Long-term Impact on Gastrointestinal Symptoms, Quality of Life and Nutritional Adequacy after Group Intervention in patients with Irritable Bowel Syndrome

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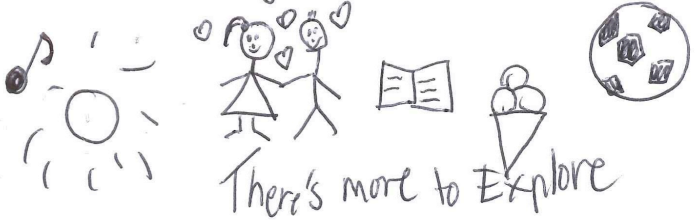
Ok! It's time to 

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Abstract

Background: Irritable bowel syndrome (IBS) is a common functional gastrointestinal disorder often associated with complex clinical manifestations. There is no cure for IBS, however potent management strategies have been proposed, including the FODMAP diet. Haukeland University Hospital provides group based IBS interventions. There is a need for critical evaluation of group-based management of IBS.

Aim: To quality assess the long-term impact of the group based IBS intervention offered at Haukeland University Hospital through measurements of gastrointestinal symptoms, quality of life and nutritional intake in IBS intervention participants.

Methods: We measured gastro intestinal impact, quality of life and nutritional adequacy through the IBS Symptom Severity Score; Visceral Sensitivity Index; Short-form Nepean Dysepsia Index questionnaires and 3-day Food Diaries at baseline and 6 and 12 months after intervention in 20 IBS intervention participants.

Results: We found a significant change in Visceral Sensitivity in one group (P=0.027), but we found no significant change in IBS symptom severity in neither of the groups. We found no significant change in quality of life, BMI, energy intake, fibre intake nor macronutrient distribution in neither of the groups.

Conclusion: We cannot conclude that gastro intestinal impact, quality of life and nutritional adequacy will change after IBS intervention at Haukeland University Hospital. The study scope make generalisation difficult. Further assessment of IBS management is necessary.

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List of Abbreviations

IBS:	Irritable Bowel Syndrome
GI:	Gastro Intestinal
FODMAP:	Fermentable Oligosaccharides Disaccharides Monosaccharies And Polyols
NICE:	National Institute for Health and Care Excellence
HUS:	Haukeland Universitets Sjukehus
LMS:	Lærings og Mestrings-Senteret
LMF:	Landsforeningen Mot Fordøyelses-sykdommer
QOL:	Qualify of Life
VSI:	Visceral Sensitivity Index
BMI:	Body Mass Index
GSA:	Gastrointestinal Symptom-Specific Anxiety
24HrR:	24 Hour Recall
REK:	Regionial Komité for Medisink og Helsefaglig Forskningsetikk
SEM:	Standard Error of the Mean
SD:	Standard Deviation
RDI:	Reccomended Dietary Intake
SAT:	Saturated Fatty Acid
MUFA:	Monounsaturated Fatty Acids
PUFA:	polyunsaturated fatty acids
NCGS:	Non Coeliac Gluten Sensitivity

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1 Introduction

1.1 Definition

Irritable bowel syndrome (IBS) is as a common and chronic functional gastrointestinal (GI) disorder(1). A functional disorder is characterised by the absence of any structural, physiological or biochemical abnormalities(1, 2). There is no gold standard definition of Irritable Bowel Syndrome (IBS) and its descriptions have commonly alternated (2-5).

1.2 Prevalence

Resent estimation of global prevalence of IBS is set to 11 per cent(2, 6), however, a prevalence as high as 30 per cent has also been suggested(2). In Norway, the prevalence is estimated to 8 per cent(7). Estimations can vary quite substantially largely depending on the diagnostic tools used. Furthermore, it is expected that approximately 30 per cent of people who experience symptoms will not consult physicians(6).

1.3 Aetiology and pathophysiology

The aetiology behind IBS has not been identified(3), however, several pathophysiological attributes have been proposed.

Visceral hypersensitivity is believed to be prevalent in many IBS patients and have been proposed as a clinical marker(8, 9), for instance measured through tolerance level upon intestinal balloon insertions or soup ingestion(10).

Much attention has been devoted to the gut- brain axis and visceral hypersensitivity with its systemic consequences(8, 9, 11-13). Visceral sensitivity intertwines the complex neuro-endocrine system connecting the gut- brain and the central nervous system, including the concept of perception(8). It has been proposed that visceral hypersensitivity is responsible for the exaggerated motility response seen in IBS (either positive or negative exaggeration; i.e. for example either diarrhoea or constipation)(8, 13, 14).

Then what may cause visceral hypersensitivity and what are the possible systemic consequences? We do not know the cause of hypersensitivity, however several potential contributors have been suggested.

Genetics seem to impact individual visceral hypersensitivity (4, 15).

It has been suggested that inflammation or injury to the gastro intestinal tract may contribute to visceral hypersensitivity (12). Up to 30 per cent of the IBS population report the onset of symptoms to have occurred after an acute gastroenteritis(16). In Bergen developed post infectious IBS after the giardia outbreak in 2004(17).

Furthermore, microbiotic dysbiosis has recently gained much attention across many fields of medical research including associations with visceral hypersensitivity(18). Faecal transplant has successfully been performed, however research on IBS is scarce (19).

In terms of exaggeration of visceral hypersensitivity several stimulants have been identified, for instance coffee and stress(20).

1.4 Diagnosis

IBS is diagnosed in congruence with the Rome III criteria, with absence of alarm symptoms and exclusion of organic disease (21).

Table 1*. Rome III Irritable Bowel Syndrome diagnostic criteria(22).*

Diagnostic criteria * Must include both of the following:
1. Abdominal discomfort** or pain associated with two or more of the following at least 20% of the time: a. Improvement with defecation b. Onset associated with a change in frequency of stool c. Onset associated with a change in form (appearance) of stool
2. No evidence of an inflammatory, anatomic, metabolic, or neoplastic process that explains the subject's symptoms

* Criteria fulfilled at least once per week for at least 2 months prior to diagnosis
** "Discomfort" means an uncomfortable sensation not described as pain.

The alarm symptoms could include(23):

-Anaemia

-Gastro intestinal bleeding,

-Weight loss

-Family history of cancer, inflammatory bowel disease or coeliac disease

-Recent and/or rapid change in bowel habits,

-Persistent diarrhoea

-Persistent constipation

-Age above 45

Exclusion of organic disease should involve investigation for prevalence of inflammatory, anatomic, metabolic, or neoplastic process. It can be argued that the process of eliminating organic disease should involve(23, 24):

-Gastroscopy, colonoscopy, x ray of small intestines, abdominal ultrasound

-Condition specific clinical examinations and blood samples

Nevertheless, the process of diagnosing IBS largely depends on the individual physician(24).

As one would expect, the process of diagnosing IBS can be costly and time consuming(24). However, diagnosed IBS patients commonly seek medical attention. Therefore, it can be argued that thorough investigations (in combination with patient reassurance and explanations) may in fact prove economically sane(24, 25).

1.5 Clinical picture

The clinical picture of the IBS patient may vary substantially and is often complex (26, 27). It has been suggested that future research will identify multiple disorders which currently constitute the IBS diagnosis (15, 28).

The key gastro intestinal symptoms include pain/discomfort, bloating (with or without gas) and disturbed bowel habits(14, 27). Otherwise nausea may be prevalent, as well as mucous in stools(29). Constipation predominant IBS is slightly more prevalent than diarrhoea predominant IBS, however, a combination of the two is also common(28).

Severity of symptoms varies from tolerable to severe. Prevalence of symptoms may vary from daily to occasionally (both between and within patients)(24).

Cases of functional dyspepsia, coeliac disease and IBS may present with similar symptoms(30). IBS may occur together with other gastro intestinal conditions such as for instance coeliac disease (where the gastro intestinal impact can not be attributed the other identified gastrointestinal condition)(24).

Other conditions such as chronic fatigue symptom, anxiety and depression are often seen in IBS patients. However, this cannot explain IBS(31-34).

