÚC:

5. Trong suốt 4 tuần qua, ông/bà có bất kỳ vấn đề nào trong công việc ông/bà hoặc các hoạt động hàng ngày thường xuyên khác do kết quả của bất kỳ vấn đề (chẳng hạn như cảm giác chán nản hoặc lo lắng)? **(Khoanh tròn vào mỗi lựa chọn phù hợp)**

| | Có (1) | Không (2) |
|---|-----------|--------------|
| Cắt giảm số lượng thời gian ông/bà dành cho công việc hoặc các hoạt động khác | 1 | 2 |
| Thực hiện ít hơn ông/bà muốn | 1 | 2 |
| Đã không làm việc hoặc thực hiện hoạt động khác như một cách cẩn thận như bình thường | 1 | 2 |

HOẠT ĐỘNG XÃ HỘI:

6. Vấn đề cảm xúc gây ảnh hưởng tới các hoạt động xã hội bình thường của ông/bà với gia đình, ông/bà bè, hàng xóm, hoặc các nhóm thể nào?

(Khoanh tròn vào lựa chọn phù hợp)

| | |
|----------|---|
| Không hề | 1 |
| Hơi | 2 |
| Vừa | 3 |
| Nặng | 4 |
| Rất nặng | 5 |

ĐAU:

7. Mức độ cơ thể đau trong 4 tuần qua?

(Khoanh tròn vào lựa chọn phù hợp)

| | |
|-----------|---|
| Không đau | 1 |
| Rất ít | 2 |
| Ít | 3 |
| Vừa | 4 |
| Nhiều | 5 |
| Rất nhiều | 6 |

8. Trong 4 tuần qua, mức độ thường xuyên của cơn đau ảnh hưởng đến công việc bình thường của ông/bà (bao gồm cả công việc bên ngoài nhà và nội trợ)?

(Khoanh tròn vào lựa chọn phù hợp)

| | |
|---------------|---|
| Không lúc nào | 1 |
| Một chút | 2 |
| Vừa | 3 |
| Nhiều | 4 |
| Rất nhiều | 5 |

NĂNG LƯỢNG VÀ CẢM XÚC:

9. Những câu hỏi này là về ông/bà cảm thấy như thế nào trong suốt 4 tuần qua. Với mỗi câu hỏi, xin vui lòng cung cấp cho các câu trả lời đến gần nhất với cảm giác của ông bà. **(Khoanh tròn vào lựa chọn thích hợp)**

| | Tất cả thời gian | Hầu hết thời gian | Nhiều thời gian | Thỉnh thoảng | Một chút | Không lúc nào |
|---|------------------|-------------------|-----------------|--------------|----------|---------------|
| a. Ông/bà có cảm thấy rất hăng hái | 1 | 2 | 3 | 4 | 5 | 6 |
| b. Ông/bà trở nên lo lắng? | 1 | 2 | 3 | 4 | 5 | 6 |
| c. Ông/bà cảm thấy rất buồn chán mà không gì có thể cổ vũ ông/bà lên? | 1 | 2 | 3 | 4 | 5 | 6 |
| d. Ông/bà cảm thấy bình tĩnh và yên bình? | 1 | 2 | 3 | 4 | 5 | 6 |
| e. Ông/bà có nhiều năng lượng? | 1 | 2 | 3 | 4 | 5 | 6 |
| f. Ông/bà cảm thấy chán nản? | 1 | 2 | 3 | 4 | 5 | 6 |
| g. Ông/bà có cảm thấy uể oải? | 1 | 2 | 3 | 4 | 5 | 6 |
| h. Ông/bà trở nên là người hạnh phúc? | 1 | 2 | 3 | 4 | 5 | 6 |
| i. Ông/bà có thấy mệt mỏi? | 1 | 2 | 3 | 4 | 5 | 6 |

HOẠT ĐỘNG XÃ HỘI:

