

# **Evaluation of a guided self-help intervention for irritable bowel syndrome –**

## **An interdisciplinary eHealth approach**

Master Thesis in Clinical Nutrition

**Mari Liltvedt Andersen**



Department of Clinical Medicine (K1)

National Centre of Competence in Functional Gastrointestinal Disorders,

Department of Medicine, Haukeland University Hospital

The faculty of Medicine and Dentistry

University of Bergen

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## FOREWORD/ACKNOWLEDGEMENTS

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Bergen, November 2017

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## ABSTRACT

**Background:** Irritable bowel syndrome (IBS) is the most common functional gastrointestinal disorder, defined by recurrent abdominal pain or discomfort, associated with defecation and/or altered bowel habits. Due to the lack of structural etiology, and curative therapy, these patients have been treated symptomatically. The treatment is recommended to be individualized, where the options are a combination of guidance on diet and lifestyle, pharmacological therapy and psychological interventions. The worldwide prevalence is high and it contributes to reduced quality of life and major healthcare costs. There is a need for treatment that can shorten the waiting line for patient education, reduce healthcare costs and help more people independently of geographic location, therefore an eHealth program was developed and implemented.

**Aim:** The primary aim of the prospective, open pilot study, was to evaluate whether the eHealth program could be effective as a healthcare measure. This was assessed, based on the effect of the program itself, but also in comparison with the effect of the current program; the physical IBS-school at LMS.

**Design and methods:** 52 patients who had got the IBS-diagnosis from either their general practitioner (D93) or by a specialist in gastroenterology (k58), were included in the 6 months long study. They participated in the web-based, interdisciplinary, self-management program. The program was based on 5 different modules with professional content, each compiled by gastroenterologist, physiotherapist, psychiatrist and clinical dietitian. It was implemented in Checkware's technical platform by Helse Bergen- Section for eHealth. To assess the effect of the program, the participants were asked to complete the six questionnaires; Rome III criteria, IBS-QOL, IBS-SSS, HADS, RAND-36 and NKFM at three time points; at baseline, and after 3- and 6 months, in addition to CSQ-8, at 3 months after the start-up. Control group 1 and 2 consisted of IBS-patients, which participated in the regular, physical, IBS-school at LMS and an extended, physical, IBS-school at LMS, respectively.

**Results:** Of the 52 study participants included in the eHealth program, 40 completed the 3 months evaluation and 31 completed the 6 months evaluation. The analysis of *eHealth program (I)* followed the participants who completed the 6 months evaluation. 4 out of 5 IBS symptoms significantly improved *from baseline to after 3 months*, with a mean overall reduction of 64.4 mm (95% CI: 37.6, 91.3 mm,  $p=0.00004$ ). 5 out of 8 IBS-QOL subscale

scores increased significantly between the latter two time points, with a mean overall improvement of 9.2 (95% CI: 4.2, 14.1,  $p=0.001$ ). In *control group 1*, mean overall IBS symptoms and mean IBS-QOL overall, numerically improved from *baseline to after 3 months*, with 7.0 (95% CI: -21.8, 35.8,  $p=0.617$ ) and 3.9 (95% CI: -7.5, 15.3,  $p=0.485$ ), respectively. In the *eHealth program (I)*, 3 out of 5 IBS symptoms significantly improved from *baseline to after 6 months*, with a mean overall reduction of 78.7 (95% CI: 37.4, 120.0,  $p=0.001$ ). 7 out of 8 IBS-QOL subscale scores improved significantly between the latter time points, with a mean overall improvement of 10.1 (95% CI: 5.9, 14.3,  $p=0.00003$ ). In *control group 2*, the overall IBS symptom scores numerically decreased from *baseline to after 6 months*, with a mean of 32.3 (95% CI: -5.6, 70.2,  $p=0.094$ ).

**Conclusion:** In this prospective, open pilot study, we found statistically significant improvement in IBS symptoms and health-related quality of life, according to IBS-QOL. There was also a greater mean improvement in symptoms- and IBS-QOL scores when compared with the control groups, but neither of the scores in the control groups were statistically significant changed. However, it indicates that the eHealth program is not less effective than the IBS-school at LMS. Altogether, it leads us to the conclusion that the eHealth program can be effective as a healthcare measure.

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## LIST OF ABBREVIATIONS

BDA: British Dietary Association

BSFS: Bristol Stool Form Scale

CBT: cognitive-behavioral therapy

FGIDs: Functional gastrointestinal disorders

FODMAPs: Fermentable oligo-, di-, mono-saccharides and polyols

GI: Gastrointestinal

GIT: Gastrointestinal tract

GP: general practitioners

HR-QOL: health-related quality of life

IBS: Irritable Bowel Syndrome

IBS-C: IBS with constipation

IBS-D: IBS with diarrhea

IBS-M: Mixed IBS

IBS-school at *LMS*: IBS-school at learning and mastering centre in Bergen (Lærings- og mestringssenteret)

ICBT: internet-based cognitive behavior therapy

MT-skolen: «*Mage-tarmskolen*»; Name of the IBS eHealth program

NICE: National institute for Health and Care Excellence

NKFM: National Centre of Competence in Functional Gastrointestinal Disorders (Nasjonal kompetansetjeneste for funksjonelle Mage-/tarmsykdommer)

REC: Regional Committee for Medical and Health Research Ethics

SSRIs: selective serotonin reuptake inhibitors

TCA: Tricyclic antidepressants

VAS: Visual Analog Scale

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## **1. INTRODUCTION**

### **1.1 Functional gastrointestinal disorders (FGIDs)**

Many patients suffer from functional gastrointestinal disorders (FGIDs), but there are also many people in the general population who are bothered by symptoms related to these disorders (1). These patients have often been described as having “functional symptoms/problems”, and has due to the lack of structural etiology, been treated symptomatically (2, 3). In 2006, the Rome foundation published Rome III, that define the diagnostic criteria as well as a classification system for FGIDs (1). The classification system divides FGIDs into 6 domains for adults; “esophageal (category A); gastroduodenal (category B); bowel (category C); functional abdominal pain syndrome (category D); biliary (category E); and anorectal (category F)”, in addition to 2 domains for pediatrics GI which is divided by age: “neonate/toddler (category G); and child/adolescent (category H)” (1). Each domain consists of different subcategories, i.e.: functional bowel disorders (category C) consists of, among others, the subcategory irritable bowel syndrome (category C1) (1).

### **1.2 Irritable bowel syndrome**

Of all functional gastrointestinal disorders, IBS is the most common, which is defined by recurrent abdominal pain or discomfort, which is associated with defecation and/or altered bowel habits (4-6). Even though IBS is not a life-threatening disorder, it still contributes to significantly reduced quality of life, and major healthcare costs both directly and indirectly, by patient care and absenteeism at work (4, 5, 7, 8). It's been reported that IBS patients' quality of life, has long been underestimated, and that these patients have a lower HRQOL than patients with other diseases, like diabetes, gastroesophageal reflux disease, and end-stage renal disease (9).

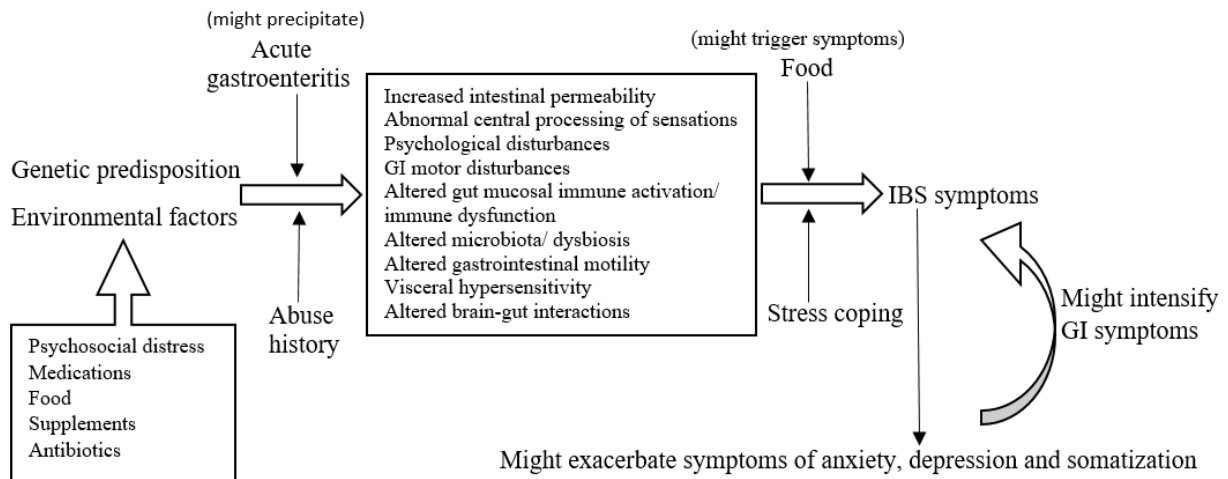
#### **1.2.1 Epidemiology**

In general, the prevalence and incidence rates of IBS differs from one country to another, depending on the study population, which criteria the study has used to define IBS and what type of study methodology has been utilized (4, 10, 11). A meta-analysis which performed a systematic review to assess the global prevalence of IBS in adults (15 years or older), involved 80 different survey populations that included 260,960 individuals worldwide (11).

They identified a worldwide IBS prevalence of 11.2% (95% CI, 9.8% -12.8%), with variations between countries and criteria used. For example, the prevalence in studies using Manning criteria was 14% (95% CI, 10.0% -17.0%), while Rome I criteria was 8.8% (95% CI, 6.8% -11.2%) and Rome II criteria were 9.4% (95% CI, 7.8% -11.1%) (11). The latter meta-analysis and other studies have found a higher prevalence in women than in men (4, 7, 10, 11), and there is a higher proportion of people suffering from IBS in individuals younger than 50, compared to those older than 50 (10, 11). Unfortunately, there is not sufficient enough data, able to determine how socioeconomic status affects the prevalence of IBS (10, 11).

### 1.2.2 Etiology and Pathophysiology

Despite the large proportion of patients suffering from IBS, the pathophysiology is still not fully understood (12, 13). Irritable bowel syndrome is a heterogeneous disorder, and it has been suggested to be a generic term for many diseases with different pathogenesis, but with the same symptoms (4, 8, 13). This means that IBS is a multifactorial syndrome, where no single abnormality is consistent for all patients with IBS symptoms (13, 14). Figure 1 shows different factors that may play a role in the pathogenesis of IBS. It has been suggested that genetic predisposition, various environmental factors and psychosocial factors can contribute to an increased vulnerability of developing IBS (8, 10). Events like enteric infection, may play a role as precipitating factors (may cause so-called “post-infectious IBS) (10, 15). All of these factors may contribute to different pathophysiological mechanisms like increased intestinal permeability, altered gut immune activation and changed microbiota (8, 10, 13). Furthermore, these various factors may contribute to a dysregulation of the brain-gut axis, which subsequently may lead to some of the pathophysiological mechanisms mentioned above (10).



**Figure 1:** Overview of different factors that possibly can play a role in the pathophysiology of IBS, made based on figure from Heidelbaugh et al and Schoenfeld (10, 13) and with some modifications from Ford et al (8).

### 1.2.3 Signs and symptoms

Typical symptoms found in IBS patients are abdominal pain and cramping, bloating/distention, constipation, loose/frequent stools and flatulence, some also experience defecation straining, urgency and sensation of an incomplete bowel movement (4, 6, 16). IBS patients can also experience that symptoms change over time, i.e.: pain location and altered stool patterns may alter from time to time (4, 16).

Patients with IBS often experience multiple comorbidities that contribute to their disease burden (4, 14, 17-19). These can be divided into gastrointestinal disorders (functional gastroesophageal reflux and functional dyspepsia), psychiatric disorders (depression, anxiety, and somatization), and finally the nongastrointestinal nonpsychiatric disorders (fibromyalgia, chronic fatigue syndrome, temporomandibular joint disorder, chronic pelvic pain, migraine headaches, interstitial cystitis and dyspareunia) (4, 14, 17-19). It has also been indicated that a proportion of diarrhea-predominant IBS patients suffer from idiopathic bile acid malabsorption (20).

### 1.2.4 Diagnosis

Because of the absence of pathology that can explain the IBS symptoms, it has been difficult to develop a non-invasive diagnostic test with high accuracy (8). Efforts have been made to develop biomarkers, but at present, no biomarkers have been identified that can diagnose IBS

better than symptom-based criteria (8, 21). The identification of IBS is therefore a symptom-based approach where the diagnosis is based on the Rome III diagnostic criteria (Figure 1) and the exclusion of organic disease (1, 3, 4, 6, 7). The Rome III criteria implies “recurrent abdominal pain associated with defecation and/or a change in stool, at least 3 days per month in the last 3 months, and with symptom onset at least 6 months before the diagnosis” (4, 6).

IBS should be diagnosed based on clinical history, physical examination and laboratory tests (4, 14). To exclude organic disease, patients who fulfill the Roma III criteria for IBS are also investigated for red flag symptoms like unintentional weight loss, fever, age of symptom onset after 50 years, rectal bleeding, anemia and family history of organic gastroenterological disease (4, 14). Only if clinically indicated, as a positive discovery of the latter, the patient should be further investigated (like a colonoscopy) to check for any anatomic and physiological abnormalities, which is what distinguishes functional bowel disorders from other GI disorders (4, 14).

IBS is subcategorized into 3 different subtypes based on their predominantly stool consistency; i) IBS with predominant constipation (IBS-C), ii) IBS with predominant diarrhea (IBS-D) and iii) IBS with irregular bowel habits (IBS-M), where the patients experience a mixture of constipation and diarrhea (4, 6, 14). Patients who fulfill the Rome III criteria for IBS, but do not have bowel habits that allow them to be accurately categorized into one of these three subtypes mentioned, are unsubtyped as having IBS-unclassified (IBS-U) (6, 14). The Bristol Stool Form Scale (BSFS) (Figure 2) is often recommended to be used as a record for stool consistency (14, 22, 23). Figure 3 presents how Bristol Stool Form Scale potentially can subtype IBS. Here, IBS is subcategorized according to the predominant stool consistency that is present more than 25% of the time (14, 23). In IBS-C, stool from type 1 and 2 on the Bristol Stool Form Scale (Figure 2), are present more than 25% of the time (14, 23), while type 6 and 7 are present less than one quarter of the time. The opposite applies for IBS-D. In IBS-M, both loose and hard stools are frequently present (14, 23), whereas with IBS-U there is no stool consistency that dominates (14, 23). It is important to note that IBS patients occasionally have normal bowel habits. Therefore, in clinical practice, one will categorize the different subtypes on the background of the largest proportion of consistency stool, that

usually dominates when the patient experiences abnormal stool (14, 23). If a patient meets the Rome III criteria, they are not only subtyped based on their predominant stool pattern, but they are also categorized by the severity of their symptoms (23). The patients are categorized into mild-, moderate- and severe IBS, or remission, depending on their symptom score (see 2.6.3 IBS-SSS) (24).

**Rome III Criteria for Irritable Bowel Syndrome (IBS) With Subtypes<sup>a</sup>**  
 Recurrent abdominal pain or discomfort<sup>b</sup> at least 3 days per month in the last 3 months associated with 2 or more of the following:

1. Improvement with defecation
2. Onset associated with a change in frequency of stool
3. Onset associated with a change in form (appearance) of stool

<sup>a</sup> Criterion fulfilled for the last 3 months, with symptom onset at least 6 months before diagnosis.  
<sup>b</sup> "Discomfort" means an uncomfortable sensation not described as pain.

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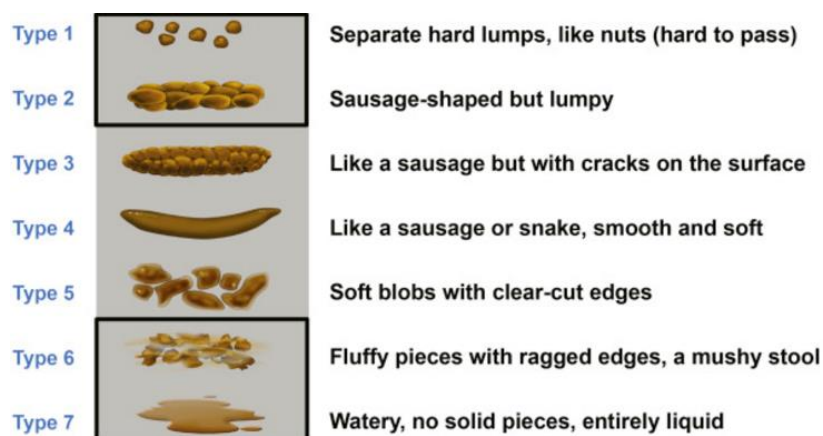
**Subtyping IBS by Predominant Stool Pattern**

1. IBS with constipation (IBS-C)-hard or lumpy stools\*  $\geq 25\%$  and loose (mushy) or watery stools\*\*  $< 25\%$  of bowel movements\*\*\*
2. IBS with diarrhea (IBS-D)-loose (mushy) or watery stools\*\*  $\geq 25\%$  and hard or lumpy stool\*  $< 25\%$  of bowel movements\*\*\*
3. Mixed IBS (IBS-M)-hard or lumpy stools\*  $\geq 25\%$  and loose (mushy) or watery stools\*\*  $\geq 25\%$  of bowel movements\*\*\*
4. Unsubtyped IBS-insufficient abnormality of stool consistency to meet criteria for IBS-C, D or M.\*\*\*

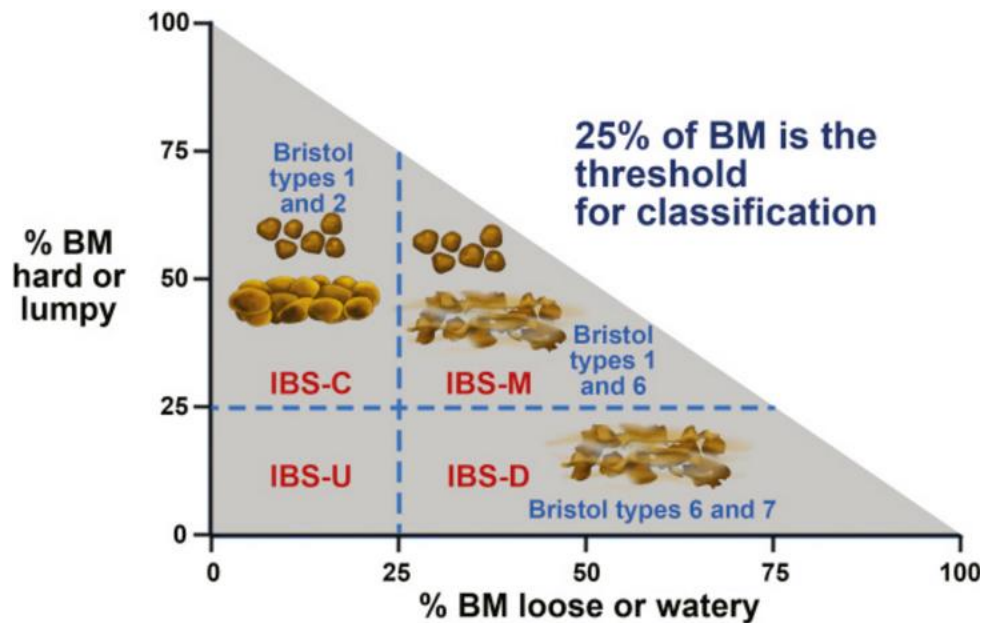
\* Bristol Stool Form scale 1-2  
 \*\* Bristol Stool Form Scale 6-7  
 \*\*\* in the absence of use of antidiarrheals or laxatives

**"Red flags" / alarm symptoms**  
 Symptom onset after age 50 years, Unexplained weight loss, fever, rectal bleeding, Unexplained iron-deficiency anemia and family history of organic gastroenterological diseases, including colon cancer, celiac disease, or inflammatory bowel disease.

**Figure 2:** Rome III Diagnostic criteria for irritable bowel syndrome and "red flags" adapted from figures from Chey et al and Longstreth et al (4, 6).



**Figure 3:** The Bristol Stool Form Scale. Lacy et al. Bowel Disorders, Gastroenterology, 2016; 150(6). P 1393-1407. Figure 2 (A) (14).



**Figure 4:** Rome IV IBS subtypes: stool form. Lacy et al. *Bowel Disorders, Gastroenterology*, 2016; 150(6). P 1393-1407. Figure 2 (B) (14).

### 1.2.5 Treatment

Currently, there is nothing that cures IBS, and since the patient group is highly heterogeneous, the treatment is recommended to be individualized based on the patient's predominant symptoms (symptom type and severity) (8, 14, 17, 25). The treatment options for IBS are a combination of guidance on diet, general lifestyle and physical activity, as well as pharmacological therapy and psychological interventions (4, 15, 26). Figure 5 shows examples of different treatment options for IBS. Although this thesis does not address all the individual treatment options, studies have evaluated both the effect and quality of evidence, as well as cost, of the various therapy alternatives (8, 27). The latter figure shows, among other things, medications that are recommended to treat specific symptoms of IBS, such as diarrhea, constipation, abdominal pain and bloating (15, 26).

#### 1.2.5.1 Non-pharmacological treatment

Because of the incomplete utility of pharmacological treatment for IBS (28), different studies have looked at the effect of different psychological treatments for irritable bowel syndrome (29). A meta-analysis showed for example that Cognitive behavioral therapy (CBT) had a

greater effectiveness, than controls in waiting line (30). This was assessed based on decreased IBS-like symptoms and improved psychological state and quality of life (QOL) (30). But it was only reduction of IBS-like symptoms, which was more effective in CBT, compared with controls who received routine standard care and medical therapy. The study also indicated that the effect of IBS could possibly be maintained by long-term follow-up (30). Another meta-analysis has shown that Mindfulness-based therapy (MBT) can also be effective in the treatment of IBS (31).

It has also been recommended to give IBS patients guidance for self-help to cope with IBS (15, 26). This contains among other things, of recommendations of inspiring patients with low physical activity to increase their level of activity, which is supported by studies, that have shown that exercise possibly can improve GI symptoms (32, 33). Dietary guidance is also one of the first-line treatments, as many IBS patients claim that specific parts of the diet can be a trigger for their symptoms (8, 15, 26). Bohn et al report that this is associated with a high degree of symptoms and reduced quality of life (34). The traditional IBS diet is compiled on the basis of the guidelines from the National institute for Health and Care Excellence (NICE) and the British Dietary Association (BDA) (35). The latter's guidelines focus among other things, on restrictive intake of alcohol, spicy and fatty food (36). Examples of general/standard advices given, based on the NICE guidelines are; "have regular meals and take time to eat", "reduce intake of alcohol and fizzy drinks", "limit fresh fruit to 3 portions per day", "people with diarrhea should avoid sorbitol (...)" and so on (26).

The effect of probiotics as an alternative treatment for IBS is controversial, and a systematic review and meta-analysis found that probiotics can enhance the overall symptoms modestly (37). They concluded that probiotics could possibly alleviate IBS-like symptoms, but in future studies it is also necessary to determine which type of probiotics is best effective and what is the optimal dose for which subgroup of patients (37). The lack of fiber as a possible cause of IBS-like symptoms, is a wide perception, and studies have shown that soluble fiber can be effective in the management of IBS, especially psyllium (25, 38-40). There has also been high interest around the effects of the low FODMAP diet, as a treatment option for irritable bowel syndrome (8, 16).



<b>Treatment options for IBS</b>
<p><b>Pharmacological treatment:</b></p> <ul style="list-style-type: none"> <li>• <u>IBS-D</u>: Antimotility agents like loperamide, 5-HT<sub>3</sub> receptor antagonists like Ondansetron, Eluxadoline, Cholestyramine (in those who suffer from bile acid malabsorption)</li> <li>• <u>IBS-C</u>: Laxatives, Linaclotide, Lubiprostone, Prucalopride</li> <li>• <u>Abdominal pain</u>: Peppermint oil, antispasmodics drugs, antidepressants (like selective serotonin reuptake inhibitors (SSRIs) and Tricyclic antidepressants (TCA))</li> <li>• <u>Bloating</u>: Rifaximin, Simethicone</li> </ul>
<p><b>Psychological interventions:</b></p> <ul style="list-style-type: none"> <li>• Stress management/relaxation therapy</li> <li>• Cognitive behavioral therapy (CBT)</li> <li>• Psychodynamic therapy</li> <li>• Hypnotherapy</li> </ul>
<p><b>Lifestyle advice:</b></p> <p><u>Guidance for self-help to cope with IBS by:</u></p> <ul style="list-style-type: none"> <li>• General lifestyle</li> <li>• Physical activity</li> <li>• Diet</li> <li>• Symptom-based medication</li> </ul>
<p><b>Dietary interventions:</b></p> <ul style="list-style-type: none"> <li>• Traditional dietary advice/general dietary advice (NICE guidelines)</li> <li>• Gluten-free diet</li> <li>• Low FODMAP diet</li> <li>• Review amount and type, and possibly adjust the fiber intake</li> <li>• Soluble fiber (like psyllium)</li> <li>• Probiotics</li> <li>• Fluid intake</li> </ul>

**Figure 5:** Treatment options for IBS, with data based on (8, 15, 26, 27, 41).

### 1.3 The low FODMAP diet

The abbreviation FODMAPs stands for fermentable oligosaccharides, disaccharides, monosaccharides and polyols (16). Oligosaccharides include galactans (galactooligosaccharides-GOS), which can be found especially in legumes, and fructans (fructooligosaccharides-FOS and inulin) found in, among others, onions, garlic, rye and wheat (42). One example of disaccharides is lactose, which can be found in dairy products like milk

and yoghurt etc. Monosaccharides consist in this context, of fructose when it is in excess of glucose, and this is present in fruits like apple, mango and pear (42). Finally, there are polyols, such as sorbitol, mannitol, maltitol, xylitol, erythritol, isomalt and so on, which are both found naturally in fruits and vegetables like apple and celery, and also used as sweeteners, and are for example present in sugar-free chewing gum (42).

### 1.3.1 Mechanisms and evidence basis

The mechanisms behind this heterogeneous group consisting of short-chain carbohydrates start with malabsorption of the FODMAPs in the small intestine (16, 42, 43). This leads to a rise in osmotic action which in turn causes more water content in the lumen of the small intestine, and also causes the small intestine to distend (16, 42, 43). Undigested FODMAPs along with increased water content goes on to the large intestine and can be fermented by microbiota to short-chain fatty acids which in turn will lead to gas production (16, 42, 43). All of this can lead to a distension of lumen of the large intestine, as well as result in different IBS-like symptoms, such as bloating, discomfort/pain, excessive flatus, alterations in bowel habits and lethargy (16, 42, 43). These mechanisms were proved to be supported by a randomized intervention study including twelve patients with ileostomy that tested this hypothesis (44). They found that when the participants followed a high FODMAP diet, they had a larger proportion of fermentable substrates as well as increased water content out of ileum, compared to when they followed a low FODMAP diet (44).

A recent meta-analysis showed that following a low FODMAP diet led to both a significant reduction in IBS-SSS score and a significant enhancement in IBS-QOL score (16). In the RCT studies that had been included, it was also found a significant improvement in typical gastrointestinal symptoms such as abdominal pain and bloating, as well as overall symptoms, at a low FODMAP diet (16). This meta-analysis and other review articles support and/or conclude that it is enough evidence to determine that the low FODMAP diet is effective in the treatment of IBS symptoms (8, 16, 41-43, 45, 46). A recent review article suggested that as much as up to 86% of the patients suffering from IBS, experience an improvement in IBS symptoms like diarrhea, flatulence, abdominal pain, constipation and so, when they are

following the diet (46). The article also emphasized that the potential effect may be dependent on dietary adherence and by dietary guidance of specialized clinical dietitians (46).

There have been conflicting results when the effect of low FODMAP diet has been compared to the effect of traditional IBS diet advice. An RCT study showed that traditional IBS diet advice based on both NICE and BDA guidelines, decreased IBS symptom similar to a low FODMAP diet (35). While for example two other studies and another meta-analysis showed that the low FODMAP diet was more effective in improving symptoms, when compared to standard dietary advice based on the NICE guidelines (47-49).

#### **1.4 Self-management/patient education**

Self-management is simply explained by "helping people to help themselves" (50), so that they can improve the way they deal with their struggles, and in this case cope with IBS better (26, 50). This includes qualified patient education, where they can learn about their condition, as well as being motivated and inspired to take care of themselves in the best possible way (50). This involves both a collection of tools and techniques that can make it easier to choose the healthiest lifestyle, and at the same time build up a good collaboration between the patient and the therapist (50). Motivation to healthy eating habits, physical activity, safeguarding mental health, guidance in the use of pharmaceuticals, in addition to managing worsening of symptoms and gaining knowledge to know when it is necessary for professional help, are some key words for help to self-care (50). A review article suggested on the background of high quality studies and descriptive overviews, which together accounted for more than 550, that such "self-management support designed to increase self-efficacy can have a positive impact on people's clinical symptoms, attitudes and behaviors, quality of life and patterns of healthcare resource use" (50). Another, smaller systematic review article, which had included eleven studies with all together 1657 IBS-patients, also concluded that self-management support can be beneficial for this group of patients (51).