Other symptoms may include; musculoskeletal pain, fatigue, stress, unexplained cold sensations and breathlessness(31, 34).

Woman are more frequently diagnosed with IBS than men, however, the impact of female hormones cannot explain IBS(6, 35). We do know that females generally tend to seek medical attention more frequently than men(24).

Patterns of socioeconomic background have not been established(6). IBS occurs across all ages, however, the prevalence seem to decrease in those above 50(6). Weight status is commonly normal or borderline over weight (36).

The IBS patient may feel socially impaired (for instance social isolation, broken relationships and inability to travel)(37, 38). Daily activities such as work and study may be compromised (affecting absenteeism, presenteeism, employment and promotion)(39).

Quality of life is often reported to be very low(35, 37, 40). Many IBS patients compare their quality of life to that expected in chronic conditions such as hepatic cirrhosis, renal insufficiency and diabetes(24).

1.6 Nutritional status

IBS has not been associated with excess mortality and it has been assumed that adverse digestion and absorption is absent (24).

The majority of IBS patients proclaim food as a major trigger of symptoms(41). A study conducted inn Sweden found that 64 per cent of the participants experienced post prandial worsening of symptoms(42).

Many IBS patients may have irregular eating patterns and restrictive diets may occur(43). A Norwegian study found the level of restriction severe enough for potential health hazard to occur(44).

The foodstuffs most commonly reported to cause adverse reactions are milk and milk products, wheat products, caffeine, certain meat, cabbage, onion, beans, spicy and fried

foods(42, 45). Studies have identified, however, that correct identifications of insulting foods can prove difficult(24).

In Norway the prevalence of lactose intolerance is estimated to be 2 per cent, whilst 8 per cent is estimated to have IBS. A recent population based study from Norway found that almost 11 per cent of Norwegians aged between 36-79 (15 500 study objects) self - reported adverse gastro intestinal symptoms upon consumption of milk products (46). It may be that lactose intolerance is greater than estimated, however, it can also be argued that milk and milk products are excluded by fault.

Gluten containing products are commonly attributed adverse health effects (for example by the media), and gluten free products are often proclaimed as the healthier option. In Britain there has been a double-digit sales growth of gluten free products in the recent years, and the rest of Europe is quickly catching up(47).

Researchers in Australia have performed a Double-Blind Randomized Placebo-Controlled Trial study and concluded that non-coeliac gluten sensitivity may indeed exist. However, the associated adverse health effects may also be attributed the fructan content (a fructooligosaccharide; a polymer of fructose molecules). The study showed that gluten-containing products often contain high levels of fructans. It may be without justification that gluten is made responsible for the adverse effects associated with non coeliac gluten intolerance(48).

Nevertheless, it can be argued that more attention should be placed on the level of nutritional adequacy in gastro intestinal disorders. In recent years, there has been an increased focus on nutrition in for instance inflammatory bowel disease (49, 50). However, it should be increasingly recognised that IBS patients (and those with other gastrointestinal disorders) may also present with a compromised nutritional status(43).

1.7 Symptom relief strategies

As our current understanding of IBS and its pathophysiology by far is definite, it proves difficult to provide treatment for IBS(24). However, several symptom relief strategies have been proposed. In general, the symptom relief strategies work from either avoidance of visceral stimulation or mending the consequences of visceral hypersensitivity.

1.7.1 The FODMAP diet

The FODMAP acronym stands for Fermentable Oligosaccharides Disaccharides Monosaccharaides And Polyols. FODMAPs are considered collectively due to their similar mode of action. FODMAPs are osmotically active short-chained carbohydrates that are more or less resistant to digestion and absorption in the small intestine. Consequently, bacterial fermentation may occur in the large intestine. This may cause luminal distension and water retention(51).

FODMAPs are widespread in foods and their mode of action applies to all humans, however, visceral sensitivity may differ. FODMAPs are not the cause of IBS, however, a dietary reduction may cause a decreased visceral stimulation(52-54).

See Table 2 for a simplistic overview of the FODMAPs and contributing factors to potential maldigestion and absorption.

Table 2. *Simplistic overview of FODMAPs and contributing factors to potential maldigestion and absorption in humans (52).*

Saccharide	Molecule size	Example food (saccharide)	Maldigestion and/or absorption
Oligo	3-9	Grain products (fructans) Legumes (galactans)	Hydrolase deficiency
Di	2	Milk products (lactose)	Lactase deficiency*
Mono	1	Fruits (free fructose)	Transport system insufficiency*
Poly	>9	Sugar free products (xylitol)	Transport system deficiency

*lactose only considered a FODMAP upon lactose intolerance
* fructose only considered FODMAP when consumed in excess of glucose as glucose aids absorption of fructose

The FODMAP diet came about approximately 10 years in Melbourne, Australia. The Melbourne scientists have since continued to develop the concept. They strive to provide up-to-date information and educational tools such as the Monash FODMAP diet smart phone and android application(55). Economic turnover goes to research and they have produced several good quality studies(53, 54, 56, 57). The FODMAP diet may also benefit other conditions of the gastro intestinal such as the inflammatory bowel diseases(58).

Performing the FODMAP diet

Phase 1*: in phase 1 the user goes on a very strict low FODMAP diet for 2-8 weeks, where the goal is to obtain a close to symptom free state. This is done in order to see identify whether a FODMAP reduction is effective (it is in 70 per cent) and in order to detect the offending foods later on. Most user experience symptom relief already in the first week and the length of phase 1 should be estimated in accordance with time of noticeable effects. If no effect has occurred after 8 weeks with correct execution of the diet, further continuation is not appropriate. If incorrect execution of the diet is suspected then phase 2 can be considered repeated(52).*

Phase 2*: in phase 2, if the user has obtained a close to symptom free state, the patient should reintroduce one FODMAP category and one food item at a time. The Australian researchers propose a recommended order, however, personal preferences can me made. The food item should be introduced in small quantities and be gradually increased. This way, each individual will find their tolerance level for the different FODMAP categories and relevant foods. If/when adverse reactions occur, the intake should be reduced back to the previously identified tolerable level. Furthermore, if/when adverse reactions occur, the patient should go back to the strict FODMAP diet regime until the symptom free state has re-emerged (perhaps 2-3 days depending on the individual). After regaining a close to symptom free state, the next food/FODMAP category can be tested. It is recommended that further use of identified foods should be left for phase 3, as the total FODMAP concentration may colour the testing of other foods. It may be of practical benefit to note down the identified tolerance level for each food item (for later recollection). As one can understand, can be a lengthy process depending on how many FODMAP groups and foods the user want to test(52).*

Phase 3*: in phase 3 the user must develop the necessary everyday management skills for long term maintenance; for instance shopping, cooking and social life aspects. The user must find a balanced intake of the foods identified in phase 2, as the total amount of FODMAPs in the diet may exceed the individual level of accepted symptoms (accumulative effect of total FODMAP intake). The user will develop skills to make calculated decisions on FODMAP intake (52).*

The founders of the FODMAP diet inform that the diet may not appropriate for all IBS patients.

The FODMAP diet is a valuable tool for mapping individual tolerance level for the different FODMAP groups and consequent foods. Future research must address the long-term impact of the diet in terms of nutritional adequacy and impact on the intestinal microbiota. Nevertheless, upon proper execution, the FODMAP diet is currently accepted as the best approach for symptom relief for IBS upon proper(52, 54, 57).

1.7.2 The NICE clinical management guidelines

The National Institute for Health and Care Excellence (NICE) is an executive non-departmental public body of the Department of Health in the United Kingdom. NICE provides widespread and research based national guidance and advice for health professionals(23).

The NICE guidelines undergo regular and thorough revisions. The last IBS guidelines were published in February 2015(23).

NICE IBS dietary and lifestyle advice

Individuals should be informed on importance of leisure and relaxation time but also physical activity. Individuals who choose to use probiotics should be advised to take the product for at least 4 weeks while monitoring the effect. Dose should be as recommended by the manufacturer. Individuals should be discouraged to use Aloe Vera for the treatment of IBS(23).