10. Trong suốt 4 tuần qua, có bao nhiêu thời gian sức khỏe thể chất của ông/bà hoặc vào vấn đề cảm xúc với các hoạt động của ông/bà trong xã hội (như khi đi thăm ông/bà bè, người thân, vv? **(Khoanh tròn vào lựa chọn phù hợp)**

| | |
|-------------------|---|
| Tất cả thời gian | 1 |
| Hầu hết thời gian | 2 |
| Nhiều thời gian | 3 |
| Thỉnh thoảng | 4 |
| Một chút | 5 |

SỨC KHỎE CHUNG:

11. Chọn mức độ với mỗi nhận định dưới đây. **(Khoanh tròn vào lựa chọn phù hợp)**

| | Chắc chắn | Chủ yếu đúng | Không biết | Hầu hết sai | Chắc chắn sai |
|---|-----------|--------------|------------|-------------|---------------|
| a. Tôi dường như bị ốm một chút dễ dàng hơn so với những người khác | 1 | 2 | 3 | 4 | 5 |
| b. Tôi khỏe mạnh như những người xung quanh | 1 | 2 | 3 | 4 | 5 |
| c. Tôi sức khỏe của đang xấu đi | 1 | 2 | 3 | 4 | 5 |
| d. Sức khỏe của tôi là tuyệt vời | 1 | 2 | 3 | 4 | 5 |

Phần 3: Bộ câu hỏi đánh giá sự lo lắng và trầm cảm tại bệnh viện

Làm ơn hãy đánh dấu vào ô phản ánh đúng nhất cảm nhận của ông/bà trong 1 tuần qua

| Câu | Phần I: Dấu hiệu lo lắng | Không | Rất ít | Một chút | Rất nhiều |
|------------|---|--------------|---------------|-----------------|------------------|
| 1 | Đột nhiên sợ hãi không có lý do | | | | |
| 2 | Cảm thấy căng thẳng | | | | |
| 3 | Mệt mỏi, chóng mặt, yếu ớt | | | | |
| 4 | Luôn trong trạng thái lo lắng, căng thẳng | | | | |
| 5 | Tim đập nhanh mạnh | | | | |
| 6 | Run rẩy | | | | |
| 7 | Cảm thấy căng thẳng tăng lên | | | | |
| 8 | Đau đầu | | | | |
| 9 | Luôn trong tình trạng hoang mang | | | | |
| 10 | Cảm thấy bồn chồn, ko ngồi yên | | | | |
| | Phần II: Dấu hiệu buồn chán | Không | Rất ít | Một chút | Rất nhiều |
| 11 | Cảm thấy ít năng lượng, chậm lại | | | | |
| 12 | Đổ lỗi cho bản thân | | | | |
| 13 | Khóc một cách dễ dàng | | | | |
| 14 | Giảm ham muốn | | | | |
| 15 | Chán ăn | | | | |
| 16 | Khó ngủ, ngủ ko lâu | | | | |
| 17 | Cảm thấy tuyệt vọng | | | | |
| 18 | Cảm thấy trống rỗng | | | | |
| 19 | Cảm giác cô đơn | | | | |
| 20 | Nghĩ về chấm dứt cuộc sống | | | | |
| 21 | Cảm giác bị mắc kẹt | | | | |
| 22 | Lo lắng quá nhiều về nhiều thứ | | | | |
| 23 | Không quan tâm đến điều gì | | | | |
| 24 | Cảm thấy mọi thứ đều đòi hỏi nhiều nỗ lực | | | | |
| 25 | Cảm giác vô dụng | | | | |

13. Steroids (như prednisolone / prednisone / budesonide / hydrocortisone):

- a) Chỉ có thể được dùng bằng đường uống
- b) Có thể được đưa vào bằng cách rửa ruột
- c) Không thể được đưa trực tiếp vào tĩnh mạch
- d) Không biết

