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WOMEN WITH IRRITABLE BOWEL SYNDROME

Aspects of quality of life and health

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The bowels are at one time constipated, at another time lax, in the same person.
How the disease has two such different symptoms I do not profess to explain.

W Cumming, London Medical Gazette, 1849

CONTENTS

ABSTRACT

Irritable Bowel Syndrome (IBS) is a common, worldwide, functional disorder affecting a significant number of people, predominantly women. Etiology and pathophysiology is insufficiently understood, but the research over the past decade has led to progress in the understanding of IBS, and it is generally accepted that the symptoms of IBS are multidetermined. However, management of IBS is still a challenge as many patients fail to respond to the therapies available. For patients with IBS the uncertainty regarding cause, diagnosis and treatment may lead to anxiety and a constant search for answers. The chronic bowel problems affect daily life and lead to a reduction in quality of life.

The overall aim was to create a model for health care and to improve health and the quality of life in Swedish women with IBS.

In this thesis a multi-methodological design was used, including qualitative (Paper I) and quantitative (Paper II and III) research methods as well as psychometric testing (Paper IV). In Paper I an overall question about women's perception of their quality of life was analysed by Burnard's content analysis. A quantitative comparative design was used to study differences in symptoms and psychological well-being over time (Paper II) after intervention, a Course of Instruction, and between groups using different laxatives (Paper III). In Paper IV the Visual Analogue Scale for Irritable Bowel Syndrome (VAS-IBS) was psychometrically tested for content and criterion validity, internal consistency, reliability, item-reduction, acceptability of the scale and simplicity.

To be healthy, without physical symptoms, and to have a satisfying social life were important issues for a good quality of life according to the women participating (Paper I). All of the women reflected on issues related to physical, mental and social health, and the need to have balance between family, work and leisure time. The majority of the women mentioned the importance of support from family and friends and they pointed out that this support affected their quality of life in a positive way. A few of the women mentioned that it was important to them to be accepted as they are, in spite of their bowel symptoms. A majority of the women participating had not understood that they have a classified disorder based on established criteria and they were not familiar with the diagnosis or with all that it implies. The women mentioned that their feelings had been hurt by the attitudes of health professionals and they felt misunderstood since the doctors and nurses had been nonchalant about their problems. The women wanted more information and instruction about IBS.

Of the 29 women participating in a Course of Instruction (Paper II), 23 completed the Gastrointestinal Symptom Rating Scale (GSRS) and the Psychological General Well-being (PGWB) Index 12 months after the course. The women perceived less Abdominal Pain ($p<0.037$) and experienced more Vitality ($p<0.045$) than before they started the course, according to the scores of the GSRS and the PGWB. There were a reduced numbers of visits to physicians ($p<0.037$) and to dieticians ($p<0.042$) (Paper II), but there were no statistically significant changes between the women's consumption of pharmacological drugs, naturopathic preparations or reported sick-leave.

There were no statistically significant differences in symptoms according to the scores of the GSRS between those women who used sodium picosulphate regularly at least once a week, and those who used other laxatives, including sporadic use of sodium picosulphate (Paper III). There was, however, a statistically significant difference in psychological well-being according to the PGWB between the two treatment groups. The women who used sodium picosulphate had higher scores (97, interquartile range 79-106), compared to the patients who used other laxative treatments (86 interquartile range 77-95; $p<0.017$), thereby indicating better psychological well-being. The difference was seen in less Anxiety ($p<0.0001$).

The psychometric testing confirmed that the VAS-IBS is an acceptable, homogeneous, patient-reported questionnaire with acceptable content and criterion validity and internal consistency reliability.

In this thesis several aspects related to quality of life and health have been identified, and discussed, namely, confirmation of the diagnosis, confirmation of the patient, instructing the patient and treating the patient's symptoms. Health care in relation to these issues can be described in a pyramid-model. The aim of this model is to help the patients to take responsibility for their illness and to improve their health and quality of life to some extent. The goal should be for the patient to perceive; good physical, mental and social health, good welfare, strength and energy, and self-fulfilment.

ABBREVIATIONS

CVI	Content Validity Index
FBD	Functional Bowel Disorders
FGID	Functional Gastrointestinal Disorder
IBD	Inflammatory Bowel Syndrome
IBS	Irritable Bowel Syndrome
IBS-A	Alternating constipation and diarrhoea Irritable Bowel Syndrome
IBS-C	Constipation-predominant Irritable Bowel Syndrome
IBS-D	Diarrhoea-predominant Irritable Bowel Syndrome
ICD	International Statistical Classification of Diseases and Related Health Problems
ICF	International Classification of Functioning, Disability and Health
GSRS	Gastrointestinal Symptom Rating Scale
HCC	Health Care Consumption
NTC	Normal Transit Constipation
PI-IBS	Postinfectious Irritable Bowel Syndrome
PGWB	Psychological General Well-Being Index
STC	Slow Transit Constipation
VAS	Visual Analogue Scale
VAS-IBS	Visual Analogue Scale-Irritable Bowel Syndrome
WHO	World Health Organisation
WHOQOL	World Health Organization Quality of Life

ORIGINAL PAPERS

This thesis is based on the following papers referred to in the text by their roman numerals:

I. Bengtsson, M. Ohlsson, B. Ulander, K. Women with Irritable Bowel Syndrome and their perception of a good quality of life. *(In review)*

II. Bengtsson, M. Ulander, K. Bergh Börgdal, E. Christensson, AC. Ohlsson, B. A Course of Instruction for women with Irritable Bowel Syndrome. *Patient Education and Counseling, In press, 2005*

III. Bengtsson, M. Ohlsson, B. (2005) Psychological well-being and symptoms in women with chronic constipation treated with sodiumpicosulfat. *Gastroenterology Nursing 28:3-12*

IV. Bengtsson, M. Ohlsson, B. Ulander, K. Development and psychometric testing of the Visual Analogue Scale for Irritable Bowel Syndrome (VAS-IBS). *(In review)*

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BACKGROUND

Introduction

The term Functional Gastrointestinal Disorder (FGID) is used to define a large group of disorders, without an identified underlying pathophysiology. According to the Rome diagnostic criteria 24 of these disorders can be classified into six subgroups based on five anatomical regions; *Functional Oesophageal Disorders, Functional Gastroduodenal Disorders, Functional Bowel Disorders, Functional Biliary Disorders*, and *Functional Anorectal Disorders*, plus *Functional Abdominal Pain* (Corazziari 2004). The subgroup Functional Bowel Disorder (FBD) includes digestive disorders with symptoms attributable to the mid or lower gastrointestinal tract. This subgroup consists of five disorders; *Irritable Bowel Syndrome, Functional Abdominal Bloating, Functional Constipation, Functional Diarrhoea* and *Unspecified Functional Bowel Disord*er, but to distinguish between these disorders is difficult since they overlap (Thompson et al. 1999). Irritable Bowel Disorder (IBS) is one of the most frequently of the FBDs, and common occurring at all ages, even among older persons (Locke et al. 2004b, Ehrenpreis 2005).

There are several reasons for performing research projects on patients with IBS; its high prevalence, severe symptoms, impact on the quality of life of the patients, socioeconomic impact, and high health care costs. However, the research being done world-wide is predominantly focused on finding the key to the disorder, and studies are mostly designed as clinical trials. By contrast, this thesis is an attempt to elucidate the patients' perspectives and put the results into clinical practise, which thereby may lead to better health care of the patients. The concept "health care" is used in this thesis to describe the work of the health care services and the professions that carry out this care included i.e. medicine and nursing (Proctor 2000), which requires a range of health care professionals each with their own unique role and knowledge (Wallace 2002). To optimise the health care of patients with IBS, health professionals need to know more about IBS and how to improve patients' health and thereby, it is to be hoped, also their quality of life.

Irritable Bowel Syndrome

Epidemiology

IBS is a global and common disorder, and has previously been presented as a disorder of civilization. IBS has been described in all continents, also in developing countries, in rural as well as in urban communities (Gwee 2005). The incidence as well as prevalence of IBS varies between countries, due to the diversity of the defining criteria of IBS (Hungin et al 2003, Bommelaer et al. 2004, Gwee 2005), but cultural aspects and the access to health care influence the figures (Gwee 2005). It is difficult to estimate incidence and prevalence since not all persons with bowel-symptoms seek help from health care professionals (Drossman et al. 1993, Phillips 1999). The incidence in Sweden is estimated to be 200 per 100 000 (Agreus et al. 1995). These data can be compared with the incidence of inflammatory bowel diseases (IBD), as Mb Crohn, 4-7 per 100 000, and ulcerous colitis, 15 per 100 000 (Lindgren 2004), which means that at a primary care centre it is more likely for the physician to set the diagnosis IBS than the diagnosis IBD. The overall prevalence of IBS in Europe is estimated to be 10 % (Hungin et al. 2003), but the prevalence appears to be much lower in some countries, i.e., Norway (5.5%), Netherlands (6.2%), Belgium (6.7%) and Spain (7.3%), and higher in Sweden, United Kingdom and Italy (12%) (Hungin et al. 2003, Gwee 2005). IBS affects women more often than men among those who seek health care. In western societies female patients outnumber men by 2:1 (Chang & Heitkemper 2002, Wilson et al. 2004), but in Asia men are more likely to be diagnosed, since they have easier access to medical care due to cultural factors (Gwee 2005).

A diagnosis based on classification

IBS has traditionally been considered as a diagnosis of exclusion rather than a primary diagnosis, since there are no observable biochemical and/or structural abnormalities to be found (Cash & Chey 2004). In the absence of any objective marker, Adrian Manning and associations (1978) at the end of the 1970s, created the first symptom-based criteria for diagnosing the FBDs, the Manning criteria. Critical voices were raised because these criteria did not catch all the patients, due to differences in symptoms between women and men (Smith et al. 1991). Kruis et al. (1984), in the 1980s, developed another approach to distinguish IBS from organic disease. They included physical signs and laboratory findings, with greater weight than the symptoms. Improvements on the Maning and Kruise criteria, recommended by a panel of experts, resulted in the Rome I criteria (Drossman et al. 1993). In 1999 this consensus was modified into the Rome II criteria (Table 1) (Thompson et al. 1999). During 2006 a new version, the Rome III criteria are planned to be published. The Rome criteria have become widely applied and are used in clinical practise as well as in clinical trials.

Table 1. The criteria for the diagnosis Irritable Bowel Syndrome according to the Rome II consensus

At least 12 weeks, which need not be consecutive, in the preceding 12 months, of abdominal discomfort or pain that has two of three features:
(1) Relieved with defecation; and/or
(2) Onset associated with a change in frequency of stool; and/or
(3) Onset associated with a change in form (appearance) of stool.

Supportive symptoms of IBS:
1. Fewer than 3 bowel movements a week
2. More than 3 bowel movements a day
3. Hard or lumpy stools
4. Loose (mushy) or watery stools
5. Straining during a bowel movement
6. Urgency (having to rush to have a bowel movement)
7. Feeling of incomplete bowel movement
8. Passing mucus (white material) during a bowel movement
9. Abdominal fullness, bloating or swelling

(Thompson et al. 1999; p 1144)

IBS is characterised by abdominal pain in combination with altered bowel habits and bloating, and the symptoms are present either continuously or intermittently (Thompson et al. 1999). IBS can be divided into three subtypes based on the pattern of the presenting symptoms; constipation-predominant (IBS-C), diarrhoea-predominant (IBS-D) and alternating constipation and diarrhoea (IBS-A). The diagnosis IBS-C can be based on one or more of the points 1, 3 or 5 and none of points 2, 4 or 6 of the supportive symptoms of IBS in the Rome II criteria (Table 1). By contrast, the diagnosis IBS-D can be based on one or more of the points 2, 4 or 6 and none of points 1, 3 or 5 (Table 1) (Thompson et al. 1999). No criteria have been suggested by the experts of the Rome II committee for the IBS-A subgroup, but exclusion criteria have been described in the literature as; " not fitting either the definitions of IBS-C or IBS-D" (Tillisch et al. 2005), or "mixed pattern of altered bowel habits" (Simrén et al. 2001a). However, patients with IBS-A have reported rapid alternations in bowel habits and short durations of symptom exacerbation and remission (Tillisch et al. 2005).

IBS-A has been presented as the most common of the subtypes of IBS, and may occur in half of the cases (Wilson et al. 2004). However, there are also reports showing that the subtypes occur with equal frequency (Camilleri & Choi 1997, Dapoigny et al. 2004). Since the patients' symptoms are unstable over time, many patients with IBS-C and IBS-D shift to IBS-A with time (Mearin et al. 2004). Furthermore, the distribution of IBS subtypes differs according to criteria, geographical location and population (Guilera et al. 2005). There is even a possibility that IBS-C and IBS-D are different conditions, since there is a diversity of symptoms and the different conditions respond to different treatments (Müller-Lissner et al. 2001). It is also difficult to distinguish patients with IBS-C from patients with chronic Functional Constipation, as well as between IBS-D and Functional Diarrhoea, since these conditions overlap (Table 2) (Prather 2004, Corazziari 2004).

Table 2. The criteria for the diagnosis Functional Constipation and Functional Diarrhoea in the Rome II consensus

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Functional constipation

At least 12 weeks, which need not be consecutive, in the preceding 12 months of two or more of:
(1) Straining in > ¼ defecations;
(2) Lumpy or hard stools in > ¼ defecations;
(3) Sensation of incomplete evacuation in > ¼ defecations;
(4) Sensation of anorectal obstruction/blockade in > ¼ defecations;
(5) Manual manoeuvres to facilite > ¼ defecations (e.g., digital evacuation, support of the pelvic floor); and/or
(6) < 3 defecations/week
Loose stools are not present, and there are insufficient criteria for IBS.

Functional diarrhoea

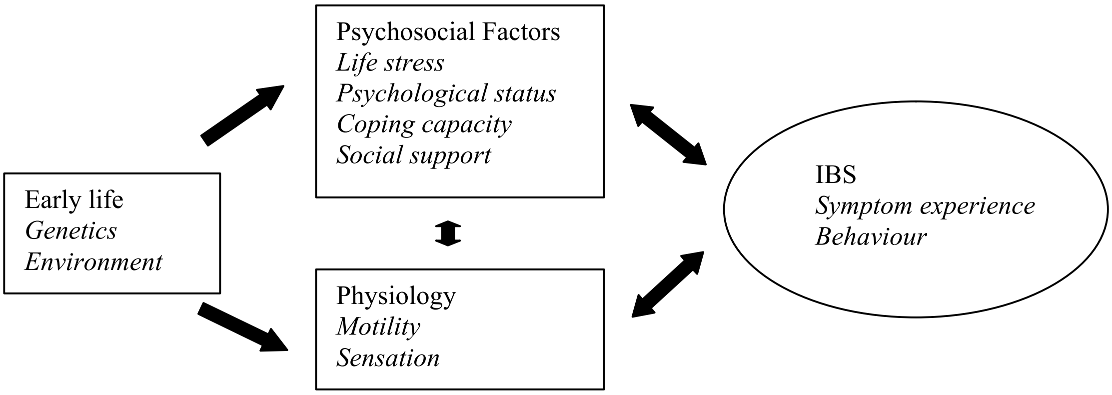
At least 12 weeks, which need not be consecutive, in the preceding 12 months of:
(1) Liquid (mushy) or watery stools;
(2) Present > ¾ of the time; and
(3) No abdominal pain

(Thompson et al. 1999; p 1145

Perspectives on etiology and pathophysiology

According to Lacy and Lee (2005) the symptoms of IBS, abdominal discomfort, irregular bowel movements, bloating, and rectal urgency, were described already in antiquity by Hippocrates. But no explanation for the symptoms was offered until the beginning of the 20th century. Until the 1980s the dominant view of IBS was that external stress in combination with the patient's neurotic behaviour caused the symptoms (Lacy & Lee 2005). Fortunately, the understanding of IBS has changed in recent years, but several issues concerning IBS are still unsolved.

Early life factors can later in life influence the patient's psychosocial experience and physiological function, and generate gastrointestinal symptoms in a vulnerable patient. The inter-relationship between the patient's psychosocial status and physiology will affect how the patient experiences the symptoms, the patient's reaction, as well as the clinical outcome (Drossman 2005). This interaction between physiological, psychological and environmental factors, which contribute to the patient's symptoms, can be explained by a biopsychosocial model (Figure 1) (Drossman 2005).