Diet and nutrition should be assessed and several general advices should be given (Table 3) in addition to the above outlined. If individual´s symptoms persist despite the above mentioned advice, single food avoidance and/or exclusion diets (such as the low FODMAP diet) should be prompted. Such management should only be given by health professional with expertise in the management strategy(23).

Table 3. *The NICE general diet and nutrition advice(23).*

Have regular meals and take time to eat
Avoid missing meals or leaving long gals between eating
Drink at least 8 cups of fluid per day, especially water or other non-caffeinated drinks*
Restrict ta and coffee to 3 cups per day
Reduce intake of alcohol and fizzy drinks
It may be helpful to limit intake of high-fibre foods*
Reduce intake of resistant starch* which is often found in processes or re-cooked foods
Limit fresh fruit to 3 portions per day (a portion should be approximately 80 g)
Individuals with diarrhoea should avoid sorbitol*
Individuals with wind and bloating may find it helpful to eat oats and linseeds (up to 1 tablespoon per day)

* non-caffeinated drinks- such as herbal teas
* high fibre foods- such as wholemeal or high-fibre flour and breads, cereals high in bran, and whole grains such as brown rice
* resistant starch- starch that resists digestion in the small intestine and reaches the colon intact
* sorbitol-an artificial sweetener found in sugar-free sweets (including chewing gum) and drinks, and in some diabetic and slimming products.

NICE pharmacological therapy advice

Pharmacological management should be based on nature and severity of the symptoms(23).

NICE psychological intervention advice

Those who do not respond to other treatment should be considered for psychological intervention (cognitive behavioural therapy, hypnotherapy and/or psychological therapy)(23).

NICE complementary and alternative medicine advice

Use of acupuncture nor reflexology is recommended (23).

1.7.3 Other symptom relief strategies

Fatty, smoked and spicy foods

Many with IBS experience worsening of symptoms upon consumption of fatty, smoked or spicy foods. Fatty foods stimulate gastro intestinal reflexes, smoked and spicy foods have been said to be irritants of the gastrointestinal tract in IBS. For instance, chilly contains capsaicin, which may contribute to abdominal pain and burning(59, 60).

Fermented food products

Fermented food products have been recommended due to possible effects of microbiota and bacterial lactose digestion (61).

Lactase supplementation

Lactase supplementation has proven to be efficient in aiding lactose digestion, however, results have been conflicting most likely due to individual requirements. Furthermore, the cost of regular use is relatively high(62).

Peppermint oil

A meta analysis published in 2014 found that 9 of 13 studies on enteric coated pepper mint oil were superior to placebo in regards to reduction in abdominal pain(63). Its effect is attributed smooth muscle relaxation and was found to be safe for consumption. However, it is acknowledged that future studies should address long term effects, as the majority of the studies have looked at the short-term effects(63).

Posture and breathing technique

Awareness of breathing technique and body posture may aid management of IBS. A randomised trial found that adolescents with IBS had their level of anxiety reduced after yoga (64).

1.8 Provision of health services

Patient dissatisfaction regarding health services has been common amongst IBS patients(24). Perhaps not surprising considering there is no cure, and only relatively recently has management strategies become available. Furthermore, many IBS patients have had their symptoms attributed ´psychosomatic´ disorders. Today it is acknowledged that IBS symptoms may be exaggerated by central nervous stimulation, however it is not considered the cause(20, 24).

It´s reassuring that the topic of gastrointestinal health seems to increasingly interest health workers worldwide. Nevertheless, knowledge gaps on IBS is still prevalent(65). Both in Australia and England the necessity and complexity of IBS management has been acknowledged through the provision of regular FODMAP training for professionals(66).

As health professionals we strive to provide best practice and provision of health services. IBS is often multi dimensional and an interdisciplinary approach may be necessary.

1.9 IBS Intervention at Haukeland University Hospital

Since 2013 Lærings og Mestringssenteret (LMS) through Haukeland Universitets Sjukehus (HUS) has regularly offered a group based IBS-interventions for IBS patients.

The goals set out by LMS are(67):
- To provide resources for improvement of day to day management and quality of life
- Have dialog with different professions
- Connect with others in the same situation

IBS intervention participation requires general practitioner referral. The participation of family or others does not demand referral. Place of residence is irrelevant. Both the cost of the intervention and potential cost of travel may be covered(67).

The intervention takes place over two days. For an overview of the programme see appendix 1.

In short, the gastroenterologist provides information on prevalence, symptoms, pathophysiology and different therapies. The psychiatrist provides information on stress, control and coping mechanisms. The clinical dietician provides information on general diet and diet for IBS management (including the FODMAP diet). The physiotherapist informs on importance of breathing technique and sitting posture.

Representatives from Landsforeningen Mot Fordøyelses-sykdommer (LMF), informs about their work and the intervention includes a session on patient rights.

Note that the intervention programme will vary between the different interventions due to feedback and other impulses. The programme as seen in appendix 1 is from November 25 and 26, 2013.

1.10 Study rationale

The present study is a quality assurance study of the IBS intervention available to IBS patient at LMS/HUS. Quality assurance can be defined as ´a program for the systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met´(68). See appendix 2 for the initial study description.

The authors of this paper have not been familiarized with other studies performing a quality assessment of an IBS intervention of this kind.

A study of this kind is very important as IBS is a highly prevalent disorder with complex and widespread clinical manifestations, and the need for adequate management is essential.

The aim of this study was to quality assess the long term impact of the IBS intervention provided by LMS/HUS on IBS patients and their gastrointestinal symptoms, quality of life (QOL) and nutritional intake.

The objectives were to
-Identify the long-term practical implementation of the provided symptom control strategies
-Measure gastrointestinal symptoms before and after intervention
-Measure visceral sensitivity index before and after intervention
-Measure quality of life before and after intervention
-Analyse nutritional adequacy in terms of BMI, kcal intake, fibre intake, macro nutrient distribution and specific food frequency intake before and after intervention.

It was hypothesised that the IBS intervention is associated with reduced IBS symptoms, improved quality of life and nutritional adequacy.

2 Research Methods

2.1 Study design

The study is a quality assurance study of the long-term health effects of the IBS intervention programme offered at Haukeland University Hospital through Lærings-og Mestrings-senteret.

2.2 Participant recruitment

IBS patients for this study were recruited from IBS interventions that took place November 25-26, 2013 (n21), March 27-28, 2014 (n25) and April 22-23, 2014 (n27) (total N73). Of the 73 IBS intervention participants, 20 participants were recruited for this study (Figure 1).

Figure 1. *Participant participation recruitment flow. Of the 73 IBS intervention participants, a total of 39 participants provided the questionnaires necessary for inclusion in the study at baseline, and 34 participants did not and were excluded. Of the 39 who were included, 10 participants were uninterested in continuation of the study, 7 participants had received a different diagnosis and 2 participants could not be reached. A total of 20 participants were recruited for this study.*

2.3 Participant groupings and parameters

For the November participants the data was collected at baseline and approximately 12 and 15 months after intervention (interval I and II). These participants have been assigned group A and function as a 12 and 15 month parameter (Figure 2).

For the March and April participants the data was collected at baseline and approximately 6 and 10 months after intervention (interval I and II). These participants have been assigned group B and function as a 6 and 12 month parameter (Figure 2).

Group a represents the participants amongst the group A participants whom reports being on the FODMAP diet. Group b represents those of the group B participants reporting to be on the FODMAP diet (Figure 2).