14. Steroids thường gây ra tác dụng phụ:

- a) Chỉ sau khi đã được sử dụng trong một thời gian dài và với liều lượng cao
- b) Ngay lập tức và thậm chí sau khi dùng liều nhỏ
- c) Không phải là vĩnh viễn và sẽ biến mất sau khi đã ngưng điều trị
- d) Không biết

15. Thuốc ức chế miễn dịch được dùng cho bệnh nhân viêm ruột để:

- a) Ngăn ngừa nhiễm trùng ở ruột do vi khuẩn
- b) Giảm viêm ở ruột
- c) Không biết

16. Sulphasalazine:

- a) Điều khiển mức độ sulphur (lưu huỳnh) trong máu
- b) Có thể được sử dụng để giảm tần số của những đợt cấp
- c) Không thể được sử dụng để ngăn chặn đợt cấp của bệnh
- d) Không biết

17. Một ví dụ về một loại thuốc immunosuppressive sử dụng trong bệnh viêm ruột là:

- a) Sulphasalazine
- b) Mesalazine
- c) Azathioprine
- d) Không biết

18. Nếu một người phụ nữ có bệnh Crohn:

- a) Cô ấy có thể gặp khó khăn trong thụ thai mang thai
- b) Cô không nên có con
- c) Luôn có những biến chứng khi mang thai
- d) Cô ấy nên dừng lại tất cả các loại thuốc trong thời gian mang thai
- e) Không biết

19. Bệnh nhân hút thuốc tăng khả năng mắc bệnh:

- a) Viêm loét đại tràng
- b) Bệnh Crohn
- c) Không biết

20. Câu nào trong số này là sai?

- a) Viêm loét viêm đại tràng có thể xảy ra ở mọi lứa tuổi
- b) Các sự kiện căng thẳng và ảnh hưởng cảm xúc có liên kết với sự khởi đầu của viêm loét đại tràng
- c) Viêm loét viêm đại tràng là phổ biến nhất ở châu Âu và Bắc Mỹ
- d) Bệnh nhân có viêm loét đại tràng có tăng nguy cơ phát triển ung thư ruột
- e) Không biết