A study by Joc et al (52) also support these findings. They assessed the quality of life in 83 IBS patients before and after the patients were educated with information about the disease, were given guidance on lifestyle and diet, course of the disease and pharmacological options.

The participants got guidance from doctor and nurse, individually at the outpatient clinic, and they also received written information as well. Joc et al concluded that the education significantly improved the quality of life and significantly reduced the patients' IBS associated complaints, and that education is central in the treatment of IBS patients (52).

### **1.5 Internet-based treatment**

There is limited research on web-based treatment of IBS patients, assembled by a gastroenterologist, physiotherapist, psychiatrist and a clinical dietitian, such as the intervention in this Master's thesis. But one example is a pilot study where 40 IBS patients were recruited for an internet-based self-management program, lasting for 12 weeks (53). The results showed no significant improvement in self-efficacy or quality of life, but self-reports showed that information given about IBS lead to a significantly increased knowledge about the disorder, within the participants (53). Various studies have also shown that internet-based cognitive behavior therapy (ICBT) can have a positive effect on IBS patients (54-57), both at enhancing IBS-like symptoms and quality of life (54, 56), but also at being a cost-effective treatment (55). Another RCT study concluded on the background of the 143 IBS-patients participating, that "structured patient group education (IBS school)" is a better alternative than written information, in the treatment of IBS (58). This was based on the results where they found that the IBS school gave the participants a greater insight and knowledge about IBS, as well as it enhanced the IBS-like symptoms and IBS-related anxiety to a greater extent (58). These limited but uplifting, and somewhat mixed findings requires further research, to identify more of the potential effect, internet-based treatment can have on IBS patients.

### **1.6 Objective**

The objective with this master thesis was to develop the educational content of the eHealth program, as well as creating and implementing the content into Checkware's technical platform, in cooperation with Helse Bergen - Section for eHealth. A separate electronic platform for control group 1 was also created in cooperation with Helse Bergen. Finally, patients were recruited to the pilot study. The primary aim of the study was to evaluate whether the eHealth program could be effective as a healthcare measure. This was assessed based on the intermediate aims 1 and 2. The first aim, was to evaluate improvement in IBS-

symptoms and health-related quality of life, from baseline to after 3- and 6 months.

Intermediate aim 2 was to assess the possible improvement in symptoms and quality of life in the control groups, and compare the improvements of the eHealth program with the two control groups.

## **2. SUBJECTS AND METHODS**

### **2.1 The study**

The study was a prospective, open, pilot study, where quantitative methodology was used for analysis. The study was initiated by National Centre of Competence in Functional Gastrointestinal Disorders (NKFM) at the Department of Medicine, at Haukeland University Hospital. The study was conducted by the above in cooperation with the faculty of Medicine and Dentistry at the University of Bergen.

### **2.2 Planning of the project**

The project idea about an internet-based school was initiated by Birgitte Berentsen, the project manager of the school, and was applied for and received financial funds the first time in May 2015. Subsequently, a project work-, medical specialist, and supervision group, as well as international partners were established to be responsible for each of their tasks. During autumn 2015 and spring 2016, the professional content was developed and implemented in Checkware's technical platform by Helse Bergen- Section for eHealth, among other tasks.

Regional Committee for Medical and Health Research Ethics (REC), approved the main application of the project protocol which had been compiled by Birgitte Berentsen, September the 5<sup>th</sup> 2016, with the REC number 2016/1098 (appendix 1 and 2). New request to include a 15-year-old in the project was sent, and a new REC approval with the alterations was received October the 13<sup>th</sup> 2016 (appendix 3). We also applied for an inclusion of 100 patients in the control group, and we got REK approval for this 07.12.2016 December the 7<sup>th</sup> 2016 (appendix 4).

The author of this master thesis was assigned to the project in January 2016. The educational content in the eHealth program was further developed and improved from August 2016, until start-up, by clinical dietitians Ingrid Skjold, Mari Folden Oppegård and the author of this thesis. The participants were recruited in September 2016, whereas the internet-based school lasted from November to May. The control group 1 consisting of patients attending the

regular IBS school at LMS were included in the study between March and September 2017. Control group 2 contained patients who participated at an extended IBS-school at LMS in October 2015.

### **2.3 Recruitment of patients**

Patients in the study group were recruited from the waiting list of the IBS-school at learning and mastering centre (LMS) in Bergen. Patients included had been diagnosed with IBS and referred to this school by their general practitioner (diagnostic code D93) or specialist in gastroenterology (diagnostic code K58). Comorbidities were not controlled for, and were not a reason for exclusion. All participants were contacted by phone, by healthcare professionals, affiliated with the project. Exceptions were one of the patients, who was recruited directly from an appointment with his specialist in gastroenterology and one patient who was recruited directly from the project leader. 52 patients fulfilled the inclusion criteria and were therefore included in the study. 40 of these patients completed the 3 months evaluation, and 31 completed the 6 months evaluation.

An age range in the study group, between 18-70 was set. The upper age limit was set to ensure compliance, as older people are more likely to experience technical difficulties with an internet-based school, compared to younger people with more internet experience. We set a lower limit of 18, as the professional content is not designed for a pediatric view. There were also technical challenges, supporting the lower limit of 18, as the legislation has an age limit of 15 to get a Bank-identification (BankID) (59), which is necessary to log into the internet-based school. We still chose to include one patient at the age of 15, with a motivated mother also suffering from IBS, who could log in with her BankID-number on behalf of the patient. The same age range (18-70) was set in control group 1, while data from control group 2 were already collected and age range was set.

**Table 1:** Inclusion and exclusion criteria in the study group

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> <li>• Got the IBS diagnostic code from either their general practitioner (D93) or by a specialist in gastroenterology (k58)</li> <li>• Participants between 18-70 years of age</li> <li>• Written consent form</li> <li>• Completed baseline questionnaires (both by post and electronically)</li> </ul>	<ul style="list-style-type: none"> <li>• Pregnancy</li> <li>• Surgery affecting the gastrointestinal tract, during the study</li> <li>• Attending the IBS-school at LMS during the course of the study</li> </ul>

**Table 2:** Inclusion and exclusion criteria in the control groups

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> <li>• Got the IBS diagnostic code from either their general practitioner (D93) or by a specialist in gastroenterology (k58)</li> <li>• Written consent form</li> <li>• Completed baseline questionnaires (both by hand and electronically)</li> </ul>	

## 2.4 Intervention

The eHealth program is a guided self-help intervention program where the participants learn how to cope with their disease, based on quality assured information. Figure 5 shows the 6-8 weeks' program and how it is designed in an interdisciplinary manner, separated into 5 modules. The educational content is presented through text, images, videos, animation and home based assignments. Module 1 consists of among other things, an introduction about IBS by gastroenterologist Trygve Hausken, and further more detailed information about the functioning of the gastrointestinal tract and what IBS is. In Module 2, the physiotherapist, Eirik Østvold, introduces, among other things, proper body awareness and posture, and how to achieve proper breathing techniques. The content presented by the clinical dietitian Synne Ystad, in Module 3, contains lifestyle and simple dietary advice based on NICE guidelines. Module 4 consists of among other things, an introduction to cognitive therapy by psychiatrist Jørn Bødtker. Furthermore, it presents how body and mind work together and the participant



will learn about mindfulness and eventually be introduced to exposure therapy. In Module 5, participants get supervised through the dietary intervention of the low FODMAP diet by clinical dietitian Synne Ystad. Together with clinical dietitian Ingrid S. Skjold they present inspirational and motivational cooking films (Appendix 5 contains a low FODMAP diet brochure, which is a compressed version of Module 5 in the internet-based gastrointestinal school). The participants could go through the internet-based school in their own speed and gain access to a module when they had finished the previous one.

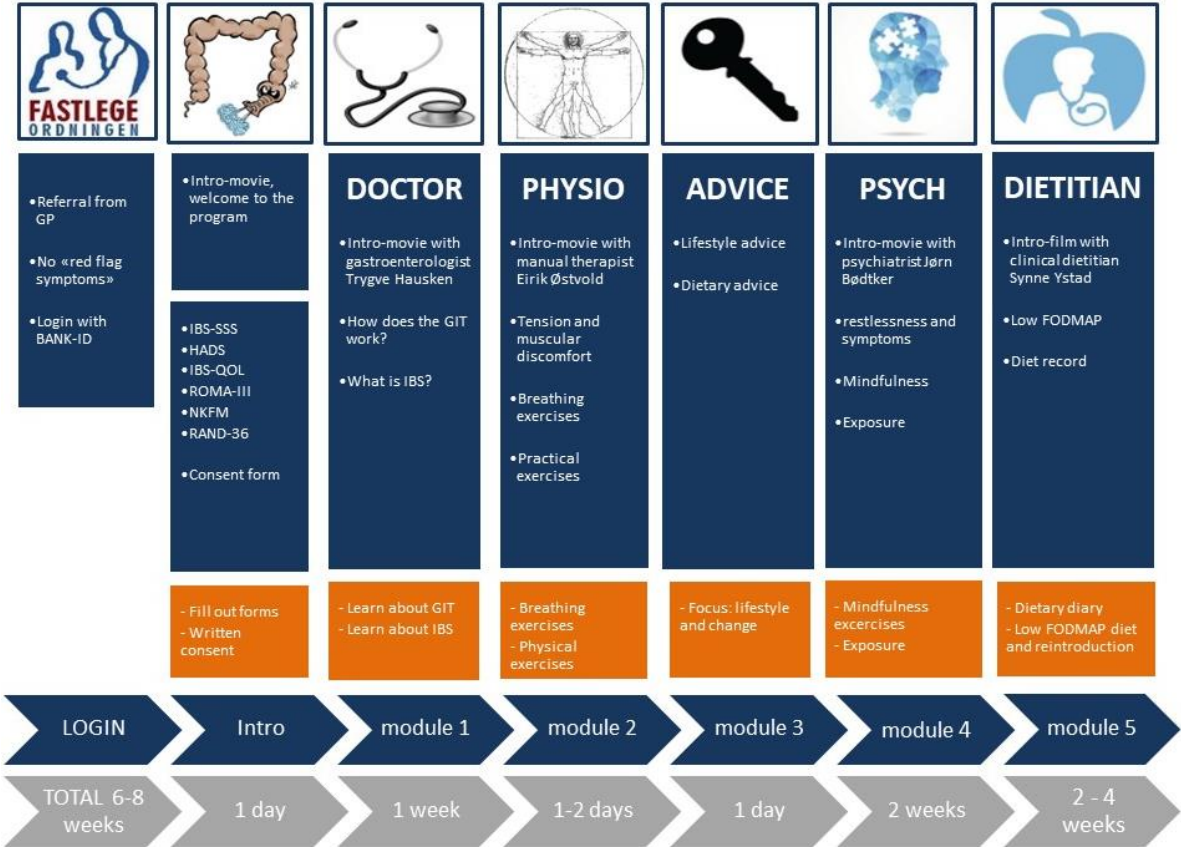
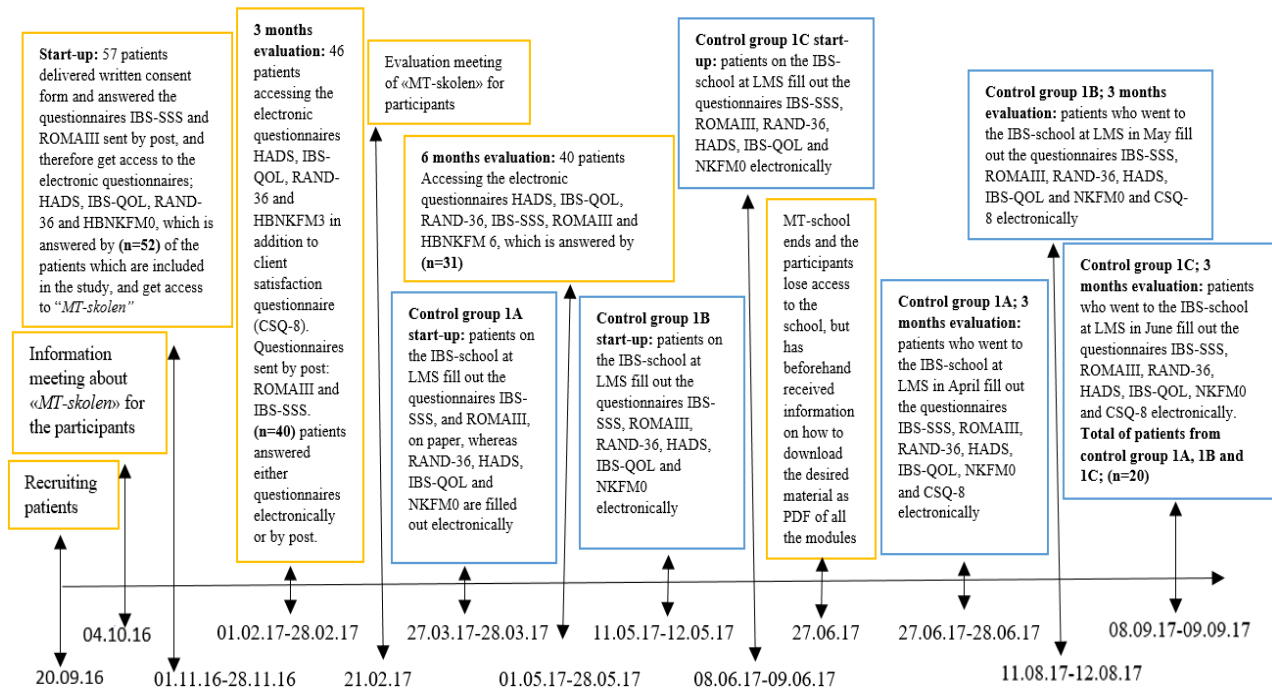


Figure 5: The IBS eHealth program content and timeline.

## 2.5 Study design and implementation



**Figure 6:** Overview of the timeline for the course of the study. The yellow boxes represent the study group participating in the eHealth program, the blue boxes represent control group 1 participating in the IBS-school at LMS.

### 2.5.1 Study group

**Prior to the intervention:** The patients who had been referred to the IBS-school at LMS from their GP or specialist in gastroenterology, were given a phone call, to be offered to participate in this pilot study. Those who wanted to attend to the eHealth program, were invited to an information meeting about the internet-based school. The project leader, as well as those who had contributed to the academic content, such as clinical dietitians, gastroenterologist, psychiatrist and the master student in clinical nutrition, also came and presented the content of the module they had been professionally responsible for. The participants were also informed about ethical considerations, and the patients who wanted to participate filled out the content form to be included in the study (appendix 5). The patients who didn't have the opportunity to come to the information meeting, got the necessary information equivalent to the meeting, in the post, including the information and content form they could fill out and send back in the post (appendix 6 contains the additional write with information about the content of the eHealth program).

Due to the license delay of the IBS-SSS and Rome III criteria questionnaires, these could not be electronically developed in Checkware's platform and were sent by the post, while the four other questionnaires RAND-36, HADS, HBNKFM and IBS-QOL were developed and completed by the participants electronically. This was the case both at startup and at 3 month's evaluation, while within 6 month's of evaluation, all questionnaires were developed electronically, which is shown in Table 3. When the participants had signed written consent, and completed both the baseline questionnaires sent by post and electronically, they got access to the IBS eHealth program (*MT-skolen*).

**eHealth program:** The duration of the eHealth program was individual for each participant, but the assumed time use was in advance about 6-8 weeks. The study in total lasted for 6 months. The study participants had the opportunity to ask, clinical dietitian Mari F. Oppegård and the student in clinical nutrition, questions related to the program during the whole intervention, especially nutrition-related questions.

**After the intervention:** To evaluate the effect of the eHealth program, the participants completed medical questionnaires before start-up, and 3- and 6 months after the start of the internet-based school. These questionnaires were based on their quality of life and symptoms associated with IBS. The differences in the measurements before and after the eHealth program were evaluated, to see whether the program had a significant effect on participants or not. After the intervention, all the patients who had participated in the eHealth program, were invited to an evaluation meeting. Here they had the opportunity to provide feedback regarding the program, as well as meeting the same professions as from the information meeting, and having the possibility to ask any professional questions regarding things that were unclear in the content.

**Table 3:** Overview of the timetable for the various medical questionnaires in the study group.

<b>Baseline questionnaires</b>	<b>3 months' questionnaires</b>	<b>6 months' questionnaires</b>
<u>By post:</u>	<u>By post:</u>	<u>By post:</u>
IBS-SSS Rome III criteria	IBS-SSS Rome III criteria	
<u>Electronically:</u>	<u>Electronically:</u>	<u>Electronically:</u>
HADS IBS-QOL RAND-36 HBNKFM 0	HADS IBS-QOL RAND-36 HBNKFM 3 CSQ-8	IBS-SSS Rome III criteria HADS IBS-QOL RAND-36 HBNKFM 6

### 2.5.2: Control groups

#### Control group 1:

In addition to evaluate the effect of the eHealth program in itself, we wanted to compare it to the effect of the current program for the IBS-patients, the two-day physical IBS-school at “LMS”. Three regular schools, each in April, May and June 2017 were used as control group 1, which got the same questionnaires as used in the eHealth program. The patients were offered to be a part of the control group when they physically attended to the IBS-school at LMS. If they wanted this, they got information about the study, and ethical considerations and finally filled out consent form and got registered for the study. The IBS-school in April got two of the baseline questionnaires by hand, due to license delay, but received the 3-month’s evaluation electronically. Both the schools in April and June, got all the questionnaires electronically, as shown in Table 4. The effect of the physical IBS-school at LMS, when looking at the differences in the measurements between the baseline and 3-month’s evaluation, where compared with the same differences between baseline and 3-month’s evaluation in the eHealth program.

#### Control group 2:

Unfortunately, there wasn’t enough time to get the 6 months’ evaluations from the IBS-school in April, May and June 2017 in this master thesis, therefore control group two is based on earlier data. The participants in control group 2 completed questionnaires when they attended a two-day extended IBS-school at LMS in October 2015, and got the same questionnaires in the post 6 months after the school. These participants obviously didn’t complete all the questionnaires as in the eHealth program, but only NKFM, Rome III criteria and IBS-SSS, as shown in Table 5. The effect of the extended IBS-school at LMS, when looking at the differences in the measurements between the baseline and 6-month’s evaluation, where compared with the same differences between baseline and 6-month’s evaluation in the eHealth program.

**Table 4:** Overview of the timetable for the various questionnaires in control group 1.

	<b>Baseline questionnaires</b>	<b>3 months' questionnaires</b>
<b>IBS-school at LMS in April 2017:</b>	<u>By hand:</u>	<u>By post:</u>
	IBS-SSS Rome III criteria	
	<u>Electronically:</u>	<u>Electronically:</u>
	HADS IBS-QOL RAND-36 HBNKFM 0	IBS-SSS Rome III criteria HADS IBS-QOL RAND-36 HBNKFM 3 CSQ-8
<b>IBS-school at LMS in May 2017:</b>	<u>Electronically:</u>	<u>Electronically:</u>
	IBS-SSS Rome III criteria HADS IBS-QOL RAND-36 HBNKFM 0	IBS-SSS Rome III criteria HADS IBS-QOL RAND-36 HBNKFM 3 CSQ-8
<b>IBS-school at LMS in June 2017:</b>	<u>Electronically:</u>	<u>Electronically:</u>
	IBS-SSS Rome III criteria HADS IBS-QOL RAND-36 HBNKFM 0	IBS-SSS Rome III criteria HADS IBS-QOL RAND-36 HBNKFM 3 CSQ-8

**Table 5:** Overview of the timetable for the various questionnaires in control group 2.

	<b>Baseline questionnaires</b>	<b>6 months' questionnaires</b>
	<u>By hand:</u>	<u>By post:</u>
<b>Extended IBS-school at LMS in October 2015:</b>	NKFM Rome III criteria IBS-SSS	NKFM6 Rome III criteria IBS-SSS

## 2.6 Questionnaires used

The standardized questionnaires used in this study were selected questions from Rome III Diagnostic Criteria for Functional Gastrointestinal Disorders (Rome III-criteria), Irritable Bowel Syndrome-Quality of Life questionnaire (IBS-QOL), Irritable Bowel Syndrome Severity score system (IBS-SSS), Hospital Anxiety and Depression Scale (HADS) and The

RAND-36 Measure of Health- Related Quality of Life (RAND-36). The questionnaires were sent to the participants and were asked to be filled out, before the start of the eHealth program, as well as 3 and 6 months after the start-up.

National Centre of Competence in Functional Gastrointestinal Disorders (NKFM) forms were used in three different versions relative to the time of the study; HBNKFM0, HBNKFM3 and HBNKFM6. Client satisfaction questionnaire (CSQ-8) was added to the 3 months evaluation. Due to approved license to use, the questionnaires *IBS-QOL*, *HADS*, *RAND-36* and *NKFM* were completed by patients electronically, while *Rome III* and *IBS-SSS* were sent to the patients by mail, at baseline and after 3 months. At 6 months, all data collection was carried out electronically. All the data are subjective, which leads to the questionnaires giving raw data that are based on patient-reported outcome (PRO).

#### 2.6.1 Rome III criteria (appendix 7)

The Rome III Diagnostic Criteria for Functional Gastrointestinal Disorders were developed in 2006 by the Rome foundation, with the aim of having a classification system of the disorders that could be used both in research and clinical care (1). The process with the Rome III criteria extends over a 15-year long period, from the beginning with Roma I to Roma II and now the latest modifications and updates in Roma III (1).

Rome III consists of, criteria for diagnosing *Functional Gastroduodenal Disorders* (e.g. functional dyspepsia) and *Functional Bowel Disorders* (e.g. IBS) (1, 7, 60). In the study, 34 questions from these Criteria were selected to confirm which of the patients had IBS and what subgroup they possibly belonged to, according to Rome III, after being given the IBS diagnosis by their GP/gastroenterologist. The Rome III criteria would also confirm who had either IBS-like symptoms and/or symptoms related to functional dyspepsia and if they belonged to the subgroup postprandial distress syndrome. (1, 7, 60).

### 2.6.2 Irritable Bowel Syndrome – Quality of Life Measure (IBS-QOL appendix 8)

IBS-QOL is a health-related quality of life (HR-QOL) questionnaire, compiled to measure how and in what grade IBS and the treatment of its symptoms affects these patients' quality of life (61-63). IBS-QOL has been confirmed to be a validated questionnaire with high consistency and high reproducibility (61-63). The questionnaire comprises of 34 questions, all with the same response scale 1-5; "1. Not at all, 2. Slightly, 3. Moderately 4. Quite a bit 5. Extremely/A great deal" (63). The scoring system is calculated as demonstrated in fig 7 below. IBS-QOL consists of eight subscale scores; dysphoria (8 questions), Interference with Activity(7 questions), Body Image (4 questions), Health Worry (3 questions), Food Avoidance (3 questions), Social Reaction (4 questions), Sexual (2 questions), and Relationships (3 questions)" (63). The transformation of the score gives a possible range score between 0-100, where 0 indicates poor quality of life, whereas 100 indicates maximum quality of life (63).

$$\text{Score} = \frac{\text{The sum of the items} - \text{lowest possible score}}{\text{Possible raw score range}} * 100$$

**Figure 7:** The transformation formula used to calculate the total and the eight subscale scores for IBS-QOL. Patrick et al. A Quality-of-Life Measure for Persons with Irritable Bowel Syndrome (IBS-QOL): User's Manual and Scoring Diskette for United States Version. *University of Washington, 2007* (63).

### 2.6.3 IBS-SSS (appendix 9)

IBS-SSS is a validated and standardized questionnaire used to assess the severity of the patient's IBS-symptoms (24). The form consists of five questions concerning severity of abdominal pain, frequency of abdominal pain, severity of distension, satisfaction with bowel habits and the symptoms' interference on the patient's life in its entirety. Each of the questions can give a value from 0 to 100, by utilizing a 100-point visual analogue scale (VAS), which can give a possible total score between 0-500 (24).

The severity of the symptoms is categorized, based on the total score, into mild (75-175), moderate (175-300) and severe (>300), while a score less than 75 considers the patient as in remission(24). A reduction in the score by at least 50, indicates a significant clinical improvement of the patient's IBS-like symptoms (24).

#### 2.6.4 HADS – Hospital Anxiety and Depression scale (appendix 10)

HADS is a validated questionnaire that was developed in 1983 by Sigmund and Snaith, with the aim of identifying if patients in non-psychiatric hospital clinics, suffered from anxiety disorders and/or depression (64, 65). The questionnaire is a cost-effective screening tool and is used largely both for research and in clinical practice, and despite the questionnaire's "tittle" it's also been validated when it has been implemented in community settings and primary care medical practice (64, 66, 67). The questionnaire consists of a total of 14 items, of which 7 of them constitute the subscale depression, and the remaining 7 constitute the subscale anxiety (68). Each question can give a value from 0 to 3, which can give a possible total score between 0-21 for both depression and anxiety, separately (67). The severity of the patient's mood state is categorized, based on the total score of each of the two subscales into normal /non-case (0-7), mild (8-10), moderate (11-14) and severe (15-21) range (67, 68). The cutoff score for HADS total is a score of 16 or above (65, 69).

#### 2.6.5 The RAND-36 Measure of Health-Related Quality of Life (HRQoL) (RAND-36) (appendix 11)

RAND-36 is possibly the most widely used questionnaire applied to assess a person's quality of life, based on their health (70). This means how the health effects a person's mental, physical and social life, and also how it influences his/her functioning in everyday life (70). RAND-36 consists of 36 questions which are identical to SF-36 which was customized based on the medical Outcomes Study (MOS) (1, 70). The Knowledge Center for Health Services at the Institute of Public Health translated RAND-36 into Norwegian which is used in this thesis (71).

The 36 questions are divided into eight categories; “physical functioning (10 questions), role limitations due to physical health (4 questions), role limitations due to emotional problems (3 questions), energy/fatigue (4 questions), emotional well-being (5 questions), social functioning (2 questions), pain (2 questions) and general health (5 questions)”(1, 70). In addition, there is one single question which constitutes the category “health change”. The possible range score is between 0-100, whereas the higher score, indicates a better health (1, 70).



### 2.6.6 National Centre of Competence in Functional Gastrointestinal Disorders (NKFM) (appendix 12-16)

The questionnaires NKFM0 (appendix 12) and NKFM6 (appendix 13) was made by National Centre of Competence in Functional Gastrointestinal Disorders with the purpose of being used as evaluation forms for the IBS-school at LMS. The forms also allowed gathering of self-reported medical history and general medical information such as age and sex. NKFM0 was filled out by the patients when they attended the IBS-school, and NKFM6 was sent in the post and filled out by the patients 6 months later. In cooperation with clinical dietitian Mari Folden Oppegård, the researcher developed three other versions of the original form, HBNKFM0 (appendix 14), HBNKFM3 (appendix 15) and HBNKFM6 (appendix 16), used at the start, and 3- and 6 months after the start-up in the eHealth program, respectively.

NKFM0 consists of 14 questions which give a broad view about the patient's background and disease history. NKFM6 consists of 7 questions, whereas 2 of the items are about the patient's background, 2 items contain questions about the low FODMAP diet, and 3 questions concerns the patient's assessment and experience of the IBS school.

HBNKFM0 consists of 18 questions, in addition to 2 sub questions, where the first 16 items are identical to the questions from the original NKFM0. The next 2 questions and 2 sub questions about their experience of the low FODMAP diet are modified to ease the comparison to 3- and 6 months. HBNKFM3 contains 22 questions, in addition to 5 sub questions. The first 16 items consisting of the patients' background and history are identical to the original form, whereas the next question and 5 sub questions about the low FODMAP diet, are formatted related to the time in the study. This questionnaire also includes 5 questions related to the participant's degree of satisfaction with the different modules. The different response options were "not at all", "slightly", "moderately", "quite a bit" and "a great deal". HBNKFM6 contains 12 items, where the questions about the patients' history of illness are cut down to 1 item, whereas the 1 question and the 5 sub questions about the low FODMAP diet, are reformatted related to the time in the study. The 5 remaining questions are about the participant's degree of satisfaction with the different modules, as mentioned in HBNKFM3.

### 2.6.7 CSQ-8 Client Satisfaction Questionnaire (appendix 17)

The validated Client Satisfaction Questionnaire (CSQ-8), was originally developed in 1979 by Larsen, Attkisson, Hargreaves and Nguyen (72, 73). The questionnaire consists of 8 items in addition to 2 open-ended questions, which we utilized with the purpose of it being a useful measure of the patient's satisfaction and experience of the service, as well as getting their feedback on the eHealth program (73). Each question can give a value from 1-4, where "1" reflects the lowest level of satisfaction, and "4" reflects the highest, which can give a total score between 8-32 (72, 73).