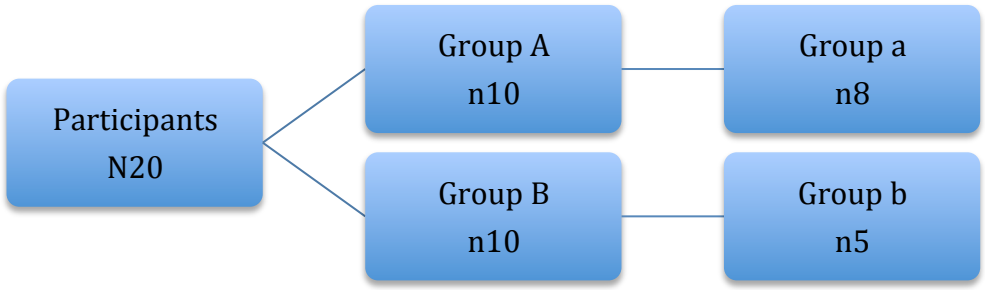

Figure 2. *Participant grouping. Of the 20 participants recruited for this study, 10 were recruited from the November IBS intervention (group A) and 10 were recruited March IBS and April IBS intervention (group B). Of the group A participants, 8 reported being on the FODMAP diet after intervention (group a), and of the group B participants 5 reported being on the FODMAP diet (group b).*

2.3.1 Collective consideration

Group A and B have also been considering collectively and likewise for group a and b. The groups are then referred to as group A+B and a+b (Figure 3).

Group A+B function as a parameter for all participants, group a+b function as a parameter for all participants on the FODMAP diet.

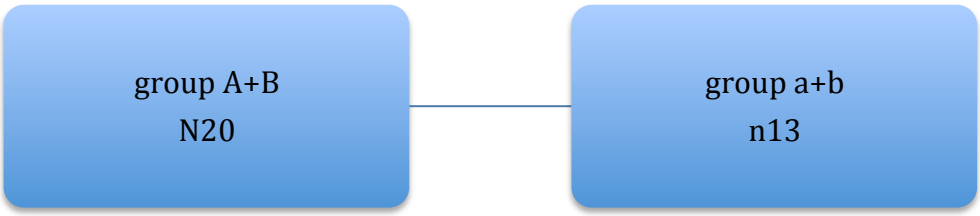

Figure 3. *Collective consideration. Group A and B constitute group A+B and group a and b constitute group a+b. Group A+B function as a parameter for all participants, group a+b function as a parameter for all participants on the FODMAP diet.*

2.4 Data collection methods

Data were collected through repeat and single measure questionnaires.

2.4.1 Repeat measure data collection

The participants received the questionnaires by mail a few weeks prior to the relevant IBS intervention and were asked to return the questionnaires during the intervention. The participants, whom delivered the questionnaires at baseline, received the same set of questionnaires (along with a pre-stamped envelope) at post intervention at the relevant group interval I. The participants were asked to return the questionnaires as quickly as possible. Contact information was provided for potential enquiries.

All participants were contacted on telephone approximately 1-2 weeks after receiving the repeat measure questionnaires. When necessary, extra sets of questionnaires were provided. The main intention was to establish whether further continuation of the study was appropriate. Participants were considered appropriate if the current diagnosis was IBS and continuation of the study was of interest.

2.4.2 Single measure data collection

The single measure questionnaires were completed through telephone interviews at post intervention at the relevant group intervals II.

2.5 The repeat measure intervention questionnaires

The repeat questionnaires intend to report the main findings and serve as pre and post intervention parameters. The repeat measure questionnaires are the IBS-SSS, VSI and SFN-DI questionnaires and the 3-day food diary.

2.5.1 The IBS-Symptom Severity Score questionnaire

The Irritable Bowel Syndrome Symptom Severity Score *(IBS-SSS)* questionnaire (appendix 3) is a 4-item scale developed by Francis et al. It serves as a simple method of monitoring the progress of the gastrointestinal aspects of IBS(69).

The IBS-SSS questionnaire has been considered reproducible and sensitive to change(69).

The highest possible score is 500 and the lowest possible score is 0. According to this instrument, scores of 75 to 175 indicate mild cases, scores of 175 to 300 indicate moderate cases, and 300 and above indicate severe cases. Subjects scoring below 75 may be considered to be in remission. Subject without IBS can score up to 75 and in individuals with IBS scores below 75 may be indicative of remission(69).

The lower the points score the lower the IBS symptom score and vice versa. In other words, the lower score the lower the symptoms. A decrease in score will therefore indicate improvement.

2.5.2 The Visceral Sensitivity Index questionnaire

The Visceral Sensitivity Index (VSI) questionnaire (appendix 4) is a 15-item scale developed by Labus et al, which serves to assess gastrointestinal symptom-specific anxiety (GSA) in patients with IBS.

Labus et al found the VSI to be valid and reliable instrument for its purpose (70). Lind et al translated the Norwegian version of the VSI scale and they found its validity to be satisfactory (71).

The VSI scale investigates the level of distress associated with specific activities or situations. It does so by ranging each scenario from level 1 (strongly agree) up to level 6 (strongly disagree). The highest score possible is 90 and the lowest score possible is 5 (70).

The lower the total point scores the higher the grade of the GSA and vice versa. In other words the lower the score the higher the symptoms. An increase in point score will therefore indicate improvement. *Note that this is opposite to IBS-SSS and the SF-NDI questionnaire*.

2.5.3 The Short Form-Nepean Dyspepsia Index questionnaire

The Short Form Nepean Dyspepsia Index (SF-NDI) questionnaire (appendix 5) is a 10-item scale developed by Talley et al and it was originally developed to assess quality of life in patients with functional dyspepsia (72).

As the name suggest, this is revised version and the original version was a 42-item scale. Arsland et al found the SF-NDI to be a reliable, responsive and clinically valid tool for measurement of QOL also for patients with subjective food hypersensitivity. Further, the validity of the Norwegian version was found to be satisfactory(73).

The SF-NDI scale investigates QOL in regards to tension; influence on daily activities, eating/drinking; knowledge/control and work/study. Each scenario is ranked from 1 to 5(72). The highest score possible is 50 and the lowest score possible is 10.

The lower the total point scores the higher the QOL and vice versa. In other words, the lower the score the lower the symptoms. A decrease in point will therefore indicate improvement.

2.5.4 The Three-day food diary

Participants were asked to keep a thorough 3-day food diary (appendix 6) in which one of the days preferably representing the weekend. The 3-day food diary is per format used at the department of clinical nutrition institute 1 at HUS. The weighed 3-day food diary has been considered a good tool for retrieving nutrition data but its practicality is discussed(74).

Note that only group B was provided the 3-day food diary and therefore the nutritional data obtained is greater for group B compared to group A.

2.6 The single measure questionnaires

The single measure questionnaires intend to report supplementary findings and serve *post intervention parameters* only. The single measure questionnaires are the Anthropometry, Knowledge base, Roma III, Clinical picture, 2trategy implementations, FODMAP diet, General diet, IBS intervention feedback and the 24HrRecall questionnaires.

Norene Grytten Kjøsnes developed the structure of these questionnaires.

2.6.1 The 24 Hour Recall

Participants were asked to describe the food intake on a regular day and the number of days per week this food intake would resemble this description (appendix 7). The 24 hr recall has been recognised for its practicality but its representation of usual intake is questionable(74).

2.6.2 The Anthropometry questionnaire

This questionnaire (appendix 8) was developed in order to undertake appropriate anthropometric considerations. The participants provided information on weight and weight history, height and PAL.

2.6.3 The Knowledge base questionnaire

This questionnaire was developed in order to investigate the level of which the IBS intervention was the source of knowledge obtained on dietary management. The participants provided information on diet history, potential health consultations/engagements and their sources of knowledge in general (appendix 9).

2.6.4 The Roma III IBS questionnaire

This questionnaire was developed in order to establish whether the participants fulfil the ROMA III IBS requirements (appendix 10).

2.6.5 The Clinical picture questionnaire

This questionnaire was developed in order to further investigate the clinical picture and the course of treatment of the participants. For instance, the participants were asked to grade their everyday stress-level, psychological health and QOL using the visual analogue scale from 0-10 (level increase with increased number)(appendix 11).

2.6.6 The Strategy implementation questionnaire

This questionnaire was developed in order to establish which of the IBS management strategies provided had been implemented. The participants informed about their potential implementation of the FODMAP diet and the associated experience (appendix 12).