Figur 1. A conceptual model for IBS showing the inter-relationship between early life, psychosocial and physiological factors and the patient's symptoms. (Modified version, Drossman 2005, p S252)

Predisposing factors

Genetic factors, i.e. low levels of interleukins and cytokines (Gonsalkorale et al. 2003), may predispose to the development of IBS, but early environmental factors, such as social learning, are also important predisposing factors (Levy et al. 2001). This leads to the question of which is the predominant factor; genetics or the environment. Probably they coexist (Levy et al. 2001).

Episodes of sexual and physical abuse have been identified as another predisposing factor (Olden 2002). The co-occurrence of any abuse makes the patient's symptoms more severe and refractory to ordinary treatment. These traumas can sometimes lead to post-traumatic stress (Drossman 1994, 1997).

Since many women suffer from IBS, the role of sex hormones has been raised. For example, women with IBS have reported changes in bowel habits and symptoms during their menstrual cycle (Heitkemper et al. 2003) and pregnancy (Chiloiro et al. 2001). Men with IBS have lower levels of testosterone and luteinizing hormone compared with healthy men (Houghton et al. 2000), which may also support the theory that sex hormones have a part in IBS. However, the role of gender in IBS requires further investigation in relation to hormones, behaviour and functional consequences.

A small group of patients with IBS have reported a beginning of their symptoms after gastroenteritis, so-called postinfectious IBS (PI-IBS) (Spiller 2003). Even evidence of ongoing low-grade inflammation in the bowels (Gwee et al. 2003), and increased numbers of mast cells in the colon have been identified in connection with IBS (O'Sullivan et al. 2000a). However, not all patients with gastroenteritis develop IBS, and the prevalence of IBS is not higher in countries with a high incidence of gastroenteritis (Gwee 2005). The relationship between gastroenteritis and IBS is established, but the precise mechanism for PI-IBS is unknown and further studies are needed.

Theories regarding the pathophysiology

The pathophysiology of IBS seems to be heterogeneous and complex, and there is a lack of an objective marker, which could explain the reason for the patient's symptoms. Today we do know that dysregulation of the nervous system, increased visceral sensitivity and altered intestinal motility are important subjects related to IBS.

The gastrointestinal tract is controlled by a complex nervous system, involving the enteric, sympathetic and parasympathetic nervous system. These systems interact and are responsible for the communication between the brain and the gut, called brain-gut axis (Wood et al. 1999). The enteric nervous system, sometimes called as "the little brain", functions independently of the central nervous system, and the peptides involved play a major role concerning motility and secretion (Caudell 1994). In the brain-gut axis several neurotransmitters and peptides are present, and they are released when the enteric nervous system is stimulated. One important neurotransmitter is serotonin (5-hydroxytrptamine, 5-HT), which can be divided into at least 14 receptor subtypes, and among these 5-HT1, 5-HT2, 5-HT3, and 5-HT4 dominate in the gastrointestinal tract (Goyal & Hirano 1996). Serotonin regulates gastrointestinal activity, and mood as well as cognition in the central nervous system and contributes to the dysmotility, visceral hypersensitivity and secretion function (Gershon 2005).

Patients with IBS have an increased visceral hypersensitivity, which was shown already at the beginning of the 1970s by Ritchie (1973). He showed that patients with IBS, at that time called "colon irritable", perceived pain at low volumes and pressures when a balloon was inflated in their colon. Naliboff et al. (1997) confirmed this, and showed that these patients also had a lower pain threshold than controls. Later, other researchers have reported that patients with IBS are also more sensitive in other gastrointestinal organs (Costantini et al. 1993, Holtmann et al. 1997). According to this information it would be more correct, concerning IBS, to say that the bowel is "sensitive" instead of "irritable".

Some differences in the contractile as well as in the electrical activity have been seen in the motor patterns in patients with IBS (McKee & Quigley 1993). However, these findings can not be used as diagnostic markers since they do not occur in all patients with IBS (Drossman et al. 2002). Patients with constipation are categorized in clinical trials on the basis of transit time; slow transit constipation (STC) and normal transit constipation (NTC) using measures of total intestinal transit time (Glia & Lindberg 1997). There is no agreement concerning motility patterns among patients with IBS-C and IBS-D, even if there is some difference due to total transit time; slow transit time is seen in patients with constipation (Glia & Linberg 1997) and accelerated transit time in patients with diarrhoea (Chey et al. 2001, Guirl et al. 2003). However, there is a poor correlation between defecation frequency and transit time (Mollen et al. 1997). In fact, patients with NTC, compared to patients with STC, have increased stool frequency, loose stools and urgent need for defecation. It seems that NTC is more common in patients with IBS (Glia & Lindberg 1997), and that STC should be regarded as a diffuse neuropathic digestive motor disorder (Glia & Lindberg 1998).

The colorectal motility is stimulated by distension of the stomach, i.e. food, stress and hormones (Duthie 1978, McKee & Quigley 1993). Patients with IBS have an exaggerated gastrocolonic response compared to controls (Rogers et al. 1989, Sullivan 1992). This exaggerated gastrocolonic reflex in connection with low sensory thresholds, may contribute to the patients' symptoms. Normal physiological phenomena, such as food intake, then lead to abnormal pain and symptoms (Mayer EA 1999).

Visits to health care professionals

When a person decides to contact the health care services, the person has made a judgement about the importance of her/his symptoms and their interference with her/his life (Wilson & Cleary 1995). The person has become a patient and is free to take advantage of health care resources and social services (Brülde & Tengland 2003). Not all persons with bowel symptoms characteristic of IBS seek health-care (Hungin et al. 2003). Among those who seek help most are diagnosed and treated at primary care centres, but patients may also be referred to gastroenterology clinics (Thompson et al. 2000, Simrén et al. 2001a, Hungin et al. 2003).

Today most health care professionals in Sweden, i.e. doctors, nurses, dieticians and physiotherapists, work separately and give the patient individual consultations. The routines for how patients with IBS are taken care of at a clinic should be arranged to benefit the patient and therefore health care professionals should work together (Dill & Dill 1995, Talley & Spiller 2002, Heitkemper et al. 2004) and develop national health care programmes (Hogston 1993, Dill & Dill 1995, van der Horst et al. 1998). According to several authors there is a lack of knowledge among health care professionals on how to take care of patients with IBS (Letson & Dancey 1996, Heitkemper et al. 2001, 2002, Longstreth & Burchette 2003, Richmond & Devlin 2003, Bellini et al. 2005).

Investigation due to diagnosis

The first visit to a physician begins with a systematic interview of the patient by a standard set of questions related to gastrointestinal symptoms. It is important to obtain a detailed history to identify "red flag" symptoms to discover any organic disease. "Red flag" symptoms can for example be, blood in the stools, weight loss, nocturnal symptoms and a family history of cancer (Torii & Toda 2004). IBS can not be diagnosed by physical examination, laboratory tests, endoscopic or radiologic investigations, although the patient sometimes has to undergo these tests to exclude other diseases (Olden 2002, Cash & Chey 2004, Bellini et al. 2005). By tradition physicians have used their own knowledge and judgement to make decisions on behalf of their patients, but this trend is changing (Le Var 2002). Patients of today also want information about their illness and wish to be more involved in their treatment (Coulter 1997). Patients and doctors have sometimes different perceptions of the goal of the treatment and the need of investigations, and therefore the patient's expectations need to be explored (Bijkerk et al. 2003b). If a good doctor-patient relationship is established the number of return visits can be reduced (Owens et al. 1995).

Patient education

Patients have the right and free will to make choices in relation to the investigations and treatment. They have also a right to receive appropriate information and to be instructed about their illness according to the Swedish Health and Medical Services Act (HSL 1982:763). Patients' request for knowledge (Friberg 2003), and education can be their preparation for decision making (Rankin & Stallings 2001). Health care professionals, such as physicians, nurses, dieticians, physical therapists and hospital social workers mostly teach patients individually. They provide and offer information, counselling, and education, but teaching is a complicated process, and the quality of the teaching is affected by the availability of teaching aids at the clinic (Rankin & Stallings 2001).

Information, counselling and education are sometimes used synonymously, but there are differences (Gedda 2003). Information is a one-way communication, i.e. giving instructions about x-rays or delivering a message, without any request for feedback (Rankin & Stallings 2001). Counselling is giving advice about a subject, which should lead to a different way of thinking. The patient should be helped by the health care professionals to connect her or his knowledge and experience with new knowledge (Gedda 2003). Education is a two-way communication including a goal, which the participants wish to reach, after internalising the education (Klang Söderkvist 2001). Patient education can be included in each of the four phases of health care; assessment, planning, implementation and evaluation (Klang Söderkvist 2001, Rankin & Stallings 2001).

Patient education is a holistic process that attempts to change a patient's behaviour to improve her/his health, and to increase the patient's knowledge about the disease (Rankin & Stallings 2001). The process begins with the assessment of the patient's needs and concerns. Together with the health care professional the patient's goals for desired outcomes should be set. Education is a planned activity, led by a teacher (Gedda 2003). The teaching begins with imparting information, and goes further by including a cognitive and a psychological part, with focuses on the patient's feelings and reactions (Rankin & Stallings 2001, Klang Söderkvist 2001). The outcome of education process is knowledge, where information and impressions have been worked on by the person's cognitive repertoire, affected by the environment (Hård af Segerstad et al 1996). Patient education is a continuous process, beginning at the clinic, and continues at home, where the true learning take place (Rankin & Stallings 2001). For a successful outcome, the patient needs to be motivated, and a supportive family is a benefit to the patient. Education in groups can also be of advantage, since the participants can strengthen and confirm each other (Björvell 2001).

A combination of counselling, information, and education, to improve health and to increase the patient's knowledge of their disease could be given in the form of a Course of Instruction (Bengtsson & Christensson 1996). This form of education has been used at the University Hospital of Malmö since 1995 for patients with IBD. A Course of Instruction is defined in this thesis as a planned systematic process, designed to inform and instruct, with the aim to influence the patient's behaviour and create knowledge (unpublished). Patient education in the areas of diet, exercise, and stress management have shown to be of benefit to patients with IBS (Colwell et al. 1998, Saito et al. 2004), and further development of structured education classes is needed.

Treatment regimes

In view of the fact that the etiology is unknown and that there is no cure for IBS, the treatments have to focus on the relief of the patient's symptoms. Normally treatments focus on the underlying etiology of the disease. Since patients have several symptoms, they have to relay on several pharmacological drugs (Alaradi & Barkin 2002, Drossman et al. 2002, Talley 2003). Sometimes patients perceive subjective improvements of some health aspects, but objective markers such as stool frequency can not confirm this perception (Ohlsson et al. 2005). This illustrates that psychological mechanisms are involved and the patient's relief of anxiety, expectations and desire may influence the outcome of the treatment offered (Dobrilla & Scarpignato 1994).

Traditional treatment

The physician generally sees those patients with IBS who have failed to respond to fibre, increased fluid intake and exercise, which are often recommended as a first choice of treatment based on tradition. Some patients may be helped by a fibre-rich diet, but many patients with constipation get worse (Müller-Lissner et al. 2005), since the diet slows down the transit time and increases the formatation of gases (James et al. 2003). Water is absorbed in the colon and the purpose of the extra intake of fluid is that the faeces should be softened. However, there is no proof that patients who are constipated benefit from an increased fluid intake unless the patient is dehydrated (Müller-Lissner et al. 2005). Women with IBS have been shown to be less physically active than healthy women (Lustyk et al. 2001), even if physical activity has by tradition been recommended for patients with IBS. The list of health benefits obtained from regular physical activity is long, and contains physical as well as mental improvements (Lustyk et al. 2001). Physical activity has a potential stress-reducing effect and may also provide some improvement on the gut function (Brouns & Beckers 1993). Women who are physically active also report less fatigue and feelings of incomplete evacuation following a bowel movement than physically inactive women (Lustyk et al. 2001). However, these improvements have been reported as modest and further research is needed.

Pharmacological, dietary and psychological treatment

Most pharmacological drugs currently used for the treatment of IBS are directed at alternating bowel habits. To optimize this kind of treatment patients with IBS should be divided by the physician into the IBS subgroups; IBS-C and IBS-D because of the diversity of the symptoms. However, the treatment of patients with IBS classified as IBS-A, is a challenge. Bulk-forming laxatives are commonly recommended for patients with both constipation and diarrhoea, but there is insufficient evidence to support the benefit of these drugs over placebo (Akehurst & Kaltenthaler 2001). These drugs increase the propulsive motor function by absorbing water in the intestines and soften the faeces and thereby increase their volume (Klaschik et al. 2003). However, bloating and abdominal pain may be aggravated by bulk-forming laxatives and therefore they should be introduced slowly (Talley 2003). Osmotic laxatives, i.e. saccharine, polyethylene glycol, and magnesium salts are often recommended for patients with constipation (Talley & Spiller 2002). Saccharine passes the small intestine unabsorbed, and in the colon bacteria break down the sugar into short-chained fatty acids. The pH value decreases and causes an increase of peristaltic movements. Furthermore, the osmotic pressure in the colon lumen increases and water is retained in the colon, which led to an increase in faeces volume and the stool is softened (Klaschik et al. 2003). Polyethylene glycol is not metabolised, but has a water-binding capacity, which increases the faeces volume, hardens the stools, decreases the duration of the colon passage and triggers the defecation reflex (Klaschik et al. 2003). Stimulant laxatives, i.e. sodium picosulphate, bisacodyl, and anthraquinone derivates, have effects on bowel secretion and motility. They are by tradition recommended to patients with temporary constipation only for short use, due to assumed enteric nerve or muscle damage, as well as development of tolerance. Nevertheless, patients with constipation use these types of drugs (Bengtsson & Ohlsson 2004), and therefore further studies to investigate how to prescribe and recommend these drugs are needed. Müller-Lissner et al. (2005) have presented a review of this issue and their conclusion is that stimulant laxatives in recommended doses are not harmful to the colon. Patients with diarrhoea may respond to loperamide, an opioid agonist, which does not cross the blood-brain barrier and works by decreasing intestinal transit and thereby increases the absorption of fluid. As soon as the diarrhoea is under control, the doses of loperamid should be reduced to avoid constipation, especially in patients with alternating constipation and diarrhoea (Lacy & Lee 2005).

Other types of pharmacological drugs reduce abdominal pain. Low doses of anti-depressant drugs are an alternative, but they tend to induce constipation and therefore these drugs are preferable for patients with diarrhoea (Talley 2003). Anticholinergic drugs are often recommended to reduce the exaggerated gastrocolonic response in IBS, and thereby reduce abdominal pain and diarrhoea (Talley 2003). Serotonergic agents seem to be a logical choice to treat patients with constipation as well as diarrhoea, since these types of drugs affect the underlying pathophysiology of IBS. The release of serotonin differs between these two groups of patients, so dissimilar agents have to work by targeting different 5-HT receptors in the gastrointestinal tract. Several serotonin agents are under development (Talley 2003, Farthing 2004).

Many patients with IBS believe that their symptoms are a reaction of food allergies, but it is rather the act of eating not the specific food items that causes the patients' symptoms (Lacy & Lee 2005). A detailed, 7-day diet history supported by a food and symptoms dairy, registered by a dietician, may reveal an unsatisfactory diet (Burden 2001). However, it is difficult to give general dietary advice to patients with IBS, since there is no evidence from well-designed studies to support the role of dietary modification (O'Sullivan & O'Morain 2003). However, exclusion of certain food items can be beneficial for some patients, but should be individualized and used only for patients, who complain of multiple food intolerance (Burden 2001). Certain food items have also been found to increase gastrointestinal symptoms, i.e. high consumption of coffee, soft drinks, and chewing gum (Torii & Toda 2004), as well as carbohydrates such as sorbitol, fructose and lactose (Goldstein et al. 2000). Also fat should be used sparingly by patients with IBS (Simrén et al. 2001b). There is great interest in the use of probiotics in the treatment of IBS, and the idea stems from their possible effect on the intestinal microbiota. However, no convincing evidence of their effect has been presented, and further studies are needed (Madden 2004).

Different psychological treatments such as dynamic psychotherapy (Svedlund 1983), behavioural psychotherapy (Corney et al. 1991) and cognitive behavioural therapy (Greene & Blanchard 1994) have been considered useful for patients with IBS, but most of the evidence is based on small trials with methodological limitations (Talley et al. 1996).

Patients remaining symptomatic despite optimal pharmacological treatment can be considered for hypnotherapy, which has shown to be an effective treatment of patients with IBS (Whorwell et al. 1984, 1987, Houghton et al. 1996, Gonsalkorale et al. 2002). Hypnotherapy can be carried out using a technique in which the emphasis of the hypnosis is focused on the control of gut function (not on general relaxation). The sessions are usually at weekly intervals, so that between sessions patients must practice on a daily basis with the help of an audiotape. Unfortunately it is difficult for Swedish patients with IBS to get such treatment, due to a shortage of hypnotherapists.