## **2.7 Hypothesis**

The intermediate aim 1 of the study was to evaluate whether the eHealth program is effective as a healthcare measure, by comparing quality of life and IBS-related symptoms, before and after the eHealth program. Intermediate aim 2 of the study was to assess the effect of the current program, the physical IBS school at LMS, by comparing differences in quality of life and/or IBS-related symptoms, before and after the school. Finally, the effect of the eHealth program was compared to the effect of the physical IBS school on LMS.

Null hypothesis  $H_{01}$ : The study participants will not experience any differences in quality of life and IBS-related symptoms after participating in the eHealth program.

Alternative hypothesis  $H_{a1}$  (two-sided) The participants will experience differences in quality of life and/or IBS-related symptoms after participating in the eHealth program.

Null hypothesis  $H_{02}$ : The study participants will not experience any differences in quality of life and IBS-related symptoms after participating in the physical IBS-school at LMS.

Alternative hypothesis  $H_{a2}$  (two-sided) The participants will experience a difference in quality of life and/or IBS-related symptoms after participating in the physical IBS-school at LMS.

## **2.8 Economics**

There was no extra cost associated with participating in this study. Attendance at information- and evaluation meeting was not a requirement to participate in the study, and travel fees were covered for those who came from the area outside of Bergen. Parking fees at Haukeland University Hospital were covered for all the participants.

## **2.9 Ethical considerations**

The study was approved of the Regional Committee for Medical and Health Research Ethics (REC), REK vest, in September 2016. All the participants gave informed, written consent. The participation was voluntary, which meant that the participants could withdraw at any time during the study, without any justification. The study was considered as harmless for the participants, and all data was collected unidentifiable and was treated confidentially. A research server / security group was created, where sensitive data was stored, and only people associated with the research project had access to this security group. It was also created a separate area for storing the link key between the person and the ID number, which only the project manager had access to.

In order to get a secure electronic identification when participants log in to the IBS eHealth program, the login method was chosen to correspond to security level 4, which is the highest level of security (74, 75). This means that the participants can login with either of the following login methods; Bank identification on a memory stick or mobile, Buypass on a smart card or mobile, or Commfides.

## **2.10 Statistical analysis**

The raw data from the questionnaires sent and returned by post (IBS-SSS and Rome III criteria) were plotted in the program "FileMaker Pro Database 15", and then the records were exported to Microsoft Excel. The raw data from the electronic questionnaires (RAND-36, HBNKFM -0,3,6, CSQ-8, HADS, IBS-QOL and at the 6 months evaluation also IBS-SSS and Rome III criteria) were directly exported to SPSS files. Statistical analysis of all data was performed by using the statistical program SPSS statistic version 24.0.

Descriptive statistics were conducted on different variables in the questionnaires to identify e.g. frequencies, means, standard deviation and normal distribution. All the data were checked for the latter, by using the normality tests Kolmogorov-Smirnov and Shapiro Wilk test in SPSS.

On parametric distributed data, paired t-test, unpaired t-tests and repeated measures one-way ANOVA were run. In the analysis of data from the eHealth program, paired t-tests like paired-Samples t-test and repeated measures one-way ANOVA were used, as the data was measurements from different time points, but from the same patients. In the analysis of the data from control group 2; the extended IBS-school at LMS, unpaired t-test like summary independent-samples T-test were used. This because the data consisted of measurements from different time points on unequal groups. Nonparametric data from the eHealth program were analyzed by Wilcoxon matched-pairs signed rank test, because as mentioned, the data was from measurement of equal groups.

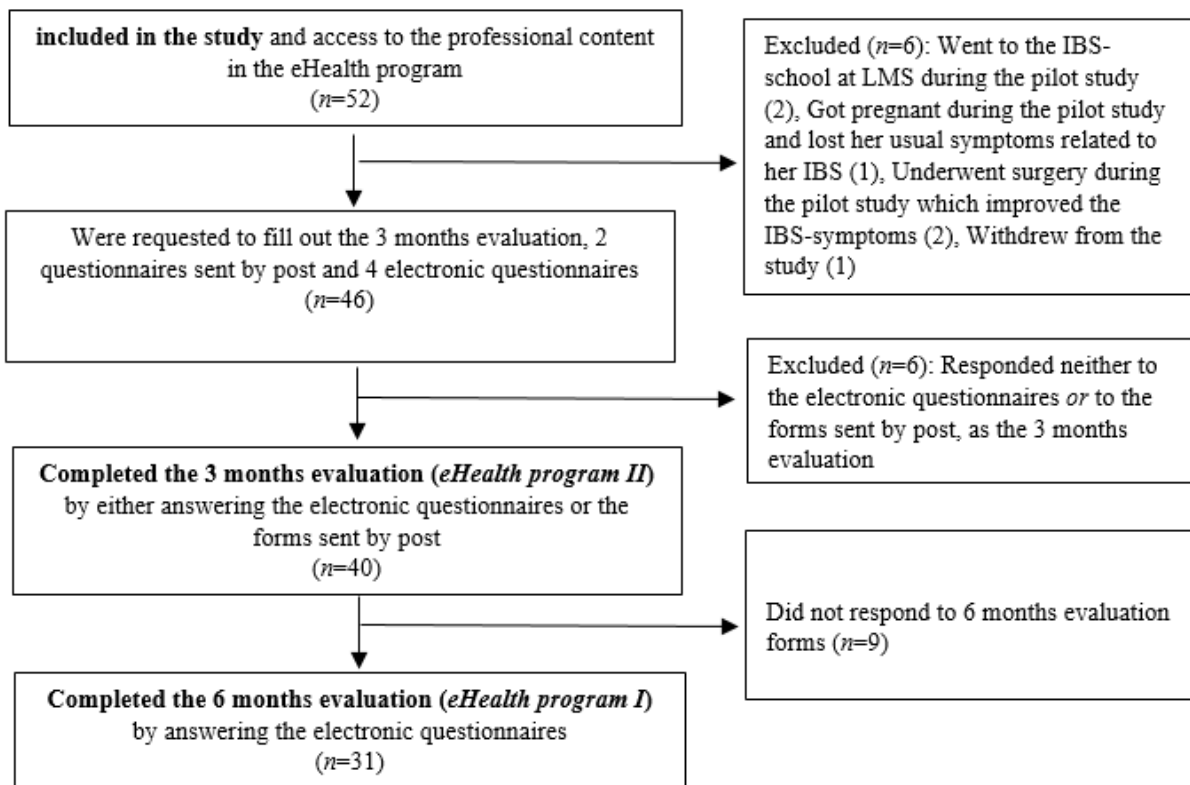
These tests were used to compare the mean of the measurements at the three different time points, baseline and after 3- and 6 months, to investigate if there was a statistically significant difference between them. The tests were not supplemented with a multiple comparisons test, but the actual p-values were reported. This requires a more critical view on the p-values that are just below 0.05. Correlation analysis between IBS-SSS sum score and IBS-QOL overall score were performed at baseline and after 3- and 6 months, using Pearson correlation test. P-values <0.05 were regarded statistically significant. All the reported P-values are based on two-sided tests. The normally distributed data are illustrated in simple bars with data reported as mean (SD). All values given as the latter are mean  $\pm$  1 standard deviation. Where the data is not normally distributed and a nonparametric test is performed, the data are illustrated in box plots with data reported as median (IQR) and minimum and maximum value.

### **3. RESULTS**

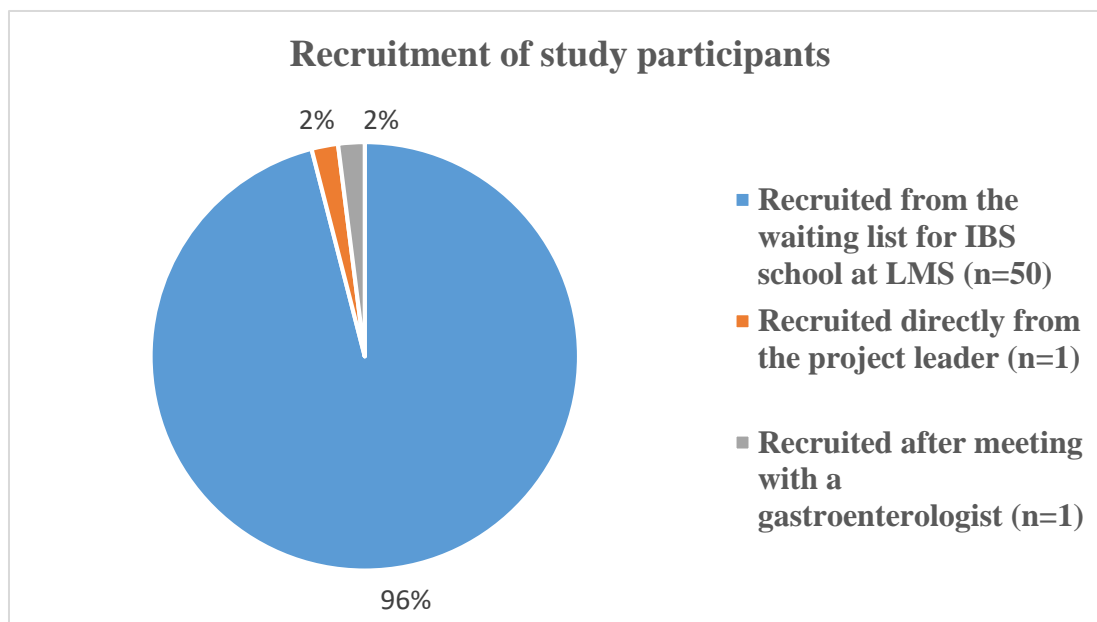
#### **3.1 Patient recruitment, responses and demographics**

63 patients agreed to attend the study, whereas 57 submitted written consent form and returned the completed questionnaires sent by post. These patients got access to the internet-based gastrointestinal school, and before start-up they were supposed to complete the four electronic questionnaires. Only 52 of the participants completed these questionnaires and were therefore included in the study, which is shown in Figure 8, and the rest of the patients were excluded. Six of these participants were excluded during the course of the study. One because of pregnancy, two got operated, two attended the IBS-school at LMS during the study, and one of the patients withdrew from the pilot study. 46 of the attendants were asked to fill out the questionnaires at the 3 months evaluation, whereas 40 of the participants completed either the electronic questionnaires *or* the questionnaires sent by post. 31 of the patients completed the questionnaires in the 6 months evaluation.

Because of a high drop-out rate during the program, analyze (I) is based on the 31 participants who completed the 6 months evaluation, which is called eHealth program (I). Analyze (II) is based on the 40 patients who completed the 3 months evaluation, which is called eHealth program (II). *n* varies slightly from questionnaire to questionnaire. Figure 9 shows that most of the included participants were recruited by phone, among those who already had been referred to the physical IBS-school at “LMS” in Bergen.



**Figure 8:** A flow chart over the recruitment and the patient responses by May 28, 2017. 40 patients completed the eHealth program and completed the 3 months' evaluation, whereas 26 of the patients completed the 6 months' evaluation.



**Figure 9:** Distribution of how the patients were recruited, among those who were included in the study (n=52).

### 3.2 Results from the participants who completed and responded the 6 months evaluation; eHealth program (I)

The first analyze (I) of the eHealth program, have assessed the mean and individual responses of the 31 study participants who completed the entire eHealth program and responded to the 6 months evaluation. Some of the participants have not completed all of the questionnaires, so *n* will vary from form to form.

#### 3.2.1 Study population and baseline characteristics

Baseline characteristics of the 31 that completed the 6 months evaluation (eHealth program (I)), are compared to the 52 patients included in the study, in Table 6.

**Table 6:** Baseline demographic of the 52 patients included in the study, compared to the 31 that completed the eHealth program and 6 months evaluation (I).

<b>PARTICIPANTS</b>	<b>Total included in the study (n=52)</b>	<b>eHealth program (I) (n=31)</b>	<b>eHealth program (I) (n=26 missing data; 5)</b>	<b>Mean difference (Std. Error difference) p-value</b>
Female/male	36/16	23/8	19/7	
Mean age (range), years	37.6 (15-66)	38 (20-56)	36.9 (20-56)	
<b>Severity of symptoms</b>				
IBS-SSS sum score, mean (SD)	296.8 (88.1)	-	282.5 (82.5)	-14.4 (20.7)
Median	290.0	-	250.5	1: p=0.490
Range	145-500	-	160-500	
<b>IBS severity</b>				
Mild	n = 5 (10%)	-	n = 2 (8%)	
Moderate	n = 23 (44%)	-	n = 13 (50%)	
Severe	n = 24 (46%)	-	n = 11 (42%)	
<b>IBS-QOL overall score</b>			(n=30 missing data; 1)	
mean (SD)	45.8 (18.2)	-	50.0 (19.5)	-4.2 (4.3)
Range	8.8-90.4	-	8.8-90.4	1: p=0.333
<b>ROME III criteria</b>				
<b>IBS-diagnosis</b>				
(yes/no/insufficient information)	29 (55.8%)/ 2 (3.8%)/ 21 (40.4%)	21 (67.7%)/ 0 (0%)/ 10 (32.3%)	- - -	
<i>n</i> (%)				

1 = Total included in the study vs eHealth program (I)

P-value is based on summary independent-Samples T test with mean difference (SD)

### 3.2.1.1 Gender and age

Among the 52 included participants in the study, 36 were female (69%). Of the 31 patients who completed the 6 months evaluation and are hence a part of the eHealth program (I), 23 were female (74%). The mean age among the 52 included was 37.6 years (range, 15-66 y), and among the 31 in the eHealth program (I) it was 38.0 (20-56).

### 3.2.1.2 IBS severity

Table 6 shows baseline mean IBS-SSS sum score for the 52 study participants included in the study, as well as for those who completed the 6 months evaluation; eHealth program (I). Because of missing data on this questionnaire, eHealth program (I) contains only 26 (*n*) participants. The score for the 52 included in the study was 296.8 (range, 145-500), while it was 282.5 (range, 160-500) for eHealth program (I), but the difference wasn't statistically significant ( $p=0.490$ ). The distribution of the IBS severity was for the 52; mild=5 (10%), moderate=23 (44%), severe=24 (46%), and for the eHealth program (I); mild=2 (8%), moderate=13 (50%) and severe=11 (42%).

### 3.2.1.3 IBS-QOL

The baseline mean IBS-QOL overall scores for the 52 study participants included in the study, and for those who completed the eHealth program (I) were 45.8 and 50.0, respectively (Table 6). The difference was not statistically significant ( $p=0.333$ ). Due to missing data on this questionnaire, eHealth program (I) contains of 30 (*n*) participants, instead of 31.

### 3.2.1.4 ROME III criteria

Based on the ROME III criteria 29 (55.8%) of the 52 participants included in the study, would get the IBS-diagnosis at baseline, and 2 (3.8%) wouldn't (Table 6). It also shows that there was insufficient information on 21 (40.4%) of the study participants, due to misinterpretations of the questionnaire. For the 31 participants who completed the 6 months evaluation (eHealth program (I)), 21 (67.7%), 0 (0%) and 10 (32.3%), would get, not get and had insufficient information to get an IBS-diagnosis at baseline, based on the ROME III criteria.



### 3.2.2 The control groups and their baseline characteristics

In control group 1, there were 20 patients that were recruited from the IBS-school which fulfilled the baseline *and* the 3 months questionnaires. In control group 2, 71 patients were recruited from the IBS school and filled out the baseline questionnaires, but only 32 of them filled out the 6 months questionnaires.

**Table 7:** Baseline demographic of the participants in control group 1 and 2.

<b>PARTICIPANTS</b>	<b>Control group 1 (n=20)</b>	<b>Control group 2 (n=71)</b>
<b>Female/male</b>	17/3	59/10 (missing data; 2)
<b>Mean age (range), years</b>	45 (33-68)	35.8 (15-67) (missing data;1)
<b>Severity of symptoms</b>		
IBS-SSS sum score, mean (SD)	286.8 (62.5)	298.0

#### 3.2.2.1 Gender, age and IBS severity

Of the 20 participants in control group 1, 17 (85%) of the were women (Table 7). The average age was 45 years (range, 33-68 y), and the IBS severity mean score at baseline was 286.8. Of the 71 patients included in control group 2 at baseline, 59 (86%) were women. The average age was 35.8 (range, 15-67), and the IBS severity mean score at baseline was 298.0.

### 3.2.3 Changes during the eHealth program (I); differences between baseline, 3- and 6 months

#### 3.2.3.1 IBS-QOL

We were interested in assessing whether the participants would experience an improved health-related quality of life (HRQOL), according to IBS-QOL, during the eHealth program, by comparing the scores at baseline and 3- and 6 months after the start of the school.

Table 8 shows a statistically significant enhancement between baseline and 3 months after the start-up, in IBS-QOL overall score ( $p=0.001$ ) and in the five subscale scores; food avoidance ( $p=0.004$ ), health worry ( $p=0.032$ ), interference with activity ( $p=0.004$ ), dysphoria ( $p=0.0002$ )

and social reaction ( $p=0.039$ ). When comparing the scores between baseline and 6 months after the start-up, it showed a statistically significant improvement in IBS-QOL overall score ( $p=0.00003$ ) and in seven out of eight subscale scores; body image ( $p=0.048$ ) food avoidance ( $p=0.045$ ), health worry ( $p=0.003$ ), interference with activity ( $p=0.0001$ ), dysphoria ( $p=0.000002$ ), relationships ( $p=0.009$ ) and social reaction ( $p=0.036$ ). The subscale score “sexual” showed a numerically higher score at 3 and 6 months when compared to baseline, but neither of these differences were statistically significant.

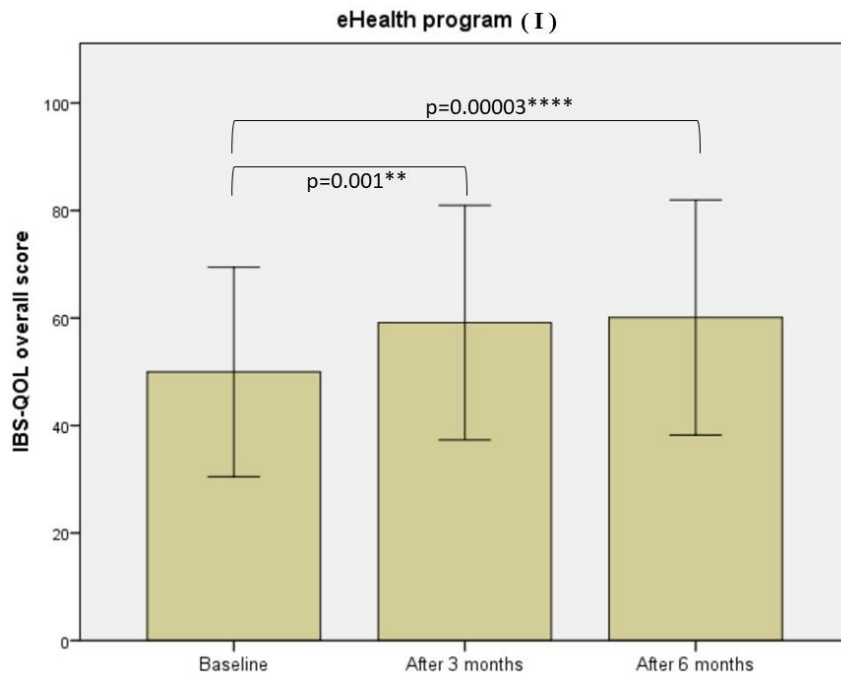
We also wanted to compare the scores differences between baseline and 3 months, baseline and 6 months, and also between 3 and 6 months to look at the whole development during the eHealth program. In this way, we could investigate whether the participants continued to benefit from the eHealth program after passing 3 months until reaching 6 months after the start-up. When looking at these three scores all together it showed that IBS-QOL overall score and five of the subscale scores (body image, health worry, interference with activity, dysphoria, relationship and sexual) had numerically higher scores at 3 months compared to baseline, and even higher numerical scores at 6 months compared to 3 months. But neither of these values were statistically significant, when comparing the scores between 3 and 6 months. Figure 10 and 11 illustrate mean (SD) or median (IQR) for IBS-QOL overall score and the eight subscale scores, for the participants who completed the 6 months evaluation (I), at baseline and 3- and 6 months after the start-up.

**Table 8:** IBS-QOL overall score (0-100) and the eight subscale scores (0-100) for the participants in the eHealth program (I), at baseline and 3- and 6 months after the start of the program. Values are reported as mean (SD) / median (IQR), as appropriate.

	<b>Baseline, mean (SD) / median (IQR) (n = 30)</b>	<b>After 3 months, mean (SD) / median (IQR) (n = 30)</b>	<b>After 6 months, mean (SD) / median (IQR) (n = 30)</b>	<b>p-values</b>
<b>Overall score IBS-QOL</b>	50.0 (19.5)	59.1 (21.8)	60.1 (21.9)	1: p=0.001** 2: p=0.00003**** 3: p=0.649
Body Image	43.8 (20)	50.2 (20.6)	50.3 (23.4)	1: p=0.054 2: p=0.048* 3: p=1.000
Food Avoidance	31.1 (24.4)	39.4 (25.5)	35.8 (25.5)	1: p=0.004** 2: p=0.045* 3: p=0.252
Health Worry	62.5 (33.3-75.0)	66.7 (41.7-83.3)	66.7 (47.9-85.4)	1: p=0.032* 2: p=0.003** 3: p=0.156
Interference with Activity	48.2 (22.1)	58.5 (26.2)	61.4 (24.7)	1: p=0.004** 2: p=0.0001*** 3: p=0.236
Dysphoria	50.2 (25.8)	63.5 (26.1)	64.9 (26.8)	1: p=0.0002*** 2: p=0.000002***** 3: p=0.619
Relationships	64.2 (25.2)	69.2 (29.9)	70.0 (26.0)	1: p=0.107 2: p=0.009* 3: p=0.795
Social Reaction	54.0 (20.9)	60.8 (21.5)	60.6 (22.0)	1: p=0.039* 2: p=0.036* 3: p=0.932
Sexual	68.8 (34.4-87.5)	75.0 (50.0-87.5)	75.0 (50.0-90.6)	1: p=0.064 2: p=0.113 3: p=0.672

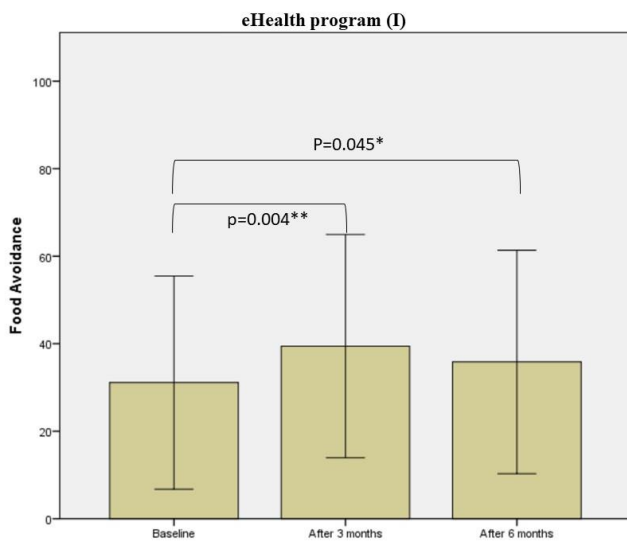
1 = Baseline vs after 3 months, 2 = Baseline vs after 6 months, 3= After 3 months vs after 6 months  
P-values are based on paired-Samples T test with mean (SD) (Overall, food avoidance, body image, interference with activity, dysphoria, relationships, social reaction) or Wilcoxon matched-pairs signed rank test with median (IQR) (health worry, sexual).

\* = p < 0.05, \*\* = p < 0.005, \*\*\* = p < 0.0005, \*\*\*\* = p < 0.00005, \*\*\*\*\* = p < 0.000005

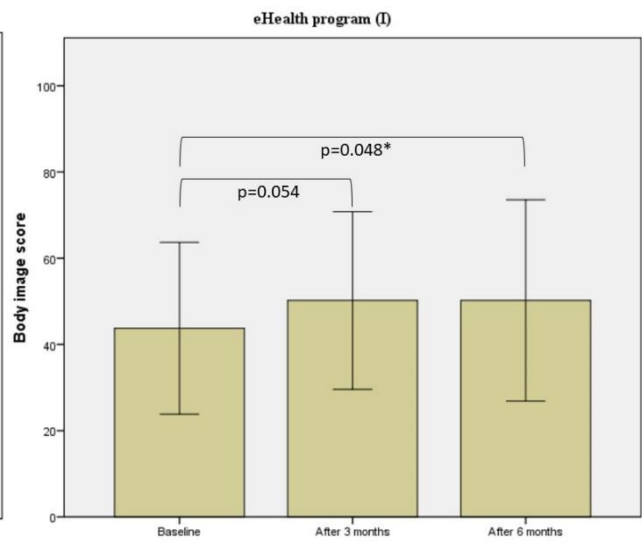


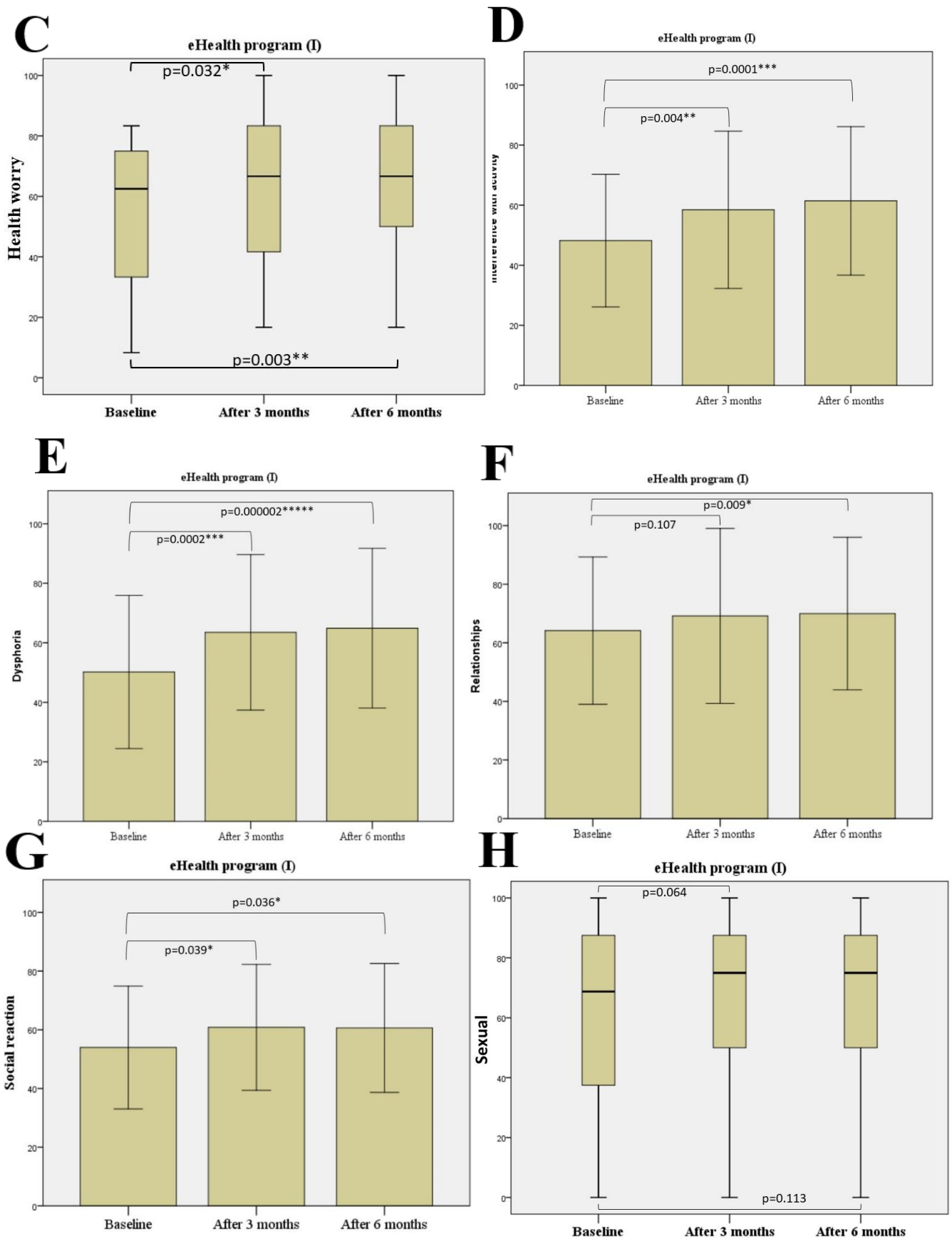
**Figure 10:** IBS-QOL overall score for the participants in the eHealth program(I), at baseline and 3- and 6 months after the start of the program. Values are reported as mean (SD).

**A**



**B**





**Figure 11:** The eight IBS-QOL subscale scores for the participants in the eHealth program(I); food avoidance (A), body image (B), Health Worry (C), Interference with Activity (D), Dysphoria (E), Relationships (F), Social Reaction (G) and Sexual (H), at baseline and 3- and 6 months after the start of the program. Values are reported as mean (SD) (in simple bars; A, B, D-G) or median (IQR) with minimum and maximum value (in box plots; C, H), as appropriate.