2.6.7 The FODMAP diet questionnaire

This questionnaire was developed in order to investigate the manner in which the FODMAP diet had been executed. For instance, the process of diet phase 1 and 2 and 3 was thoroughly investigated. Further, the level of compliance and symptom relief was examined (appendix 13).

2.6.8 The General diet questionnaire

This questionnaire was developed in order to further investigate the general diet of the IBS participants and highlight possible trends in the diet (appendix 14).

2.6.9 The IBS intervention feedback questionnaire

This questionnaire (appendix 15) was developed in order to investigate the level of achievement of the goals and intentions of the IBS intervention as they were described in the intervention description. The participants also provided information on whether further follow would be desirable.

2.7 Statistical analyses

The data were analysed using GraphPad Prism® software for Macintosh (Version 6.0, California, US). The normality of the distributions was graphically evaluated through histograms and Q-Q plots when appropriate. Paired t-tests were run for data considered parametric, and Wilcoxon Signed Rank Tests were run for data considered non parametric. The criterion for significance (alpha) was set to 0.05.

Prior to the utilisation of Graphpad, necessary data processing and extrapolation was undertaken in Excel for Macintosh (Version 2011) and through the web based programme Kostholdsplanleggeren (Version KP 2014)(75).

Kostholdsplanleggeren(75) served as the main tool for analysing the raw nutritional data (3-day food diaries and 24hrRs) before further data processing in Graphpad.

The data are expressed through median values (25,75 percentile) for the nutritional data, otherwise as the mean (standard deviation/confidence intervals. The range has also been reported when considered appropriate.

2.8 Ethical considerations

It is not required to seek ethical study approval when undertaking a quality assurance study. Participant information has been treated confidentially as appropriate. The local ethical committee (REK) has been consulted (appendix 16).

3 Results

3.1 Questionnaire response

There was a one hundred per cent response rate for the single measure questionnaires at interval II.

In regards to the repeat questionnaires, only the IBS- Symptom Severity Score questionnaire had a one hundred per cent response rate. The Visceral Sensitivity Index questionnaire had a 95 per cent response rate, and the Short Form- Nepean Dyspepsia Index questionnaire had a 75 per cent response rate (Table 4).

Table 4. *Repeat and single measure questionnaire response in group A+B (N20) and a+b (n13). Presented as the number of questionnaire response and the corresponding per cent. *groups*

Questionnaire	Time of collection	Group A+B N20 (%)	Group a+b n13 (%)
3 days food diary	pre & post	8(40) *	5(40)*
IBS-SSS*	pre & post	20(100)	13(100)
VSI*	pre & post	19(95)	12(90)
SF-NDI*	pre & post	15(75)	9(70)

***** note that only group B were provided 3-day food diaries
***** IBS Symptom Severity Score
***** Visceral Sensitivity Index
***** Short Form- Nepean Dyspepsia Index
* group A is the 12 & 15 month parameter; group B is the 6 & 10 month parameter
group A+B are all participants considered collectively
group a+b are those participants in group A and B on the FODMAP diet

3.2 Participant characteristics

Age

The mean age of the male participants was 35 years (range; 23-43). The mean age of the female participants was 46 years (range; 28-72)(Table 5).

Physical activity level

Of the males, 2 of 5 reported the highest physical activity level (3), whilst 2 reported the lowest physical activity level (1). Amongst the females, 80 per cent reported a PAL 2, and no participant reported the highest PAL (Table 5).

IBS duration

The mean length of IBS duration for the males was 14 (range; 3-35). The mean length of IBS duration for the females was 17 (range 2.5-50)(Table 5).

Other gastro intestinal disorders

All participants fulfilled the Rome III criteria for IBS. In addition, 25 per cent reported having an additional GI disorder. One reported having lactose intolerance, coeliac disease was prevalent in 2 participants, and 2 participants reported having oesophageal hernia (Table 5).

Other disorders

Seventy per cent reported having one or more additional condition in addition to the IBS. Fifteen per cent reported having hemochromatosis. Chronic migraine was also prevalent in 15 per cent. Two participants reported having depression and anxiety and two reported having chronic fatigue syndrome (Table 5). See appendix 17 for the full list of additional disorders.

Table 5. *Participant characteristics in group A+B (N20) as they were presented at post intervention interval II. Data are expressed as mean ±SD where appropriate. Based on the Characteristics; Clinical picture and Roma III questionnaires. *groups*

	Male n=5	**Female n=15**
Age	35(±8)	47(±13)
BMI	27(±6)	26(±6)
Physical Activity level*	n2=1 n1=2 n2=3	n3=1 n12=2 n0=3
IBS duration (years)	14(±13)	17(±13)
Fulfils Roma III criteria IBS	n=5	n=15
IBS diarrhoea predominant	n=3	n=2
IBS constipation predominant	n=1	n=7
IBS mixed	n=1	n=6
Other GI disorders	n=1	n=4
Other disorders	n=4	n=10

* PAL Physical activity level; 1= low level, 2=intermediate, 3=high level.
* group A is the 12 & 15 month parameter , group B is the 6 & 10 month parameter
group A+B are all participants considered collectively

3.3 Symptom control strategy implementations

Of the 24 IBS symptom control strategies that were provided during the IBS intervention, 85 per cent reported having general healthy eating habits in group A+B at post intervention (Table 6).

On the contrary, five per cent reported having implemented use of gel forming fibres and use of peppermint oil. Fifteen per cent reported use of probiotics (Table 6).

Thirteen participants (65 per cent) reported having implemented the FODMAP diet (Table 6).

Table 6. *IBS symptom control strategy implementations in group A (n10), B (n10), A+B (N20) and a+b (n13) at post intervention (approximately 15 months after for group A/a and 10 months after for group B/b). Data are presented as number of participants and the corresponding percentage. Based on the Strategy implementation questionnaire. *groups*

PROVIDED STRATEGIES	Group A n10(%)	Group B n10(%)	Group A+B N20(%)	Group a+b n13(%)
Regular meal times	8(80)	4(40)	12(60)	10(77)
Small sized frequent meals	7(70)	3(30)	10(50)	8(62)
Healthy varied eating	9(90)	8(80)	**17(85)**	8(62)
2 or more serves of fruits daily	7(70)	7(70)	14(70)	9(70)
3 or more serves of vegetables daily	8(80)	9(90)	**17(85)**	10(77)
Standard dinner plate model	8(80)	7(70)	15(75)	10(77)
Limited intake of very fatty foods	9(90)	8(80)	15(75)	9(70)
Limited intake of smoked foods	4(40)	6(60)	10 (50)	5(39)
Limited intake of spicy foods	5(50)	3(30)	8(40)	6(46)
Limited intake of alcoholic beverages	9(90)	9(90)	18(90)	13(100)
Limited intake of caffeinated beverages	4(40)	6(60)	10(50)	5(39)
Quiet ambient atmosphere during meals	8(80)	4(40)	12(60)	9(70)
Regular life style	9(90)	2(20)	11(55)	9(70)
Cultured milk products	3(30)	2(20)	5(25)	4(31)
Probiotics	0(0)	3(30)	**3(15)**	3(23)
Lactase enzyme capsules	1(10)	2(20)	**3(15)**	0(0)
Gel forming fibres	1(10)	0(0)	**1(5)**	1(8)
Pepper mint oil	1(10)	0(0)	**1(5)**	0(100)
Membership LMS	5(50)	2(0)	7(35)	3(23)
Awareness of breathing technique	5(50)	6(60)	11(55)	8(62)
Awareness of sitting posture	8(80)	5(60)	13(65)	11(85)
FODMAP books	7(70)	2(60)	9(45)	7(54)
Monash FODMAP application	3(30)	5(50)	8(40)	6(46)
FODMAP diet implementation	8(80)	5(50)	**13(65)**	**N/A**

* group A is the 12 & 15 month parameter; group B is the 6 & 10 month parameter
group A+B are all participants considered collectively , group a+b are those participants in group A and B on the FODMAP diet

3.4 Gastrointestinal symptoms

3.4.1 IBS Symptom severity score before and after intervention

In regards to the IBS-Symptom Severity Score we found no statistically significant difference between the pre and post intervention neither for group A (P=0.204) nor group B (P=0.949) (Figure 4).