Stress-management/relaxation can also be of value for patients with IBS (Shaw et al. 1991). They can take part in a stress-management programme comprising a median of six 40-minute sessions with a physiotherapist. During the sessions the patients are helped to understand the nature of their symptoms, and their relationship to stress. The patients are also informed about relaxation exercises.

In summary, the currently recommended traditional treatment for IBS, namely, fibre, increased fluid intake and exercise, is not satisfactory, but patients with IBS may have some benefit from conventional therapy such as pharmacological, dietary as well as psychological treatment. Since there is a lack of a single proven therapy for patients suffering from IBS, a multicomponent treatment regime is needed.

Living with Irritable Bowel Syndrome

Patients have to deal with this life-long disorder after the diagnosis IBS has been established. Even though IBS is not a grave or life-threatening condition the symptoms can be very severe and disabling. The symptoms often persist despite the use of recommended therapies (Hungin et al. 2003). Abdominal pain and bloating are the dominant symptoms of IBS (Bijkerk et al. 2003b, Dapoigny et al. 2004, Locke et al. 2004b), and also the most troublesome (Lee et al. 2001, Dapoigny et al. 2004). Gender differences based on symptoms have been reported (Lee et al 2001), and constipation is more common among women, while diarrhoea is more common among men (Schmulson et a. 1999, Lee et al. 2001). Women report nausea more frequently than men (Corney & Stanton 1990, Lee et al 2001), changes in the sensations of taste and smell, as well as an unpleasant sensation on the tongue (Lee et al. 2001). Even muscle stiffness in the morning (Lee et al 2001), and back pain (Corney & Stanton 1990) are more common among women. The symptoms are chronic but episodic, and sometimes stress or eating aggravate the symptoms (Dapoigny et al. 2004). Women report more often than men that all kinds of food items, even water trigger their symptoms, while men report that the symptoms can only sometimes be aggravated by specific types of food (Lee et al. 2001). Patients with IBS have several symptoms related to the gastrointestinal tract, but also a variety of extraintestinal symptoms, which are all included in the subgroup functional pain syndrome, i.e. migraine (Watson et al. 1978, Weitzel et al. 2001) and fibromyalgia (Veale et al. 1991).

Patients suffering from IBS have the impression that they are not adequately informed about how to deal with the disorder (O'Sullivan et al. 2000b). To a great extent these patients have a feeling of loneliness, and perceive that they are the only ones with this disorder (Dancey & Backhouse 1993). Generally, patients diagnosed with IBS do not talk about their bowel trouble with anyone, often due to the unsympathetic attitude of family and friends (Dancey & Backhouse 1993). The patients' feeling of illness may not depend only on the physiological symptoms, since there may be a psychological aspect to their perception of illness (Bowling 1997, Brülde & Tengland 2003). Concomitant psychiatric disorders are frequently presented in patients with IBS (Lydiard 1997, Jarrett et al 1998, Locke et al 2004a). Women are more likely than men to report anxiety, worry, depression, fatigue, and crying spells (Corney & Stanton 1990). However, the connection between physical symptoms and psychological disorders and the mechanisms involved have not been sufficiently investigated and should be further explored.

The economic impact of IBS is high, for the patient as well for the community (Talley et al. 1995, Creed et al. 2001), since the disorder mostly affects persons of working age. The total cost of IBS can be divided into three parts; direct, indirect and intangible costs (Boivin 2001). The direct costs are connected with health-care resources such as investigation and treatment (Boivin 2001), and patients with IBS spend large sums of money and time on seeking help for all kinds of treatments (Kennedy et al. 2003). Also the medical treatment of IBS contributes to the high direct costs, and the new laxative drugs, which have invaded the market in recent years are more expensive than the old ones (www.fass.se**,** 2005). The indirect costs are related to the production losses due to the patients' morbidity. Occasionally patients suffering from IBS have to take sick leave due to their symptoms (Hahn et al. 1999, Creed et al. 2001, Heitkemper et al. 2002, Zacker et al. 2004). On their way to work, they may have to seek for a toilet, and thereby come late to work (Dancey & Backhouse 1993). Some patients with IBS, may even be forced to change their job (Hahn et al 1999, Silk 2001), or may even be housebound, due to the need of access to toilet facilities (Phillips 1999). The intangible costs are connected with the patients' suffering and loss of quality of life (Boivin 2001), as the symptoms related to IBS have a considerable impact on many dimensions of daily life and thereby on the patients' overall quality of life. On the whole, women are more disabled than men by their symptoms and avoid activities in daily life to a greater extent (Corney & Stanton 1990). The two areas most disturbed by this condition are diet (including eating out), and social life (Hungin et al. 2003, Dapoigny et al. 2004).

British and American patients with IBS have reported disturbances in their social life in several areas, for instance, in work, travel, leisure and domestics activities, and in social contacts as well as in their relationships with their spouses and children (Corney & Stanton 1990, Dancey & Backhouse 1993, Silk 2001, Heitkemper et al. 2002). As many as 46% of British patients (*n*=148), mostly women, mentioned that IBS directly affected their sex life, due to pain and loss of desire (Dancey & Backhouse 1993). Moreover, 16 % of the participants in another study (*n*=358) have reported that they had turned down a date for fear of the embarrassment that might ensue during intimacy (Silk 2001).

Due to cultural aspects and the access to health care differ between countries, information about living with IBS in Sweden is needed, and Simrén et al. (2001a) have assembled some information. A summary of the results showed that Swedish female patients in general had poorer quality of life according to the scores of the questionnaires, than the participating men. The women reported more fatigue, had more depressed mood and anxiety, and their positive well-being and self-control was poorer. Since there is a lack of information, further assessments of how Swedish patients perceive living with IBS are needed. Also information about what patients with IBS perceive as a good quality of life is required, since the main goal of the treatment is to relieve the patients' symptoms and improve their health, and thereby their perceived quality of life.

Quality of life and health

The concept of quality of life

Quality of life is a comprehensive concept and there is no consensus on a definition. Experts in divergent scientific areas, for example, philosophy, psychology, sociology, medicine, and nursing have tried to characterise the concept of quality of life from different points of view (Gimmler et al. 2002), and these different paradigms differ in conception. In this thesis a multi-scientific approach of quality of life is applied. Irrespective of life-philosophy, quality of life includes all aspects of life and is often defined in terms of happiness or satisfaction (Campbell 1976, Brülde 2003), in addition to the kind of life the person wants to live (Brülde & Tengland 2003). The word "quality" can be defined as a grade of goodness (Bowling 1997) estimated along a scale with one positive and one negative end-point (Nordenfelt 1991).

The concept of quality of life is connected to the concepts of disease and health (Wulff 2002). However, a better health does not necessarily generate better quality of life, since a person's quality of life is influenced, for example, by work, personal relationship, environmental factors and social factors (Nordenfelt 1991, Brülde & Tengland 2003). Dimenäs et al. (1990) have presented a clinically applicable definition of health-related quality of life divided into three aspects, namely, health, subjective well-being, and welfare. Health refers to objective as well as subjective signs of the presence or absence of a disease and is the most important dimension in the concept of quality of life from a traditional medical point of view (Dimenäs et al. 1990). The subjective well-being refers to the person's own perception of values and beliefs, and components such as happiness, and satisfaction with life. Welfare reflects the person's situation in society assessed by objective indicators (Dimenäs et al. 1990). The person's welfare such as work, education, and economics can interfere with the concept of quality of life (Dimenäs et al 1990, Glise & Wiklund 2002), but these welfare factors are even more important in discussions about the economics of health care and political decisions than for the individual person (Nordenfelt 1991, Talley et al 1995).

The concept of health

In antiquity, medicine was an art, and for classical Greek philosophers, for instance, Plato and Aristotle, health was a matter of philosophical and ethical considerations (Gimmler et al. 2002). Medicine is today a natural science and due to different philosophical views on life and culture, the concept of health has changed into a more modern, naturalistic vision of medicine. There are today a great number of characteristics to demote health and of these essential characteristics can be grouped into two main streams; the naturalist and the normativist view (Nordenfelt 2000). The view of the naturalist contends that health can be scientifically analysed in bio-statistical or psychological terms and disease is an essential conception. In the bio-statistical concept of health, objective truths are presented, and words such as well-being, strength and balance are not used (Boorse 1977). By contrast, the normativist approach of health is holistic, but one accepts that some normative values may be needed (Nordenfelt 1991). In this thesis the normativist approach of health is applied.

Pörn (1993), Nordenfelt (1991, 2000), and Seedhouse (1986), have in different ways characterised the concept of health on an individual level in a holistic approach. The central point of their theories, classified as middle range theories, is the idea that a person's health, all or in part of, can be influenced if the individual has the ability to act and to attain goals (Nordenfelt 2000). Health, as a value and as a goal, is an important concept to discuss and to characterise, especially for patients suffering from chronic disease or unclassified symptoms.

According to Pörn (1993) it is not necessary to base a definition of health on the concept of disease, since a human being is an acting person with the ability to adapt in relation to the environment. The theory of health as ability, is based on three basic factors; *the goals of the person, the repertoire*, and *the environment*, which must be considered in relation to each other. The goal of the person is set up by the person himself and consists of several subgoals sorted in order. The highest ranking goals are the most important. The repertoire is the person's ability to act and make decisions on the basis of his own beliefs and understanding and can be divided into, the action repertoire, cognitive repertoire and the decision repertoire. The environment is consisting of external elements, for example, physical, social and cultural elements, as well as internal elements, as the person's cognitive capacity. There should be an agreement and a balance, an equilibrium, at a specific time between the goals, the repertoire and the environment in order to attain good health (Pörn 1993). A person has the ability to take action in different social situations, but health and disease can affect the pattern of behaviour. Pain and suffering, even minor pain, causes inability to act. A person's ability to act is affected by circumstances in the person's surroundings. These circumstances have to be considered as the basis (the norm) on which the expected outcomes are to be achieved (Nordenfelt 1991).

The theory of equilibrium (Pörn 1993) has been further developed by Nordenfelt (1991), who indicates that there should be a balance between a person's ability to act and the person's vital goals. The goals have to be desired by the person and not cause any damage to the person himself. Nordenfelt (1991) indicates that the goals have to be vital and important to the person. Seedhouse (1986) argues that these goals also have to be realistic. A person is healthy when she/he is able to realise all the person's vital goals given an accepted set of circumstances (Nordenfelt 1991). Variants of this concept can be created by changing the conditions.

Nordenfelt (1991) also introduces a new grade of health, "the acceptable level". Where this level is placed on the scale of health is specific for each individual, but it is somewhere between a perfect (complete) health and a poor (minimal) health. Perfect health can only occur when a person has the ability to act and has realised all vital goals, under a particular set of circumstances. At the acceptable level, a person's basic needs are provided for (Nordenfelt 1991).

Assessment of quality of life and health

A person's perception of quality of life is something personal, unique, and changes throughout life (Fayers & Machin 2000). How someone perceives their quality of life is affected, for example by health, life-experience, sex, age, culture and environment (Wilson & Cleary 1995). The World Health Organization Quality of Life (WHOQOL) Group defined quality of life as a subjective evaluation set in a cultural, social and environmental context as *"individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns"* (WHOQOL Groups 1998a p. 551). Analogously to this description, quality of life is in this thesis defined as the person's own subjective perception of life from the point at which the measurement was performed.

The traditional medicine of today is based on objective facts and scientific research. However, in order to evaluate the response to treatments in objective terms or of the survival is inadequate for patients with chronic diseases (Bowling 1997). To get a more complete evaluation both objective and subjective aspects should be considered (Dimenäs et al 1990, Wilson & Cleary 1995). Information about quality of life and health, as well as different aspects of a life worth living, is needed to understand a patient's perception of a treatment and thereby influence the process of health care (Wilson & Cleary 1995, Bowling 1997, Gimmler et al. 2002). To evaluate the different dimensions and aspects of these topics is complicated, since a person's health and quality of life, as well as the person's perception of her/his life and life situation, changes over time and is affected by conscious and subconscious actions (Ferrans 1990). When health care professionals or researchers are deciding on which measurement to use, they have to focus on the purpose of the measuring as well as the context in which it is to be used (Bowling 1997). They have to decide whether the measurement should be a generic, a disease-specific or a preference-based measurement (Jönsson 1996). Measurements evaluated for reliability, validity and responsiveness are most appropriate (Polit et al. 2001). The type of scoring to use must be considered, and whether the scores have to be easily analysed in relation to other objectives (Bowling 1997). In general, scales which have a broad range of possible responses are preferable (Naliboff et al. 1999).

In clinical practise it is difficult to estimate the symptomatic changes occurring in patients on the basis of their descriptions, and there is a need to objectivate the patients' perception of their symptoms (Yacavone et al. 2001, Bijkerk et al. 2003a). Although there is a growing interest in assessing effectiveness of interventions, there is no consensus regarding the preferred outcome measure (Bijkerk et al. 2003a). A literature search, using the Medline and the Chinahl database, showed that there are several disease-specific questionnaires available to evaluate different aspects and parts of health and quality of life in patients with IBS (Table 3).

Table 3. Example of symptom-based and health-related quality of life questionnaires for patients with Irritable Bowel Syndrome

Questionnaires	Items	Domains	Referenses
Symptom-based questionnaires			
Gastrointestinal Symptom Rating Scale	15	Abdominal Pain Syndrome Reflux Syndrome Indigestion Syndrome Diarrhoea Syndrome Constipation Syndrome	Svedlund 1988, Dimenäs et al. 1993, 1995
Functional Bowel Disorder Severity Index	3	NA	Drossman et al. 1995
Irritable Bowel Severity Scoring System	5	Part 1: Severity Score	Francis et al. 1997
	18	Part 2: Other IBS data	
Adequate Relief	1	NA	Mangel et al. 1998
Gastro Questionnaire	54	NA	Leibbrand et al. 2002
Gastrointestinal Symptoms	7	NA	Poitras et al. 2002
Health-related quality of life questionnaires			
Irritable Bowel Quality of Life Questionnaire	30	Emotional Mental Health Health Belief Sleep Energy Physical Function Diet Social Role Physical Role Sexual Role	Hahn et al. 1997
Irritable Bowel Quality of Life measurement	34	Dysphoria Interference with Activity Body Image Health Worry Food Avoidance Social Reaction Sexual Role Relationship Symptom Frequency Index Symptom Bothersome Index	Patrick et al. 1998
Summary of the Irritable Bowel Syndrome Questionnaire	26	Bowel Symptoms Fatigue Activity Limitations Emotional Dysfunction	Wong et al. 1998
Functional Digestive Disorder Quality of Life Questionnaire	43	Daily Activities Anxiety Diet Sleep Discomfort Coping with Disease Control of Disease Stress	Chassany et al. 1999
IBS-36	36	NA	Groll et al. 2002
Quality of Life Index	25	NA	Poitras et al. 2002

The identified questionnaires showed reasonable psychometric and methodological qualities (Revicki et al. 2000, Yacavone et al. 2001, Bijkerk et al. 2003a), but none of the questionnaires is optimal in all aspects (Bijkerk et al. 2003a). The identified questionnaires have too many (15 items or more) or inadequate questions (focus on pain) to assess outcomes of interventions in daily clinical practise, and are therefore not suitable to be used. A more appropriated measuring instrument for this purpose is needed. Therefore a patient-reported, short (less than 15 items) and reliable measuring questionnaire, uncomplicated to calculate and easy to understand for patients as well as for health care professionals could be of help. This questionnaire should serve as a complement to the anamnesis and measure the response to the treatment of symptoms as well as of general well-being in patients with IBS.

AIMS

The overall aim of this thesis was to create a model for health care to improve the health and quality of life in Swedish women with IBS.

The specific aims were:

- To gather information on the perception of what constitutes a good quality of life for women with IBS, and map areas to be further explored (Paper I).

- To determine the effects of a Course of Instruction on the long-term outcome of symptoms, psychological well-being, health-care requirements, medication, and sick-leave from work or school as well as the participant's perception of the course (Paper II).

- To examine whether women with chronic functional constipation, who use laxatives containing sodium picosulphate, have different symptoms and psychological well-being from women who use other laxatives, and to decide, on the basis of the results, how to prescribe and recommend pharmacological drugs containing sodium picosulphate (Paper III).