### 3.2.3.2 IBS-SSS

#### 3.2.3.2.1 Mean scores

Analysis of the symptom scores of the patients participating in the eHealth program (I) was performed, to investigate whether there was a significant difference between the symptom scores at the three time points; at baseline and 3- and 6 months after the start-up of the school.

Table 9 shows a statistically significant improvement from baseline to after 3 months, in IBS-SSS sum score ( $p=0.00004$ ) and in four out of five IBS symptoms; severity of abdominal pain ( $p=0.033$ ), frequency of abdominal pain ( $p=0.01$ ), dissatisfaction with bowel habits ( $p=0.012$ ) and interference with life in general ( $p=0.0002$ ). When comparing the scores between baseline and 6 months after the start-up, it showed a statistically significant enhancement in IBS-SSS sum score ( $p=0.001$ ), and in three out of five IBS symptoms; severity of abdominal pain ( $p=0.042$ ), dissatisfaction with bowel habits ( $p=0.016$ ) and interference with life in general ( $p=0.00046$ ).

Some of the scores decreased significant from baseline to 3 months and reduced numerically even more from 3 months to after 6 months (IBS-SSS sum score and Q5), but neither of these scores between 3- and 6 months were statistically significant ( $p=0.383$  and  $p=0.448$ ), respectively. One of the scores decreased significantly from baseline to after 3 months but then remained stable until 6 months after the baseline measurement, p-value (0.676) showed no statistically significant difference between the mean score after 3- and after 6 months. The rest of the scores decreased significant or numerically from baseline to 3 months, and increased from 3 months to 6 months to a significantly lower or numerically lower score than at baseline (Q1, Q2, Q3), but neither of these scores between 3- and 6 months were statistically significant ( $p=0.667$ ,  $p=0.083$  and  $p=0.658$ ), respectively.

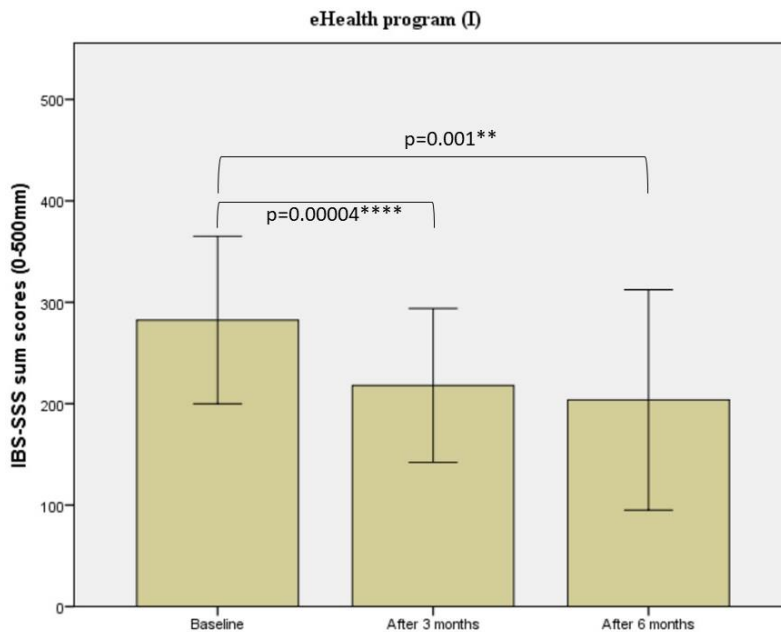
**Table 9:** IBS-SSS sum score (0-500) and the five subscale scores Q1-Q5 (0-100) for the participants in the eHealth program (I), at baseline and 3- and 6 months after the start of the program. Values are reported as mean (SD) / median (IQR).

Symptoms	Baseline, mean (SD) / median (IQR)	After 3 months, mean (SD) / median (IQR)	After 6 months, Mean (SD) /median (IQR)	p-values
<b>IBS-SSS sum score (n=26)</b>	282.5 (82.5)	218.0 (75.8)	203.7 (108.6)	1: p=0.00004**** 2: p=0.001** 3: p=0.383
<b>Q1: Severity of abdominal pain (n=16)</b>	48.1 (19.2)	36 (14.1)	37.9 (20.0)	1: p=0.033* 2: p=0.042* 3: p=0.667
<b>Q2: Frequency of abdominal pain (n=18)</b>	66.7 (27.2)	46.7 (26.3)	60.0 (28.7)	1: p=0.01* 2: p=0.460 3: p=0.083
<b>Q3: Severity of abdominal distension (n=21)</b>	40.0 (32.0-52.0)	37.0 (27.5-50.0)	38.0 (27.0-48.5)	1: p=0.204 2: p=0.287 3: p=0.658
<b>Q4: Dissatisfaction with bowel habits (n=25)</b>	70.0 (52.5-98.0)	59.0 (36.0-72.0)	59.0 (34.5-71.5)	1: p=0.012* 2: p=0.016* 3: p=0.676
<b>Q5: Interference with life in general (n=25)</b>	67.6 (18.9)	55.1 (22.2)	51.9 (25.2)	1: p=0.0002*** 2: p=0.00046*** 3: p=0.448

1=Baseline vs after 3 months, 2= Baseline vs after 6 months, 3= After 3 months vs after 6 months

P-values are based on Wilcoxon matched-pairs signed rank test with median (IQR) (severity of abdominal distension, dissatisfaction with bowel habits) or paired-Samples T test / repeated measures one-way ANOVA with mean (SD) (IBS-SSS sum score, severity of abdominal pain, frequency of abdominal pain, interference with life in general).

\* = p < 0.05, \*\* = p < 0.005, \*\*\* = p < 0.0005

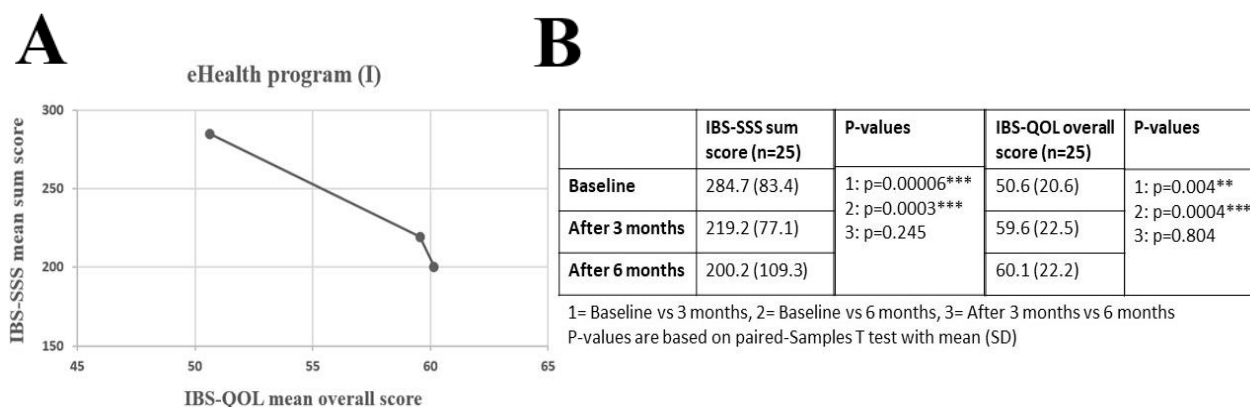


**Figure 12:** IBS-SSS sum score for the participants in the eHealth program (I), at baseline, and 3- and 6 months after the start of the program. Values are reported as mean (SD).

### 3.2.3.2.2 IBS-SSS vs IBS-QOL

Figure 13 illustrates the comparison of the development of IBS-SSS mean sum score from baseline to after 3- and 6 months, to the development of the mean IBS-QOL overall score, at the same points, in the eHealth program (I). Due to different number (*n*) of patients in the two questionnaires, and to compare the patients pairwise, the total number of patients is reduced to a total of 25 from the earlier analysis of the eHealth program (I). The scores are almost identical to those of the earlier analysis showed in Table 9 and 10, and the development was the same. The IBS-SSS sum score improved significantly from baseline to after 3 months ( $p=0.00006$ ) and significantly from baseline to after 6 months ( $p=0.0003$ ), with the greatest mean difference from baseline to 3 months. The same development was seen in IBS-QOL, with a significantly improvement from baseline to both after 3 months ( $p=0.004$ ) and after 6 months ( $p=0.0004$ ), with the greatest mean difference between baseline and 3 months.





**Figure 13:** Comparison of the development of the mean IBS-SSS sum score to the development of the mean IBS-QOL overall score, at baseline and after 3- and 6 months (A), along with the different values at the three time points with n=25 (B). Values are reported as mean (SD).

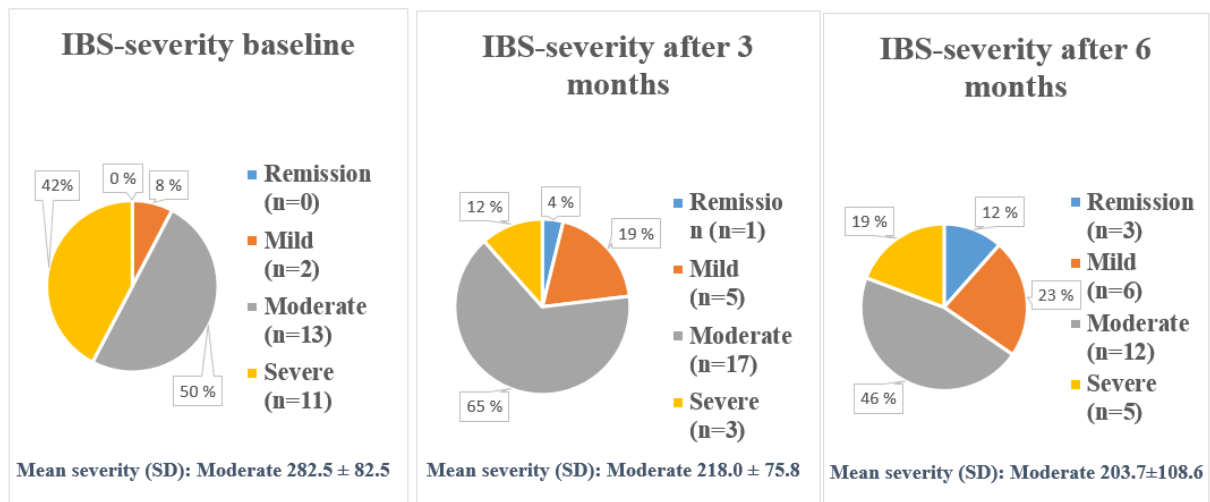
### 3.2.3.2.3 Individual responses

Figure 14 and Table 10 show the individual responses of the study participants who completed the 6 months evaluation in the eHealth program (I).

Figure 14 illustrates the distribution of IBS-severity at the three different time points; baseline and after 3- and 6 months. In the three categories, the proportion changed in mild from 2 (8%) to 5 (19%) and further to 6 (23%), at baseline and after 3 and 6-months respectively. The proportion change in moderate was from 13 (50%) to 17 (65%) and 12 (46%), and finally in severe the proportion change was from 11 (42%) to 3 (12%) and 5 (19%), respectively. The proportion of participants in remission changed from 0 at baseline to 1 (4%) after 3 months, and 3 (12%) after 6 months.

Table 10 shows how many of the participants who significantly improved their IBS symptoms, according to the IBS-SSS sum score, by reducing the score by at least 50. 11 (42.3%) out of 26 patients, significantly improved their symptom score from baseline to both after 3 and 6 months. 5 (19.2%) of the study participants did not significantly improve their symptom score from baseline to after 3 months, but did significantly improve from baseline to after 6 months. 4 (15.4%) of the participants significantly improved their score only from baseline to after 3 months, but did not contain this score stable enough that there was a significant improvement from baseline to after 6 months. Finally, there was 6 (23.1%) patients who neither significantly improved from baseline to after 3 nor 6 months after the start-up.

Of the latter group, there were oppositely, 3 of the participants who did not significantly worsen the symptom score from baseline to after 3 months, but did significantly worsen their symptom score from baseline to after 6 months.



**Figure 14:** IBS-severity at baseline versus 3- and 6 months after the start of the eHealth program

Total=26	Yes n (%)
Significant improvement (reduction by at least 50) from baseline to both after 3- and 6 months	11 (42.3%)
Significant improvement (reduction by at least 50) from baseline to after 6 months, but not a significant improvement from baseline to after 3 months	5 (19.2%)
Significant improvement (reduction by at least 50) from baseline to after 3 months, but not a significant improvement from baseline to after 6 months	4 (15.4%)
Neither a significant improvement (reduction by at least 50) from baseline to after 3 or 6 months	6 (23.1%)

**Table 10:** Individual significantly improvements in IBS-SSS sum score, of the 26 participants completed the eHealth program (I).

### 3.2.3.3 HADS

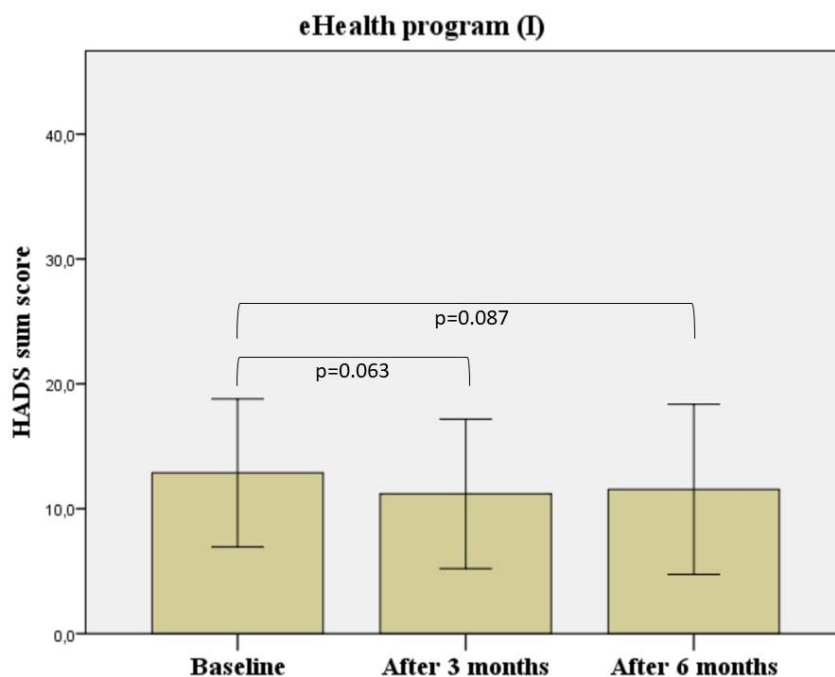
We were also interested in assessing whether the study participants would experience improved anxiety and depression, during the eHealth program, according to the HADS questionnaire. This was evaluated by comparing the mean score at baseline and 3- and 6 months after the start-up of the program (Table 11). Both means of the HADS sum score and the subscale scores of depression and anxiety, reduced numerically both from baseline to 3 and 6 months, with the lowest numerically score after 3 months for all the means, but neither of the differences were statistically significant.

**Table 11:** HADS sum score and the two subscale scores (0-21), for the participants in the eHealth program (I), at baseline and after 3- and 6 months. Values are reported as mean (SD).

	<b>Baseline, mean (SD) (n = 31)</b>	<b>After 3 months, mean (SD) (n = 31)</b>	<b>After 6 months, Mean (SD) (n = 31)</b>	<b>p-values</b>
<b>HADS sum score</b>	12.9 (5.9)	11.2 (6)	11.5 (6.8)	1: p=0.063 2: p=0.087 3: p=0.662
<b>Depression</b>	4.7 (3.2)	4.2 (2.9)	4.5 (3.1)	1: p=0.342 2: p=0.700 3: p=0.455
<b>Anxiety</b>	7.5 (4.0)	7.0 (3.9)	7.1 (4.4)	1: p=0.416 2: p=0.390 3: p=0.949

1=Baseline vs after 3 months, 2= Baseline vs after 6 months, 3= After 3 months vs after 6 months

P-values based on paired-Samples T test with mean (SD).



**Figure 15:** HADS sum score for the participants in the eHealth program (I), at baseline, and 3- and 6 months after the start of the program. Values are reported as mean (SD).

#### 3.2.3.4 RAND-36

The second questionnaire used to assess whether the patients would experience an improved health-related quality of life (HRQOL), during the eHealth program, was RAND-36. This was evaluated by comparing the scores at baseline and 3- and 6 months after the start-up of the program. Table 12 shows a numerically higher score at 3 months compared to baseline at the six categories; general health, pain, energy/fatigue, role limitation due to emotional problems, physical functioning and social functioning, but none of these differences were statistically significant. The seven categories; general health, pain, emotional well-being, health change, role limitation due to emotional problems, physical functioning and social functioning, had a numerically higher score after 6 months compared to baseline, but only “pain” was significantly different ( $p=0.008$ ). None of the scores between 3 and 6 months, were significantly different. The category energy/fatigue ended up with a numerically lower median score after 6 months, compared to baseline, but this was not statistically significant.

**Table 12:** The nine RAND-36 categories for the participants in the eHealth program (I), at baseline and after 3- and 6 months. Values are reported as mean (SD) / median (IQR), as appropriate.

	<b>Baseline, mean (SD) / median (IQR)</b>	<b>After 3 months, mean (SD) / median (IQR)</b>	<b>After 6 months, mean (SD) / median (IQR)</b>	<b>p-values</b>
General health	45.9 (22.0)	48.0 (20.0)	53.0 (23.5)	1: p=0.569 2: p=0.060 3: p=0.146
Pain	35.0 (22.5-55.0)	45.0 (22.5-57.5)	47.5 (35.0-67.5)	1: p=0.332 2: p=0.008* 3: p=0.065
Energy/fatigue	30.0 (15.0-40.0)	35.0 (15.0-60.0)	25.0 (10.0-60.0)	1: p=0.306 2: p=0.628 3: p=0.490
Emotional well-being	72.0 (60.0-80.0)	68.0 (60.0-84.0)	80.0 (60.0-88.0)	1: p=0.159 2: p=0.060 3: p=0.565
Health change	50.0 (50.0-75.0)	50.0 (25.0-75.0)	75.0 (50.0-75.0)	1: p=0.718 2: p=0.190 3: p=0.134
Role limitation due to emotional problems	66.7 (33.3-100.0)	100.0 (33.3-100.0)	100.0 (0.0-100.0)	1: p=0.227 2: p=0.585 3: p=0.139
Role limitation due to physical health	25.0 (0.0-50.0)	25.0 (0.0-75.0)	25.0 (0.0-75.0)	1: p=0.137 2: p=0.260 3: p=0.837
Physical functioning	80.0 (75.0-95.0)	90.0 (75.0-95.0)	90.0 (70.0-95.0)	1: p=0.310 2: p=0.199 3: p=0.516
Social functioning	56.5 (21.2)	60.6 (27.5)	61.1 (27.4)	1: p=0.344 2: p=0.412 3: p=0.915

1 = Baseline vs after 3 months, 2 = Baseline vs after 6 months, 3 = After 3 months vs after 6 months

P-values are based on paired-Samples T test or repeated measures one-way ANOVA with mean (SD) (social functioning, general health) or Wilcoxon matched-pairs signed rank test with median (SD) (pain, energy/fatigue, emotional well-being, health change, role limitation due to emotional problems, role limitation due to physical health, physical functioning).

### 3.2.3.5 HBNKFM0,3,6; Low FODMAP diet

Table 13, 14 and 15 show the various questions regarding the low FODMAP diet, at baseline, and after 3- and 6 months. At baseline, 21 (75%) of the participants had followed a low FODMAP diet earlier, and 14 (50%) were still following the diet (Table 13). 3 months after the start of the eHealth program, 21 (75%) answered that they had tried the FODMAP diet after guidance in the program, whereas 18 (86%) of these patients still followed the diet at that time point. 6 months after the start-up, 22 (79%) answered that they had tried the FODMAP diet after the guidance in the program, whereas 15 (68%) of these patients still followed the diet at that time point. Table 14 and 15 shows a greater spread in the degree of experienced symptom relief of the diet, compared to Table 13.

**Table 13:** Questions regarding the low FODMAP diet from HBNKFM0, at baseline.

<b>Baseline (n=28)</b>	
<b>Have you followed the low FODMAP diet earlier? Yes/no n (%)</b>	<b>21(75%) / 7(25%)</b>
<b>1) Do you follow the low FODMAP diet at the moment? Yes/no n (%)</b>	<b>14(50%) / 14(50%)</b>
1A) if yes, how long have you followed the diet? (mean, n=14)	16.3 months
1B) If yes, to what extent have you experienced a symptom relief of the diet? (mean, n=14)	Not at all (n=0) Slightly (n=3, 21.4%) Moderately (n=1, 7.1%) Quite a bit (n=6, 42.9%) A great deal (n=4, 28.6%)

**Table 14:** Questions regarding the low FODMAP diet from HBNKFM3, after 3 months.

After 3 months (n=28)	
<b>Have you followed the low FODMAP diet after you got guidance in the eHealth program? Yes/no (%)</b>	<b>21 (75%) / 7(25%)</b>
1A) if yes, have you reintroduced the FODMAP groups (mean, n=21)? Yes/no n (%)	13 (62%) / 8 (38%)
1B) Do you still follow a low FODMAP diet (mean, n=21)? Yes/no n (%)	18 (86%) / 3 (14%)
1C) To what extent have you experienced a symptom relief of the diet (mean, n=21)?	Not at all (n=1) 4.8% Slightly (n=3) 14.3% Moderately (n=4) 19.0% Quite a bit (n=7) 33.3% A great deal (n=6) 28.6%

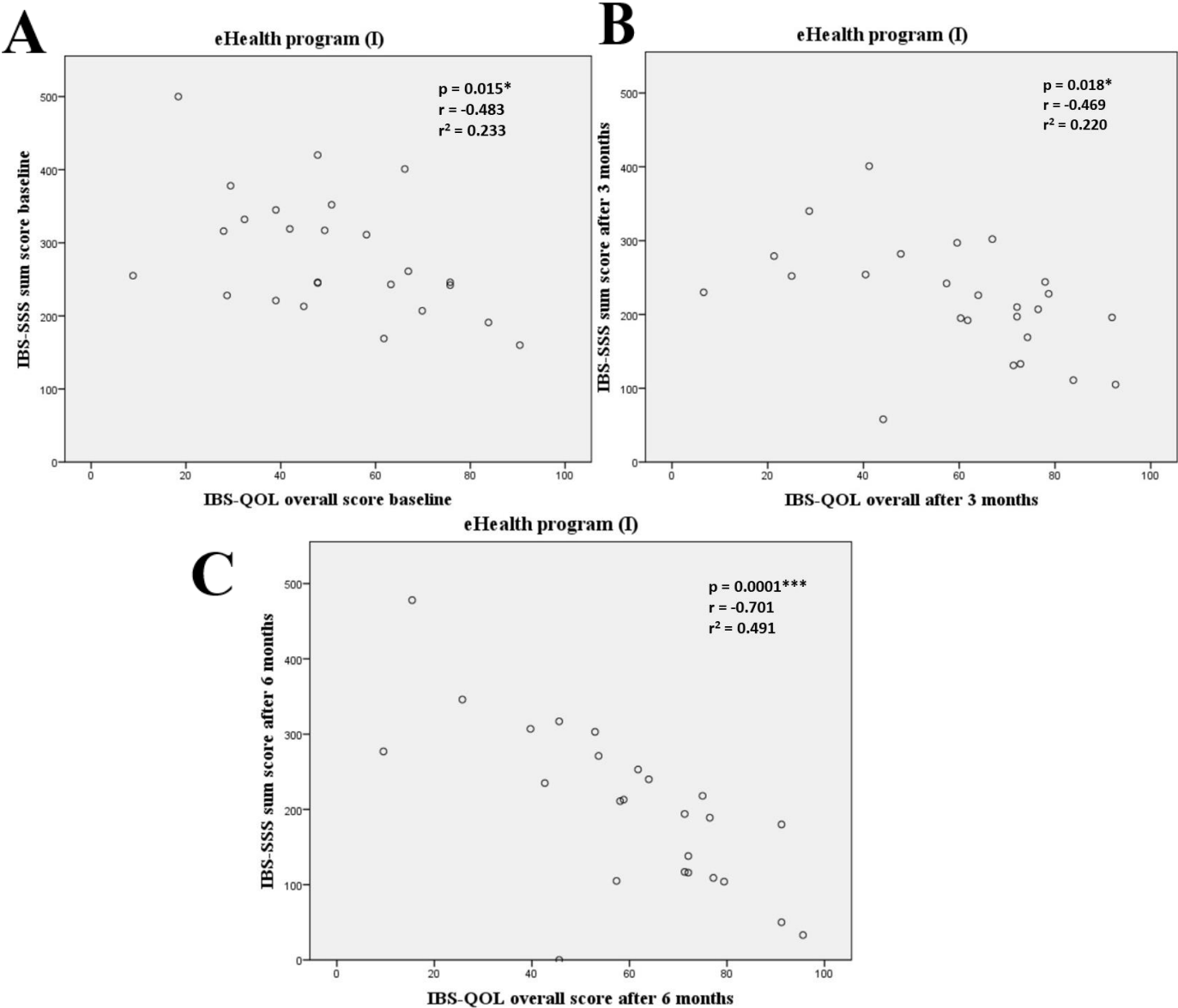
**Table 15:** Questions regarding the low FODMAP diet from HBNKFM6, after 6 months.

After 6 months (n=28)	
<b>Have you followed the low FODMAP diet after you got guidance in the eHealth program? Yes/no (%)</b>	<b>22 (79%) / 6 (21%)</b>
1A) if yes, have you reintroduced the FODMAP groups (mean, n=22)? Yes/no n (%)	16 (73%) / 6 (27%) 15 (68%) / 7 (32%)
1B) Do you still follow a low FODMAP diet (mean, n=22)? Yes/no n (%)	Not at all (n=2) 9.1%
1C) To what extent have you experienced a symptom relief of the diet (mean, n=22)?	Slightly (n=3) 13.6% Moderately (n=2) 9.1% Quite a bit (n=10) 45.5% A great deal (n=5) 22.7%

### 3.2.3.6 Correlation analysis

Correlation analysis were performed between IBS-SSS sum score and IBS-QOL overall score, at baseline, and 3- and 6 months after the start of the eHealth program (I). The number of patients was reduced to 25, due to some missing data, and to have equal sample, same as illustrated in Figure 13. All the analysis showed a statistically significant negative correlation.

The correlation analysis showed a statistically significant negative correlation between IBS-SSS sum score and IBS-QOL overall score, at baseline ( $r = -0.483$ ,  $r^2 = 0.233$ ,  $p = 0.015$ ), at 3 months after the start-up ( $r = -0.469$ ,  $r^2 = 0.220$ ,  $p = 0.018$ ), and after 6 months ( $r = -0.701$ ,  $r^2 = 0.491$ ,  $p = 0.0001$ ). It also showed that at baseline, at 3 months and at 6 months, the proportion of the variation in IBS-QOL explained by the variation in IBS-SSS sum score was 23.3%, 22.0% and 49.1%, respectively. This shows that a high severity of IBS-like symptoms is correlated with reduced quality of life, which suggests that an improvement in IBS-like symptoms will increase the quality of life. Figure 17 illustrates the correlations.



**Figure 17:** Pearson correlation showed a significant and negative correlation between IBS-SSS sum score and IBS-QOL overall score at baseline (A), after 3 months (B) and after 6 months (C).



### 3.2.4 Comparison of the results from the eHealth program (I) with control group 1

#### 3.2.4.1 IBS-QOL

We were interested in comparing the IBS-QOL mean difference, between baseline and after 3 months, of the eHealth program (I) and control group 1. The latter control group consisted of three regular, physical IBS-schools at LMS in April, May and June 2017. Table 16 and 17 shows that the score from control group 1 numerically increased from baseline to after 3 months, with a mean difference of -3.9, but it was not statistically significant ( $p=0.485$ ). On the other hand, the score from the eHealth program (I) increased significantly between the same to time points, with a mean difference of 9.2 ( $p=0.001$ ) (Table 17).

**Table 16:** IBS-QOL overall score (0-100) for the participants in control group 1, at baseline and 3 months after the school. Values are reported as mean (SD).

	<b>Baseline, mean (SD) (n=20)</b>	<b>After 3 months, mean (SD) (n=20)</b>	<b>p-value</b>
<b>IBS-QOL overall score</b>	39.2 (17.8)	43.1 (27.3)	1: $p=0.485$

P-value is based on paired-Samples T test with mean (SD)

**Table 17:** IBS-QOL overall (0-100) differences between baseline and after 3 months, in the eHealth program (I) and control group 1. Differences are given as mean (95% CI).