In group A, 7participants had a 10 or more point IBS symptom severity score decrease, whilst 3 participants had a 10 or more point increase (Figure 4).

In group B, 5 had had a 10 or more point decrease whilst 4 had had an increase (Figure 4).

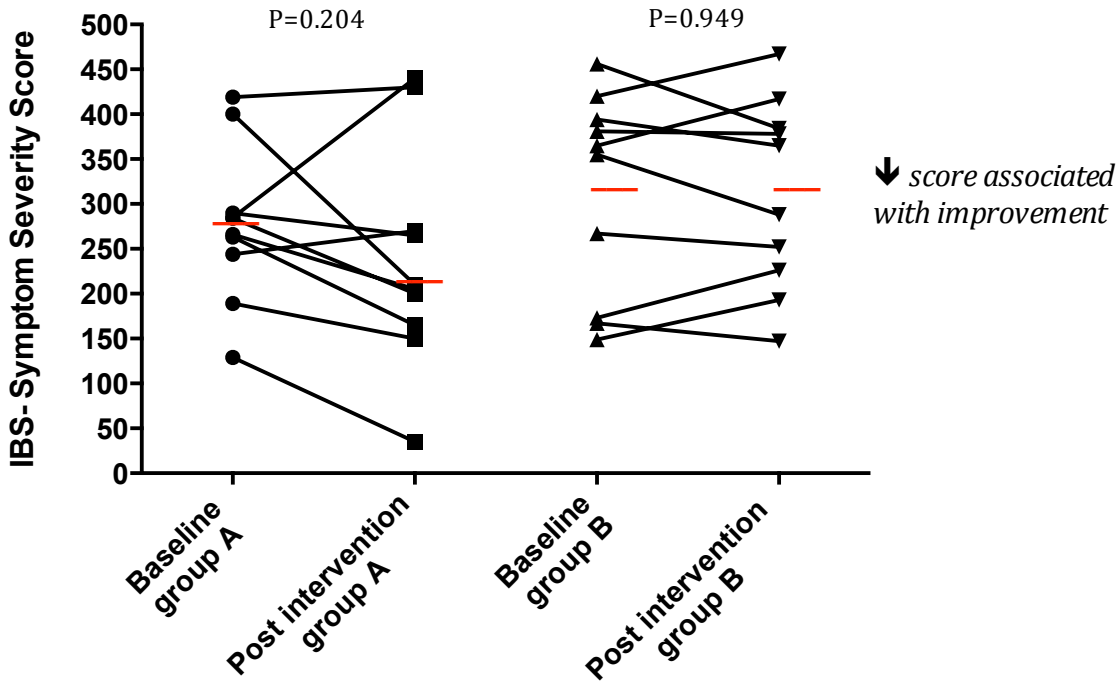

Figure 4. *IBS-Symptom Severity Scores for group A (n10) and B (n10) at baseline and post intervention (approximately 12 months after for group A, and 6 months for group B). For group A the mean was 277 at baseline and 237 at post intervention, for group B the mean was 313 at baseline and 312 at post intervention (in red). Data is presented as each individual participant. Group A is the 12 month parameter; group B is the 6 month parameter. Based on the IBS Symptom Severity Score questionnaire.*

When considering the groups collectively, we also found no statistically significant difference in group A+B (P=0.233) or in group a+b (P=0.301) (Figure 5).

In group A+B, 12 participants had a 10 or more point IBS symptom severity score decrease, whilst 3 participants had a 10 or more point increase (Figure 5).

In group a+b 8 participants had a 10 or more point decrease, versus 4 who had an increase (Figure 5).

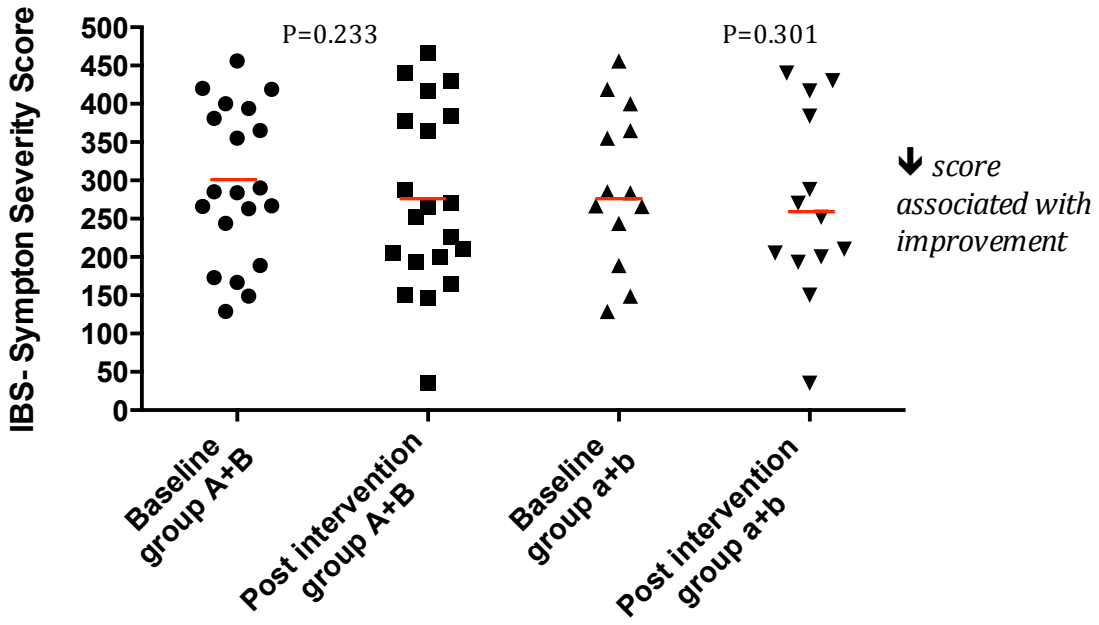

Figure 5. *IBS-Symptom Severity Scores for group A+B (N20) and a+b (n13) at baseline and post intervention (approximately 12 months after for group A/a, and 6 months after for group B/b). The mean for group A+B was 295 at baseline compared to 274 at post intervention. The mean for group a+b was 293 at baseline compared to 267 at post intervention (in red). Data are expressed as each individual participant. Group A/a is the 12 month parameter; group B/b is the 6 month parameter. Group a and b represent those in group A and B on the FODMAP diet. Based on the IBS Symptom Severity Score questionnaire.*

Mean difference

Both group A and B had a mean IBS Symptom Severity Score reduction from baseline to post intervention, however, the reduction was by far greatest in group A (Table 7).

When considering the groups collectively we also saw a reduction in both group means from baseline to post intervention, however the differences between the groups was now less (Table 7).

Table 7. *IBS-Symptom Severity Score and the corresponding size of the difference in group A (n10), group B (n10), group A+B (N20) and a+b (n13) at baseline and post intervention (approximately 12 months for group A/a and 6 months for group B/b). Data are presented as mean (±SEM). Based on IBS-Symptom Severity Score questionnaire. *groups*

Group	**Mean (±SEM) Baseline**	**Mean (±SEM) Post intervention**	**↑ /* ↓+**	**Size of change***
Group A	277 (±27)	237 (±39)	↓	40
Group B	313 (±36)	312 (±34)	↓	1
Difference*	**36**	**75**		**39**
Group A+B	295 (±22)	275 (±26)	↓	20
Group a+b	293 (±28)	267 (±34).	↓	26
Difference*	**2**	**8**		**6**

* ↑= increase compared to baseline ↓=decrease compared to baseline (note that size of the arrow indicates size of change)
↓+ indicate that a *decrease* is associated with an *improvement* in symptoms
* Size of change *within the same group*
* Difference between *group A and B*
* group A is the 12 & 15 month parameter; group B is the 6 & 10 month parameter
group A+B are all participants considered collectively , group a+b are those participants in group A and B on the FODMAP diet

3.4.2 Visceral Sensitivity Index before and after intervention

In regards to the Visceral Sensitivity Index we found no statistically significant difference between the pre and post intervention for group A (P=0.069) nor group B (P=0.252) (Figure 6).