- To develop and test psychometrically the Visual Analogue Scale for Irritable Bowel Syndrome (VAS-IBS) (Paper IV).

METHODOLOGY

Design

In this thesis a multi-methodological design was used, including qualitative (Paper I) and quantitative (Paper II and III) research methods as well as psychometric testing (Paper IV) (Table 4). In Paper I an overall question about women's perception of quality of life was analysed by Burnard's content analysis. A quantitative comparative design was used to study differences in symptoms and psychological well-being over time (Paper II) and between groups (Paper III). Correlational design was used when studying connections between different variables (Paper III-IV). In Paper IV the VAS-IBS was psychometrically tested for content and criterion validity, internal consistency, reliability, item-reduction, acceptability of the scale and simplicity.

Table 4. Overview of samples, design, measurements, and data collection used in the different studies and the analysis which are presented in this thesis.

	Paper I	**Paper II**	**Paper III**	**Paper IV**
Sample patients	30	29	86	55
Recruited from	Hospital	Hospital	Hospital Primary care centre Advertisement	Hospital Newly referred to hospital
Design	Qualitative	Quantitative Intervention Longitudinal	Quantitative Comparative Correlational	Quantitative
Data collection	Postal questionnaire Oral dialogue	Postal questionnaire at baseline, 1, 6, 12 months	Postal questionnaire	Postal questionnaire Expert panel
Time duration	Nov 2002-May 2003	Nov 2002-May 2004	Feb-Sep 2002	Nov 2002-Nov 2004
Measurements	Overall item	GSRS PGWB HCC Content of the Course*	GSRS PGWB Use of Laxatives	GSRS PGWB VAS-IBS CVI
Analysis	Content analysis	Comparative statistics over time	Comparative statistics between groups	Psychometric tests

GSRS = Gastrointestinal Symptom Rating Scale, PGWB = Psychological General Well-Being Index, HCC = Health Care Consumption,VAS-IBS = Visual Analogue Scale for Irritable Bowel Syndrome, CVI = Content Validity Index *The Content of the Course of Instruction was completed at the hospital

All patients participating provided information in two self-administered questionnaires, the Gastrointestinal Symptom Rating Scale (GSRS) and the Psychological General Well-Being (PGWB) Index at least once. Some of the participants in the studies in this thesis have answered them additionally due to the study design. For each study (Paper I-IV) additional, specific questionnaires related to the aim of the study were used (Table 4). In Paper IV an expert panel (*n*=9) was consulted, and the members of this panel completed a Content Validity Index (CVI).

All questionnaires except the questionnaire about the content of the Course of Instruction in Paper II, were sent by mail with a covering letter, including information related to the specific study situation as well as name and phone number to the person in charge of the study. The completed questionnaires used in Paper I and baseline in Paper II, were handed in at the hospital. Otherwise the participants also received a prepaid envelope together with the set of questionnaires to facilitate the return of the completed questionnaires. If a response was not received within four weeks, a reminder and a new packet of questionnaires were sent out.

Sample and data collection

Overall inclusion and exclusion criteria

Female patients, between 18 and 65 years of age, with bowel symptoms for at least three months, but without liver or kidney diseases, chronic pulmonary or heart diseases, serious mental diseases or other serious disorders such as a history of malignancy, were included (Paper I-IV). Only a few men with required health profile were identified (Paper I-IV). They were excluded due to the differences in symptoms and perceptions of quality of life between women and men (Thompson et al. 1997, Simrén et al. 2001a, Lee et al. 2001). The participants in Paper I, II and IV were diagnosed as with IBS (Table 1), and the participants in Paper III were diagnosed as having chronic Functional Constipation (Table 2). The diagnoses IBS and Functional Constipation were based on the Rome II criteria for FBD (Thompson et al. 1999). The participating patients' diagnosis was confirmed by their medical records, checked by a registered nurse as well as a physician. The designs of the studies in this thesis have also made it possible for the participants to take part in more than one study (Figure 2).

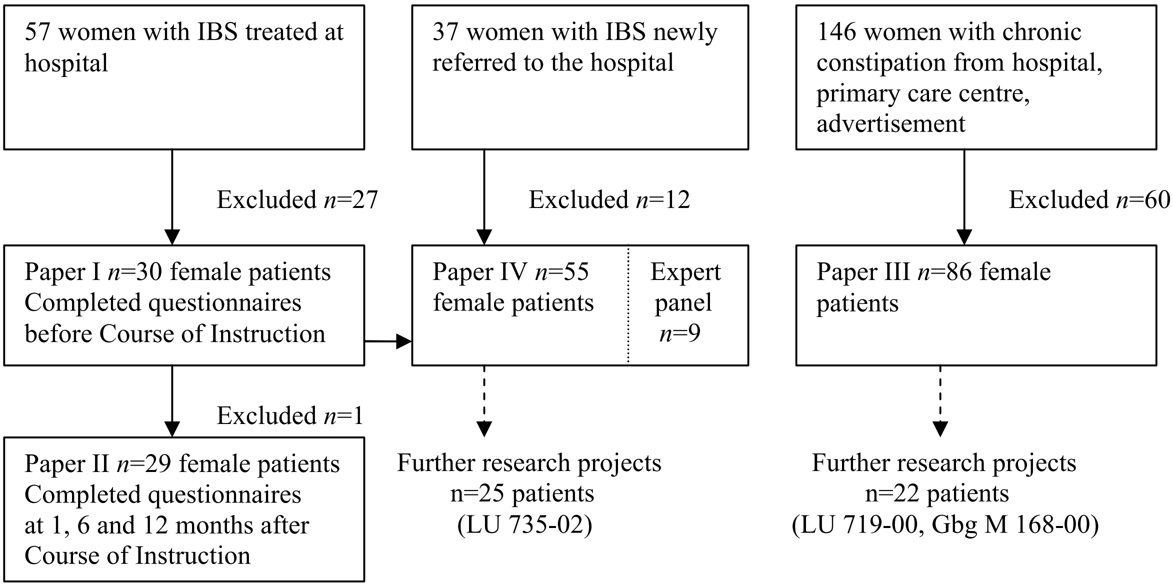


Figure 2. Overview of the samples in Paper I-IV.

All participants included in Paper I, II and IV were recruited from the Division of Gastroenterology and Hepatology, Department of Medicine at Malmö University Hospital. In Paper III participants were also recruited from the Department of Surgery at Malmö University Hospital, one primary care centre in Malmö and by advertisement. The reasons for refraining are listed in Table 5. It was difficult to recruit participants and the number excluded was high.

Table 5. Overview of the identified, included and excluded participants in the studies which are presented in this thesis.

	Paper I*	Paper II*	Paper III	Paper IV
Identified *n*	57	57	146	94
Excluded *n* (percent)	27 (47)	28 (49)	60 (41)	39 (58)
did not reply	8	8	0	8
lack of time/not interested	7	7	55	21
no symptoms at the moment	6	6	0	6
had adequate knowledge	2	2	0	4
did not complete the study	4	5	0	0
did not meet the inclusion criteria	0	0	5	0
Included *n*	30	29	86	55

*Participants in Paper I and II are recruited from the same sample

Paper I and II - Perception of quality of life and a Course of Instruction

To identify suitable participants diagnosed as with IBS, an inquiry was made among patients who had visited the hospital between 1 January 1998 and 31 August 2002. In a review of the register of diagnoses, 57 women were found, and these women had all been referred from a diversity of primary care centres. All the women identified were invited to take part in an intervention programme, a Course of Instruction, called the "IBS-School". Of the women identified 34 accepted participation, but four of them did not come to the initial meeting. However, 30 women (median age 38.5, range 20-65) started the Course of Instruction (Paper II), but one woman did not complete the course and was not included in the analyses in Paper II. Questionnaires were sent to the 30 women participating and they answered a single, all-inclusive, self-administered question *"What is your perception of a good quality of life?"* (Paper I), as well as the following questionnaires, the GSRS, the PGWB and the Health Care Consumption (HCC) (Paper II). The questionnaires were assembled at the hospital before the women started their Course of Instruction, to prevent the results from being influenced by the contents of the course or by other participants. When the women handed in their completed questionnaires, there was time for a short conversation between each participant and the author.

Directly after the women had finished the last session of the Course of Instruction at the hospital, they completed a questionnaire on the contens covered in the course. To follow up the participants' symptoms and psychological well-being, the participants completed the GSRS, and the PGWB at 1, 6 and 12 months after finishing the course.

At 12 months the women again provided information about their health-requirements and completed the HCC questionnaire. The response rates of the questionnaires calculated in this study, the GSRS, the PGWB, the HCC and the Content of the Course of Instruction, are given in Paper II, figure 3. The participants also completed the VAS-IBS (first version), to collect information for further calculations (Paper IV).

After Paper II had been accepted for publication, further information related to quality of life and health aspects have been collected from the participants. A new package of questionnaires was sent out to the participants two years after they had finished the Course of Instruction. At the same time the women provided further information about their lifestyle changes related to the Course of Instruction. Furthermore, the VAS-IBS includes one item concerning the participants' perception of their quality of life scored on a visual analogue scale (VAS). To assess whether abdominal pain and bloating interfere with quality of life, further calculations (Pearson's correlation test) on the collected data used in Paper IV have been performed.

Paper III - Health aspects due to laxatives

Between February and September 2002, women with chronic, functional constipation were recruited from the hospitals, primary care centres, and by advertisement in the daily press. In total 146 women were contacted by mail as well as by phone. Of these, 91 agreed to participate in the study. Five women were excluded on the basis of the inclusion criteria. Altogether, 86 women were included. The reason most of the women gave for not taking part in the study (*n*=55) was that the study was of no personal value to them, and some of them were dissatisfied with the attitude they had met and the care they had earlier been offered by health professionals (Figure 2).

The participants completed a questionnaire designed as a case report form, about their medical treatments, as well as the GSRS and the PGWB. The women were divided into two groups based on which laxative treatment they used at the time of enrolment, namely, those who used sodium picosulphate regularly at least once a week, and those who used other laxatives, including sporadic use of sodium picosulphate. The author contacted the participants by phone, in the cases where the questionnaires about medical treatment were not acceptably completed.

Thirty-five women (median age 51; range 29-64 years) were using sodium picosulphate regularly at least once a week. These women had used sodium picosulphate over a median time of 10 years (range 3 months - >20 years). Most of the participants in this group (63 %) were recruited by advertisement.

Fifty-one women (median age 47, range 27-65 years) were using sodium picosulphate sporadically and other laxative treatments such as lactulose, polyethylene glycol, orlistate and naturopathic preparations with or without motility-inducing herbs. It was relatively common in this group, that the patients combined several kinds of drugs. The majority of this group (76.5 %) was recruited by the hospital.

This study was based on the participants' own information, in combination with documentation in their medical records. A comparison of symptoms and psychological well-being between the two groups was performed at a given point in time.

Paper IV - A new questionnaire

Two separate samples were used in this study, an expert panel as well as women with IBS (Figure 2). The expert panel consisted of two professors, three physicians specialised in gastroenterology and four registered nurses (five men and four women). They have all established national esteem because of their knowledge in the field and meet patients with IBS in their daily clinical practise. The members of the expert panel were chosen from minor hospitals as well as from University Hospitals. The experts' assignment was to give their opinion on the content validity of the VAS-IBS (first version) by the use of the CVI. The questionnaire, together with a letter of information was mailed to the members of the expert panel in November 2004. A reminder was sent out to one member who had not responded (a nurse), but no reply was received, due to her absence from work because of pregnancy.

To identify female patients an enquiry was made among patients who had visited the hospital between 1 January 1998 and 31 August 2002, and among those who had been referred for a second opinion to the same hospital between 15 May 2003 and 15 May 2004. The purpose was to find women who had had their symptoms over long as well as short periods of time, and had been treated by different physicians. In total, 94 female patients who were given the diagnosis IBS, verified by the patients´ medical record, were identified and of these 55 (median age 35 years, range 26-49) were included. The women participating were at the time of recruitment also offered participation in further research projects (Paper II or LU 735-02). The questionnaires, the GSRS, the PGWB and the VAS-IBS (first version), were sent to the participants by mail together with written information.

Questionnaires

Gastrointestinal Symptom Rating Scale

The GSRS is a Swedish, disease-specific questionnaire designed to evaluate gastrointestinal symptoms. It was originally constructed as an interview-based rating scale (Svedlund et al. 1988) in analogy with the Comprehensive Psychological Rating Scale (Åberg et al. 1978), and was later modified to become a self-administered, patient-reported questionnaire (Dimenäs et al. 1993, Dimenäs et al. 1995). The questionnaire includes 15 items divided into five syndromes (Table 6), based on a factor analysis (Dimenäs et al. 1995). Each item is valued on a seven-grade Likert scale, which is a composite measure of attitudes that involves summation of scores on a set of questions to which the respondents are asked to indicate their opinions along a continuum of agreement (Bowling 1997, Polit et al. 2001). The scores of the GSRS give a total range-value between 15 and 105 and the highest score "seven" denotes the most pronounced symptoms and "one" denotes no symptoms at all. The data can be presented as a total score (Glia & Lindberg 1997), or by a mean value, in which the score of the syndromes are divided by the number of items included (Dimenäs et al. 1996, Simrén et al. 2001a). The GSRS has been psychometrically tested on patients with gastroesophageal reflux disease, and has shown good reliability and construct validity. The GSRS has been used on patients with IBS (Simrén et al. 2001a) and chronic constipation (Glia & Lindberg 1997). Furthermore, the GSRS has been tested on a Swedish population and norm values have been described by Dimenäs et al. (1996).

Psychological General Well-Being Index

The PGWB is a generic, self-reported questionnaire to be used to measure positive and negative feelings of psychological well-being and distress (Dupuy 1984). The questionnaire includes 22 items divided into six dimensions (Table 6). The respondents rate their agreement on each of the items on a six-grade Likert scale (Bowling 1997, Polit et al. 2001), which gives a total range-value between 22 and 132. The higher the value, the better is the patient's psychological well-being. The PGWB has been psychometrically tested, and has been found to have a high degree of reliability and validity in both population-based and mental health samples (Dupuy 1984, Naughton et al. 1996), and can be used in different cultures (Naughton et al. 1996). Norm values for a Swedish population have been described by Dimenäs et al. (1996).

Table 6. The different syndromes in the Gastrointestinal Symptom Rating Scale (GSRS) and the domains in the Psychological General Well-being (PGWB) Index

	Number of items		Number of items
GSRS	15	PGWB	22
Reflux Syndrome	2	Anxiety	5
Abdominal Pain Syndrome	3	Depressed mood	3
Constipation Syndrome	3	Positive well-being	4
Indigestion Syndrome	4	Self-control	3
Diarrhoea Syndrome	3	General health	3
		Vitality	4

Health Care Consumption

For the objective evaluation of health care requirements related to IBS, a questionnaire, designed as a case report form was developed (Paper II). The questionnaire was judged by experts in the field and evaluated for face validity. The questionnaire is divided into three parts, namely, health-care consumption, pharmacological treatment, and sick-leave from work or school. The participants information about their visits to health care professionals or other persons related to their treatment of IBS and the number of visits, doses and name of pharmacological drugs and naturopathic preparations as well as the number of days of treatment at a hospital and the number of days of sick-leave due to IBS.

Content of the Course of Instruction

To elucidate the participants' opinion on the content of the Course of Instruction (Paper II), the participants were provided with a questionnaire, which has been used for a decade for the same purpose for patients with IBD (Bengtsson & Christensson 1996). This questionnaire was judged by experts in the field and evaluated for face validity. The questionnaire includes in total 21 items divided in two parts. In part one (total 15 items) there are three items about each issue in the course (medical care, physical activity, stress management, diet and health insurance); one item graded on a four grade Likert scale and two open items. In part two, there are six open items in which the respondents could write their own comments on their perception of the course, for instance, positive and negative aspects of the course, suggestions for improvements, recommendations to other, fulfilled expectations and the benefits gained.

Use of Laxatives

For an objective evaluation of the use of pharmaceutical drugs related to constipation, a self-reported questionnaire, designed as a case report form, was developed (Paper III). The participants were asked to give the name of the drug, the start of the treatment, the doses and changes of doses over time. In the cases where the answers were inadequate the patients were contacted by phone. The questionnaire was evaluated for face validity by experts in the field.