<b>Symptoms</b>	<b>eHealth program (I): Baseline versus after 3 months (n=30)</b>		<b>Control group 1; regular IBS- school at LMS Baseline versus after 3 months (n=20)</b>	
	Mean differences (95% CI)	p-value	Mean differences (95% CI)	p-value
<b>IBS-QOL overall score</b>	9.2 (4.2, 14.1)	0.001**	3.9 (-7.5, 15.3)	0.485

P-values are based on paired-Samples T test

\*\* =  $p < 0.005$

### 3.2.4.2 IBS-SSS

We were also interested in comparing the IBS-SSS mean difference, between baseline and after 3 months, of the eHealth program (I) and control group 1. The latter control group consisted of three regular, physical IBS-schools at LMS in April, May and June 2017. Table 18 and 19 shows that the score from control group 1 numerically decreased from baseline to after 3 months, with a mean difference of 7.0, but it was not statistically significant (p=0.617). On the other hand, the score from the eHealth program (I) decreased significantly between the same to time points, with a mean difference of 64.4 (p=0.00004) (Table 19).

**Table 18:** IBS-SSS sum score (0-500) for the participants in control group 1, at baseline and after 3 months. Values are reported as mean (SD).

Symptoms	Baseline, mean (SD) (n=20)	After 3 months, mean (SD) (n=20)	p-value
<b>IBS-SSS sum score</b>	286.8 (62.5)	279.8 (78.5)	0.617

P-values is based on paired-Samples T test

**Table 19:** IBS-SSS sum score (0-500) differences between baseline and after 3 months, in the eHealth program (I) and control group 1. Differences are given as mean (95% CI).

Symptoms	eHealth program (I): Baseline versus after 3 months (n=26)		Control group 1; regular IBS- school at LMS Baseline versus after 3 months (n=20)	
	Mean differences (95% CI)	p-value	Mean differences (95% CI)	p-value
<b>IBS-SSS sum score</b>	64.4 (37.6, 91.3)	0.00004****	7.0 (-21.8, 35.8)	0.617

P-values are based on paired-Samples T test

\*\*\*\* = p < 0.00005

### 3.2.5 Comparison of the results from the eHealth program (I) with control group 2

#### 3.2.5.1 IBS-SSS

We were interested in comparing the IBS-SSS mean difference, between baseline and after 6 months, of the eHealth program (I) and control group 2. The latter control group consisted of IBS-patients, participating in a two-days, extended, physical IBS-school at LMS in October 2015. Table 20 and 21 shows that the score from control group 2 numerically decreased from baseline to after 6 months, with a mean difference of 32.3, but it was not statistically significant ( $p=0.094$ ). On the other hand, the score from the eHealth program (I) decreased significantly between the same to time points, with a mean difference of 78.7 ( $p=0.001$ ) (Table 21). The comparison of the development in eHealth program (I) and control group 2 is illustrated in Figure 16.

**Table 20:** IBS-SSS sum score (0-500) for the participants in control group 2, at baseline and after 6 months. Values are reported as mean (SD).

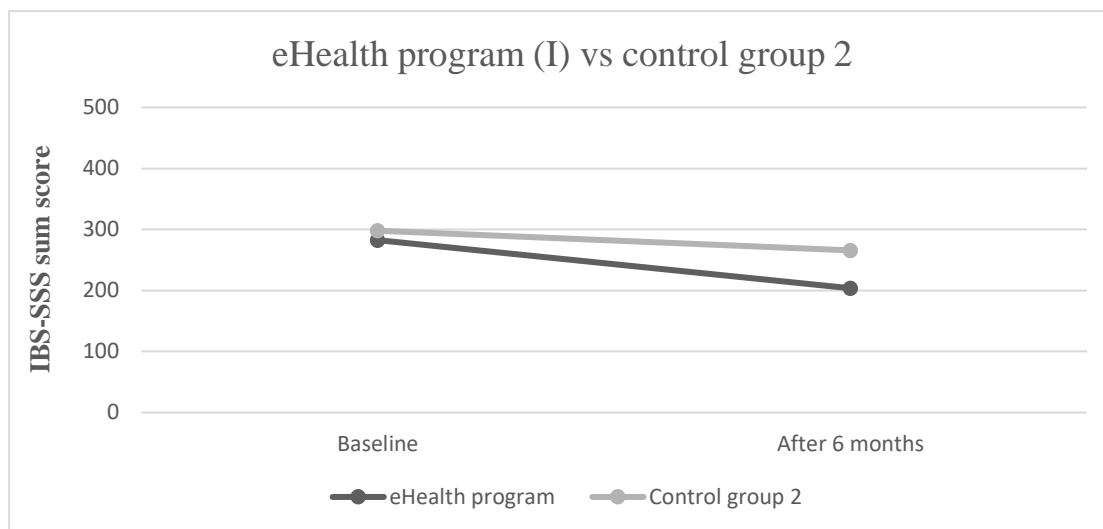
Symptoms	Baseline, mean (SD) (n=71)	After 6 months, mean (SD) (n=32)	p-values
<b>IBS-SSS sum score</b>	298.0 (83.0)	265.7 (103.3)	$p=0.094$

P-value is based on summary independent-Samples T test

**Table 21:** IBS-SSS sum score (0-500) differences between baseline and after 6 months, in the eHealth program (I) and control group 2. Differences are given as mean (95% CI).

Symptoms	eHealth program (I): Baseline versus after 6 months		Control group 2; extended IBS- school at LMS Baseline versus after 6 months	
	Mean differences (95% CI)	p-values	Mean differences (95% CI)	p-values
<b>IBS-SSS sum score</b>	78.7 (37.4, 120.0)	$p=0.001^{**}$	32.3 (-5.6, 70.2)	$p=0.094$

P-values is based on paired-Samples T test (eHealth program (I)), and summary independent-Samples T test (control group 2).



**Figure 16:** Comparison of the development of the mean IBS-SSS sum score from baseline to 6 months after, between the participants at the eHealth program (I) and the participants in the control group 2 participating at the extended IBS-school at LMS. Values are reported as mean (SD).

### 3.3 Results from the participants who completed the 3months evaluation, eHealth program (II)

In the second analyze (II) of the eHealth program, the mean and individual responses of the 40 study participants who completed the eHealth program and responded to the 3 months evaluation, were assessed. Some of the participants have not completed all of the questionnaires, so *n* will vary from form to form.

#### 3.3.1 Study population and baseline characteristics of eHealth program (II)

Baseline characteristics of the 40 patients that completed the 3 months evaluation (eHealth program (II)), are compared to the 52 included in the study, in Table 22.

**Table 22:** Baseline demographic of the 52 patients included in the study, compared to the 40 that completed the eHealth program and 3 months evaluation (II).

<b>PARTICIPANTS</b>	<b>Total included in the study (n=52)</b>	<b>eHealth program (II) (n=40)</b>	<b>Mean difference (Std. Error difference) p-value</b>
<b>Female/male</b>	36/16	26/14	
<b>Mean age (range), years</b>	37.6 (15-66)	37.1 (15-56)	
<b>Severity of symptoms</b>			
IBS-SSS sum score, mean (SD)	296.8 (88.1)	293.1 (80.9)	-3.7 (17.9)
Median	290.0	295.0	1: p=0.837
Range	(145-500)	(149-500)	
<b>IBS severity</b>			
Mild	n = 5 (10%)	n = 3 (7.5%)	
Moderate	n = 23 (44%)	n = 18 (45%)	
Severe	n = 24 (46%)	n = 19 (47.5%)	
<b>IBS-QOL overall score</b>			
mean (SD)	45.8 (18.2)	48.4 (17.5)	-2.6 (3.8)
Range	8.8-90.4	8.8-90.4	1: p=0.490

1 = Total included in the study vs eHealth program (II)

P-value is based on summary independent-Samples T test with mean difference (SD)

### 3.3.1.1 Gender and age

Among the 52 included participants in the study, 36 were female (69%). Of the 40 patients who completed the 3 months evaluation and are hence a part of the eHealth program (II), 26 were female (65%). The mean age among the 52 included was 37.6 years (range, 15-66 y), and among the 40 in the eHealth program (II) it was 37.1 (15-56).

### 3.3.1.2 IBS severity

Table 22 shows baseline mean IBS-SSS sum score for the 52 study participants included in the study, as well as for the analyze of those who completed the 3 months evaluation; eHealth program (II). The score for the 52 included in the study was 296.8 (range, 145-500), while it

was 293.1 (range, 149-500) for the eHealth program (II), but the difference wasn't statistically significant ( $p=0.837$ ). The distribution of the IBS severity was for the 52; mild=5 (10%), moderate=23 (44%), severe=24 (46%) and for the eHealth program (II); mild=3 (7.5%), moderate=18 (45%), severe=19 (47.5%).

### 3.3.1.3 IBS-QOL

The baseline mean IBS-QOL overall score for the 52 study participants included in the study, and for those who completed the eHealth program (II) were 45.8 and 48.4, respectively (Table 22). The difference was not statistically significant ( $p=0.490$ ).

## 3.3.2 Changes during the eHealth program (II): differences between baseline and 3 months

### 3.3.2.1 CSQ-8

Table 23 shows the mean (SD) scores of the eight questions from the Client Satisfaction Questionnaire (CSQ-8), as well as the mean of item means and mean total score, for both the participants in the eHealth program (II) and control group 1, as a part of the 3 months evaluation. For the eHealth program, most of the questions lie on a mean score around 3, with a mean of item means at 2.98, which shows a generally good satisfaction with the program. Of the 8 questions “the quality of the service” (Q1) was rated the lowest mean score (2.69), and “recommendation to a friend” Q4 with the highest (3.36). Mean total score for the eHealth program was 23.86, compared to control group 1, which had a mean total score of 24.8. The two mean scores were not statistically significant from each other ( $p=0.427$ ).

**Table 23:** 8 Client satisfaction questions (73), Q1-Q8 (1-4) and mean total score (8-32) for the participants in the eHealth program (II) and control group 1 at the 3 months' evaluation.

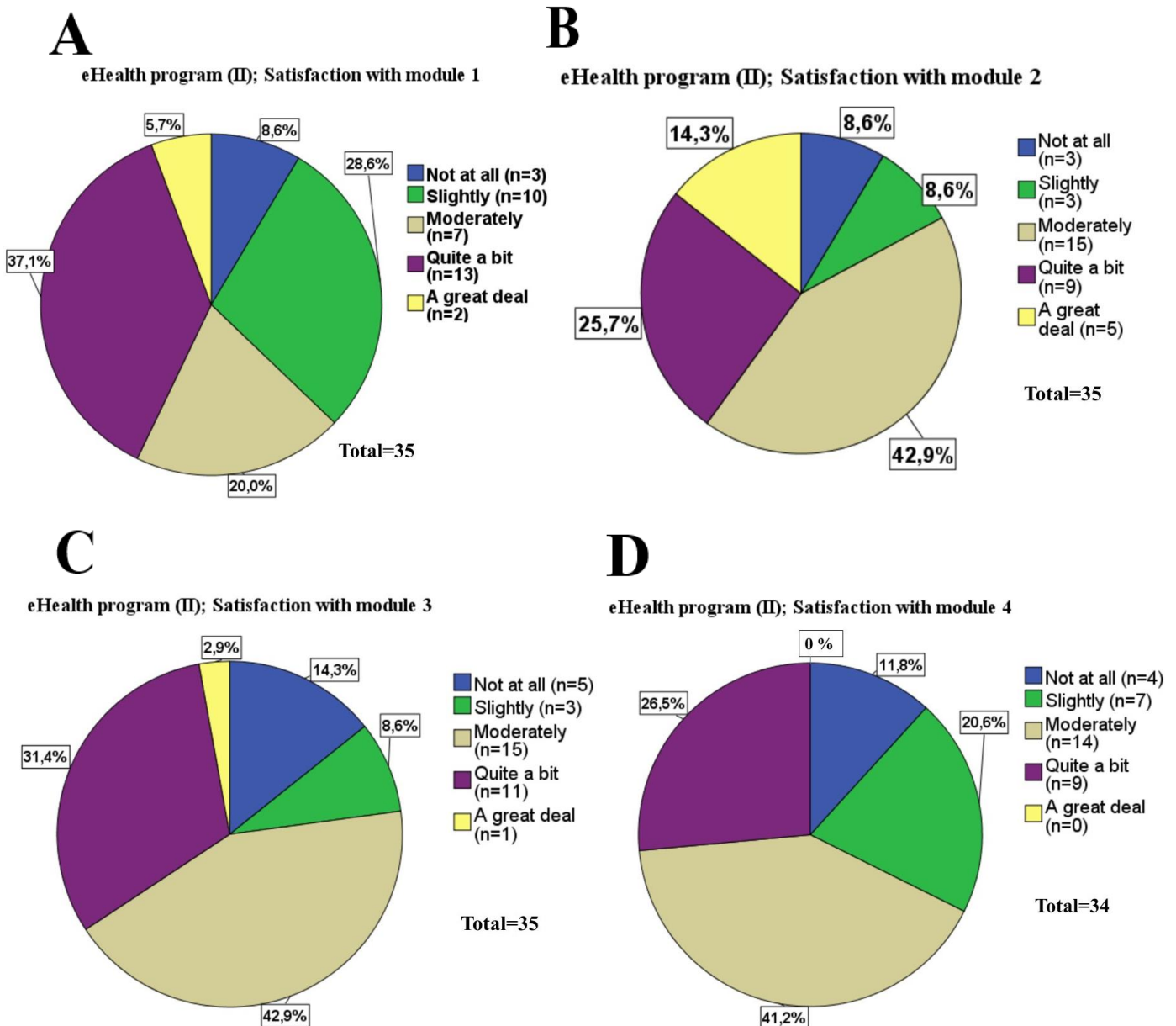
	<b>eHealth program (II)</b>	<b>Control group 1; physical IBS school at LMS</b>	<b>p-value</b>
	degree of satisfaction from 1-4 mean (SD) (n=36)	degree of satisfaction from 1-4 mean (SD) (n=20)	
Q1: How would you rate the quality of service you have received?	2.69 (0.67)	2.95 (0.76)	
Q2: Did you get the kind of service you wanted?	2.89 (0.52)	3.15 (0.59)	
Q3: To what extent has our program met your needs?	2.78 (0.76)	2.75 (0.91)	
Q4: If a friend were in need of similar help, would you recommend our program to him or her?	3.36 (0.64)	3.65 (0.49)	
Q5: How satisfied are you with the amount of help you have received?	2.92 (0.77)	2.65 (0.75)	
Q6: Have the services you received helped you to deal more effectively with your problems?	3.00 (0.68)	3.15 (0.67)	
Q7: In an overall, general sense, how satisfied are you with the service you have received?	3.03 (0.74)	3.0 (0.73)	
Q8: If you were to seek help again, would you come back to our program?	3.19 (0.82)	3.5 (0.69)	
mean total score (sum of all the items)	23.86 (4.19)	24.8 (4.26)	1: p=0.427
Mean of item means	2.98 (0.73)	3.1 (0.76)	

1 = mean total score eHealth program (II) vs control group 1

P-values are based on Summary independent-samples T test

### 3.3.2.2 HBNKFM3; eHealth program (II)

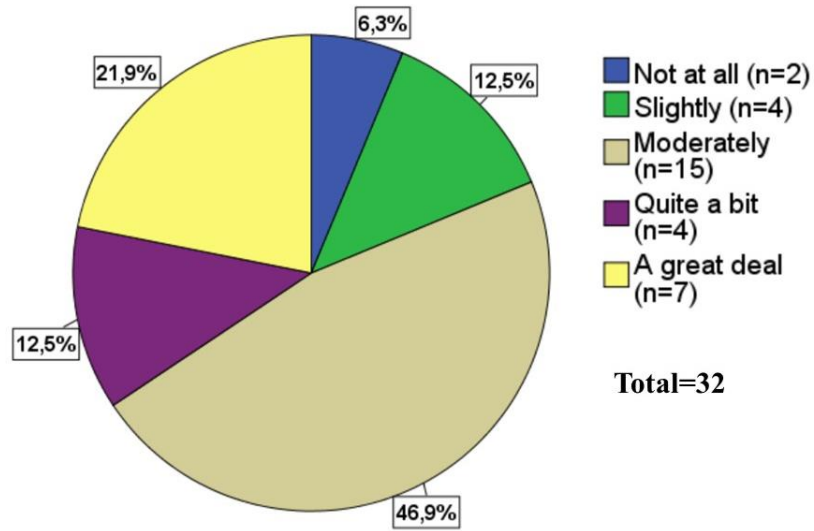
Figure 18 illustrates the patients' degree of satisfaction with the different modules in the eHealth program (II). 35 of the study participants who completed the HBKNKFM3 questionnaire, at the 3 months' evaluation, answered how satisfied they were with Module 1 (with gastroenterologist). The same amount gave their feedback on module 2 (with physiotherapist) and module 3 (about lifestyle and dietary advice with clinical dietitian). Only 34 of them evaluated module 4 (with psychiatrist), and only 32 out of the 35, reported their satisfaction regarding module 5 (about the low FODMAP diet with clinical dietitian). This might be due to the fact that they had only finished the first three and not yet started the last two modules, at the 3 months' evaluation. Based on the pie chart, it may look like the largest proportion was most satisfied with module 5 and least with module 4.





# E

## eHealth program (II); Satisfaction with modul 5



**Figure 18:** Degree of satisfaction of the different modules in the eHealth program (analyze II); module 1 (A), module 2 (B), module 3 (C), module 4 (D) and module 5 (E).

## 4. DISCUSSION

There are limited studies on such a web-based treatment for IBS patients, with an interdisciplinary approach, that we have implemented and conducted. The interdisciplinary approach is based on the fact that IBS is a heterogeneous disorder, with the suggestion of being a generic term for many diseases with different pathogenesis, but with the same symptoms (4, 8, 13). Because IBS is a heterogeneous disorder that cannot be cured, the treatment has so far mainly been recommended to be individualized and be based on the patient's predominant symptoms (8, 14, 17, 25). Due to the fact that the treatment options for IBS patients are wide, ranging from pharmacological treatment, psychological interventions and guidance on diet, lifestyle and physical activity (4, 15, 26), this eHealth program was developed interdisciplinary by gastroenterologist, physiotherapist, clinical dieticians and psychiatrist. This web-based program covers many of the treatment fields for IBS patients, which might be the reason for the successful results of this program. It might also support that IBS is a heterogeneous group that needs to be treated individually with different approaches, or in a combination of the different treatment options.

### 4.1 Main findings

The primary aim of this prospective, open, pilot study, was to evaluate whether the eHealth program could be effective as a healthcare measure. This was assessed, based on the effect of the program itself, but also in comparison with the effect of the current program; the physical IBS-school at LMS. 52 participants were included in the study. 40 of these patients completed the 3 months evaluation and their data were the basis of the analysis of the eHealth program (II), whereas 31 completed the 6 months evaluation and were the basis of the analysis of the eHealth program (I).

In the analysis of eHealth program (I), mean IBS-SSS sum score and 4 out of 5 IBS symptoms, significantly improved from *baseline to after 3 months*. Improvements were also seen from *baseline to after 6 months*, where mean IBS-SSS sum score and 3 out of 5 IBS symptoms significantly decreased. Individually, 20 (76.9%) of the 26 participants either improved their IBS-SSS sum score significantly from baseline to after 3- or 6 months, and the distribution of IBS severity from baseline to after 3- and 6 months shifted toward better severity categories.

Enhancement in the participants quality of life was assessed according to IBS-QOL from *baseline to after 3 months*, where mean IBS-QOL overall score and 5 out of 8 IBS-QOL subscale scores significantly increased. From *baseline to after 6 months*, the mean IBS-QOL overall score and 7 out of 8 IBS-QOL subscale scores significantly improved. The only subcategory in the RAND-36 questionnaire that showed a significant improvement, was “pain”. The rest of the categories did not alter significantly, neither from baseline to after 3 nor 6 months. The HADS sum score and the subscale scores anxiety and depression numerically decreased from baseline to after 3- and 6 months, but neither of the improvements were statistically significant. The correlation analysis between IBS-SSS sum score and IBS-QOL overall score, at baseline, and after 3- and 6 months, showed that all of them were statistically significant negative correlated. The ROME III criteria questionnaire contained a lot of "insufficient information", which made the utilization of the data difficult. In *control group 1*, mean overall IBS symptoms and mean IBS-QOL overall, numerically improved from *baseline to after 3 months*, but it was not statistically significant. In *control group 2*, the overall IBS symptom scores numerically decreased from *baseline to after 6 months*, but neither were statistically significant.

In the analysis of the 40 participants who completed the 3 months evaluation (eHealth program (II)), showed a generally good satisfaction with the program, based on CSQ-8. According to HBNKFM3, it looked like the largest proportion of the participants were most satisfied with module 5 (low FODMAP diet with clinical dietitian), and least satisfied with module 4 (with psychiatrist).

## **4.2 Discussion of main findings**

### 4.2.1 Study group and sample size

Due to the drop-out throughout the study we found it important to evaluate whether the 52 participants included differentiated from the groups who completed 3 and/or 6 months evaluations. Gender distribution and mean age, at baseline, in the eHealth program (I) and (II) are quite similar to the 52 originally included, differentiating with a slight increase in the proportion of women and having a narrower age range in the eHealth program (I). There was

a small reduction from the mean baseline IBS-SSS sum score of the 52 (296.8) till the eHealth program (II) (293.1) and a slightly larger reduction from the 52 till the eHealth program (I) (282.5), but neither of them were statistically significant. The proportion of the different categories of baseline severity didn't differentiate so much between the three groups. The baseline demographics of the mean IBS-QOL overall score, for the 52 included in the study, and for the participants in the eHealth program (II) and (I) was 45.8, 48.4 and 50.0, respectively. Neither of these slight increases from the 52 included in the study, were statistically significant. This indicates that the analysis of the participants in the eHealth program (II) and (I) may represent the 52 originally included in the study, which again might be representative for the IBS population who seek specialist healthcare services.

Interestingly, the dropouts had a higher mean IBS-SSS sum score and a lower IBS-QOL overall score. In terms of age, the dropouts were among the oldest and youngest participants. From the 52 included in the study and up to 3 months (eHealth program (II)), it was the age range between 57-66 who dropped out. Similarly, from the 52 included in the study up to 6 months (eHealth program (I)), it was the age range between 15-19 and between 57-66 who dropped out. This indicates that the eHealth program might be best suited for the age range around 20-60 years. We did not initially include participants under the age of 18 years (except one), since the educational program does not have a pediatric design. There are obviously individual differences, but our results demonstrated that the initially set age-range was appropriate. It is therefore possible to suggest that the eHealth program is more suitable for participants aged 20-60 years. The eHealth program may not be suitable for younger participants, and older may find it too technically challenging.

#### 4.2.2 The questionnaires responded by the participants in the eHealth program (I)

##### 4.2.2.1 IBS-SSS and IBS-QOL

There were significant improvements in mean IBS-SSS sum score and a large proportion of IBS symptoms, from baseline to both 3- and 6 months after the start of the program, in the participants who completed the 6 months evaluation (eHealth program (I)). There were also significant improvements in mean IBS-QOL overall score and a large proportion of its

subscale scores, between the same time points, for the participants who completed the eHealth program (I). There is limited research on the same type of interdisciplinary web-based treatment for IBS patients, like the one we have conducted. However, some similar studies regarding internet-based treatments for IBS patients both support and contradict our results, as e.g. one internet-based self-management program showed no significant improvement in quality of life (53), while two internet-based cognitive behavior therapy studies showed significant improvement on IBS symptoms and quality of life (54, 55). A study by Jøc et al (52) used another educational platform; an outpatient clinic in addition to written information, but included much of the same content as in the eHealth program. They concluded that the IBS patients had significantly improved their quality of life and significantly reduced their IBS-related complaints (52).

The correlation analysis between IBS-SSS sum score and IBS-QOL overall score, at baseline, and after 3- and 6 months, showed that all of them were statistically significant negative correlated. That indicates that the severity of IBS symptoms is correlated with reduced quality of life. These findings are supported by Mönnikes (9) and De Gucht (76), which conclude that the severity of IBS symptoms directly correspond to the effect on total HRQOL. And patients who experience worse IBS symptoms, have a more reduced quality of life, than those with milder sufferings (9). De Gucht (76) also conclude that the patient's perception and coping of the disease, have an indirect impact on their HRQOL. One of the primary intentions with the eHealth program is to help the patients to cope with the disease better, and as the results showed significantly improved IBS symptoms and quality of life, this might successfully have been one of the reasons.

#### 4.2.2.2 Comparison of the eHealth program (I) with control group 1 and 2

The differences in mean IBS-SSS sum score and mean IBS-QOL overall score, between baseline and after 3 months in control group 1, improved numerically less than in the eHealth program (I), between the same scores and time point (as shown in Table 17 and 19). The same was assessed in control group 2, which had a numerically lower mean difference in IBS-SSS sum score, between baseline and 6 months, than the eHealth program (I), at the same scores and time point (as shown in Table 21). Neither of the differences in control group 1 and 2

were statistically significant, which makes the comparisons difficult. Anyway, this indicates a trend toward the conclusion that the eHealth program is not less effective than the IBS-school at LMS. This is somewhat contradictory to, for example, a previous RCT study that concluded that in the treatment of IBS, "structured patient group education (IBS school)" is a better alternative than written information (58). However, this is not completely comparable to the eHealth program as it contains more than just written information.

### **4.3 Limitation of the study**

#### 4.3.1 study group and sample size

One major weakness of the study is the high dropout rate. This is something we feared, when increasing the risk of it, by choosing a duration of the study period as long as 6 months. Even though age and gender were quite similar in the eHealth program (I) and (II) as the 52 included participants, and there were no statistically significant differences between mean IBS-SSS sum scores between those mentioned, there will still be an uncertainty on whether the dropouts may have affected the other results, and possibly in both directions.

A possible weakness of the study is that we have not controlled, whether the patients have participated in other treatment options, during the study period. Two of the participants reported less symptoms after surgery during the study period, and one reported the same incident due to pregnancy, which we therefore excluded, to avoid falsified positive results. However, we did not control for this or other similar cases (like pregnancy) systematically, within the other participants. We have also not controlled whether the patients suffer from other comorbidities. This might be a limitation with the study, but it's also important to remember that IBS is a heterogenous group (8), and we wanted the study population to be as representative for the IBS population as possible. This is also due to the long-term goal of implementing the eHealth program nationally, as a low-threshold offer, for all patients with IBS, regardless of this. At the same time, it's worth mentioning that this is neither controlled for in control group 1 nor 2, which might have affected all of the groups in the same way, which might have given all of the groups the same starting point at the comparison.

#### 4.3.2 Control groups and samples sizes

Due to ethical considerations, the written consent form that the participants received at the IBS school at LMS had to be signed *before* completing the questionnaires. This resulted in most of the participants responding to the different questionnaires after the first day of the course. Ideally, they should have replied to the questionnaires *before* they started the course, which makes this a weakness, as they already might have had a positive effect when they completed the questionnaires. The implementation of a separate electronic platform for control group 1 was dependent on Helse Bergen-Section for eHealth. The 6-month delay of this, which had nothing to do with the master student, meant that this was not started before April. This resulted in a low number of patients in this control group (n = 20), which makes the control group 1 weak. Another weakness with the control groups is that the IBS school at LMS is not a validated gold standard (yet), but only developed based on the participants' satisfaction and feedback.

#### 4.3.3 Evaluation of the placebo effect

Since our study is not a randomized, blinded, placebo-controlled trial, the placebo effect will be essential to evaluate here. This familiar phenomenon has often been demonstrated in clinical research (77). It has been assessed that participants in studies receiving the placebo product have nevertheless experienced unexplained symptom relief (77). The quality of the relationship between the patient and the therapist, the subject's belief in the product/intervention as well as their expectations, are among other possible factors that might be associated with the placebo effect (78). The fact that the participants in the eHealth program were involved in such treatment, where they might have felt that they were taken seriously and finally got some tools that could help them, can itself have provided an expectation of an effect. This might have resulted in a placebo effect and positively affected the results. The fact that the patients know that they are participating in a guided intervention by experts in their respective fields (gastroenterologist, physiotherapist, clinical dietitian, psychiatrist) might also have amplified the expectation of an effect. Despite few meetings during the study period, participants may have felt a certain interaction with the people affiliated with the project, which in turn may have contributed to a potential placebo effect. We chose to use only validated questionnaires (except the NKFM questionnaire), to reduce

the potential placebo effect. For the same reason, we also chose to compare the results of the eHealth program with two control groups. The participants in these control groups had physically attended to the IBS-school at LMS, where the expectation of an effect is also present. As discussed by Miller (77) the possible placebo effect in IBS trials, can be reduced by having a study duration longer than 12 weeks as well as lowering the frequency of follow-up meetings. This might again enhance the statistical power (77). Our study lasted for a total of 6 months, and had few meetings along the way (only 2 voluntary meetings regarding information- and evaluation), which might have reduced some of the placebo effect in the study.

#### 4.3.4 The questionnaires

First of all, one limitation with the study is that all of the data are based on the self-reported data from the questionnaires. Another limitation about the questionnaire is that two of the questionnaires (IBS-SSS and ROMEIII), were completed by participants in two different ways, on paper at baseline and after 3 months, and electronically after 6 months, due to license delay. Although the intention was that the electronic questionnaires would match the printed editions as well as possible, there would still be two different formats, which gave the possible rise to different interpretations of the questionnaires and bias that couldn't be adjusted for.