In group A, 4 participants had a 5 or more point Visceral Sensitivity Index point increase, whilst 1 participants had had a 5 or more point decrease (Figure 6).

In group B, 3 participants had had a 5 or more point increase whilst had had a decrease (Figure 6).

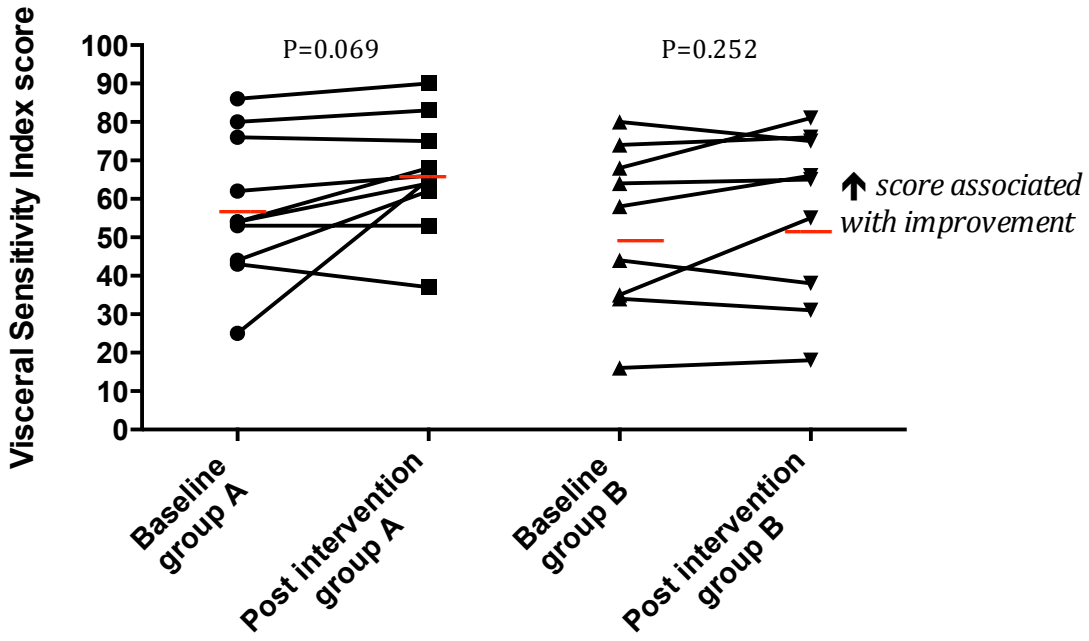

Figure 6. *Visceral Sensitivity Index for group A (n10) and B (n9) at baseline and post intervention (approximately 12 months after for group A, and 6 months after for group B). For group A the mean was 58 at baseline and 66 at post intervention, for group B the mean was 53 at baseline and 56 at post intervention (in red). Data are presented as each individual participant. Group A is the 12 month parameter; group B is the 6 month parameter. Based on the Visceral Sensitivity Index questionnaire.*

When considering the groups collectively, we found no statistically significant difference in group a+b (P=0.133).
However, we did find a statistically significant difference in group A+B (P=0.027) (Figure 7).

In group a+b, 4 participants had an increase and 3 participants had a decrease *(Figure 7)*.

In group A+B, 7 participants had a 5 or more point Visceral Sensitivity Index point increase, whilst 3 participants had a 5 or more point decrease *(Figure 7)*.

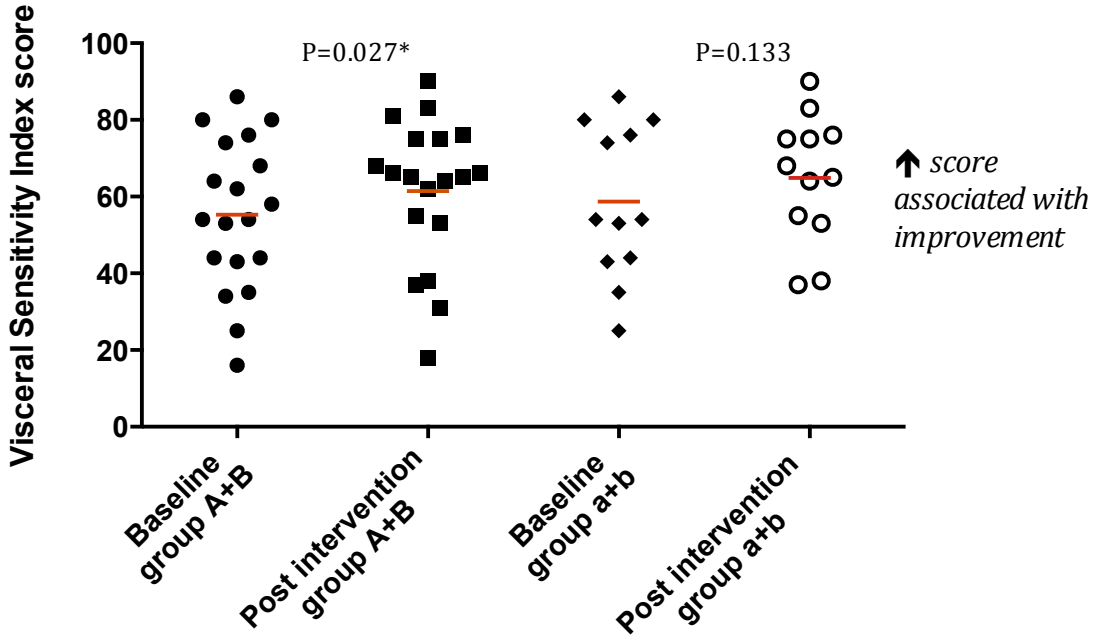

Figure 7. *Visceral sensitivity Index for group A+B (n19) and a+b (n12) at baseline and post intervention (approximately 12 months after for group A/a, and 6 months after for group B/b). The mean for group A+B was 55 at baseline compared to 62 at post intervention. The mean for group a+b was 59 at baseline compared to 65 at post intervention. Presented as each individual participant. Group A is the 12 month parameter; group B is the 6 month parameter. Group a and b represent those in A and B on the FODMAP diet. Based on the Visceral Sensitivity Index questionnaire.*

Mean difference

Both group A and B had a mean increase in Visceral Sensitivity Index scores at baseline and post intervention. Group A had the greatest increase (Table 8).

When considering the groups collectively, both groups also had an increase from baseline to post intervention. The increase was differentiated only by one point (Table 8).

Table 8. *Mean (±SEM) Visceral Sensitivity Index score and the corresponding size of the difference in group A (n9), B (n10), A+B (n19) and a+b (n12) at baseline and post intervention (approximately 12 months for group A/ a, and 6 months for group B/ b).* Data are expressed as the mean (±SEM). Based on the *Visceral Sensitivity Index questionnaire. *groups*

Group	Mean (±SEM) Baseline	Mean (±SEM) Post intervention	↑+ / ↓*	Size of change*
Group A	58 (±6)	66 (±5)	↑	**8**
Group B	53 (±7)	56 (±7)	↑	**3**
Difference*	**5**	**43**		**5**
Group A+B	55 (±5)	62 (±4)	↑	**7**
Group a+b	59(±6).	65 (±5)	↑	**6**
Difference*	**4**	**3**		**1**

* ↑= increase compared to baseline ↓=decrease compared to baseline
↑+ indicate that a *increase* is associated with an *improvement* in symptoms
* size of change *within the same group*
* difference between *group A and B*
* group A is the 12 & 15 month parameter; group B is the 6 & 10 month parameter

3.5 Quality of life

3.5.1 Short form- Nepean Dyspepsia Index before and after intervention

In regards to the Short Form-Nepean Dyspepsia Index we found no statistically significant difference between the pre and post intervention scores for group A (P=0.598) nor B (P=0.347) (Figure 8).