Content Validity Index

The content validity of the VAS-IBS (first version) in Paper IV, was judged by experts in the content area, who completed a CVI constructed for this study. The CVI consisted of instructions and 31 questions concerning the content of the VAS-IBS. Each member of the expert panel marked the relevance of the content, agreement of the definition, and the relevance of the scale for each of the nine items in the VAS-IBS (Haynes et al. 1995, Ulander et al. 1993) point scale (4 reflects total relevance and 1 indicates total irrelevance) (Lynn 1985). The level of agreement was set to no more than one panel member scoring an item as less than 3 (Lynn 1985).

The all-inclusive, single, self-administrated question

It is important that a researcher always identifies his or her perceptions, experience and knowledge of the research area before entering the particular field (Malterud 2001). The pre-understanding of the content in this thesis consisted of my prior experience as a registered nurse, working at the Division of Gastroenterology and Hepatology, Department of Medicine at Malmö University Hospital, where I, during the 15 years had met patients suffering from FBDs as well as other gastroenterologic and hepatologic diseases.

The optimal way to collect qualitative data is by interviews, which is a professional form of dialogue (Kvale 1997). The dialogue is a teamwork between the researcher and the participant. Since I had a lot of pre-understanding there was a risk that my own feelings and knowledge about IBS could have subconsciously influenced the data collection (Kvale 1997). Therefore only one, all-inclusive, written question concerning the participants' view of the quality of life was chosen, "W*hat is your perception of a good quality of life?"*. The purpose of the study in Paper I was to gather information of what women with IBS consider a good quality of life, but also to map areas to be further explored. For this reason it was preferable to use a written question in order to be able to collect information from a larger group of women rather than performing a few interviews. To use only one, all-inclusive, self-administered, single, global and item-specific question may appear to be insufficient, but a single question can provide information on all aspects of a phenomenon, and a summary of an individual's perception (Youngblut & Casper 1993). The study question was discussed extensively in the research group, and the expression *quality of life* was chosen in favour of *health-related quality of life*, in the hope of getting a wider response, beyond health aspects. The all-inclusive question about quality of life was adapted to the HCC questionnaire.

The study design in Paper I gave the participants an opportunity to provide oral information when they handed in the questionnaires including the quality of life question. The short dialogues, which took place between the participants and me, were summarised in notes on the topics the women talked about. The dialogue was spontaneous, and structured questions were not used, and I was conscious of the importance of always remaining open-minded. During the dialogue, the women produced new and important information, which could indirectly affect their quality of life. These discussions were summarised and categorized as; *Patients' view of caring and nursing* (Paper I).

The Course of Instruction

The Course of Instruction was developed and given by a group of clinicians employed at the hospital, specialized in IBS, and with a specific interest in instruction for patients with this disorder. This group of lecturers (all women) included one physician (BO), two registered nurses (MB, KU), one dietician (EBB), and one medical social worker (ACC). I was one of the nurses, and apart from lecturing, I coordinated all practical matters and was present throughout the course to assist the participants. The course consisted of lectures on various subjects, including medical care, physical activity, stress management, diet and health insurance. Four lectures, of two hours' duration each, including a short break during which the participants could have informal discussions, were held in a lecture room at the hospital. Lecturing with an interactive approach, group exercises and written material were used. Self-help brochures and summaries of each lecture were provided.

After a short introduction to the course, led by the me, the physician (BO) gave the first lecture, explaining that IBS symptoms constitute a recognised disorder, and discussed anatomy and physiology, the pathophysiology of functional bowel disorders, the investigations and treatment. The second lecture was conducted by me and the other registered nurse (KU), since we had specialized knowledge and long experience of physical activity and stress-management. We focused on how to initiate physical activities and gave an overview of stress and stress-management. During this lecture there was also time for the participants to practice diaphragmal breathing and muscle relaxation. The dietician (EBB) gave the third lecture and focused on nutritional requirements, healthy eating habits, regular meals as well as diets suitable for patients with IBS. The first part of the final lecture was given by the medical social worker (ACC). She focused on the Swedish health insurance system and the patient's rights and on private insurances. The participants were informed about the Swedish Association of People with Stomach and Bowel Diseases and the ways in which the association can be of help to patients with IBS and their relatives. The second part of the last session consisted of a group discussion between the participants and all the lecturers.

Data analysis

Qualitative analysis

One way to analyse data is by qualitative categorisation and this type of analysis method can be used as a first step to identify and characterise different factors which can be further investigated (Wallén 1996, Polit et al. 2001). The analysis of the texts from the participants' self-reported, all-inclusive question concerning their perception of a good quality of life (Paper I) was inspired by the concept of Burnard's (1991) method of thematic content analysis. The aim of his method is to construct a detailed and systematic list of prominent themes and patterns addressed in the collected narrative data and to link these in categories. Burnard's analysis method includes 14 stages to be followed and is built on grounded theory established by Glaser and Strauss as well as from various works on manifest content analysis (Burnard 1991). During the analysis of the data I tried to bracket my pre-understanding and not let it influence the results. I saw the participants as experts on the researched area.

The analyses of the data collected in Paper I, preceded in the following manner. In the first phase I read through all the answers to familiarise myself with the data. Then the text was reread several times and notes were taken throughout the reading in order to grasp words or phrases carrying a meaning of importance concerning the perceptions of a good quality of life. As many headings as necessary to describe all aspects of the content were noted. Inspired by the first reading, categories appearing to deal with the same content were subsequently sorted into categories. This list of categories and sub-headings was worked through to delete duplicates. To increase validity, one of my supervisors (KU) reflected over the categories, and we (MB, KU) discussed the listed categories and sub-headings. Adjustments were made and the outcome of the discussion was a new list. Each of the participant's answers was then worked through to ensure that the categories and sub-headings in the final list covered all aspects of their answers. The content in the questionnaires was coded according to the final list of categories. The answers in each sub-heading were counted, and the data were thereby quantified. During the writing up process I referred back to the participants´ original answers and stayed close to the original meanings. Selected participants could not check the final list of categories, as Burnard (1991) recommends, since the participants had taken part in further research projects (Paper II) and thereby could have been influenced by these. All categories and sub-headings concerning perceptions of quality of life are presented as results in Paper I, Table 3. The final phases according to Burnard's method of thematic content analysis should be to link the results to the literature. No articles based on the same question as in Paper I, have been found in Medline or in Chinahl, but studies including similar questions are presented in Paper I, Table 1.

To confirm the dependability, to verify the results and to estimate the saturation of the collected data in Paper I, fifteen other women who suffered from IBS, answered the same question under similar conditions. The analysis of these new data identified no additional categories or sub-headings.

The questionnaire about the content of the Course of Instruction included open items, which were summarised in Paper II. To get a better overview of the results, these items where later analysed by content manifest analysis into categories (Table 7) by the use of Burnard's thematic content analysis (1991).

Statistical analysis

Descriptive statistics and different statistical calculations were used and are described in each Paper. The collected data from Paper II and III were regarded as non-symmetrically distributed, and therefore non-parametric statistical methods were used (Altman 1991). Friedman Rank test (Paper II) and Wilcoxon Signed Rank test (Paper II, III) were used for calculations of the GSRS and PGWB over time (Paper II), and Mann-Whitney U-test (Paper III) for comparing two independent groups. Only a few questions in GSRS and PGWB were missing and they were replaced by the mean value of the dimension. The Wilcoxon Signed Rank test was used to assess the changes in health care consumption, medications, and sick-leave during the year before and after the Course of Instruction (Paper II).

The descriptive statistics were presented as median, interquartile range (q^1-q^3) and range (Paper I-III). In Paper III data were also presented as the 95 % confidence intervals (CI) for means, to compare with the scores from the normal population. In Paper II the response rates to the GSRS and the PGWB were presented as percent as well as in number of patients. The patients' perceptions of the content of the Course of Instruction (Paper II) were also presented descriptively.

Furthermore, the Spearman's Rank test was used to calculate the correlation between items and domains in the GSRS and PGWB (Paper II, III), and to calculate the correlation between age and the GSRS and PGWB in Paper III. Pearson's test of correlation was used to correlate between items in the VAS-IBS (Paper IV) and between the GSRS, PGWB and VAS-IBS. The Chi-square test was used when comparing the groups of patients, with their satisfaction of laxative treatment (Paper III).

The VAS-IBS was psychometrically tested (Paper IV) to study whether it measured the construct of interest, and how the questionnaire behaved in relation to a variety of conditions. The collected data were normally or approximately normally distributed, checked by the One-sample Kolmogorov-Smirnov test (Altman 1991). The VAS-IBS was psychometrically tested for content and criterion validity, internal reliability consistency, item-reduction, scale acceptability, simplicity and velocity. The different methods of validation are described in detail in Paper IV.

All statistical analyses were carried out using the statistical package SPSS 11.0 for Windows^R. A p value of <0.05 was considered as statistically significant.

Ethical aspects

The collected data and the results of a study should reflect the truth of a specific phenomenon. Guidelines for performing research are governed by law and ethical principles, and a researcher has to make an attempt to create a good environment for the participants and avoid fraud and fabrication of data (Polit et al. 2001, Kazdin 2003). The ethical principles approved by the World Medical Association Declaration of Helsinki (1996) including ethical principles for medical research involving human subjects concerning, protection of life, health, privacy and dignity of the persons, as well as the Good Clinical Practice guidelines (Hutchinson 1997) have guided the work with this thesis and the studies. All studies presented in this thesis have been approved by the local Ethics Committee of Lund University; LU-510-02 (Paper I, II and IV), LU 541-01 (Paper III), and LU 735-02 (Paper IV). The potential participants were treated as autonomous individuals and they all decided voluntarily whether to participate in an investigation or not. All participants gave written, informed consent before being signed up for participation in any of the studies.

The women included were informed about the study (aim, design and method) orally as well as in writing. They were informed that the participation was voluntary and that they could withdraw, at any time during the study, without consequences concerning further treatment. The participants were given the possibility to contact the author by phone or mail during the studies. The participants were guaranteed confidentiality and no one outside the research group has had access to their identity. All collected data were kept according to the law about personal information (Personal Data Act. SFS 1998:204).

FINDINGS

The findings of the studies in Paper I-IV are presented in relation to the following headings: *Perception of a good quality of life* (Paper I), *A Course of Instruction* (Paper II), *Health aspects due to use of laxatives* (Paper III), and *Development and psychometric testing of a new questionnaire* (Paper IV).

Perception of a good quality of life

To be healthy, without physical symptoms, and to have a satisfying social life are important issues for a good quality of life according to the women participating (Paper I). All of the women reflected on issues related to physical, mental and social health, and the need to have a balance between family, work and leisure time. The majority of the women noted the importance of support from family and friends and they pointed out that this support affected their quality of life in a positive way. A few of the women stated that it was important to them to be accepted as they are, in spite of their bowel symptoms. Furthermore, they wanted to have control over their lives and be able to reach prearranged goals.

However, the women wanted to be relieved of their illness and have a normal life. They described mostly factors and situations with focus on their bowel problems and they indicated that the bowel symptoms had forced them to make changes in their lifestyle. Eating and elimination are concrete examples of basic areas, which are daily affected by the IBS. The inconveniences caused by the symptoms are perceived to generate health problems, physical as well as psychological, and the women described the two health-aspects as one overall issue. The patients' symptoms affect their quality of life, and there was a statistically significant correlation between *Quality of life* and *Abdominal Pain* ($p<0.001$) as well as between *Quality of life* and *Bloating and Flatulence* ($p<0.002$) (unpublished data). Despite the negative influence of IBS, the women described experiences that made them feel happy and satisfied with life.

The women's perceptions of what constitutes a good quality of life were summarised in five broad categories as follows: *Physical and mental health, Social health, Welfare, Strength and energy* and *Self-fulfilment* (Paper I, Table 3).

The outcomes of the dialogues were divided into three main topics; *Search for help, IBS as a diagnosis*, and *Information and instruction*. A majority of the women participating had not understood that they suffered from a classified disorder based on established criteria and they were not familiar with the diagnosis or with all that it implies. The women were told by their physicians that there was no observable biochemical and/or structural abnormality to be found and consequently, they did not suffer from a physical disease. The women mentioned that their feelings had been hurt by the attitudes of health professionals and they felt misunderstood since the doctors and nurses had played down their problems. The women wanted more information and instruction concerning IBS and wanted to meet other women in the same situation, to verify that they were not alone.

A Course of Instruction

Of the 29 women participating in the Course of Instruction, 23 completed the GSRS and the PGWB at 12 months after the course and of these, 18 completed all the follow-up questionnaires. One year after the women had completed the Course of Instruction (n=23), they perceived less *Abdominal Pain* (p<0.037) and experienced more *Vitality* (p<0.045) than before they started the course, according to the scores of the GSRS and the PGWB (Paper II, Table 1). A correlation between *Abdominal Pain* and greater *Vitality* were seen at baseline *(*p<0.032) as well as at 12 months (p<0.049). However, the women did not perceive that their quality of life had improved (p<0.970) (unpublished data). Out of 29 participants, 17 completed the same questionnaires after two years after completing the Course of Instruction. Statistical analysis was not performed since the number of answers was few.

Furthermore, the study showed that the number of *visits to physicians* (p<0.037) and to *dieticians* (p<0.042) had decreased (Paper II), but there were no statistically significant changes in the women's consumption of pharmacological drugs, naturopathic preparations or reported sick-leave (Paper II).

After finishing the Course of Instruction, the 24 women completed the questionnaire on the content of the course. The open questions in the questionnaire were summarized in Paper II, and the result of the manifest content analysis, performed later is presented in Table 7.

Table 7. The participating women's (n=24) comments on the Course of Instruction.

The women's answers	**Number of answers**
Good understanding of my health problems	24
Enjoyed meeting others	15
The course was too short	9
Positive that health professionals showed interest in me	7
Information should have been given at the time when I got the diagnosis of IBS	4
Smaller groups (fewer than 8)	3

The women stated that they had appreciated all the different subjects discussed concerning their bowel problems, but that it was difficult to identify the most important aspect of the instruction. Two years after finishing the Course of Instruction the majority of the women reported that they had in some way used the information they had been given at the course. This had led to improvement in their lives in some extent.

Health aspects due to laxatives

The findings in Paper III showed that there were no statistically significant differences in symptoms between those women who used sodium picosulphate regularly at least once a week, and those women who used other laxatives, including sporadic use of sodium picosulphate, according to the scores of the GSRS (Paper III, Table 6). However, there was a statistically significant difference in psychological well-being between the two treatment groups according to the calculation of the PGWB (Paper III, Table 3). The women who used sodium picosulphate had higher scores, with a median value of 97 (interquartile range 79-106), compared to the women who used other laxative treatments who had a median value of 86 (interquartile range 77-95; $p<0.017$), thereby indicating better psychological well-being. The difference was seen in less *Anxiety* ($p<0.0001$). However, when the women who used other laxatives ($n=14$) were included in a clinical drug trial (Ohlsson et al. 2005), their symptoms as well as their psychological well-being was improved according to the scores in the GSRS and PGWB after the screening period, but before the introduction of the drugs. The improvements were seen in less *Abdominal Pain* ($p<0.011$) and less *Constipation* ($p<0.042$) (Paper III, Table 7) as well as in less *Anxiety* ($p<0.003$) and better *Self-Control* ($p<0.009$) (Paper III, Table 4). Also the total sum of the GSRS was lower ($p<0.046$) and the total sum of the PGWB was higher ($p<0.003$). These improvements were not seen among the women who used sodium picosulphate ($n=8$).

Furthermore, few of the women participating were satisfied with their laxatives treatment. Among the women who used sodium picosulphate regularly only 11% ($n=35$), and in the group who used other laxative treatment 29% ($n=51$) were satisfied with their treatment.

Development and psychometric testing of a new questionnaire

The items in the VAS-IBS were generated from the literature and the first version of the VAS-IBS included nine items, which captured three dimensions, namely, *Physical symptoms, Mental health*, and *Quality of life*. Physical symptoms included six items concerning, *Overall bowel symptoms, Abdominal Pain, Diarrhoea, Constipation, Bloating/Flatulence,* and *Vomiting/Nausea.* Mental health included one item concerning the patient's *Perception of her/his mental well-being.* Quality of life included two items; *Well-being during the previous week* and *Perception of her/his quality of life.*

The psychometric testing confirmed that the VAS-IBS is an acceptable, homogeneous patient-reported questionnaire with acceptable content and criterion validity and internal consistency reliability. The expert panel agreed that the VAS-IBS captures the main physical concerns that women with IBS might present, and all members except one thought that the VAS-IBS might be useful in clinical practise. The members of the expert panel suggested some changes, and their suggestions are given in Table 8.

Table 8. Suggestions from the expert panel members for items to be added and deleted from the VAS-IBS.