Another aspect is that some of the participants reported that it was time consuming to fill out all of the questionnaires (6 + CSQ-8), at three different times (baseline, after 3 months, after 6 months), and in addition split it up in two different ways (by post and electronically). If all the questionnaires had been electronic all the way, it would also have been much more convenient for us to get a systematic overview, along the way, over respondents of the various questionnaires. It would therefore have been much easier for both the project workers and also the participants, if all of the questionnaires had been electronically. This might also have increased the likelihood of compliance and less dropouts.



#### 4.3.4.1 IBS-SSS

A weakness with the IBS-SSS questionnaire (see appendix 9) is that if one of the subscale scores questions remains unanswered, the participant will still get a total score. For example, if a participant answer "no" that they do not suffer from abdominal pain at the moment (1a) then it is natural that they will let (1b), which ask for the severity of abdominal pain, be unanswered. This will then most likely give the correct outcome on total score, but give less number ( $n$ ) to the actual subscale score (1b); "severity of abdominal pain", as we have no value of the patient. One possibility is to override writing "0" on these examples but then one's own interpretation of the form will become subjective, which is why the master's student has chosen not to do so. In addition, some participants have answered "no" on (1a) and yet scored a low score of (1b), which makes it clear that patients may interpret the questionnaire differently, and override will not be the right solution. Oppositely some patients have answered yes on (1a) and left (1b) unanswered.

Subsequently, most of the time, it may be "right" with lower ( $n$ ) on the subscale score than the sum score, due to patients suffering from different IBS like symptoms. Some patients might for example not suffer from abdominal distention (no responded value on this subscale, but still get a value on the sum score), but from abdominal pain. This will therefore not affect the sum score, but other times will different interpretations might lead to missing data that affects the total sum. This can therefore result in an incorrectly reduced total sum score. However, this applies for the questionnaire in both forms (and therefore in all questionnaires sent out at the different time points, at baseline and after 3- and 6 months), and might therefore equalize the bias. Since this master thesis has contained 431 variables per participant, there has been no capacity to go through each variable and optionally remove any patient due to errors/weaknesses with the implementation of this standardized questionnaire. The master student has therefore dealt with the sum score values that have come from the raw data of the participants, but noted this weakness with the questionnaire. However, this is corrected for the subscale scores, resulting in smaller number ( $n$ ) of participants, so that all variables have been compared in pairs with equal groups.

#### 4.3.4.2 Rome III criteria

One of the inclusion criteria was that the patients had gotten the IBS-diagnosis from either their general practitioner (D93) or by a specialist in gastroenterology (K58). Given the idea that the eHealth program should be a low-threshold healthcare service, we did not set Rome III criteria as an additional inclusion criterion. However, we were still interested to see if the patients would get the IBS-diagnosis based on the Rome III criteria by filling out this questionnaire. Unfortunately, this form caused some confusion due to the format layout, which resulted in some missing data. Many participants misinterpreted that the questions 44-50 are sub-questions to question 43, because they are indented below this question. This has resulted in some male participants believing that question 44-50 are intentionally for women, as well as question 43, and let all of these questions be uncompleted (they wrote on the side “I am a man” and skipped these questions). It also looked like some female participants have uncompleted questions 44-50, when they have completed “no” on question 43, and thought they were dependent of each other. Altogether, it gave us a lot of "insufficient information to provide an IBS diagnosis", hence not useful to use the questionnaire. Some gastroenterologists believe that not everyone suffering from irritable bowel syndrome will fulfill the ROME III criteria for IBS, and that you should not trust these criteria blindly. Even though the ROME III criteria are presently the most accepted tool, at standardizing the IBS-diagnosis(77), there are arguments that these criteria are not validated enough and that they are seldom utilized in clinical practice(79), and also that they only have a moderately ability to classify all of the IBS patients accurately(80).

#### 4.3.4.3 HBNKFM 0,3,6 low FODMAP diet

It is important to emphasize that the HBNKFM questionnaires are not validated, and thus only used and interpreted as satisfaction and feedback from the participants. Of the 14 patients who responded that they followed a low FODMAP diet at baseline, a percentage between 78.6 % (answered either moderately, quite a bit or a great deal) and 100% (answered either slightly, moderately, quite a bit or a great deal), answered that they had experienced a symptom relief of the diet in some degree. This is supported by earlier studies, where e.g. Nanayakkara et al (46), suggested that as much as 86% of the patients suffering from IBS experience an improvement in IBS symptoms, when they are following the diet. However, a great limitation

with the questionnaire is that it only asks the participants who still follow the diet, about their experience with symptom relief. It's reasonable to believe that the patients who still followed the diet at baseline, are the ones that do have experienced a symptom relief of the diet. When we made the questions, it would possibly have been better to ask all the participants who had *tried* the diet, on what kind of experience they had made, regarding symptom relief. This is a great limitation, when interpreting the rest of the answers.

6 patients answered that they experienced a symptom relief a great deal, after attending the eHealth program for 3 months, and only 5 answered the same after 6 months. A possible reason might have been an unsuccessful reintroduction of the FODMAPs. The percentage of the participants who had followed the diet after guidance in the eHealth program and reintroduced the FODMAPs, were 62% after 3 months and 73% after 6 months. This might support that a long-term follow-up, with dietary guidance by a clinical dietitian, like e.g. Nanayakkara et al (46) have suggested, might play a major role in the potential effect of the diet.

#### **4.4 Possible improvements**

##### 4.4.1 The questionnaires

The problem with the IBS-SSS questionnaire might be avoided by being created in a way that forces the patient to complete all the questions before proceeding, and if he/she hasn't completed all the necessary questions, the participant shouldn't get a total score. Generally, in the results, the number of completed (n) varies from questionnaire to questionnaire, so the same applies to the rest of the forms. In this way, it will not be possible for the participant to skip any of the individual questions or questionnaires.

A suggestion for improvement could also be removing question *1a* and *2a* on IBS-SSS, which might make every participant answering *1b* and *2b*. Since some of the sub-questions on IBS-SSS require the participants to "drag" an arrow on the VAS score that describes them best, instead of putting a cross at a line on a sheet, like the paper edition, there is always a chance that someone won't understand that this is what they are supposed to do. It may therefore be

wise to make a little explanation box on the page, and to spend even more time trying to make generally everything in the eHealth program as simple as possible to use.

#### 4.4.2 The eHealth program

Unlike the physical IBS school at LMS, the patients who participate in the eHealth program do not meet other people in the same situation whom they can exchange advices and experiences with. A suggestion for possible improvement can be the signing up for an organized meeting, where participants have the opportunity to meet others, and thereby feel less alone in their situation.

Furthermore, the program should be improved in the sense that it is easier to monitor patient use of the program. Based on the present development of the program, we didn't have this opportunity, which made it impossible for us to differentiate between which of the patients who had utilized the program in a great extent from those who hadn't. Another aspect of further development of the eHealth program is user perspective and user involvement, whereas patient feedback is important for possible improvements with the program.

#### **4.4 Further research**

There is a need for more patients to test the eHealth program, in order to be more certain about the effect of the program. There is also a need for better control groups, with larger (n) in both the study population and the control group. To investigate the effect of this program further, future research could contain a RCT study. This could e.g. investigate the effect of the eHealth program compared to the effect of other validated treatment options. This will strengthen the results, as well as give more insight to whether the results could have been caused by chance. Furthermore, in the recruitment of more participants, a suggestion can be to screen and evaluate which patients are motivated for this kind of program. It requires self-discipline and that they set aside time for it, and not all the patients are motivated for that. All the potential participants we tried to recruit to the eHealth program, wanted to participate. We should have put more emphasis on what it was going to require of the participants, to avoid dropouts, due to this. It might therefore be a suggestion in the future to be more realistic on

how motivated the patient are, and who would rather be better suited on e.g. a two-day physical IBS school.

The long-term goal of this pilot study and a further expansion of the study, have along the way, been to implement the eHealth program nationally as a primary healthcare offer through the general practitioner system, requiring that enough participants have showed an effect of the program. The underlying objective of this, is to reduce the waiting line for patient education for functional gastrointestinal diseases by giving them quick access to the eHealth program. This will give them help with self-help, based on "knowledge is empowerment". This could also be a tool for general practitioners (GP), and also resulting in better distribution of the work between the primary and specialist health care.

If the eHealth program becomes implemented nationally as a healthcare measure, the eHealth program could in the future, be used to create a quality register for functional gastrointestinal disorders. This could provide information on the patient's experience of different treatment options, as well as data of e.g. the patients' symptoms and severity, drug use and so on. Examples of future studies, could be comparison of the development of the use of the eHealth program and drug use, or comparison of development of IBS symptoms and quality of life, vs use of the eHealth program.

Another aspect with this program is the cost-effectiveness. Since the worldwide prevalence of IBS is as much as around 11.2% (11), and it contributes to major healthcare costs, both directly by patient care and indirectly by absenteeism at work (4, 5, 7, 8), it's important to have an available treatment option, which doesn't contribute to major health care costs. As discussed by Mishima et al (81), it's important that the patients are well educated about their disease, which will help them cope with it better, and hopefully reduce their symptoms without unnecessary cost expenditures and without adverse side effects. An earlier study on ICBT conducted by Ljótsson et al concluded that it could be a cost-effective treatment option (55). The eHealth program can be a cost-effective treatment option for IBS patients in the future, by being a cheap, easily accessible to patients independently of geographic location, with quick access, and with quality assured content.

## 5. CONCLUSION

- IBS symptoms significantly improved from baseline to both 3- and 6 months after the start of the eHealth program.
- Health-related quality of life significantly improved from baseline to both 3- and 6 months after the start-up.
- IBS symptoms were significantly and negatively correlated with quality of life, at baseline and after 3- and 6 months. This supports previous data that the severity of IBS symptoms directly corresponds to the effect on total HRQOL.
- The mean improvement in IBS symptoms and IBS-QOL scores were lower in both control groups, compared to the eHealth program, but none of the changes in the control groups were statistically significant. However, this suggests that the eHealth program is not less effective than the current program; the IBS-school at LMS.
- Results from the Client Satisfaction Questionnaire showed a generally good satisfaction with the program.

Altogether, the positive results from our pilot study, support the conclusion that the eHealth program can be effective as a healthcare measure. There is a need for more patients to test the eHealth program, in order to be more certain about the effects and duration of the effects of the program. Based on our results, it supports that it's worth further investment in the project, so that the eHealth program may become a nationally cost-effective treatment option for IBS patients in the future.

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## **7. APPENDIX**

Appendix 1: Research Protocol

Appendix 2: REC approval

Appendix 3: REC approval of alterations in the project

Appendix 4: REC approval of inclusion of patients in the control group

Appendix 5: Information and consent form

Appendix 6: Additional write about the content of the eHealth program

Appendix 7: Rome III-criteria

Appendix 8: IBS-QOL

Appendix 9: IBS-SSS

Appendix 10: HADS

Appendix 11: RAND-36

Appendix 12: NKFM0

Appendix 13: NKFM6

Appendix 14: HBNKFM0

Appendix 15: HBNKFM3

Appendix 16: HBNKFM6

Appendix 17: CSQ-8

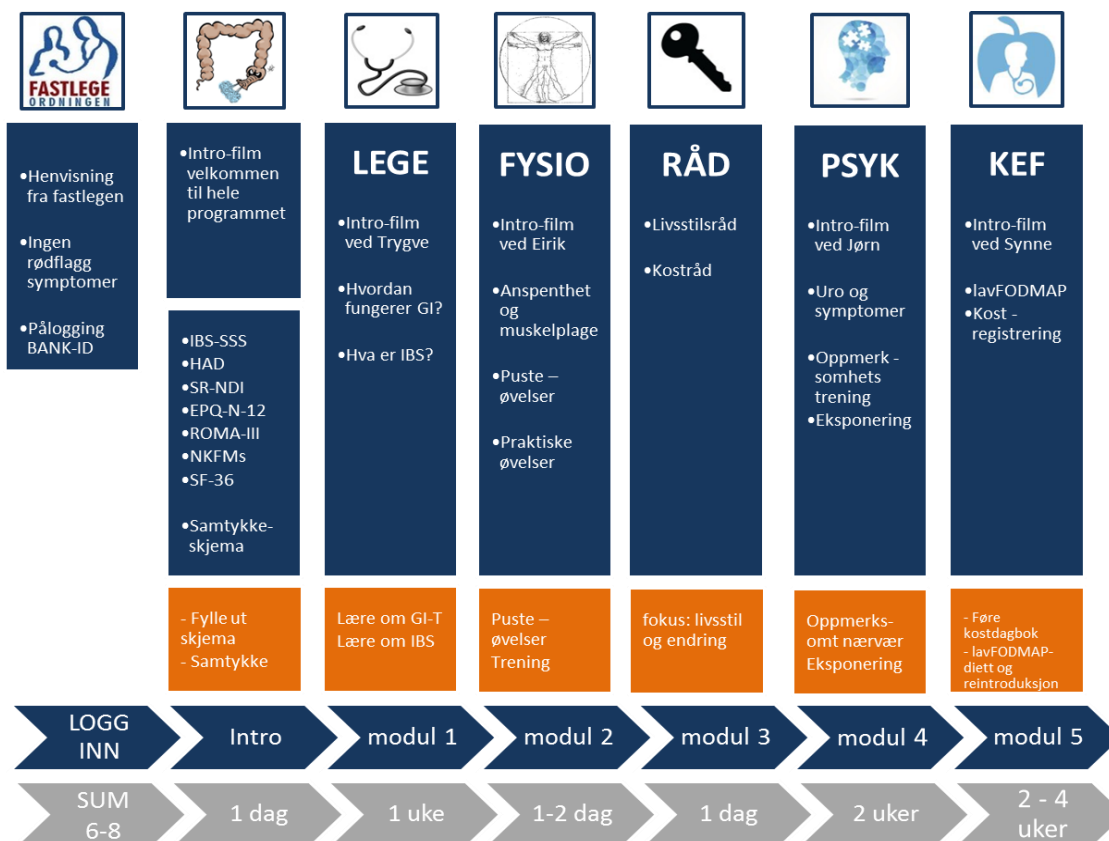
Appendix 18: Abstract “Kliniske ernæringsfysiologers forening tilknyttet forskerforbundet (KEFF)” conference

Appendix 19: Videos from the eHealth program

## Appendix 1: Research Protocol



*Kommentar til forskningsprotokoll: For Mage-tarmskolens innhold se eget vedlegg (160 sider). Magetarmskolen består av 5 moduler hvor modul 1,2 og 4 er pasientopplæring og modul 3 og 5 er kostholdsintervensjon. Forskningsprotokoll for kostholdsbehandling er beskrevet nedenfor.*



## Forskningsprotokoll

### Kostbehandling ved irritabel tarm – Magetarm-skolen på nett

<b>Bakgrunn</b>	<p>Flere mennesker med IBS rapporterer at spesifikke matvarer induserer og/eller forverrer deres symptomer. Typiske ”problemassosierte matvarer” omfatter fet mat, stekt mat, sterkt krydret mat, røkt og sterkt saltet mat, hvete/gluten, mye kostfiber, alkohol, koffeinholdig drikke (kaffe, te, cola, energidrikker) og matvarer med høyt innhold av tungtfordøyelige karbohydrater (FODMAPs). En lav FODMAP-diett er den eneste vitenskapelig beviste kostholdsterapien for lindring av IBS-symptomer, og blir i økende grad valgt som førstebehandling (1,2,3). Tungtfordøyelige karbohydrater blir ikke absorbert tilstrekkelig i tynntarmen, og vil være osmotisk aktive og fermenteres, noe som kan resultere i luftplager, smerte og forstyrret avføringsmønster. Kostbehandling ved IBS har det overordnede mål om et <u>mest</u> mulig variert kosthold med <u>minst</u> mulig symptomer. Dette innebærer å ikke kutte ut alt som <i>mistenkes</i> å gi problemer, men heller det man gjentatte ganger har <i>erfart</i> gir problemer. Ved å først redusere FODMAPs i kosten, for så å systematisk reintrodusere FODMAP-gruppene, vil man redusere risikoen for et utilstrekkelig inntak av viktige næringsstoffer og dermed sikre et fullverdig kosthold (4).</p>
<b>Mål</b>	Identifisere om tverrfaglig veiledet selvhjelp sammen med veiledet lavFODMAP-kostholdsintervensjon leder til endringer i pasientrapporterte symptomer og livskvalitet hos pasienter med irritabel tarm.
<b>Studiedesign og metode</b>	Denne studien er en prospektiv, åpen studie. Det skal benyttes kvantitativ metode for analyse.
<b>Tidsramme</b>	Etter inklusjon skal pasienten veiledes i lavFODMAP-dietten over internett (2-6 uker) av klinisk ernæringsfysiolog.
<b>Inklusjonskriterier</b>	<p>Pasienten må ha diagnosen irritabel tarm, enten fra fastlegen ved ROMA-kriteriene eller som en ekskluderingsdiagnose ved spesialisthelsetjenesten. Pasienten skal ikke ha «rød-flagg» symptomer som feber, blod i avføringen, eller diare om natten (under søvn).</p> <p>Antall deltagere: 60 (ønskelig 50-50 menn/kvinner) Alder: 18 -70 år</p>

<p><b>Datainnsamling</b></p>	<p>Pasienten skal besvare medisinske spørreskjema a) før oppstart, b) 3 måneder etter oppstart, c) 6 måneder etter oppstart.</p> <p>Følgende spørreskjema skal besvares:</p> <ol style="list-style-type: none"> <li>1) Gradering av mageplager (IBS-SSS)</li> <li>2) Spørreskjema om mageplager (ROMA III)</li> <li>3) Spørsmål om uro og bekymring (EPQ-N-12)</li> <li>4) Spørsmål som handler om hvordan du oppfatter helsen din (RAND-36)</li> <li>5) Personlighetstest (NEO-PI-3 og NEO-FFI-3)</li> <li>6) Spørsmål om angst og depresjon (HAD)</li> <li>7) Spørsmål om livskvalitet i forbindelse med mageplager (IBSQOL)</li> <li>8) NKFM's spørreskjema om symptomer, hyppighet og sykehusbesøk.</li> </ol> <p>Alder Høyde Vekt</p>
<p><b>Database</b></p>	<p>Database lagres ved sykehusets Forskningsserver. Kun prosjektleder har tilgang til nøkkel.</p> <p>Software: Filemaker Pro 14.0, SPSS, Microsoft Office</p>
<p><b>Innhold/intervensjon</b></p> <p>Fase 1 (Modul 3)</p> <p><b>Generelle livsstilsråd</b></p> <p>Tidsbruk</p> <p>Media</p>	<p>I modul 3 av mage-tarmskolen, får pasienten opplæring i generelle livsstilsråd for irritabel tarm (NICE guidelines) (5), og blir oppfordret til å følge disse gjennom hele behandlingen. Det blir også gjennomgått kostholds faktorer og anbefalinger for fiberinntak og magetarm-problemer.</p> <p>1 dag</p> <p>Tekst og film</p>

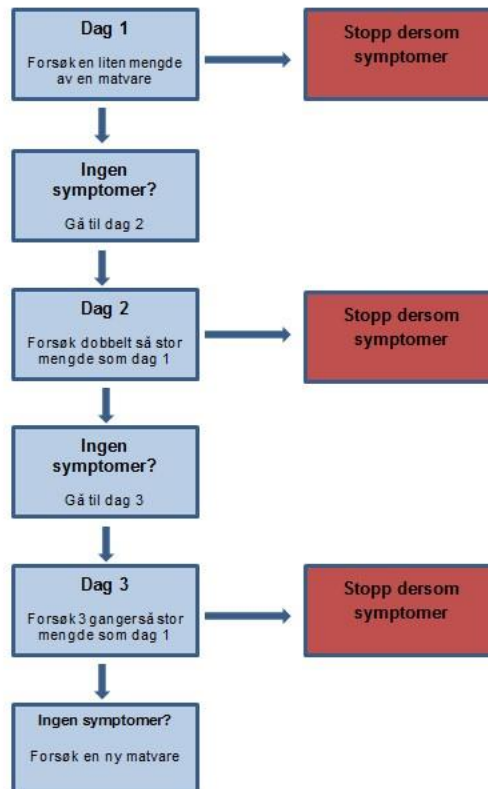
<p>Fase 2 (Modul 5)</p> <p><b>FODMAP- reduisert kost</b></p>	<p>Dersom pasienten ikke opplever tilfredsstillende symptomlindring etter de tidligere modulene, skal de gå videre til modul 5 og prøve FODMAP-reduisert kosthold.</p> <p>FODMAP-reduisert kosthold skal følges i 2-6 uker, avhengig av grad av symptomlette.</p> <p>Pasientene får i denne modulen grundig opplæring i hva dietten består av, kilder til tungfordøyelige karbohydrater og hvordan man kan sette sammen et balansert kosthold lavt på FODMAPs. Pasienten får opplæring i fordøyelsen, næringsstoffene, FODMAPs og kilder, samt tilgang til praktiske matlagings-</p>
<p>Tidsbruk</p> <p>Media</p>	<p>filmer.</p> <p>I denne modulen har pasienten mulighet til å kontakte en klinisk ernæringsfysiolog via HelseNorge.no. Spørsmål vil bli besvart mandag og fredag, og pasienten vil motta en SMS når svar foreligger på HelseNorge.no.</p> <p>2-6 uker</p> <p>Tekst, lister og oppskrifter med utskriftsvennlig versjoner, filmer (animasjonsfilmer og filmer fra kjøkken) og Podcast (lydfil).</p>



Fase 3 (Modul 5)

**Reintroduksjon av FODMAP-grupper**

Etter 2-6 uker med et lav FODMAP kosthold, til pasienten er symptomfri, skal pasienten teste toleransen for hver enkelt FODMAP-gruppe. Pasienten får steg-for-steg informasjon om hvordan reintroduksjonen skal gjennomføres, og får forslag til testmatvarer og mengder. Under reintroduksjon av matvarer anbefales pasienten å følge denne modellen:



Målet er at pasienten står igjen med et kosthold uten unødvendige restriksjoner og reduserte plager (reduksjon på minst 50 poeng ved IBS-SSS) av sin irritable tarm.

<p><b>Referanser</b></p>	<ol style="list-style-type: none"> <li>1. Muir JG, Gibson PR. The Low FODMAP Diet for Treatment of Irritable Bowel Syndrome and Other Gastrointestinal Disorders. <i>Gastroenterology &amp; hepatology</i>. 2013;9(7):450-2.</li> <li>2. Shepherd SJ, Parker FC, Muir JG, Gibson PR. Dietary triggers of abdominal symptoms in patients with irritable bowel syndrome: randomized placebo-controlled evidence. <i>Clinical gastroenterology and hepatology : the official clinical practice journal of the American Gastroenterological Association</i>. 2008;6(7):765-71.</li> <li>3. Magge S, Lembo A. Low-FODMAP Diet for Treatment of Irritable Bowel Syndrome. <i>Gastroenterology &amp; hepatology</i>. 2012;8(11):739-45.</li> <li>4. British Dietetic Association evidence-based guidelines for the dietary management of irritable bowel syndrome in adults. McKenzie YA, Alder A, Anderson W, Wills A, Goddard L, Gulia P, Jankovich E, Mutch P, Reeves LB, Singer A, Lomer MC, Gastroenterology Specialist Group of the British Dietetic Association. <i>J Hum Nutr Diet</i>. 2012 Jun;25(3):260-74.</li> <li>5. NICE guidelines [CG61]. Irritable bowel syndrome in adults: diagnosis and management. National Institute for Health and care Excellence. 2015.</li> </ol>
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## Appendix 2: Approval from Regional Committees for Medical and Health Research Ethics (REC)



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<b>Region:</b>	<b>Saksbehandler:</b>	<b>Telefon:</b>	<b>Vår dato:</b>	<b>Vår referanse:</b>
REK vest	Øyvind Straume	55978497	05.09.2016	2016/1098/REK vest
			<b>Deres dato:</b>	<b>Deres referanse:</b>
			14.06.2016	

Vår referanse må oppgis ved alle henvendelser

Birgitte Berentsen  
Medisinsk avdeling

### 2016/1098 Mage-tarmskolen på internett og mobilapplikasjon

**Forskningsansvarlig:** Helse Bergen HF, Helse Bergen **Prosjektleder:** Birgitte Berentsen

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK vest) i møtet 18.08.2016. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10, jf. forskningsetikkloven § 4.

#### Prosjektomtale

*Studien skal identifisere om veiledet selvhjelp over internett leder til endringer i abdominale symptomer og livskvalitet hos pasienter med irriterbar tarmsyndrom. 60 pasienter skal igjennom et 7-9 ukers opplærings- og behandlingsopplegg (Mage-tarmskolen) hvor de veiledes igjennom 5 tverrfaglige moduler utviklet av spesialister innen gastroenterologi, manuellterapi/fysioterapi, psykiatri/psykosomatikk, og klinisk ernæringsfysiologi. Studiens mål er å påvise nytteeffekter i form av forbedret livskvalitet, reduksjon av abdominale symptomer, gi ny kunnskap om tverrfaglig pasienttilnærming, samt danne grunnlag for et fremtidig nasjonalt prosjekt.*

#### Vurdering

##### Forsvarlighet

Data skal innsamles via spørreskjema. Søknaden og datainnsamlingen fremstår som velbegrunnet, og komiteen har ingen innvendinger til søknad eller protokoll.

##### Informasjonsskrivet

Informasjonsskrivet må være noe tydeligere på hva selve Mage-tarmskolen handler om, og hvorfor deltakerne blir rekruttert til studien. Revidert informasjonsskriv må ettersendes til REK vest.

##### Prosjektslutt og håndtering av data

Prosjektslutt er satt til 01.08.2026 og koblingsnøkkel skal destrueres ved projektslutt. REK vest har ingen innvendinger til dette. Det fremgår av søknaden at data skal lagres i låst skap på prosjektleder sitt kontor. Komiteen setter som vilkår at lagring gjøres i tråd med forskningsansvarlig (Helse Bergen HF) sine rutiner.

#### Vilkår

- Informasjonsskrivet skal revideres i tråd med ovennevnte merknad og ettersendes REK vest.
- Lagring av personidentifiserbare data må gjøres i tråd med forskningsansvarlig sine rutiner.

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**Besøksadresse:**  
Armauer Hansens Hus (AHH),  
Tverrfloy Nord, 2 etasje, Rom  
281. Haukelandsveien 28

**Telefon:** 55975000  
**E-post:** rek-vest@uib.no  
**Web:** <http://helseforskning.etikkom.no/>

All post og e-post som inngår i saksbehandlingen, bes adressert til REK vest og ikke til enkelte personer

Kindly address all mail and e-mails to the Regional Ethics Committee, REK vest, not to individual staff

**Vedtak**

REK vest godkjenner prosjektet på betingelse av at ovennevnte vilkår tas til følge.

*Sluttmelding og søknad om prosjektendring*

Prosjektleder skal sende sluttmelding til REK vest på eget skjema senest 01.02.2027, jf. hfl. §

12. Prosjektleder skal sende søknad om prosjektendring til REK vest dersom det skal gjøres vesentlige endringer i forhold til de opplysninger som er gitt i søknaden, jf. hfl. § 11.

*Klageadgang*

Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK vest. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK vest, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Ansgar Berg  
Prof. Dr.med  
Komitéleder

Øyvind Straume seniorkonsulent

**Kopi til:**postmottak@helse-bergen.no;

## Appendix 3: REC approval of alterations in the project



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<b>Region:</b>	<b>Saksbehandler:</b>	<b>Telefon:</b>	<b>Vår dato:</b>	<b>Vår referanse:</b>
REK vest	Øyvind Straume	55978497	13.10.2016	2016/1098/REK vest
			<b>Deres dato:</b>	<b>Deres referanse:</b>
			10.10.2016	

Vår referanse må oppgis ved alle henvendelser

Birgitte Berentsen  
Medisinsk avdeling

**2016/1098 Mage-tarmskolen på internett og mobilapplikasjon**  
**Forskningsansvarlig:** Helse Bergen HF **Prosjektleder:** Birgitte Berentsen

Vi viser til søknad om prosjektendring datert 10.10.2016 for ovennevnte forskningsprosjekt. Søknaden er behandlet av leder for REK vest på fullmakt, med hjemmel i helseforskningsloven § 11.

**Vurdering**

*Ønsket endring*

Prosjektendringen innebærer å inkludere en 15-åring i prosjektet.

REK vest ved leder vurderte saken.

*Vurdering*

Deltakelse i studien kan være fordelaktig for 15-åringen. Vi vurderer dette til å være en forsvarlig endring å gjennomføre, og har ingen innvendinger.