21. Việc kiểm tra ruột già với một dụng cụ linh hoạt được gọi là:

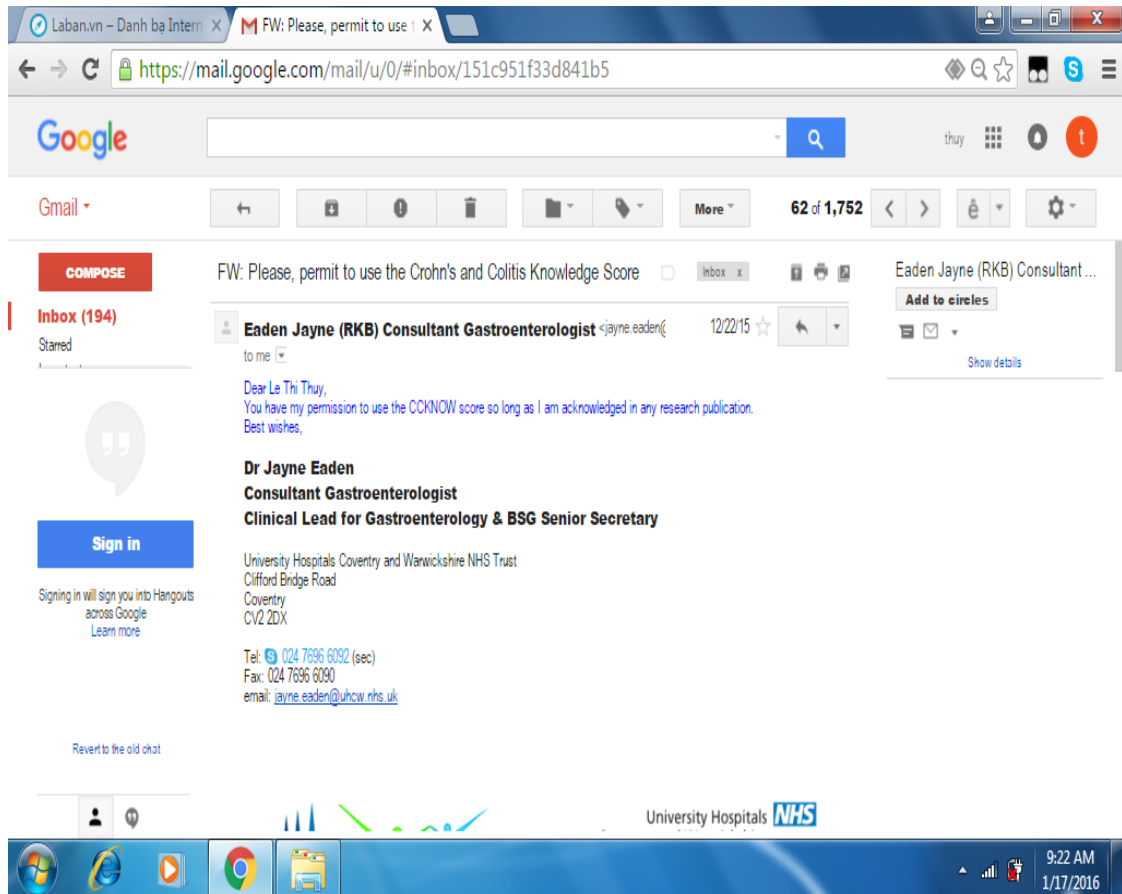
- a) Rửa ruột
- b) Sinh thiết
- c) Nội soi đại tràng
- d) Không biết

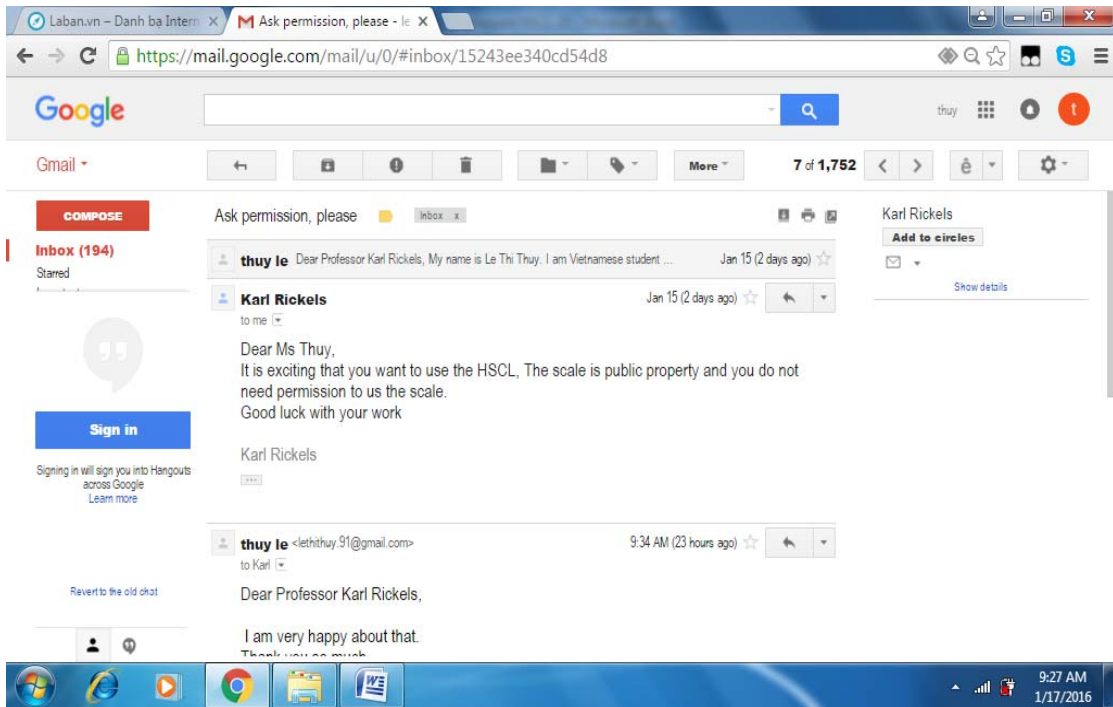
22. Bệnh nhân nam sử dụng Sulphasalazine:

- a) Làm giảm bớt khả năng sinh sản mà có thể phục hồi
- b) Làm giảm bớt khả năng sinh sản mà không thể phục hồi
- c) Thuốc không ảnh hưởng tới khả năng sinh sản nam giới
- d) Không biết

APPENDIX F

PERMISSION FOR USING INSTRUMENTS





APPENDIX G

ADDITIONAL STATISTICAL ANALYSIS

Tests of Normality

| | Kolmogorov-Smirnov ^a | | | Shapiro-Wilk | | |
|-------------------------------------|---------------------------------|----|-------|--------------|----|------|
| | Statistic | Df | Sig. | Statistic | df | Sig. |
| BMI | .122 | 30 | .200* | .938 | 30 | .083 |
| Knowledge about disease 24 items | .170 | 30 | .027 | .924 | 30 | .035 |
| sum ANXIETY and DEPRESSION | .072 | 30 | .200* | .975 | 30 | .696 |
| Quality Of Life | .187 | 30 | .009 | .800 | 30 | .000 |

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

APPENDIX H

The correlation between BMI, anxiety and depression, knowledge about disease and eight domains of SF-36 scale

| Domains of SF- 36 scale | BMI | Anxiety and Depression | Knowledge of IBD | | | |
|---------------------------|--------|------------------------|------------------|-----------------------|-------------|-----------------------------|
| | | | IBD complication | General IBD knowledge | Diet of IBD | Medication or Treatment IBD |
| Physical functioning | .351** | -.519** | .421** | .471** | .341** | .264** |
| Physical health | .282** | -.518** | .556** | .605** | .388** | .441** |
| Emotional problems | .295** | -.500** | .536** | .593** | .403** | .417** |
| Vitality (Energy-Fatigue) | .253** | -.581** | .343** | .310** | .074 | .197* |
| Emotional well-being | .253** | -.541** | .332** | .341** | .004 | .235* |
| Social Functioning | .324** | -.501** | .493** | .493** | .301** | .313** |
| Pain | .262** | -.437** | .482** | .450** | .221* | .338** |
| General Health | .138 | -.581** | .370** | .414** | .314** | .262** |

*P < .05, **p < .01

BIOGRAPHY

NAME: Le Thi Thuy

DATE OF BIRTH: 09 January 1981

PLACE OF BIRTH: Hanoi, Vietnam

INSTITUTION ATTENDED: Hanoi Medical University, 2001-2005;
Bachelor of general Nursing
Mahidol University, 2015-2016
Master of Nursing Science (Adult Nursing)

POSSITION AND OFFICE: Lecturer, Fundamental of Nursing
Department, Faculty of Nursing, Hanoi
Medical College, Hanoi, Vietnam
Office phone: (+84) 4.37320693 ext 245 Fax: (+84) 37322556.

EMPLOYMENT ADDRESS No. 35, Doan Thi Diem Street, Quoc Tu
Giam commune, Dong Da district, Hanoi,
Vietnam
Workplace telephone number:
(84)04.37326303
Email: lienhe@yhn.edu.vn
Website: www.yhn.edu.vn

HOME ADDRESS No 27- 385 alley – Luong The Vinh street-
Nam Tu Liem distrist – Hanoi
Telephone: 04.35531165
Mobile telephone: (84)989558900.
Email: lethithuy.91@gmail.com