Items to be added	Items to be deleted
Sensation of incomplete evacuation	Overall item concerning bowel symptoms
Urgency of defecation	Vomiting and nausea
Evaluation of the patient's daily life	Well-being latest week or Concerning quality of life
Food intolerance	

The concurrent validity was the chosen approach to establish the criterion validity, and was measured by a calculation of the correlation between the VAS-IBS and the GSRS as well as between the VAS-IBS and the PGWB. All correlations were statistically significant and in the expected directions with p-values between <0.0001 and <0.003 (Paper IV, Table II). The lowest value was seen between the item *Vomiting and Nausea* in the VAS-IBS and the dimension Reflux in the GSRS (-0.391, $p<0.003$). This dimension in the GSRS also contains items about reflux-symptoms. A comparison of the specific item about *Vomiting and Nausea* in the GSRS and in the VAS-IBS was performed and this correlation was higher (-0.810, $p<0.0001$). The overall VAS-IBS showed a high degree of internal consistency reliability as indicated by Cronbach´s alpha internal consistency reliability coefficient (0.836) (Paper IV, Table III), and each of the nine items had a high alpha value (0.77-0.83).

VAS as the chosen scaling method for the scoring of the items seemed to be the correct choice according to the expert panel as well as to the calculations. Frequency distributions for item response options were well distributed (Paper IV, Table IV). Scale scores spanned the entire scale range in all items except two; the item concerning *Overall bowel symptoms* (0-89), and the item concerning *Bloating and Flatulence* (0-96). The mean scores were situated near the scale midpoint (40-60) in all items except three; the item concerning *Overall bowel symptoms* (34.4), the item concerning *Bloating and Flatulence* (32.2), and the item concerning *Vomiting and Nausea* (65.0). All scale scores were in the acceptable range for skewness (Paper IV, Table IV). Item floor and ceiling effects were low and ranged from 1.8 to 9.1% (item floor effects) and from 0 to 27.3% (item ceiling effects). However, the item concerning *Vomiting and Nausea* (27.3) was above the limit at 20 %, set for the study.

The results of the VAS-IBS were simple to calculate and a conclusion based on the results was easily reached. The internal validity was high, since all items were fulfilled.

The VAS-IBS has been translated into English by a native English speaking person (KR), who was aware of the intent of each item and of the scale as a whole. After that we looked at the original Swedish version and the translated items, and resolved the discrepancies, since it is better that a translation is performed by a team (Streiner & Norman 2003). The next step will be the "back-translation", by a person who has neither seen the originals nor is aware of the purpose of the scale, before the VAS-IBS can be used in English.

DISCUSSION

General discussions of the findings

When the women with IBS were asked to describe what to them constitutes a good quality of life they mainly illustrated situations and factors which affected their physical, mental and social life negatively due to the symptoms created by IBS (Paper I). The main complaints of the women were the amount of abdominal pain and bloating and the resulting effect these symptoms have on the women's activities and their daily lives. The inconveniences IBS created were undesirable and the women could not perceive, enjoy and appreciate certain things in life, since the disorder restricted their freedom. The women wanted to be able to take part in social activities, have a job, have good finances and be accepted in spite of their illness. Patients with IBS generally look as healthy as anyone else and their symptoms can not be seen. The women tried to hide their distress even when they were in pain. Despite that, the symptoms of IBS have a great impact on the relationships with other persons.

It was obvious that the women were not satisfied with their situation, and consequently not with their quality of life. The women's description of their situation is in line with the results of various investigations performed using different self-reported questionnaires (Whitehead et al. 1996, Hahn et al. 1999, Simrén et al. 2001a, Lee et al. 2001, Creed et al. 2001). It is obvious that women suffering from IBS have a reduced quality of life.

From the patients' perspective, two major concerns have been identified, namely, lack of information, and lack of respect. The concept IBS was unknown to them, and they were not aware of the fact that IBS is acknowledged as a definable diagnosis (Thompson et al.1999). The women had been informed that they did not suffer from a physical disease, since their body functions were normal and a pattern of deviant statistical results were not present (Paper I). Nevertheless, the women had persistent symptoms affecting their quality of life. The lack of information about IBS among the women may depend on health care professionals', doctors as well as nurses, own lack of knowledge (Letson & Dancey 1996, Heitkemper et al. 2001, 2002, Richmond & Devlin 2003, Bellini et al. 2005). Of the Province of Pisa in Italy, only 35.7% of the general practitioners (*n*=28) were familiar with the Rome II criteria (Bellini et al. 2005). In a survey among nurses in the United Kingdom (*n*=253), it was found that the majority of nurses felt it difficult to work with these patients and they had also inadequate knowledge regarding this disorder (Letson & Dancey 1996). Also nurses in the United Stated have requested more instruction regard IBS (Heitkemper et al. 2001). To my knowledge, no information about Swedish health care professionals' insight into IBS is available. However, only a few registered nurses in Sweden have special gastroenterology education and most of them have their focus on patients with IBD and liver diseases. Most patients are treated at primary care centres, and not at gastroenterology clinics at a hospital.

The women had to cope not only with the poor understanding of the symptoms, but also with the negative attitude of health care professionals. The women wanted their illness to be confirmed and meet respect. However, this perceived ignorance among health care professionals is not unique to Sweden. The negative attitudes of doctors and nurses have also been described in other countries, i.e. the United Kingdom (Dancey & Backhouse 1993), in the United States (Heitkemper et al. 2002), in Canada (Meadows et al. 1997), and in Ireland (O'Sullivan et al. 2000b).

The essence of the women's lived experiences was to be healthy without physical symptoms and to have a good quality of life. But to improve quality of life is difficult, since the concept quality of life consists of several domains (WHOQOL Group 1998b), and physiological, psychological and environmental factors are involved in the picture of illness (Drossman 2005). In patients with IBS there is a disequilibrium between the patient's goals, the repertoire and the environment. For a patient to be able to attain an acceptable level of health there is a need for a balance between these three parts. If one of the parts is improved, the patient's health (Pörn 1993), and thereby quality of life will to some extent, also be improved. The patients need information to developing their own strategies and taking control of the illness. To attain improvements in the health of the patients, health care professionals must be knowledgeable and interested in the patient and the underlying disorder. In this thesis four areas related to the women's goals, repertoire, and environment have been identified; *confirmation of the diagnosis, confirmation of the patient, instructing the patient,* and *treating the patient's symptoms.* These identified areas should be considered for planning health care for patients, women as well as men, with IBS. All patients seeking health care service should be treated equally irrespective of gender. However, the care of each patient must be individualised. Unfortunately there is a lack of information how men with IBS perceive their illness, but men as well as women ought to have an explanation and information of their symptoms, to be confirmed in their illness, and have their symptoms treated.

Confirmation of the diagnosis

The women reported a pattern of going from one physician to another, to get an explanation to their symptoms. The process of making a diagnosis of IBS involves exclusion of other possible causes for bowel disorders. This can led to many investigations with negative outcome. The women were frustrated when they were not given a reason to the cause of their problems. When it is established that the patient has IBS, it is not enough to inform the patient that there are no objective markers to be found. It is important to explain that she/he has a classified illness with a name, IBS, which confirms the patient's complains (Brülde & Tengland 2003). The patient can thereby inform family and friends that the symptoms are connected to an illness, and can be a valid excuse for deviating behaviour (Brülde & Tengland 2003). It is to be hoped that this leads to a better understanding and sympathy for the patient. It might also help the patient to explain to her/his employer and workmates her/his absences from work. By having a diagnosis the patient also has right to social benefits and health insurances.

Today IBS is acknowledged as an established diagnosis and is included in the Swedish version of the international classification of diseases the National Board of Health and Welfare (1997), as K58.0 Irritable Bowel with diarrhoea, K58.9 Irritable Bowel without diarrhoea, and as K59.9 Functional Bowel Disease Unspecified. To improve classification of all disease-related conditions and health-related domains the International Classification of Functioning, Disability and Health (ICF) (WHO 2001), was published in 2001. The purpose of this system is to classify the consequences of patients' symptoms and to provide a unified language to be used world-wide. In this classification all aspects of human health and well-being are included and are described in the context of the human body, the individual person and the society. Positive as well as negative aspects of the patient's situation as well as the environment are taken into consideration. This classification system seems to be useful for health professionals in contact with patients suffering from IBS, since the patients' problems are so complex.

Confirmation of the patient

Women suffering from IBS should be accepted as they are and it is important for them to be believed and to have their symptoms confirmed by health care professionals. When a patient comes to a clinic, the patient wants to meet respect and be confirmed (Paper I). It is important to focus on why the patient has come and how the patient feels. Health care professionals should try to understand and to meet the patient, not the disease (Hellström 2000), and show sympathy (Gustavsson & Pörn 1994, Gustavsson 2000). To establish good communication in an allowing climate is essential in good relationships (Gustavsson & Pörn 1994, Gustavsson 2000), and physicians who are good listeners are favoured by patients (Meadows et al. 1997). To obtain better communication patients should see the same physician at each visit.

The women participating in Paper I may have handled their situation better, if health care professionals had shown consideration and interest in them. When the women took part in the Course of Instruction (Paper II), the fact that the instructors took them seriously, was regarded as positive. One month after having completed the course the women also tended to register the highest psychological well-being scores (91.0) according to the total sum of the PGWB (unpublished data). Also the women participating in Paper III improved some of their scores in the GSRS and the PGWB when they were included in a clinical trial, even before the drugs were introduced. Simply the fact that the women were in focus and had been given attention, may have improved their health (Ohlsson et al. 2005).

Health care professionals should offer information and support to patients about their illness according to the Swedish Health and Medical Services Act (HSL 1982:763). The women participating in Paper I perceived that the health care professionals had little knowledge about IBS, and were not able to provide support other than to prescribe medication. A greater knowledge among health care professionals about IBS and an awareness of living with this disorder, leads to more empathy, understanding and practical help (Gustavsson & Pörn 1994, Letson and Dancey 1996, Gustavsson 2000). It is important that health care professionals are conscious of the latest scientific and medical literature in their encounter with these patients (Norton 1996).

By experience, patients with IBS often account for a high percentage of long phone calls to an outpatient clinic, asking for advice. Instead of a nurse with basic education a specialised nurse, called an IBS nurse with specific knowledge about the syndrome, may be of advantage for these patients. The IBS nurse could offer information, for instance, about investigation, treatment, and medication (Dill & Dill 1995). The nurse could also help the patient to create opportunities to develop coping strategies and offer support (Drossman et al. 2000).

Instructing the patient

IBS seems to be an illness that occurs in an information vacuum, and patients with IBS request more information and knowledge about IBS (Dancey & Backhouse 1993, O'Sullivan et al. 2000b, Paper I). Health care professionals must be aware that this lack of knowledge is a problem for the patients.

The women who had taken part in the Course of Instruction (Paper II) were informed about medical care, physical activity, stress management, diet and health insurance, and how these subjects affect and interact with health. To profit from these lectures, the participants have to be activated and become involved. One year after the women had completed the course they perceived less abdominal pain and experienced more vitality than before the course (Paper II). However, the women did not perceive any improvements in their quality of life. The lectures had inspired them to change their life-style. These results are in accordance with the findings of Colwell et al. (1998) as well as Saito et al. (2004). The women had used the information they had been given at the course, which had led to improvement in their lives to some extent. The improvements in their health might be due to the fact that the women had more knowledge about IBS, and had had their symptoms confirmed. It might also be due to the fact that the women had become a member of the treatment team, which is an important aspect of treatment.

There were only few changes in the women's health care requirements after the Course of Instruction, and thereby no remarkable economic benefits were achieved. However, the women who took part in the course reported, even before the course, a low average rate of absence from work (<3.5 days/year). This in comparison to other studies (Drossman et al. 1993, Heitkemper et al. 2002) and in comparison with women without IBS (4.4 days/year) (Heitkemper et al. 2002). Some of the women stated that their work is of importance to them (Paper I), and that they had worked even on days they did not feel very well.

However, the same concept of educational programme has been practiced on patients having IBD in Malmö since 1995 (unpublished data) and in Stockholm (Oxelmark et al. 2005), but no improvements concerning the patient health aspects have been found. The diversity of results between patients with IBS and IBD may due to several reasons. The diagnosis Mb Crohn and ulcerative colitis are based on known organic pathohistological findings, and the patients are properly informed about the diagnosis. Since patients with IBD have a diagnosis and a name of their illness, they can also search information by their own. The health care professionals are well educated about IBD and there are special IBD nurses at most hospitals. Another possible reason may be the differences in management regimes. For patients with IBD there are established health care programmes since long time ago. There is no cure of IBD, but the treatment is potential and relieves the patients' symptoms..

Treating the patient's symptoms

It is a challenge to treat patients with IBS, and guidelines concerning care and nursing could be of help. Health care professionals ought to be aware of the strong psychological mechanisms involved, which independently might affect the outcomes of the treatment given. It is especially difficult to treat patients with IBS, since to a great extent they respond to placebo even though they had failed to respond to conventional treatment (Vase et al. 2003, 2005, Forbes et al. 2005, Ohlsson et al. 2005, Pitz et al. 2005). Patients with refractory constipation were improved already during the run-in period, before introducing the drug of oxcytocin or placebo (Paper III). When comparing each group before and after treatment, only in the group who had used placebo there was a statistically significant increased score for constipation (oxcytocin; $p<0.055$ and placebo; $p<0.023$) (Ohlsson et al. 2005). The frequencies of the drug-administration, and the length of the screening period as well as the length of the study, are predictors of the response to placebo (Pitz et al. 2005). The patients' expectations and the health care professionals' enthusiasm (Dobrilla & Scarpignato 1994), as well as just having been given attention, may also be possible explanations for the response.

Most patients with chronic constipation are dependent on laxatives to achieve acceptable bowel movements. There was a lack of documentation in hospital records, indicating that the women did not inform their doctors or nurses of their use of laxatives, which they were not "permitted" to use. Patients and health care professionals have together the responsibility for the patients' treatment. Patients should leave correct information, which is essential for shared decision marking of which treatment to be used. However, it is the health care professionals' duty to record and collect important information, which can not be denied. Doctors and nurses can recommend patients with chronic constipation to use sodium picosulphate when they fail to respond to ordinary therapies. Since the psychological well-being was better for the women who used sodium picosulphate (Paper III), and that regular use of these pharmaceutical drugs leads to only a moderate increase in doses over an observation time of several years, without severe side-effects (Bengtsson & Ohlsson 2004), it seems wise to let patients with constipation use these drugs openly and without guilt.

Because there is no consistent biological marker of IBS, patients are diagnosed only by their reported symptoms. The patients' perceived health not only defines their condition but also serves as the primary outcome to measure the impact of treatment. It is difficult in clinical practise to estimate the symptomatic changes occurring in patients based on their descriptions. There is a need to objectivate the patients' subjective symptoms and their subjective well-being into numbers. Abdominal pain and bloating/flatulence can be very severe and are the most bothersome symptoms for patients with IBS (Bijkerk et al. 2003b, Dapoigny et al. 2004). The VAS-IBS (Paper IV) is designed to detect differences in five main areas of complaint related to bowel symptoms, and is intended to be of use in clinical practise as a complement to the anamnesis. The questionnaire could be used to estimate the degree of the patients diverse complains, and to get a predictor of what is the most troublesome for the patient. The VAS-IBS seems to be a valid and reliable questionnaire and appears to be user-friendly, for patients as well as for health professionals. The questionnaire is easy to complete and unproblematic to calculate. It is to be hoped that the VAS-IBS will be used in clinical practise in different situations to quantify the impact that gastrointestinal symptoms may have on patients with IBS. The questionnaire can be used at baseline and after pharmacological as well as other types of treatment to evaluate the effects.

A model for health care

It is important for the patient and the community that the goal of health care is to improve the patient's symptoms and psychological well-being until a cure has been identified. There is a need for a comprehensive health care model for patients with IBS that takes into account the severity of managing the patients' complaints. The focus of the model should be at the primary care level but the model must include a longitudinal plan of health care also including the secondary care level (Figure 3). The successful care of a patient with IBS requires health care professionals to be interested in the patient and the disorder. Health care professionals should be supportive to the patient and see the patient as the head of the health care team and not just a recipient of health care (Rankin & Stallings 2001). By working in a team together with the patient, health care professionals also gain a broader knowledge of the subject.