**Vedtak**

*REK vest godkjenner prosjektendringen i samsvar med forelagt søknad.*

*Klageadgang*

Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK vest. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK vest, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Ansgar Berg  
Prof. Dr.med  
Komitéleder

Øyvind Straume seniorkonsulent

**Kopi til:** [postmottak@helse-bergen.no](mailto:postmottak@helse-bergen.no)

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**Besøksadresse:**  
Armauer Hansens Hus (AHH),  
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**E-post:** rek-vest@uib.no  
**Web:** <http://helseforskning.etikkom.no/>

All post og e-post som inngår i  
saksbehandlingen, bes adressert til REK  
vest og ikke til enkelte personer

Kindly address all mail and e-mails to  
the Regional Ethics Committee, REK  
vest, not to individual staff

## Appendix 4: REC approval of inclusion of patients in the control group



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<b>Region:</b> REK vest	<b>Saksbehandler:</b> Trine Anikken Larsen	<b>Telefon:</b> 55978496	<b>Vår dato:</b> 07.12.2016	<b>Vår referanse:</b> 2016/1098/REK vest
			<b>Deres dato:</b> 21.11.2016	<b>Deres referanse:</b>

Vår referanse må oppgis ved alle henvendelser

Birgitte Berentsen  
Medisinsk avdeling

### 2016/1098 Mage-tarmskolen på internett og mobilapplikasjon

#### **Forskningsansvarlig: Helse Bergen HF Prosjektleder:**

Birgitte Berentsen

Vi viser til søknad om prosjektendring datert 21.11.2016 for ovennevnte forskningsprosjekt. Søknaden er behandlet av leder for REK vest på fullmakt, med hjemmel i helseforskningsloven § 11.

#### **Vurdering**

##### *Omsøkt endring*

Prosjektleder søker om å øke antall deltakere i studien.

##### **Vurdering**

Forskergruppen ønsker å sammenlikne spørreskjemabesvarelsen til pasienter som deltar i denne studien med pasienter som er henvist til Gastroseksjonen, Medisinsk avdeling, og innkalt til vanlig IBS-skole ved Læring og Mestringssenteret i Helse Bergen. De nye pasientene vil motta samme spørreskjema som i denne studien.

REK vest har ingen innvendinger til at nevnte pasientgruppe inkluderes i studien, men setter som vilkår at det innhentes samtykke fra disse pasientene på tilsvarende måte som den opprinnelige pasientgruppen. REK vest ber om at det sendes inn i revidert informasjonsskriv tilpasset pasientgruppen som nå skal inkluderes.

#### **Vilkår**

- Det må innhentes aktivt samtykke fra den nye pasientgruppen som skal inkluderes i studien. Informasjonsskrivet sendes til REK vest.

**Vedtak**

*REK vest godkjenner prosjektendringen på betingelse av at ovennevnte vilkår tas til følge.*

**Klageadgang**

Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK vest.

Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK vest, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Marit Grønning Prof.

Dr.med. komitéleder

Trine Anikken Larsen  
seniorkonsulent

**Kopi til: [postmottak@helse-bergen.no](mailto:postmottak@helse-bergen.no)**

## Appendix 5: Information and consent form



### **Forespørsel om deltakelse i forskningsprosjektet: «Mage-tarmskolen»**

#### **Bakgrunn og hensikt**

Dette er et spørsmål til deg om å delta i en forskningsstudie ved Haukeland Universitetssykehus. Formålet med studien er å identifisere om veiledet selvhjelp over internett leder til endringer i mageplager og livskvalitet hos personer med irritable tarm. Forskningsstudien skal også kvalitetssikre Mage-tarmskolen som helsetiltak.

#### **Hva innebærer studien?**

Som deltager skal du gå igjennom et opplæring -og behandlingsprogram via internett. Du veiledes igjennom 5 tverrfaglige moduler utviklet av spesialister innen gastroenterologi, manuellterapi/fysioterapi, psykiatri/psykosomatikk, og klinisk ernæringsfysiologi. Innholdet er en sammensetting av tekst, film, videosnutter og bilder. Det vil ta deg 7-9 uker og jobbe igjennom programmet. Det høres kanskje litt lenge ut, men flere uker er nødvendig når vi veileder deg igjennom den siste delen av programmet; kostholdsveiledning i modul 5.

Hele den elektroniske plattformen er utviklet av Helse Bergen's Seksjon for eHelse. Når du logger deg på bruker du høyeste sikkerhetsnivå 4, for eksempel bankbrikken din (BANK-ID).

Studien innebærer en statistisk analyse av medisinske spørreskjemaene som du får elektronisk tilgang til. Ved å signere på dette samtykkeskjemaet samtykker du også til at vi kan ta kontakt med deg 3 måneder etter din deltagelse ved Mage-tarmskolen. Om 3 og 6 måneder vil vi ta kontakt med deg og be deg fylle ut de samme skjemaene en gang til.

#### **Mulige fordeler og ulemper**

Ved å delta i studien gir du Helse Bergen muligheten til å evaluere Mage-tarmskolen som tverrfaglig helsetiltak, samt hjelpe oss til å forbedre helsetiltaket. Studien involverer ingen ekstra undersøkelser som innebærer ubehag eller risiko.

#### **Hva skjer med informasjonen om deg?**

Det er frivillig å delta i studien. Om du nå sier ja til å delta, kan du senere når som helst og uten å oppgi noen grunn, trekke tilbake ditt samtykke. Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien.

Alle opplysningene om deg vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. Et tilfeldig nummer blir tildelt opplysningene som lagres om deg. Det er bare prosjektleder i studien som vil ha tilgang til nøkkelen som kobler dine spørreskjemabesvarelser til deg, og dette vil lagres separat fra dataene vi samler inn. Når studien er over vil din personlige informasjon destrueres, og dataene vil lagres anonymt. Det vil da ikke være mulig å koble din identitet til dine besvarelser.

Det vil ikke være mulig å identifisere deg i resultatene fra studien når disse publiseres.



**Ytterligere informasjon om studien finnes i kapittel A, og dine rettigheter finnes i Kapittel B. Ved ytterligere spørsmål, kontakt Birgitte Berentsen, Nasjonal Kompetansetjeneste for Funksjonelle Mage-tarmsykdommer, tlf 55 97 29 99 eller epost [birgitte.berentsen1@helse-bergen.no](mailto:birgitte.berentsen1@helse-bergen.no).**

### **Kapittel A: Utdypende forklaring om hva studien innebærer**

Kriteriet for deltagelse i forskningsstudien, «Mage-tarmskolen», er at du har fått diagnosen «irritabel tarm» hos fastlegen eller på sykehuset hos spesialisthelsetjenesten. Det er viktig at du ikke opplever det som vi kaller for «rød-flagg symptomer» som blod i avføringen, feber, uforklarlig raskt vekttap eller diare om natten mens du sover.

Denne forskningsstudien skal identifisere om veiledet selvhjelp over internett leder til endringer i mageplager og livskvalitet hos personer med irritabel tarm.

Du vil bli bedt om å fylle medisinske spørreskjema før du begynner på «Mage-tarmskolen». Skjemaene er listet opp nedenfor. Vi vil kontakte deg igjen 3 og 6 måneder etter deltagelsen, og be deg fylle ut de samme skjemaene en gang til. Det tar ca. 30 minutter å fylle ut skjemaene, per gang. Vi vil analysere besvarelsene du har gitt i skjemaene og gjøre en statistisk analyse for å se om dine mageplager og livskvalitet har endret seg etter deltagelsen i «Mage-tarmskolen». Det vil ikke være mulig å identifisere deg eller dine besvarelser i materialet som publiseres etter studien.

Studien vil ikke medføre noen økonomiske utgifter for deg som deltager.

### **Kapittel B: Informasjon om dine rettigheter**

#### **Personvern**

Opplysninger som registreres om deg er besvarelser på følgende skjema:

- 1) Gradering av mageplager (IBS-SSS)
- 2) Spørreskjema om mageplager (ROMA III)
- 3) Spørsmål om uro og bekymring (EPQ-N-12)
- 4) Spørsmål som handler om hvordan du oppfatter helsen din (RAND-36)
- 5) Personlighetstest (NEO-PI-3 og NEO-FFI-3)
- 6) Spørsmål om angst og depresjon (HAD)
- 7) Spørsmål om livskvalitet i forbindelse med mageplager (IBS-QOL)
- 8) NKFM's spørreskjema om symptomer, hyppighet og sykehusbesøk.

Informasjonen du gir oss vil registreres og lagres i en elektronisk database på en forskningsserver ved Haukeland Universitetssykehus. Denne databasen vil ikke inneholde identifiserbar informasjon om deg. Ditt navn og besvarelsene som tilhører deg vil kodes med et tilfeldig nummer. Nøkkelen til koden er det bare prosjektleder som har tilgang til.

Helse Bergen HF, Haukeland Universitetssykehus ved administrerende direktør er forskningsansvarlig.

#### **Informasjon om utfallet av studien**

Årsrapporter som presenterer resultater fra foretakets forskningsprosjekter er offentlig tilgjengelige på <http://helse-bergen.no/NKFM> og/eller <http://forskingsprosjekter.ihelse.net/>. Vi viser også til våre forskningsnettsider på: <http://www.helse-bergen.no/fagfolk/forskning/>.

<b>Skjema for samtykke til deltakelse i forskningsprosjekt - Voksne over 16 år</b>		
Prosjekttittel <b>Kvalitetssikring av «IBS-skole» som helsetiltak</b>		Prosjektnummer
Prosjektleders navn Birgitte Berentsen		Klinikk/avdeling Nasjonal Kompetansetjeneste for Funksjonelle Magetarmsykdommer, Medisinsk Avd., HUS
Det er frivillig å delta i studien. Dersom du ønsker å delta, undertegner du denne samtykkeerklæringen. Om du nå sier ja til å delta, kan du senere når som helst og uten å oppgi noen grunn, trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte prosjektleder.		
Jeg er villig til å delta i forskningsprosjektet:		
Navn med blokkbokstaver		Fødselsnummer (11 siffer)
Dato	Underskrift	
<b>Fylles ut av representant for forskningsprosjektet</b>		
Jeg bekrefter å ha gitt informasjon om forskningsprosjektet:		
Dato	Underskrift	Brukerkode (4-tegnkode)
Eventuelle kommentarer:		

## Appendix 6: Additional write about the content of the eHealth program



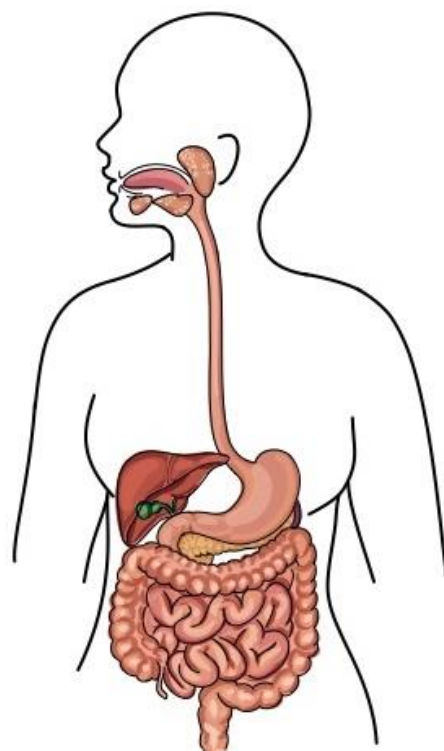
Til

Her kommer nødvendig informasjon for å kunne være med vårt forskningsprosjekt, samt litt informasjon om Mage-tarmskolen.

Mage-tarmskolen er en internettbasert skole som består av 5 moduler. I *modul 1* vil du bli introdusert for lege Trygve Hausken, hvor du blant annet får kunnskap om hvordan fordøyelsessystemet fungerer og hva irritabel tarm er. I *Modul 2* vil du bli introdusert for fysioterapeut Eirik Østvold, hvor du vil lære om sammenhengen mellom irritabel tarm og anspenhet og muskelplager, samt få demonstrasjon i riktig pusteteknikk. I *modul 3* vil du bli introdusert for klinisk ernæringsfysiolog Synne Ystad, hvor du vil lære om generelle kost- og livsstilsråd. I *modul 4* vil psykiater Jørn Bødtker introdusere kognitiv terapi, samt gi deg hjemme-øvelser i oppmerksomhetstrening og eksponering. I *modul 5* vil klinisk ernæringsfysiolog Synne Ystad og klinisk ernæringsfysiolog Ingrid Sjørgard Skjold gi opplæring i lavFODMAP-dietten, samt gi tilgang på matlagingsfilmer. I denne siste modulen, vil du også få muligheten til å stille spørsmål til en klinisk ernæringsfysiolog dersom det er noe du lurer på.

Dersom du har lyst, kan du se introduksjonsvideoen til Mage-tarmskolen med «Silje»:

[https://youtu.be/JBTm\\_7GD4wM](https://youtu.be/JBTm_7GD4wM)



**Vedlagt har vi sendt samtykkeskjema og 2 spørreskjema som du må skrive under på og sende tilbake til oss, helst så fort som mulig, for å kunne delta i studien.**

*Dersom vi har fått samtykkeskjema og spørreskjema underskrevet fra deg vil du bli registrert som deltaker i vårt forskningsprosjekt. Du vil dermed bli tilsendt en tekstmelding med en link hvor du kan logge deg på. Du kan selv disponere når du har tid til å gjennomføre skolen. Vi anbefaler å reflektere og sette av tid til å utføre hjemme-oppgavene slik at du får størst mulig utbytte av Mage-tarmskolen.*

*Vi håper du setter av tid til å svare på spørreskjemaene du får på starten av Mage-tarmskolen, samt ettersendt etter fullføring av skolen, slik at vi kan kvalitetssikre og dermed videreutvikle en nasjonal Mage-tarmskole som kan hjelpe enda flere personer med irritabel tarm.*

*Vi har tro på at økt forståelse og kunnskap vil gi økt trygghet og mulighet for bedre mestring av kronisk/tilbakevendende plager. Vi håper derfor at denne hjelp til selvhjelp vil bidra til at du får et stort utbytte av Mage-tarmskolen!*

*Vi ønsker deg lykke til!*

Med vennlig hilsen

Nasjonal kompetansetjeneste for Funksjonelle Mage-tarmsykdommer,  
Medisinsk avdeling, Haukeland Universitetssykehus



## Appendix 7: Rome III criteria

### ROME III SPØRRESKJEMA – MAGEPLAGER

13	I løpet av de siste 3 måneder, hvor ofte har du følt deg ubehagelig mett etter et vanlig stort måltid?	Aldri	Mindre enn 1 dag i måneden	En dag i måneden	2-3 dager i måneden	En dag i uka	Mer enn 1 dag i uka	Hver dag
14	Har du hatt denne ubehagelige metthetsfølelsen etter måltid i 6 måneder eller lenger?	Nei			Ja			
15	I løpet av de siste 3 måneder, hvor ofte har du ikke kunnet fullføre et vanlig stort måltid?	Aldri	Mindre enn 1 dag i måneden	En dag i måneden	2-3 dager i måneden	En dag i uka	Mer enn 1 dag i uka	Hver dag
16	Har du hatt dette problemet med ikke å kunne fullføre et vanlig stort måltid i 6 måneder eller lenger?	Nei			Ja			
17	I løpet av de siste 3 måneder, hvor ofte har du hatt smerter eller brenning midt i magen, over navlen, men ikke i brystet?	Aldri	Mindre enn 1 dag i måneden	En dag i måneden	2-3 dager i måneden	En dag i uka	Mer enn 1 dag i uka	Hver dag
18	Har du hatt denne smerten eller brenningen i 6 måneder eller lenger?	Nei			Ja			
19	Kom og forsvant denne smerten eller brenningen fullstendig i løpet av samme dag?	Sjelden/aldri	Noen ganger	Ofte	Det meste av tiden	Alltid		
20	Hvor alvorlig var vanligvis smerten eller brenningen i midten av magen, over navlen?	Svært mild	Mild	Moderat	Sterk	Svært sterk		
21	Ble denne smerten eller brenningen påvirket av spising?	Ikke påvirket av spising		Mer smerter etter spising		Mindre smerter etter spising		
22	Ble denne smerten eller brenningen lindret av å ta syrenøytraliserende midler?	Sjelden/aldri	Noen ganger	Ofte	Det meste av tiden	Alltid		
23	Ble denne smerten eller brenningen vanligvis bedre eller forsvant den etter at du hadde hatt avføring eller luftavgang fra endetarmen?	Sjelden/aldri	Noen ganger	Ofte	Det meste av tiden	Alltid		
24	Når denne smerten eller brenningen begynte, hadde du vanligvis endring i antall avføringer (enten hyppigere eller sjeldnere avføring)?	Sjelden/aldri	Noen ganger	Ofte	Det meste av tiden	Alltid		
25	Når denne smerten eller brenningen begynte, hadde du vanligvis løsere eller hardere avføring?	Sjelden/aldri	Noen ganger	Ofte	Det meste av tiden	Alltid		
26	I løpet av siste 3 måneder, hvor ofte har du hatt plagsom kvalme?	Aldri	Mindre enn 1 dag i måneden	En dag i måneden	2-3 dager i måneden	En dag i uka	Mer enn 1 dag i uka	Hver dag
41	I løpet av siste 3 måneder, hvor ofte har du hatt ubehag eller smerter noe sted i magen?	Aldri	Mindre enn 1 dag i måneden	En dag i måneden	2-3 dager i måneden	En dag i uka	Mer enn 1 dag i uka	Hver dag
42	Har du hatt kun smerter (ikke ubehag eller blanding av ubehag og smerter)?	Sjelden/aldri	Noen ganger	Ofte	Det meste av tiden	Alltid		

43	For kvinner: Har du kun hatt dette ubehaget eller smerten i forbindelse med menstruasjonsblødning, og ikke til andre tider?	Nei	Ja	Ikke aktuelt fordi jeg ikke har menstruasjon				
44	Når du hadde denne smerten, hvor ofte hemmet eller begrenset den daglige gjøremål (for eksempel arbeid, gjøremål i hjemmet eller sosiale aktiviteter)?	Sjelden/aldri	Noen ganger	Ofte	Det meste av tiden	Alltid		
45	Har du hatt dette ubehaget eller smerten i 6 måneder eller lenger?	Nei		Ja				
46	Hvor ofte ble ubehaget eller smerten i magen bedre eller forsvant etter at du hadde hatt avføring?	Sjelden/aldri	Noen ganger	Ofte	Det meste av tiden	Alltid		
47	Når dette ubehaget eller smerten begynte, hadde du hyppigere avføring?	Sjelden/aldri	Noen ganger	Ofte	Det meste av tiden	Alltid		
48	Når dette ubehaget eller smerten begynte, hadde du sjeldnere avføring?	Sjelden/aldri	Noen ganger	Ofte	Det meste av tiden	Alltid		
49	Når dette ubehaget eller smerten begynte, hadde du løsere avføring?	Sjelden/aldri	Noen ganger	Ofte	Det meste av tiden	Alltid		
50	Når dette ubehaget eller smerten begynte, hvor ofte hadde du hardere avføring?	Sjelden/aldri	Noen ganger	Ofte	Det meste av tiden	Alltid		
52	I løpet av de siste 3 måneder, hvor ofte har du hatt færre enn tre (0-2) avføringer hver uke?	Sjelden/aldri	Noen ganger	Ofte	Det meste av tiden	Alltid		
53	I løpet av de siste 3 måneder, hvor ofte har du hatt hard eller klumpete avføring?	Sjelden/aldri	Noen ganger	Ofte	Det meste av tiden	Alltid		
60	I løpet av de siste 3 måneder, hvor ofte har du hatt 4 eller flere avføringer i løpet av en dag?	Sjelden/aldri	Noen ganger (ca 25 % av tiden)	Ofte	Det meste av tiden	Alltid		
61	I løpet av de siste 3 måneder, hvor ofte har du hatt løs, grøtete eller vandig avføring?	Sjelden/aldri	Noen ganger	Ofte	Det meste av tiden	Alltid		
66	I løpet av de siste 3 måneder, hvor ofte har du vært oppblåst eller utspilt i magen?	Aldri	Mindre enn 1 dag i måneden	En dag i måneden	2-3 dager i måneden	En dag i uka	Mer enn 1 dag i uka	Hver dag
68	I løpet av de siste 3 måneder, hvor ofte har du hatt vedvarende smerter i midten eller på høyre side øverst i magen?	Aldri	Mindre enn 1 dag i måneden	En dag i måneden	2-3 dager i måneden	En dag i uka	Mer enn 1 dag i uka	Hver dag
69	Varte denne smerten 30 minutter eller lenger?	Sjelden/aldri	Noen ganger	Ofte	Det meste av tiden	Alltid		
70	Bygget denne smerten seg opp til en vedvarende, sterk smerte?	Sjelden/aldri	Noen ganger	Ofte	Det meste av tiden	Alltid		
71	Forsvant denne smerten fullstendig mellom hver gang den kom?	Sjelden/aldri	Noen ganger	Ofte	Det meste av tiden	Alltid		
72	Hindret denne smerten deg i vanlige aktiviteter, eller førte den til at du øyeblikkelig oppsøkte lege eller legevakt?	Sjelden/aldri	Noen ganger	Ofte	Det meste av tiden	Alltid		

## Appendix 8: IBS-QOL

DAGENS DATO: \_\_\_\_\_  
                  DAG      MÅNED      ÅR

DELTAKERS/PASIENTS ID:

### **VENNLIGST LES DETTE NØYE**

PÅ DE FØLGENDE SIDENE VIL DU FINNE UTSAGN OM TARMPROBLEMER (IRRITABEL TARM-SYNDROM) OG HVORDAN DE PÅVIRKER DEG.

FOR HVERT UTSAGN BER VI DEG VELGE DET SVARET SOM PASSER BEST TIL DEG, OG SLÅ EN RING RUNDT TALLET FORAN SVARET DITT.

HVIS DU ER USIKKER PÅ HVA DU SKAL SVARE, BER VI DEG SVARE SÅ GODT DU KAN. DET FINNES INGEN RETTE ELLER GALE SVAR.

SVARENE DINE VIL BLI BEHANDLET STRENGT KONFIDENSIELT.

HVIS DU HAR NOEN SPØRSMÅL, BER VI DEG KONTAKTE:

**\*\*OPPGI NAVN OG ADRESSE PÅ SENTER HER\*\***

Sporreskjema om livskvalitet ved irritable tarm-syndrom (IBS-QOL) er utviklet av Ph.D. Donald L. Patrick, University of Washington, Dr. Douglas A. Drossman, University of North Carolina, Novartis Pharmaceuticals Corporation og Novartis Pharma AG.

Forfatterne har felles copyright til IBS-QOL og alle oversettelser av det.

## Hvordan du føler deg

Vi ber deg tenke over livet ditt den siste måneden (de siste 30 dagene), og se på utsagnene nedenfor. Hvert utsagn har fem ulike svar. For hvert utsagn ber vi deg slå en ring rundt tallet foran det svaret som best beskriver dine følelser.

1. Jeg føler meg hjelpelos på grunn av tarmproblemene mine. *(Slå ring rundt ett tall.)*
  - 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT
  
2. Jeg blir flau på grunn av lukt som skyldes tarmproblemene mine. *(Slå ring rundt ett tall.)*
  - 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT
  
3. Det er plagsomt for meg at jeg bruker mye tid på toalettet. *(Slå ring rundt ett tall.)*
  - 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT
  
4. Jeg føler meg sårbar for andre sykdommer på grunn av tarmproblemene mine. *(Slå ring rundt ett tall.)*
  - 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT
  
5. Jeg føler meg tykk/oppblåst på grunn av tarmproblemene mine. *(Slå ring rundt ett tall.)*
  - 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT

Vennligst fortsett på neste side



6. Jeg føler at jeg mister kontrollen over livet mitt på grunn av tarmproblemene mine. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT MYE
7. Jeg føler at jeg gleder meg mindre over livet på grunn av tarmproblemene mine. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT MYE
8. Jeg føler meg utilpass når jeg snakker om tarmproblemene mine. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT
9. Jeg føler det er deprimerende å ha tarmproblemer. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT
10. Jeg føler meg isolert fra andre på grunn av tarmproblemene mine. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT

Vennligst fortsett på neste side

11. Jeg må passe på hvor mye mat jeg spiser på grunn av tarmproblemene mine. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT
12. Tarmproblemene gjør seksuell aktivitet vanskelig for meg. *(Slå ring rundt ett tall.)*  
*(Hvis dette er uaktuelt for deg, slå ring rundt "IKKE I DET HELE TATT".)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT
13. Jeg føler meg sint og ergerlig for at jeg har tarmproblemer. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT
14. Jeg føler at jeg irriterer andre på grunn av tarmproblemene mine. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT MYE
15. Jeg bekymrer meg for at tarmproblemene mine skal bli verre. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT MYE

Vennligst fortsett på neste side

16. Jeg føler meg irritable på grunn av tarmproblemene mine. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT
17. Jeg bekymrer meg for at folk tror at jeg overdriver tarmproblemene mine. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT MYE
18. Jeg føler at jeg får gjort mindre på grunn av tarmproblemene mine. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT MYE
19. Jeg må unngå stressende situasjoner på grunn av tarmproblemene mine. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT MYE
20. Tarmproblemene mine gjør at jeg får mindre lyst på sex. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT MYE

Vennligst fortsett på neste side

21. Tarmproblemene mine begrenser hva jeg kan ha på meg. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT MYE
22. Jeg må unngå fysisk anstrengende aktiviteter på grunn av tarmproblemene mine. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT MYE
23. Jeg må passe på hva slags mat jeg spiser på grunn av tarmproblemene mine. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT
24. På grunn av tarmproblemene mine er det vanskelig for meg å omgås folk som jeg ikke kjenner godt. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT
25. Jeg føler meg slapp og sløv på grunn av tarmproblemene mine. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT

Vennligst fortsett på neste side

26. Jeg føler at jeg er "uren" på grunn av tarmproblemene mine. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT MYE
27. Lange reiser er vanskelige for meg på grunn av tarmproblemene mine. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT
28. Jeg føler meg oppgitt og frustrert over at jeg ikke kan spise når jeg vil på grunn av tarmproblemene mine. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT
29. Det er viktig å være i nærheten av et toalett på grunn av tarmproblemene mine. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT
30. Livet mitt dreier seg om tarmproblemene mine. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT MYE

Vennligst fortsett på neste side

31. Jeg bekymrer meg for å miste kontrollen over endetarmen og avføringen. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT MYE
32. Jeg er redd for at jeg ikke vil klare å få avføring. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT
33. Tarmproblemene mine virker forstyrrende på forholdet til mine nærmeste. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT
34. Jeg føler at ingen forstår tarmproblemene mine. *(Slå ring rundt ett tall.)*
- 1 IKKE I DET HELE TATT
  - 2 LITT
  - 3 MODERAT
  - 4 EN GOD DEL
  - 5 SVÆRT MYE

## Appendix 9: IBS-SSS

### GRADERING AV MAGEPLAGER

(Aliment Pharmacol Thor 1997; 11:305-402)

1. a) Er du for tiden plaget med magesmerter?

JA

NEI

Sett kryss over  
Ja eller Nei

Ikke fyll  
ut feltene  
under:

b) Hvis ja, hvor alvorlige er disse magesmertene?  
(Sett kryss på linjen for beskrivelsen som passer best)



c) Anslå antall dager du har smertene i løpet av en 10 dagers periode

Eksempel: 4 betyr at du har vondt i magen i 4 av 10 dager.  
Har du vondt i magen hver dag, skriver du 10.

Antall dager med smerte:  x 10

2. a) Er du for tiden plaget med oppblåsthet eller stinnhet i magen (som du ikke forbinder med menstruasjon)?

JA

NEI

Sett kryss over  
Ja eller Nei

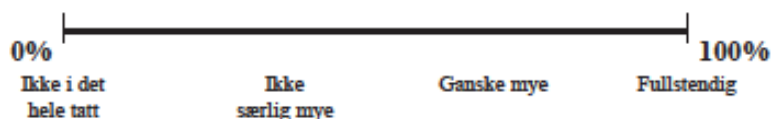
b) Hvis ja, hvor alvorlig er denne oppblåstheten/stinnheten?  
(Sett kryss på linjen for beskrivelsen som passer best)



3. Hvor fornøyd er du med avføringsmonsteret ditt?  
(Sett kryss på linjen for beskrivelsen som passer best)



4. I hvor stor grad foler du at mageplagene dine påvirker eller forstyrrer livet ditt?  
(Sett kryss på linjen for beskrivelsen som passer best)



Sum

## Appendix 10: HADS

### HADS – Hospital Anxiety and Depression Scale

Leger er klar over at følelser spiller en viktig rolle ved de fleste sykdommer. Dersom legen din kjenner til følelsene dine, vil han eller hun være i bedre stand til å hjelpe deg.

Dette spørreskjemaet er utformet for å hjelpe legen din til å forstå hvordan du føler deg. Les hvert utsagn nedenfor og **velg det svaret** som best beskriver hvordan du har følt deg de siste 7 dagene.

Ikke bruk for lang tid på å svare, din første respons på hvert spørsmål vil trolig gi et riktigere svar enn et nøye gjennomtenkt svar.