The primary focus for the patient is to get the diagnosis IBS and the illness confirmed, and to be given instruction about IBS. The patient needs to create realistic goals and exclude such environmental factors which exacerbate the symptoms. The purpose of a model for the health care of patients with IBS is to help the patient to take responsibility for her/his illness and treatment. When the patient has taken the responsibility, the patient can gain a sense of empowerment and thereby improve her/his health and quality of life. The main goal of the model, and as a result of successful health care, patients should perceive; *good physical, mental and social health, good welfare, strength and energy,* and *self-fulfilment* (Figure 3).

Primary care level

Patients primarily seek help for their symptoms at a health care centre, and the physician should diagnose patients with IBS correctly. Steps have been taken to better understand the pathophysiology, but much is still unknown. The physicians should be open about the lack of knowledge about IBS. Important information for the patients is that IBS is a diagnosis of a legitimate physiological disorder and that the symptoms can be severe but harmless. The physician has to establish a good relationship with the patient, show interest and concern, which requires an interaction with the patient. If the physician does not establish a good relationship with the patient, there is a risk that the patient goes off on her or his own track, seeks help elsewhere and uses inappropriate therapies. The patient's complaints should be taken seriously by listening actively to the patient's description of the symptoms. The VAS-IBS could be of use to confirm the patient's complaints and quantify the impact that the symptoms may have on the patient. When treating the patient it is important to focus on the most outstanding complaint, and different kinds of pharmacological drugs should be used. However, the most expensive or newest drugs are automatically not the most effective. There is no contraindication today to prescribe "forbidden" stimulant laxatives, and the patient will use these types of drugs nonetheless if she/he needs them. It is important to know that psychological mechanisms are involved, and that even placebo can be of benefit. The patient should be instructed about the underlying pathophysiology, informed about different forms of treatment, diet and a good lifestyle as well as about physical activity, and stress management. If the patient knows the factors that influence the symptoms and what to anticipate, she/he is better prepared to face the inconveniences the symptoms create. Group sessions about medications, diet, exercise programs and stress reduction might be a part of the treatment regime of patients with IBS, and instruction by a team is preferable. A Course of Instruction, which is a combination of group counselling, information, and education in groups, can be used.

Some patients with IBS require consultations with other kinds of health care professionals than a physician, i.e., an IBS nurse, dietician, physiotherapist or psychologist. The health care professionals should help the patient to set realistic expectations and goals for her/his life. To do that they need an in-depth knowledge of each patient's situation, life style, stressors, and relationships. By interviewing the patient with focus on physiological, psychological and social health aspects, risk factors which aggravate the symptoms should be identified and excluded. An IBS nurse may benefit for patients with IBS, and could preferable be situated at a primary care centre. The nurse can offer information and support, and help the patient to learn to live with the illness.

Secondary care level

A minority of all patients' with IBS require a consultation with a physician specialised in IBS. The treatment used should be followed up and the symptoms can be further evaluated with help of the VAS-IBS. If the patient fails to respond to conventional treatment, i.e., pharmacological, dietary and psychological treatment, the health care professionals must show the patients that they still believe them, and that the patients should not be afraid to try new, alternative treatments. However, arguments for and against the suggested treatments should be discussed. Hypnotherapy could be considered at this stage.

There are still many unexplored aspects concerning IBS, but hopefully in the future a third level of care can be formed.

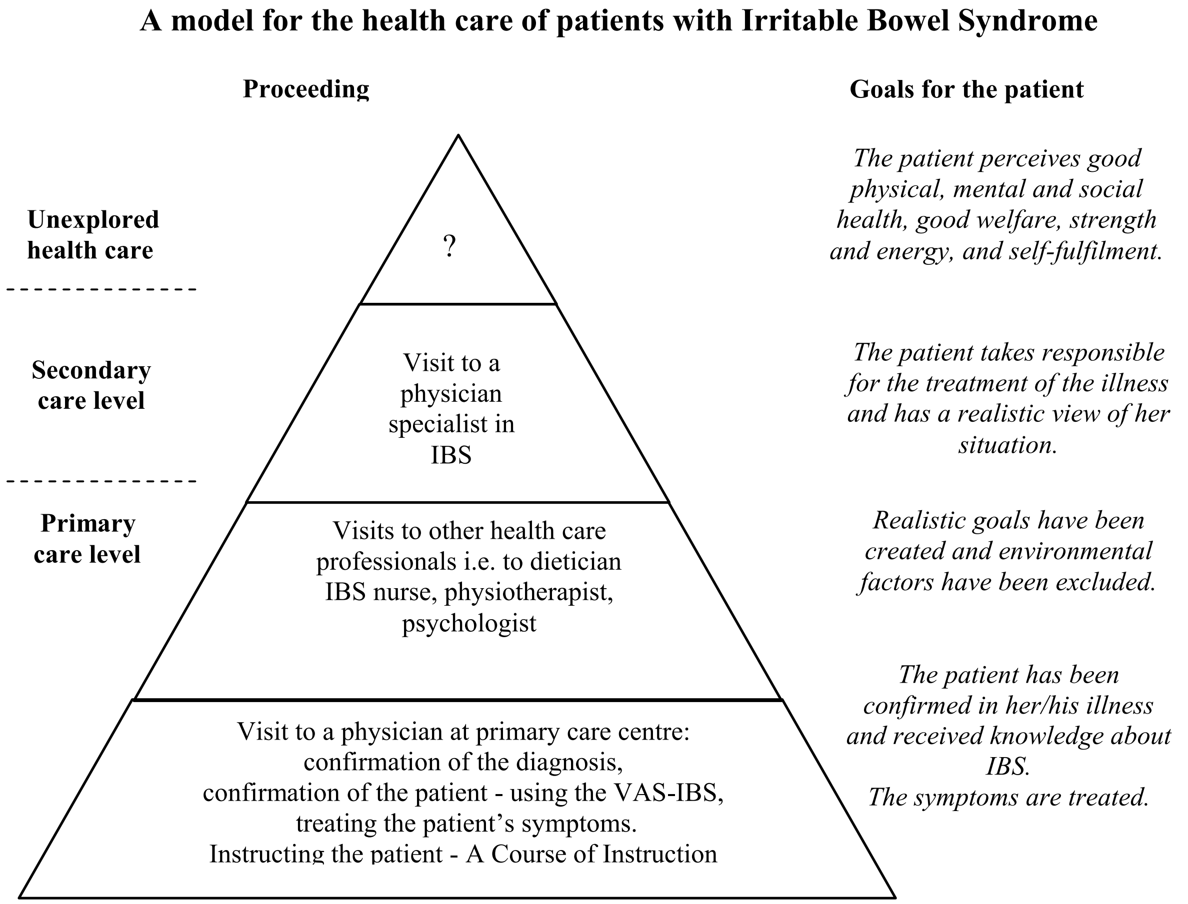


Figure 3. The pyramid model of the health care for patients with Irritable Bowel Syndrome (IBS), describing the proceedings and the goals for the patient.

Methodological consideration

There are many factors in the design of a study which may affect its outcome. In this thesis a multi-method design was used, which has given me the opportunity to move between different kinds of knowledge (Foss & Ellefsen 2002). The purpose of the studies included in this thesis, were to describe, identify, investigate, and evaluate a phenomenon. Certain questions are more open to qualitative than to quantitative inquiry and vice versa (Polit et al. 2001). Qualitative research was applied to describe what constitutes a good quality of life and to identify areas to be further explored. Quantitative research was used to investigate different kinds of treatment and to evaluate a new questionnaire. Both qualitative and quantitative research seeks the truth about an issue and can produce new knowledge. No single study can provide unchallengeable answers. By integrating different kinds of methods there could be a balance between the weaknesses of one method and the strengths of another, which could give a broader picture of the phenomenon under study (Polit et al. 2001).

The impact of recruitment method on clinical research requires consideration since it is likely to access different patient groups which can differ, for instance, in symptom severity, prior disease management, and possibly response to placebo (Lee et al. 1999). All participants included were diagnosed according to the Rome II criteria, and they had all visited a physician at least once.

In the analysis of the qualitative data I tried to bracket my pre-understanding and not let it influence the results. I saw the participants as experts on the area being investigated. However, since no single study can provide unchallengeable results or can evaluate the strengths and the weaknesses of studies (Paper I-IV), the methodological discussion is based on *trustworthiness* (Guba 1981, Lincoln & Guba 1985), *statistical conclusion validity* (Polit et al. 2001), and *clinical significance* (Polit et al. 2001, Kazdin 2003).

Trustworthiness

Trustworthiness can be described as credibility, confirmability, dependability, and transferability (Guba 1981, Lincoln & Guba 1985, Polit et al. 2001). Credibility refers to the confidence in the truth of the results, in how the investigation is carried out and the believability of the collected data (Polit et al. 2001). Confirmability refers to the neutrality and the objectivity of the results presented (Polit et al. 2001), which should not be affected by the researcher's pre-understanding or interest (Lincoln & Guba 1985). Dependability refers to the replicability of the study and the data stability over time (Polit et al. 2001). Transferability refers to the extent to which the results are referable to other settings and groups (Lincoln & Guba 1985).

The optimal way to collect qualitative data (Paper I), would have been to interview the participants about their view of a good quality of life (Kvale 1997). The only person who could perform interviews at the time was I, but I had, just before the study in Paper I was carried out, talked to 146 women with functional constipation (Paper III). These women had, during 20-45 minutes each, told me about living with a functional disorder, which had given me a lot of new information related to IBS. According to Lincoln and Gruba (1985) there is a need for the researcher to have knowledge of the context to be able to understand the phenomenon, but there is also a risk that the interviewer could deliberately or inadvertently interfere with the data collection (Kvale 1997). To avoid falsehood I was judged as not being suitable to undertake the interviews. Instead, a written question was chosen in favour of interviews. The study design also gave the participants an opportunity to give oral information when they handed in the questionnaires. A majority of the women took that chance. Apart from collecting data about the participating women's view on quality of life, the purpose was also to gather information about areas for further exploration and to describe these. For that reason it was also preferable to use a written question and thus be able to collect information from a larger group of women rather than performing only a few interviews. To avoid influences created by group discussions among the participants, the women answered the overall question at home. However, choosing a written question was a weakness, since it turned out that there was a lack of depth in the participants' answers.

To analyse qualitative data two independent analyses should be performed and the results should be compared to increase validity (Burnard's 1991). The collected data in Paper I was not very extensive, and therefore we (MB, KU, BO) decided that two independent analyses were not necessary. The categories and sub-headings listed were, however, analysed and compared by me and one of my supervisors (KU). In the presentation of the results (Paper I) citations from the participants' answers were used to make the results more trustworthy. To confirm the dependability, to verify the results and to estimate the saturation (Polit et al 2001) of the collected data in Paper I, 15 other women with IBS, answered the same question under similar conditions. When analysing the collected data from these 15 questionnaires, no additional categories or sub-headings were identified. No additional categories or sub-headings were identified. The results in Paper I have been confirmed by other sources, and can therefore be considered as being trustworthy. Two nursing students, Custance and Dahl Ottosen (2005), had come to comparable results when interviewing seven women about their experience of daily living with IBS and their contact with the Swedish health care system. Furthermore, parallels can be drawn between the conclusions made by Corney and Stanton (1990), Dancey and Backhouse (1993), Heitkemper et al. (2002), and the results of Paper I, which further confirm dependability in this study. The information about living with a functional disorder, which the participants taking part in Paper III gave Paper I (unpublished data), was also similar to the participants' stories in Paper I.

The Course of Instruction (Paper II) was performed as a non-randomized study without a control group. A randomised study with matched controls would have been preferable. Since only subjective markers can be used doing research on patients with IBS, and the symptoms due to intensity and spectra vary, it had been difficult to identify suitable matched controls. A longer follow-up period was used to compensate this weakness, as in some other studies (Colwell et al. 1998, Saito et al. 2004, Gonsakorale et al. 2002). Data collection was performed over more than one year and changes may have occurred, e.g. change of living conditions, illness in the family, and economical problems, which could have affected the participants' responses to the questions. However, if a control group had been used, waiting for participation in a Course of Instruction, there would still have been a risk of confounding placebo effects, as the controls would have been given attention during this period. Only attention by a trial improves these patients (Paper III, Ohlsson et al. 2005), and psychological factors are strongly related to the severity of a patient's symptoms and well-being (Drossman (1999).

Human research is an intrusion into personal life, and the participants' privacy should be maintained throughout a study. A researcher should ensure that research is as little intrusive as possible (Polite et al. 2001). Thereby the data about the participants' health care requirements (Paper II) were based only on their own information and not confirmed by health care records or information from the Social Insurance Office. This may be a weakness. However, the patients' information has given an overview of their health care requirements, i.e. use of medication, number of visits to health care professionals, and sick-leave due to IBS. Also in Paper III a part of the collected data was based in the participants own information. The purpose was to compare all the participants' information about their use of laxatives, with the doctors' and nurses' written information. Unfortunately there was a lack of information in the participants' medical records, since the women had not informed the health care professionals about their use of laxatives. An investigation should be based on true data, not on personal opinions or fabrication. However, there is no reason to believe that the participants taking part in Paper II and III gave false information.

On the subject of view on transferability, it was a strength to collect a variety of aspects from only a woman's point of view (Paper I-IV), since only a few men could have been included. Furthermore, it would be easier for the women participating in a Course of Instruction (Paper II) to discuss their problems in the group if only women are included. The women included (Paper I-IV) were of different ages (20-65 years of age) and had different experiences of with IBS (4-50 years). To further increase the transferability in Paper I, information from 30 participants was collected. The saturation among the participants included was not estimated, since the decision was to use all the participants' answers in order to increase the transferability.

Since only women were included in Paper I-IV, the dependability of this thesis is strong, but this selection is a weakness for transferability. IBS affects women more often than men, and therefore it is also primarily women who are included in clinical trials. However, the comprehensive areas identified in this thesis; *confirmation of the diagnosis, confirmation of the patient, instructing the patient,* and *treating the patient's symptoms,* are universally applicable and can most likely be transferred to all patients suffering from IBS, even though there are differences in symptoms between the genders.

Statistical conclusion validity

It was difficult to recruit patients to take part in the studies (Paper I-IV), and that is partly due to the treatment they had been given during the years of their illness. If the participants had been better taken care of, they would also have been more eager to play a part in the projects. It would have been unethical to advertise for more patients to take part in a Course of Instruction, since our clinic does not have the capacity to take care of these patients if they had requested further health care. The small number of women included may be a limitation contributing to insufficient power to detect a true difference. More patients have to take part in a Course of Instruction (Paper II), and further statistical calculations must be performed, before the statistical significance results can be established. On the other hand, decreased symptoms and increased psychological well-being can not be used as the only outcome on which to assess the clinical value of a Course of Instruction. Economic aspects, for example, have also to be considered.

Only the diagnosis, age and the reason for refraining are known about the women not included (Paper I-IV). It is likely that the women who took part in the Course of Instruction (Paper II), were especially interested and wanted to change their life style. There were so few men diagnosed as IBS identified (Paper I-IV), that a whole group large enough for statistical calculations was precluded. As there are differences in the symptoms in women and men, they can not be studied in the same group (Thompson 1997, Simrén et al. 2001a, Lee et al. 2001).

Postal questionnaires depend on the participants' willingness to take time to complete the questionnaires. They tend to have a lower response rate than face-to-face interviews (Polit et al. 2001). However, the response rates for the questionnaires GSRS and PGWB in Paper II were between 79 and 89 %, which were comparable to other studies (Glia & Lindberg 1997, Simrén et al. 2001a). The advantage of postal questionnaires is that they absorb little biases from the investigators and they offer the possibility of anonymity (Polit et al. 2001).

The different recruitment methods in Paper III from the hospitals, primary care centres, and by advertisement in the daily press did not appear to influence the results. There were no significant statistically differences in age, symptoms or psychological well-beingto due to recruitment method (unpublished data).

Clinical significance

The degree to which a study addresses a problem of clinical significance has to be considered (Polit et al. 2001). The information provided by the participants is of great clinical importance. To women with IBS the goal of health care should be to get relief of symptoms in order to improve their quality of life. It is also obvious that health care professionals need to change their attitude toward patients with IBS, to be able to offer better treatment and thereby achieve better results.

Different forms of patient education are becoming more and more common (Rankin & Stallings 2001), but a Course of Instruction, as in Paper II, has to be further evaluated before it can be established as part of the ordinary treatment. If this type of education is found to be of benefit, it can be given at primary care centres as well as at hospitals by health care professionals with knowledge in IBS.

The final version of the VAS-IBS has to be used in clinical practise, at primary as well as at secondary care level, before its clinical significance can be established. The capacity of the questionnaire to respond to treatments has not been judged. One of the major problems concerning the scoring system of VAS, is the lack of a definition of what should be accepted as an clinical improvement of the patients complaints.

Patients suffering from IBS are a heterogeneous group, and no biological markers are available to quantify the severity of IBS, which makes the judgments more difficult.

Parallel to the development of the VAS-IBS the Gastrointestinal Symptom Rating Scale for IBS was developed (Wiklund et al. 2003) and evaluated on patients in the USA and the UK. The idea was to construct a questionnaire which could be used in clinical research. The Gastrointestinal Symptom Rating Scale for IBS is a short, user-friendly, 13-item questionnaire, but items concerning *vomiting and nausea* are missing. A seven-point Likert scale is used for each item. Both VAS-IBS and Gastrointestinal Symptom Rating Scale for IBS could be useful in clinical practice. However, the VAS-IBS might be preferable, since it requires few calculations, and has fewer items even though the questionnaire includes an item concerning *vomiting and nausea*.

CONCLUSION AND CLINICAL IMPLICATION

IBS is still poorly understood, and it is important to legitimise the disorder. Functional disorders have in the past been handled as if they were psychological in origin, but that is not completely true. Several physiological mechanisms are involved, but none is predominant. Symptoms and impaired psychological well-being in conjunction to IBS are bothersome for the patient, and affect the patient's quality of life. In this thesis several aspects related to quality of life and health have been identified, and discussed, namely, *confirmation of the diagnosis, confirmation of the patient, instructing the patient* and *treating the patient's symptoms*. The areas identified have been studied only in women, but can most likely be transferred to all patients suffering from IBS, even thou there are differences between women and men due to symptoms and daily life activities.

A patient with IBS requires multi-disciplinary treatment, including pharmacological, psychological and dietary treatment as well as knowledge about IBS for a successful outcome (Drossman et al. 2002, Heitkemper et al. 2004, Tillisch & Chang 2005). A health care model for patients with IBS has been created. The focus of the model is at the primary care level, but the model includes also the secondary care level. This model demands multi-disciplinary efforts and requires that health care professionals have a holistic perspective. The main goal of the model, and as a result of successful health care, patients with IBS should perceive; *good physical, mental and social health, good welfare, strength and energy,* and *self-fulfilment* (Figure 3).

IN THE FUTURE

I believe that the most important thing for me to do is to spread basic information about IBS to health care professionals and students, and thus to get rid of some oldfashioned ideas about IBS. Parts of my work have already been presented at the conference Advanced Health Care Sciences of Tomorrow, Lund 2003, Läkarstämman 2003 and 2004, and at the EGENA meeting in Copenhagen 2005. I have also been invited to talk on this topic at the Nordic Gastroenterology meeting in Västerås this spring. Together with a colleague, Ann Tornberg, I organized an educational day last year about IBS for nurses working at gastroenterology units in the south of Sweden. I have also some ideas of how to organize education for health care professionals at primary care centres, which is a most important group to reach. I also hope to get the opportunity to give lectures about IBS at nursing programmes. Structured education programmes for heath care professionals as well as for students need to be developed.

The findings and outcome of this thesis revealed new research questions related to the health care of patients with IBS, as well as living with the symptoms. The findings in this thesis indicate that a Course of Instruction (Paper II) could benefit women with IBS. Further research is required to confirm the results, and it is hoped that at least additional 30 patients are to be included in this project during 2006.

The final version of the VAS-IBS (Paper IV) requires further testing by assessing the sensitivity to change in use in clinical practise. The questionnaire needs also to be properly back-translated (Streiner & Norman 2003) and tested cross-culturally for women as well as men.

In collaboration with primary care centres an intervention study, including women as well as men, is needed with implementation of the health care model. The details of the proceedings must be further developed and the model as whole must be properly evaluated. It remains to be seen whether the patients' symptoms will be reduced and the psychological well-being increased, and thereby their quality of life to some extent improved. Further, the need of an IBS nurse has to be established.

There is only sparse information on living with IBS in Sweden, and further information would be of value to improve health care as well as the patients' health and quality of life. There is no information available about the families' role and their needs of information, education and support. Qualitative interviews with a phenomenological approach could be used to collect such data.

SUMMARY IN SWEDISH

Svensk sammanfattning

Irritable Bowel Syndrom (IBS) är en av de vanligaste funktionella mag- och tarmsjukdomarna och patienter med denna sjukdom finns över hela världen. Uppskattningsvis har 12 procent av Sveriges befolkning IBS och de behandlas av läkare i primärvården eller av specialistläkare. IBS kännetecknas av besvär från mag-tarmkanalen utan någon bakomliggande påvisbar patofysiologisk eller biokemisk orsak. Enligt de symtombaserade Rom II kriterierna definieras IBS som obehag och/eller smärta i magen samt ändrad avföringskonsistens och/eller frekvens under minst 12 veckor de senaste 12 månaderna. Patienter med IBS kan beroende på besvär anses ha diarré- respektive förstoppningsdominerad IBS. Omkring 1/3 av de patienter som har IBS har en intermittent avföringsfrekvens som växlar mellan diarré och förstoppning. Orsakerna till patienternas besvär är komplexa och det är flera faktorer som kan ha betydelse för sjukdomens uppkomst. Störningar i tarmmotoriken, ökad känslighet i tarmen s.k. inre hypersensivitet, störningar i kommunikationen mellan tarmen och hjärnan s.k. ”brain-gut axis”, samt störningar i hormoner och peptider har visat sig ha en viss betydelse.

Det är fler kvinnor än män som drabbas av IBS och besvären varierar beroende på kön. Förstoppning till exempel, är vanligare bland kvinnor, medan diarré är vanligare bland män. Patienter med IBS lider också av många andra besvär, såsom gaser, trötthet, illamående och huvudvärk. Patienter som har IBS har en hög sjukfrånvaro och de utsätts för stort lidande, vilket i förlängningen även påverkar deras sociala situation och dagliga liv. Samhällets kostnad för patienter med IBS är stor eftersom de konsumerar mycket sjukvård i sin jakt efter hjälp för sina besvär.

Vid läkarbesöket är det patientens uppgifter som får ligga till grund för fortsatt utredning, men någon enhetlig utrednings- och behandlingsstrategi finns inte. Omhändertagandet av patienter med IBS är i huvudsak medicinskt inriktad och syftar till att lindra patientens besvär och öka välbefinnandet, eftersom någon botande behandling inte finns. För att reglera tarmfunktionen rekommenderas i första hand fiberrik kost, rikligt med dryck och ökad fysisk träning, vilket ofta inte är tillräckligt för att få ordning på magproblemen. Eftersom IBS inte går att bota får den medicinska behandlingen inrikta sig på att lindra patienternas besvär med hjälp av olika läkemedel. Psykologisk behandling kan ibland vara av nytta, men tillgängligheten till denna typ av vård är begränsad. Omvårdnadsåtgärder saknas helt, vilket kan anses vara en brist, speciellt för denna patientgrupp som har en så komplex sjukdomsbild.

Syftet med avhandlingen var att utarbeta en vård- och omvårdnadsmodell som förbättrar livskvalitet och hälsa hos svenska kvinnor med IBS.

Delstudie 1. Upplevelse av en god livskvalitet

För att vårdpersonal skall kunna hjälpa kvinnor med IBS att förbättra sin livskvalitet och hälsa, behöver vårdpersonalen veta mer om dessa kvinnors syn på en bra livskvalitet. Frågan *”Vad innebär en bra livskvalitet för dig?*”, fanns med som en enkel fråga i ett frågeformulär som skickades hem till 30 kvinnor med IBS som skulle påbörja en patientutbildning (Delstudie II). Kvinnorna som deltog i utbildningen var mellan 20-65 år, medelålder 39 år. De besvarade frågan skriftligt och datainsamling gjordes i samband med tre patientskolor som startades under november 2002 till maj 2003. När enkäterna lämnades in fanns det tid för ett kort samtal där kvinnorna kunde lämna ytterliggare information. De kvalitativa data som samlats in avseende livskvalitet, analyserades systematiskt med utgångspunkt från Burnards (1991) metodbeskrivning i 14 steg avseende manifest innehållsanalys.

Enkäterna visade att kvinnor som har IBS anser framförallt att en bra livskvalitet för dem innebär en god fysisk, psykisk och social hälsa. En bra social tillvaro och att inte vara drabbad av någon sjukdom stod högst på deras prioriteringslista, men de strävade också efter en bra livskvalitet utifrån ett vidare perspektiv. När kvinnorna i studien svarade på frågan har de i sin beskrivning mestadels utgått från faktorer som påverkar dem negativt med fokus på magproblemen. Det framgick tydligt av svaren att de inte var nöjda med sin situation och beskrev i huvudsak händelser som de ville undvika. Kvinnornas reflektioner kategoriserades i 16 underkategorier, vilka sammanfördes i fem huvudkategorier; *fysisk och psykisk hälsa, social hälsa, välfärd, kraft och energi* samt *förverkligande* (Delarbete I, tabell 3).

Av samtalen framkom det att flertalet inte hade förstått att de hade en klassificerad sjukdom och de visste inte heller vad syndromet innebar. Av läkaren hade de fått besked att utredningen som de gått igenom inte hade visat på något fysiskt fel, och således trodde de att de inte hade någon sjukdom. Kvinnorna berättade också att de kände sig missförstådda och kränkta av sjukvårdpersonalens bemötande, och tyckte att läkare och vårdpersonal bagatelliserat deras problem. Kvinnorna efterlyste mer information och utbildning om IBS och önskade få komma i kontakt med andra kvinnor i samma situation. När de nu blev kontaktade avseende denna studie, upplevde de det positivt att någon äntligen tog dem på allvar.

Delstudie 2. Utbildning av kvinnor med Irritable Bowel Syndrome

Kvinnor med IBS efterlyser information om sin sjukdom. För att tillgodose deras behov och för att se om systematiserad utbildning kunde påverka deras livskvalitet och hälsa anordnades en så kallad IBS skola. IBS-teamet som höll i utbildningen bestod av undervisare från olika yrkeskategorier och specialiteter. Utbildningen var förlagd till fyra träffar à två timmar var gång med avbrott för kaffe/tepaus. De 29 kvinnor, uppdelade i tre grupper, som deltog i utbildningen fick information om medicinsk vård, fysisk träning, stresshantering, näringslära samt sociala resurser. Ett år efter avslutad kurs upplevde 23 av kvinnorna mindre smärta och en högre vitalitet enligt självskattningsformulären Gastrointestinal Symptom Rating Scale (GSRS) (avseende gastrointestinala besvär) samt Psychological General Well-Being (PGWB) (avseende psykiskt välbefinnande) jämfört med före utbildningen (Delarbete II, Tabell 1). Kvinnorna hade färre besök till läkare och dietist efter att ha gått utbildningen, men där var ingen förändring av läkemedelsförbrukningen eller sjukfrånvaron. Kvinnorna var nöjda med utbildningen och hade fått en god uppfattning om sina hälsoproblem. De tyckte det var positivt att få träffa andra med samma diagnos och att sjukvårdspersonalen visade intresse för dem och deras sjukdom (Kappan, Tabell 7).

Delstudie 3. Hälsoaspekter i relation till användande av laxermedel

Sjukvårdspersonal avråder enligt tradition patienter från att använda motorikstimulerande läkemedel, t.ex. innehållande natrium picosulfat, vid långtidsbehandling av förstoppning p.g.a. risk för tarmskada. Detta är dock inte är dokumenterat. Trots avrådan används dessa läkemedel av patienter med förstoppningsproblematik. För att utforma rekommendationer för hur dessa läkemedel skall kunna användas behövdes mer information om hur dessa läkemedel påverkar hälsan hos kvinnor med kronisk förstoppning.

Totalt 86 kvinnor mellan 27 och 65 år, med kronisk förstoppning besvarade självskattningsformulären GSRS och PGWB samt lämnade information om sin förbrukning av laxermedel. Baserat på kvinnornas information delades gruppen i två delar. Grupp A; kvinnor som regelbundet använde läkemedel innehållande natrium picosulfat minst en gång per vecka (35 kvinnor), samt Grupp B; de som använde andra laxermedel samt de som sporadiskt använde natrium picosulfat (51 kvinnor). Enligt GSRS var det ingen skillnad mellan kvinnornas mag- och tarmbesvär men enligt PGWB hade kvinnorna som använde natrium picosulfat mindre ångest samt allmänt bättre psykiskt välbefinnande (Delarbete III, Tabell 3). Emellertid visade det sig att när 22 av de 86 kvinnorna i denna studie ingick i en läkemedelsstudie (oxcytocin/placebo) förbättrade kvinnorna i Grupp B (14 kvinnor) sin hälsa redan innan de provat några nya läkemedel. De hade mindre smärta, mindre förstoppning, mindre ångest och bättre självkontroll samt bättre total poäng avseende formulären i sin helhet (Delarbete III, Tabell 4 och 7).

Delstudie 4. Utveckling och validering av ett bedömningsinstrument

Det fanns ett behov av ett kort och enkelt bedömningsinstrument för att få en uppfattning om de besvär som patienter med IBS har och för att följa behandlingseffekten. Därför utvecklades Visual Analogue Scale for Irritable Bowel Syndrome (VAS-IBS) för att fånga patienters subjektiva upplevelse av sina mag- och tarmbesvär. Formuläret (första versionen) bestod av nio frågor uppdelade på tre dimensioner; fysiska besvär (sex frågor), mental hälsa (en fråga) samt livskvalitet (två frågor), alla graderade med hjälp av en visual analog skala (VAS). En expertpanel, fem läkare och fyra sjuksköterskor, bedömde VAS-IBS i relation till relevans och definition samt skalans lämplighet genom att fylla i ett index för innehållsvaliditet. En grupp bestående av 55 kvinnor med IBS fyllde i GSRS, PGWB och VAS-IBS för att undersöka VAS-IBS i förhållande till validitet och reliabilitet.

De psykometriska testerna bekräftade att VAS-IBS har hög tillförlitlighet avseende validitet, reliabilitet och intern samstämmighet. Formuläret är enkelt att använda för patienter såväl som för vårdpersonal. Den slutgiltiga versionen av VAS-IBS består av nio frågor uppdelade på tre dimensioner, *fysisk hälsa* (fem frågor besvaras med hjälp av VAS och två med ja/nej), *mental hälsa* och *livskvalitet* (vardera en fråga vilka besvaras med hjälp av VAS).

Konklusion

Fyra områden identifierades relaterade till hälsan hos kvinnor med IBS; *bekräfta diagnosen, bekräfta patienten, utbilda patienten* och *behandla patientens symtom.* Dessa områden ingår i en vård- och omvårdnadsmodell för kvinnor så väl som för män (Kappan, Figur 3), vars syfte är att förbättra hälsa och livskvalitet hos patienter med IBS. Målsättningen är att patienterna skall uppnå *fysisk, psykisk och social hälsa, välfärd, kraft och energi* samt *självförverkligande.* Patienter med IBS skall i huvudsak tas om hand i primärvården, där de skall få information om sin sjukdom och deras symtom skall behandlas. Dagens bristande omhändertagande av patienter med IBS kan bero på personalens osäkerhet och okunskap om orsakerna till patienternas besvär och de behandlingsmetoder som finns att tillgå. Därför måste sjukvårdspersonalen ha utbildning om IBS innan vård- och omvårdnadsmodellen kan få avsedd effekt.

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APPENDIX

Visual Analog Scala för Irritable Bowel Syndrome (VAS-IBS)

Visuel Analog Skala för Irritable Bowel Syndrome (VAS-IBS)

Hur har Du mått den senaste månaden med tanke på buksmärtor?

Mycket dåligt Mycket bra

____

Hur har Du mått den senaste månaden med tanke på diarrébesvär?

Mycket dåligt Mycket bra

____

Hur har Du mått den senaste månaden med tanke på förstoppning?

Mycket dåligt Mycket bra

____

Hur har Du mått den senaste månaden med tanke på uppspändhet och gaser?

Mycket dåligt Mycket bra

____

Hur har Du mått den senaste månaden med tanke på illamående och kräkning?

Mycket dåligt Mycket bra

____

Hur bedömer Du att ditt psykiska välbefinnande har varit den senaste månaden?

Mycket dåligt Mycket bra

____

Hur mycket/lite har tarmbesvären påverkat Ditt dagliga liv den senaste månaden?

Väldigt mycket Väldigt lite

____

Besväras du av täta trängningar till avföring? JA NEJ

Upplever du att tarmen är fullständigt tömd efter toalettbesök? JA NEJ

SUMMA:………………..

Bengtsson Mariette 2006-04-06