#### 1. Jeg føler meg anspent

- For det meste
- Ofte
- Noen ganger
- Ikke i det hele tatt

#### 2. Jeg gleder meg fremdeles over ting jeg pleide å glede meg over

- Absolutt like mye som før
- Ikke fullt så mye som før
- Bare litt
- Nesten ikke

#### 3. Jeg får en slags følelse av frykt som om noe forferdelig kommer til å skje

- Absolutt og ganske ille
- Ja, men ikke så altfor ille
- Litt, men det bekymrer meg ikke
- Ikke i det hele tatt

#### 4. Jeg kan le og se det morsomme i situasjoner

- Like mye som før
- Ikke like mye nå som før
- Absolutt ikke så mye nå som før
- Ikke i det hele tatt



**5. Jeg har hodet fullt av urovekkende tanker**

- For det meste
- Ofte
- Noen ganger
- En gang i blant

**6. Jeg er i godt humør**

- Aldri
- Ikke så ofte
- Noen ganger
- For det meste

**7. Jeg kan sitte rolig og føle meg avslappet**

- Ja, absolutt
- Ofte
- Ikke så ofte
- Ikke i det hele tatt

**8. Jeg føler det som om jeg fungerer langsommere enn før**

- Nesten hele tiden
- Veldig ofte
- Noen ganger
- Ikke i det hele tatt

**9. Jeg føler meg urolig som om jeg har sommerfugler i magen**

- Ikke i det hele tatt
- Noen ganger
- Ofte
- Veldig ofte

**10. Jeg har sluttet å bry meg om hvordan jeg ser ut**

- Ja, absolutt
- Jeg bryr meg ikke så mye som jeg burde
- Det kan nok hende at jeg ikke bryr meg fullt så mye
- Jeg bryr meg like mye som jeg alltid har gjort

**11. Jeg føler meg rastløs som om jeg stadig må være i aktivitet**

- Uten tvil, i en sterk grad
- I en ganske stor grad
- Ikke noe særlig
- Ikke i det hele tatt

**12. Jeg ser med glede frem til ting**

- Like mye som jeg alltid har gjort
- Heller mindre enn jeg har pleid å gjøre
- Absolutt mindre enn jeg har pleid å gjøre
- Nesten ikke i det hele tatt

**13. Jeg kan plutselig få en følelse av panikk**

- Veldig ofte
- Ofte
- Ikke så ofte
- Ikke i det hele tatt

**14. Jeg kan glede meg over en god bok eller et radio- eller TV-program**

- Ofte
- Noen ganger
- Ikke så ofte
- Veldig sjelden

**Vennligst kontroller at du har svart på alle spørsmålene.**

## Appendix 11: RAND-36

### RAND-36 Din helse

Spørsmålene under handler om hvordan du oppfatter helsen din. Disse opplysningene vil hjelpe oss til å forstå hvordan du føler deg og hvor godt du er i stand til å utføre dine vanlige aktiviteter.

Hvert spørsmål skal besvares ved å sette et kryss (X) i den boksen som passer best for deg.

1. Stort sett, vil du si at helsen din er:

Utmerket	Veldig god	God	Nokså god	Dårlig
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Sammenlignet med for ett år siden, hvordan vil du si at helsen din stort sett er nå?

Mye bedre nå enn for ett år siden	Litt bedre nå enn for ett år siden	Omtrent som for ett år siden	Litt dårligere nå enn for ett år siden	Mye dårligere nå enn for ett år siden
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. De neste spørsmålene handler om aktiviteter som du kanskje utfører i løpet av en vanlig dag. Er helsen din slik at den begrenser deg i utførelsen av disse aktivitetene nå?

Hvis ja, hvor mye? [Kryss (X) en boks på hver linje.]

	Ja, begrenser meg mye	Ja, begrenser meg litt	Nei, begrenser meg ikke i det hele tatt
a Anstrengende aktiviteter som å løpe, løfte tunge gjenstander, delta i anstrengende idrett	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b Moderate aktiviteter som å flytte et bord, støvsuge, gå en spasertur eller drive med hagearbeid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c Løfte eller bære poser med dagligvarer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d Gå opp trappen flere etasjer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e Gå opp trappen én etasje	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f Bøye deg eller gå ned på kne	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g Gå mer enn to kilometer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h Gå flere hundre meter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i Gå hundre meter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j Dusje eller kle på deg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RAND Corporation, USA, har opphavsrett til det opprinnelige skjemaet, som ble utviklet innen Medical Outcomes Study. Nasjonalt kunnskapssenter for helsehjelpen distribuerer oversettelsen av RAND-36, norsk versjon 1.

4. I løpet av de siste fire ukene, har du hatt noen av de følgende problemene i arbeidet ditt eller i andre daglige aktiviteter på grunn av din fysiske helse?

	Ja	Nei
a Kuttet ned på hvor mye tid du brukte på arbeid eller andre aktiviteter	<input type="checkbox"/>	<input type="checkbox"/>
b Fått gjort mindre enn du ønsket	<input type="checkbox"/>	<input type="checkbox"/>
c Vært begrenset i type arbeidsoppgaver eller andre aktiviteter	<input type="checkbox"/>	<input type="checkbox"/>
d Hatt problemer med å utføre arbeidet eller andre aktiviteter (for eksempel at det krevde en ekstra innsats av deg)	<input type="checkbox"/>	<input type="checkbox"/>

5. I løpet av de siste fire ukene, har du hatt noen av de følgende problemene i arbeidet ditt eller i andre daglige aktiviteter på grunn av følelsesmessige problemer (som å føle seg engstelig eller deprimeret)?

	Ja	Nei
a Kuttet ned på hvor mye tid du brukte på arbeid eller andre aktiviteter	<input type="checkbox"/>	<input type="checkbox"/>
b Fått gjort mindre enn du ønsket	<input type="checkbox"/>	<input type="checkbox"/>
c Utført arbeid eller andre aktiviteter mindre grundig enn vanlig	<input type="checkbox"/>	<input type="checkbox"/>

6. I løpet av de siste fire ukene, i hvilken grad har den fysiske helsen din eller følelsesmessige problemer påvirket dine vanlige sosiale aktiviteter med familie, venner, naboer eller andre grupper mennesker?

Ikke i det hele tatt	Litt	Moderat	Ganske mye	Ekstremt mye
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. Hvor mye kroppslige smerter har du hatt i løpet av de siste fire ukene?

Ingen	Veldig svake	Svake	Moderate	Sterke	Veldig sterke
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. I løpet av de siste fire ukene, hvor mye har smerter påvirket det vanlige arbeidet ditt (gjelder både arbeid utenfor hjemmet og husarbeid)?

Ikke i det hele tatt      Litt      Moderat      Ganske mye      Ekstremt mye

9. De neste spørsmålene handler om hvordan du føler deg og hvordan du har hatt det i løpet av de siste fire ukene. For hvert spørsmål, ber vi deg velge det svaret som best beskriver hvordan du har følt deg.

Hvor ofte i løpet av de siste fire ukene:

		Hele tiden	Mesteparten av tiden	En god del av tiden	Noe av tiden	Litt av tiden	Aldri
a	Har du følt deg full av liv?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b	Har du vært veldig nervøs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c	Har du følt deg så langt nede at ingenting kunne gjøre deg glad?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d	Har du følt deg rolig og avslappet?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e	Har du hatt mye overskudd?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f	Har du følt deg nedfor og deprimeret?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g	Har du følt deg utslitt	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h	Har du følt deg glad?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i	Har du følt deg sliten?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. I løpet av de siste fire ukene, hvor mye av tiden har den fysiske helsen din eller følelsesmessige problemer påvirket dine sosiale aktiviteter (som å besøke venner, slektninger osv.)?

Hele tiden      Mesteparten av tiden      En del av tiden      Litt av tiden      Aldri

11. Hvor RIKTIG eller GAL er hver av de følgende påstandene for deg?

	Helt riktig	Stort sett riktig	Vet ikke	Stort sett galt	Helt galt
a Det virker som om jeg blir syk litt lettere enn andre	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b Jeg er like frisk som de fleste jeg kjenner	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c Jeg regner med at helsen min blir dårligere	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d Helsen min er utmerket	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## Appendix 12: NKFM0



Kjære deltager, Tusen takk for at du svarer på disse spørsmålene. Din besvarelse er helt *anonym* og vil hjelpe NKFM til å evaluere kvaliteten ved helsetjenestetilbudet ved Haukeland Universitetssjukehus

- 1) Hva er din alder..... 2) Mann  Kvinne
  
- 2) Hvor mange ganger har du vært til time eller innlagt ved sykehus (spesialisthelsetjenesten) pga mageproblemer de siste årene? Timer hos fastlegen skal ikke telles med  
A) De siste 5 årene ..... B) Det siste året.....
  
- 3) Hvor mange ganger har du vært til time hos din fastlege pga mageproblemer de siste årene? Timer eller innleggelse på sykehus skal ikke telles med.  
A) De siste 5 årene ..... B) Det siste året.....
  
- 4) Hva er antallet gastroenterologiske undersøkelser du har vært igjennom totalt til nå?  
A) Gastroskopi..... B) Koloskopi.....
  
- 5) Opplever du plager fra andre deler av kroppen? (for eksempel muskelsmerter (fibromyalgi), hodepine, smerter fra underlivet, kronisk tretthet, depresjon, søvnproblemer) Nevn nedenfor :  
.....
  
- 6) Har du kjenneskap til hva som var den utløsende faktoren for dine symptomer? (for eksempel: infeksjon, matforgiftning, operasjon, stress) Nevn nedenfor:  
.....
  
- 7) Hvor lenge har du levd med magesmerter? (Antall år eller måneder) .....
  
- 8) Smertene har oppstått: A) Gradvis  B) Ved akutt infeksjon   
C) Etter antibiotika behandling
  
- 9) Hvor mange ganger har du vært sykemeldt pga magesmerter?  
A) Antall ganger de siste 5 årene.....  
B) Antall dager det siste året.....  
C) Antall dager den siste måneden.....

**Senterleder:**  
Prof. Jan Hatlebakk, MD., PhD  
Tel: 55 97 29 70  
[jan.qumar.hatlebakk@helse-bergen.no](mailto:jan.qumar.hatlebakk@helse-bergen.no)


**Koordinator :**  
Birgitte Berentsen, PhD  
Tel: 55972999/91545159  
[birgitte.berentsen1@helse-bergen.no](mailto:birgitte.berentsen1@helse-bergen.no)

**Postadresse:**  
NKFM, Medisinsk Avdeling  
Haukeland Universitetssjukehus, 5021 Bergen  
[www.helse-bergen.no/no/NKFM](http://www.helse-bergen.no/no/NKFM)

## Appendix 13: NKFM6

NKFM6 Spørreskjema

**HELSE BERGEN**  
Haukeland Universitetssykehus  
National Kompetansesenter for Funktionelle Mage-tarmsykdommer



Kjære deltager,

Tusen takk for at du deltar i denne studien! Dokumentene du har foran deg nå er de samme spørreskjemaene som du svarte på da du deltok på «IBS-skolen» i høst. Din besvarelse er helt anonym.

1) Hva er din alder..... 2) Mann  Kvinne

2) Opplever du at din deltagelse på IBS-skolen har hjulpet deg generelt  
 Ja  Nei  Vet ikke

3) Opplever du at din deltagelse på IBS-skolen har hjulpet deg til å  
 bedre forstå de forskjellige aspektene ved irritable tarmsyndrom  
 håndtere symptomer bedre  
 føler deg mindre alene om plagene  
 kommunisere bedre med fastlegen  
 kommunisere bedre med familie og venner  
 leve bedre med irritable tarm

4) Har du forsøkt lavFODMAP dietten ?  
 Ja  Nei

5) Opplever du at lavFODMAP-dietten gav deg symptomlette?  
 Ja  Nei

6) Vil du anbefale IBS-skolen til andre med irritable tarm?  
 Ja  Nei  Vet ikke

---

**Senterleder:**  
Prof. Jan Hatlebakk, MD., PhD  
Tel: 55 97 29 70  
[jan.gunnar.hatlebakk@helse-bergen.no](mailto:jan.gunnar.hatlebakk@helse-bergen.no)

**Koordinator:**  
Birgitte Berentsen, PhD  
Tel: 65972988/91546169  
[birgitte.berentsen1@helse-bergen.no](mailto:birgitte.berentsen1@helse-bergen.no)

**Postadresse:**  
NKFM, Medisinsk Avdeling  
Haukeland Universitetssykehus, 5021 Bergen  
[www.helse-bergen.no/nkfm](http://www.helse-bergen.no/nkfm)



## Appendix 14: HBNKFM0



### HBNKFM 0

Kjære deltager, Tusen takk for at du svarer på disse spørsmålene. Din besvarelse er helt anonym og vil hjelpe NKFM til å evaluere kvaliteten ved helsetjenestetilbudet ved Haukeland Universitetssjukehus

- 1) Hva er din alder..... 2) Mann  Kvinne
  
- 2) Hvor mange ganger har du vært til time eller innlagt ved sykehus (spesialisthelsetjenesten) pga mageproblemer de siste årene ? Timer hos fastlegen skal ikke telles med  
A) De siste 5 årene ..... B) Det siste året.....
  
- 3) Hvor mange ganger har du vært til time hos din fastlege pga mageproblemer de siste årene ? Timer eller innleggelse på sykehus skal ikke telles med.  
B) De siste 5 årene ..... B) Det siste året.....
  
- 4) Hva er antallet gastroenterologiske undersøkelser du har vært igjennom totalt til nå?  
A) Gastroskopi..... B) Koloskopi.....
  
- 5) Opplever du plager fra andre deler av kroppen? (for eksempel muskelsmerter (fibromyalgi), hodepine, smerter fra underlivet, kronisk tretthet, depresjon, søvnproblemer) Nevn nedenfor :  
.....
  
- 6) Har du kjenneskap til hva som var den utløsende faktoren for dine symptomer? (for eksempel: infeksjon, matforgiftning, operasjon, stress) Nevn nedenfor:  
.....
  
- 7) Hvor lenge har du levd med magesmerter? (Antall år eller måneder) .....
  
- 8) Smertene har oppstått: A) Gradvis  B) Ved akutt infeksjon   
C) Etter antibiotika behandling
  
- 9) Hvor mange ganger har du vært sykemeldt pga magesmerter?  
A) Antall ganger de siste 5 årene.....  
B) Antall dager det siste året.....  
C) Antall dager den siste måneden.....

**Senterleder:**  
Prof. Jan Hatlebakk, MD., PhD  
Tel: 55 97 29 70  
[jan.gunnar.hatlebakk@helse-bergen.no](mailto:jan.gunnar.hatlebakk@helse-bergen.no)

**Koordinator :**  
Birgitte Berentsen, PhD  
Tel: 55972999/91545159  
[birgitte.berentsen1@helse-bergen.no](mailto:birgitte.berentsen1@helse-bergen.no)

**Poetadresse:**  
NKFM, Medisinsk Avdeling  
Haukeland Universitetssykehus, 5021 Bergen  
[www.helse-bergen.no/no/NKFM](http://www.helse-bergen.no/no/NKFM)



10. Har du forsøkt lavFODMAP-dietten tidligere? A) Ja  B) Nei

11. Går du på lavFODMAP-dietten nå? A) Ja  B) Nei

Hvis ja, hvor lenge har du stått på lavFODMAP-dietten (antall år, måneder, uker, dager):

.....

I hvor stor grad har du opplevd at lavFODMAP-dietten har gitt deg symptomlette?

Ingenting  Liten grad  Middels grad  Stor grad  Svært stor grad

Senterleder:  
Prof. Jan Hatlebakk, MD., PhD  
Tel: 55 97 29 70  
[jan.gunnar.hatlebakk@helse-bergen.no](mailto:jan.gunnar.hatlebakk@helse-bergen.no)

Koordinator :  
Birgitte Berentsen, PhD  
Tel: 55972999/91545159  
[birgitte.berentsen1@helse-bergen.no](mailto:birgitte.berentsen1@helse-bergen.no)

Postadresse:  
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## Appendix 15: HBNKFM3



### HBNKFM 3

Kjære deltager, Tusen takk for at du svarer på disse spørsmålene. Din besvarelse er helt *anonym* og vil hjelpe NKFM til å evaluere kvaliteten ved helsetjenestetilbudet ved Haukeland Universitetssjukehus

- 1) Hva er din alder..... 2) Mann  Kvinne
  
- 2) Hvor mange ganger har du vært til time eller innlagt ved sykehus (spesialisthelsetjenesten) pga mageproblemer de siste årene ? Timer hos fastlegen skal ikke telles med  
A) De siste 5 årene ..... B) Det siste året.....
  
- 3) Hvor mange ganger har du vært til time hos din fastlege pga mageproblemer de siste årene ? Timer eller innleggelse på sykehus skal ikke telles med.  
B) De siste 5 årene ..... B) Det siste året.....
  
- 4) Hva er antallet gastroenterologiske undersøkelser du har vært igjennom totalt til nå?  
A) Gastroskopi..... B) Koloskopi.....
  
- 5) Opplever du plager fra andre deler av kroppen? (for eksempel muskelsmerter (fibromyalgi), hodepine, smerter fra underlivet, kronisk tretthet, depresjon, søvnproblemer) Nevn nedenfor :  
.....
  
- 6) Har du kjenneskap til hva som var den utløsende faktoren for dine symptomer? (for eksempel: infeksjon, matforgiftning, operasjon, stress) Nevn nedenfor:  
.....
  
- 7) Hvor lenge har du levd med magesmerter? (Antall år eller måneder) .....
  
- 8) Smertene har oppstått: A) Gradvis  B) Ved akutt infeksjon   
C) Etter antibiotika behandling
  
- 9) Hvor mange ganger har du vært sykemeldt pga magesmerter?  
A) Antall ganger de siste 5 årene.....  
B) Antall dager det siste året.....  
C) Antall dager den siste måneden.....

**Senterleder:**  
Prof. Jan Hatlebakk, MD., PhD  
Tel: 55 97 29 70  
[jan.gunnar.hatlebakk@helse-bergen.no](mailto:jan.gunnar.hatlebakk@helse-bergen.no)

**Koordinator :**  
Birgitte Berentsen, PhD  
Tel: 55972999/91545159  
[birgitte.berentsen1@helse-bergen.no](mailto:birgitte.berentsen1@helse-bergen.no)

**Postadresse:**  
NKFM, Medisinsk Avdeling  
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[www.helse-bergen.no/no/NKFM](http://www.helse-bergen.no/no/NKFM)

10. Har du gått på lavFODMAP-dietten etter at du fikk opplæring på MT-skolen? Ja/nei

(Hvis pasienten trykker ja så kommer 10.1, 10.2, 10.3 opp)

10.1: Hvor lenge har du stått på lavFODMAP-dietten? Antall år:

10.1: Hvor lenge har du stått på lavFODMAP-dietten? Antall mnd:

10.2: Har du reintrodusert FODMAP-gruppene? Ja/nei

10.3: I hvor stor grad har du opplevd at lavFODMAP-dietten har gitt deg symptomlette? Ingenting-liten grad-middels grad-stor grad-svært stor grad

10.4: Følger du fortsatt lavFODMAP-dietten? Ja/nei

I hvor stor grad hjalp modulen deg:

11: Modul 1: Kroppen og Mage-tarmsystemet med lege: Ingenting-liten grad-middels grad-stor grad-svært stor grad

12: Modul 2: Kroppsholdning og pusteteknikk med fysioterapeut: Ingenting- liten grad-middels grad-stor grad- svært stor grad

13: Modul 3: Generelle livsstilsråd: Ingenting – liten grad – middels grad- stor grad – svært stor grad

14: Modul 4: Livsmestring med psykiater: liten grad – middels grad – stor grad – svært stor grad

15: Modul 5: LavFODMAP med klinisk ernæringsfysiolog: liten grad – middels grad – stor grad- svært stor grad

**Senterleder:**  
Prof. Jan Hatlebakk, MD., PhD  
Tel: 55 97 29 70  
[jan.gunnar.hatlebakk@helse-bergen.no](mailto:jan.gunnar.hatlebakk@helse-bergen.no)

**Koordinator :**  
Birgitte Berentsen, PhD  
Tel: 55972999/91545159  
[birgitte.berentsen1@helse-bergen.no](mailto:birgitte.berentsen1@helse-bergen.no)

**Postadresse:**  
NKFM, Medisinsk Avdeling  
Haukeland Universitetssykehus, 5021 Bergen  
[www.helse-bergen.no/no/NKFM](http://www.helse-bergen.no/no/NKFM)

## Appendix 16: HBNKFM6

### HBNKFM 6

- 1) **Hvor mange ganger har du vært sykemeldt pga magesmerter?**
  - A) Antall ganger de siste 5 årene....
  - B) Antall dager det siste året....
  - C) Antall dager den siste måneden...
  
- 2) **Har du gått på lavFODMAP-dietten etter at du fikk opplæring på MT-skolen? Ja/nei (Hvis pasienten trykker ja så kommer 10.1, 10.2, 10.3 opp)**
  - 2.1: Hvor lenge har du stått på lavFODMAP-dietten? Antall år:
  - 2.1 Hvor lenge har du stått på lavFODMAP-dietten? Antall mnd:
  - 2.2: Har du reintrodusert FODMAP-gruppene? Ja/nei
  - 2.3: I hvor stor grad har du opplevd at lavFODMAP-dietten har gitt deg symptomlette? Ingenting-liten grad-middels grad-stor grad-svært stor grad
  - 2.4: Følger du fortsatt lavFODMAP-dietten? Ja/nei
  
- I hvor stor grad hjalp modulen deg:**
  - 3) Modul 1: Kroppen og Mage-tarmsystemet med lege: Ingenting-liten grad-middels grad-stor grad-svært stor grad
  - 4) Modul 2: Kroppsholdning og pusteteknikk med fysioterapeut: Ingenting- liten grad-middels grad-stor grad- svært stor grad
  - 5) Modul 3: Generelle livsstilsråd: Ingenting – liten grad – middels grad- stor grad – svært stor grad
  - 6) Modul 4: Livsmestring med psykiater: liten grad – middels grad – stor grad – svært stor grad
  - 7) Modul 5: LavFODMAP med klinisk ernæringsfysiolog: liten grad – middels grad – stor grad- svært stor grad

## Appendix 17: CSQ-8

### CSQ-8 - Client Satisfaction Questionnaire – 8

Vi håper du kan hjelpe oss med å forbedre tjenestene våre ved å svare på noen spørsmål om hjelpen du har fått. Vi ønsker at du gir din ærlige tilbakemelding, enten den er positiv eller negativ. Vennligst svar på alle spørsmålene. Vi setter også stor pris på kommentarer og forslag. Tusen takk for hjelpen.

Hvordan vil du vurdere kvaliteten på tjenestene du fikk?

- Utmerket
- God
- Grei nok
- Dårlig

Fikk du den tjenesten du ønsket?

- Nei, absolutt ikke
- Nei, ikke egentlig
- Ja, stort sett
- Ja, absolutt

I hvilken grad har programmet vårt oppfylt dine behov?

- Nesten alle behovene mine er oppfylt
- De fleste behovene mine er oppfylt
- Bare noen få av behovene mine er oppfylt
- Ingen av behovene mine er oppfylt

Hvis en venn hadde behov for lignende hjelp, ville du anbefale programmet vårt til han eller henne?

- Nei, absolutt ikke
- Nei, ikke egentlig
- Ja, stort sett
- Ja, absolutt

Hvor fornøyd er du med omfanget av hjelpen du har fått?

- Ganske misfornøyd
- Nøytral eller litt misfornøyd
- For det meste fornøyd
- Svært fornøyd

Har tjenestene du fikk hjulpet deg med å håndtere problemene dine på en bedre måte?

- Ja, de har hjulpet mye
- Ja, de har hjulpet litt
- Nei, de har egentlig ikke hjulpet
- Nei, de virker å ha gjort ting verre

Totalt sett, hvor fornøyd er du med hjelpen du har fått?

- Svært fornøyd
- For det meste fornøyd
- Nøytral eller litt misfornøyd
- Ganske misfornøyd

Hvis du skulle ha behov for hjelp igjen, ville du komme tilbake til programmet vårt?

- Nei, absolutt ikke
- Nei, ikke egentlig
- Ja, stort sett
- Ja, absolutt

Har du noen kommentarer:

Kom med evt forslag:

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## **Mage-tarmskolen på nett – veiledet selvhjelp til personer med irritabel tarm**

Mari F Oppegård<sup>1</sup>, Mari L Andersen<sup>1</sup>

<sup>1</sup>Nasjonalt kompetansetjeneste for funksjonelle mage-tarmsykdommer (NKFM), Medisinsk Avdeling, Haukeland Universitetssykehus

**Bakgrunn:** Det anslås at 1 av 10 i Norge har Irritabel tarmsyndrom (IBS) og det utgjør en stor del av konsultasjoner i allmennpraksis og utredning i spesialisthelsetjenesten. IBS medfører redusert livskvalitet for den enkelte og sykemeldinger.. (samfunnsøkonomisk). Behandlingstilbudet varierer mellom helseforetakene og oppfølging av klinisk ernæringsfysiolog er sjeldent (etterspurt). Lange ventelister på eksisterende tilbud, har medført et stort behov for ytterlige tilbud på landsbasis.

**Hensikt/målsetning:** 1) Bidra til en effektiv og god behandling og oppfølging av personer med | irritabel tarm uavhengig av bosted 2) Utvikle et tverrfaglig opplærings- og behandlingsprogram over internett og gjennom asynkron kommunikasjon med klinisk ernæringsfysiolog skal pasientene få en effektiv og trygg opplæring og oppfølging av kostrådene ved irritabel tarm. 3) Identifisere om veiledet selvhjelp over internett fører til endringer i mageplager og livskvalitet hos personer med irritabel tarm.

**Design:** En arbeidsgruppe tilknyttet NKFM bestående av leger, psykiater, klinisk ernæringsfysiologer og manuell terapeut har hatt fagansvaret for ulike deler av behandlingstilbudet og utviklet 5 tverrfaglige moduler bestående av tekst, film og bilder. Animasjonsfilmer og illustrasjoner er utviklet av videoverkstedet og filming av helsepersonell er utført av Trellevik as. Selve nettsiden er utviklet av Helse Bergen Seksjon for e-helse (Checkware). Pågående pilotstudie skal kvalitetssikre mage-tarmskolen som helsetiltak.

**Resultater:** 1.november 2016 var 63 pasienter i gang med mage-tarmskolen på nett. Pålogging skjer via NKFM sine hjemmesider og henviste pasienter logger inn ved bruk av BANK-ID. Pasientene blir veiledet gjennom 5 moduler; opplæring med gastrolege, øvelser med manuell terapeut, generelle livsstilsråd (NICE guidelines), livsmestring med psykiater og FODMAP-redusert kosthold med klinisk ernæringsfysiolog. Pasientene har mulighet til å kommunisere med en klinisk ernæringsfysiolog via en meldingstjeneste på høyeste sikkerhetsnivå 4 for personlige opplysninger inne i programmet.

**Konklusjon:** Mage-tarmskolen på nett kan bli et nasjonalt tverrfaglig behandlingstilbud til personer med irritabel tarm uavhengig av bosted.

## **Appendix 19:** videos from the eHealth program



## INTRO

- Intro med Birgitte <https://youtu.be/aJ6Lrjo328c>
- Intro med Silje <https://youtu.be/wlga--7j2Kc>

## MODUL1 (LEGE)

- Intro med Trygve <https://youtu.be/3Jk-3C8cSYw>
- Fordøyelsessystemet <https://youtu.be/1LHF3CpucQw>
- Magesekk med suppe <https://www.youtube.com/watch?v=EP0D9uCv-9I>
- Fordøyelse og absorpsjon av næringsstoffer <https://youtu.be/jBE2ZGBqfU0>

## MODUL2 (FYSIO)

- Intro med Eirik <https://youtu.be/P5ASDxkTMBo>
- Eirik med modell viser feil pustemønster <https://youtu.be/BoMhEOTpyl4>
- Eirik med modell viser god kroppsholdning <https://youtu.be/prbPUQaKBwl>

## MODUL3 (GENERELLE RÅD MED KEF)

- Intro med Synne <https://youtu.be/vofPUVztBas>

## MODUL4 (PSYKIATER)

- Intro med Jørn <https://youtu.be/WmrTmBeJwSA>

## MODUL 5 (FODMAP MED KEF)

- Intro med Synne <https://youtu.be/bkf0s46nXxc>
- Fordøyelse og absorpsjon av næringsstoffer <https://youtu.be/jBE2ZGBqfU0>
- Intro –hva er FODMAP [https://youtu.be/bCSYrL\\_AQzo](https://youtu.be/bCSYrL_AQzo)
- Hvordan FODMAP virker i tarmen og hvilke symptomer de gir <https://youtu.be/iY00VwWzsJE>
- FODMAP-gruppene og matvarer <https://youtu.be/7yjoAtaVgiA>
- Frokost og lunsj-alternativer <https://youtu.be/VU5ruaFBjJ0>
- Middag <https://youtu.be/MbwT5BvRANK>
- Smakstilsetninger <https://youtu.be/LIKx3gCGznc>
- Kostfiber og tilsetninger <https://youtu.be/uF7kwIY46aY>
- Avslutning med Silje <https://youtu.be/PnzEmVpjjYM>