In group A, 3 participants had a 5 or more point SF-NDI point decrease, whilst 2 participants had a 10 or more point increase.

In group B, 4 participants had a decrease whilst 1 had an increase.

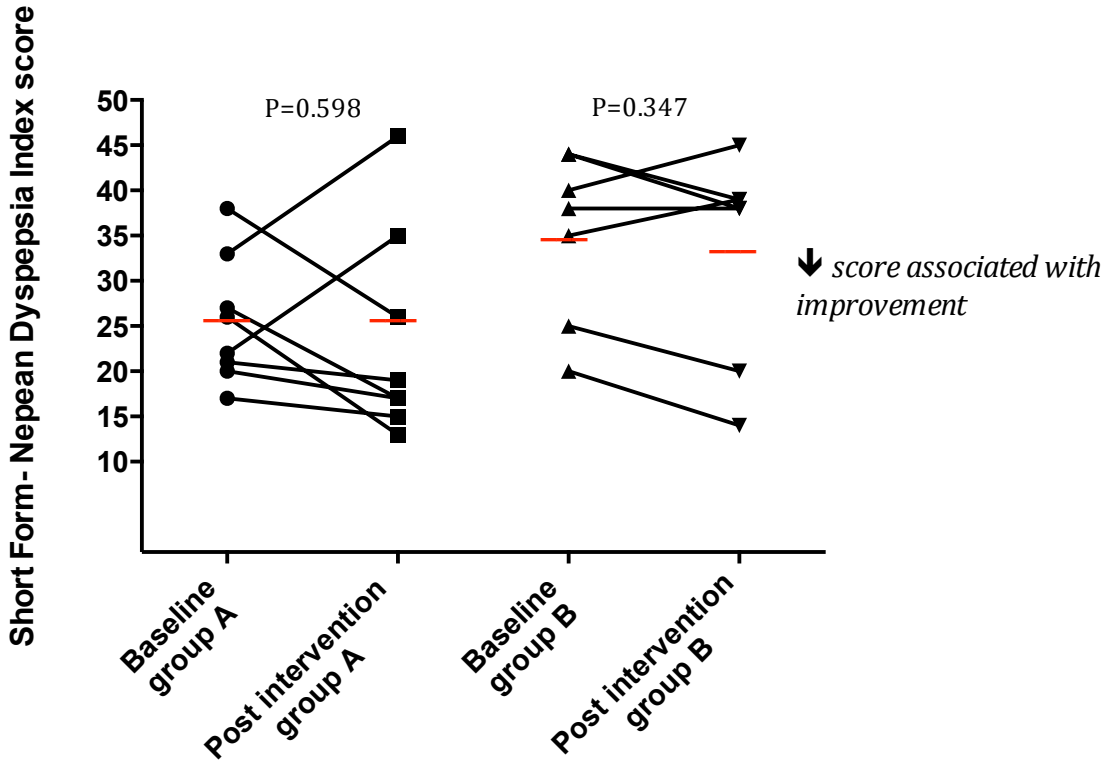

Figure 8. *Short Form-Nepean Dyspepsia Index scores for group A (n8) and group B (n7) at baseline and post intervention (approximately 12 months after for group A, and 6 months for group B). For group A the mean was 26 at baseline and 24 at post intervention, for group B the mean was 35 at baseline and 33 at post intervention. Data are presented as each individual participant. Group A is the 12 month parameter; group B is the 6 month parameter. Based on the Short Form-Nepean Dyspepsia Index questionnaire.*

Neither did we find no statistically significant difference when considering the groups collectively; group A+B (P= 0.359), group a+b (P=0.918) *(Figure 9).*

In group A+B, 7 participants had a 5 or more point Short-Form Nepean Dyspepsia Index score decrease, whilst 3 had an increase *(Figure 9)*.

In group a+b, 2 had a decrease versus 3 who had an increase *(Figure 9)*.

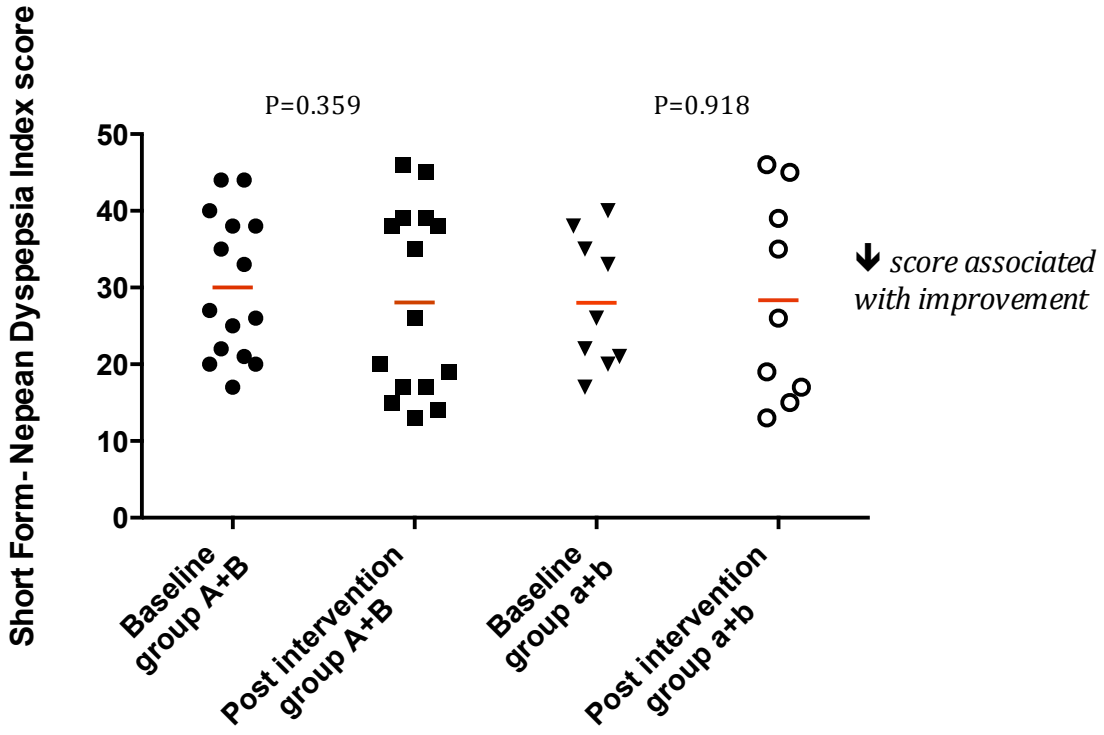

Figure 9. *Short Form-Nepean Dyspepsia Index scores for group A+B (n15) and a+b (n9) at baseline and post intervention (approximately 12 months after for group A/a, and 6 months after for group B/b). The mean for group A+B was 30 at baseline compared to 28 at post intervention. The mean for group a+b was 28 at both baseline and post intervention (in red). Data are presented as each individual participant. Group A/a is the 12 month parameter; group B/b is the 6 month parameter. Group a and b represent those in A and B on the FODMAP diet. Based on the Short Form-Nepean Dyspepsia Index questionnaire.*

Mean difference

Both group A and B had a mean Short Form Nepean Dyspepsia Index decrease from baseline to post intervention. The mean change was similar in both groups (Table 9).

When considering the groups collectively, the mean decreased in group A+B from baseline to post intervention, but it stayed the same in group a+b (Table 9).

Table 9. *Mean (±SEM) Short Form-Nepean Dyspepsia Index score and the corresponding size of the difference in group A (n7), B (n8), A+B (n15) and a+b (n10 at baseline and post intervention (approximately 12 months for group A/a and 6 months for group B/b). Data are presented as mean (±SEM).* Based on the Short *Form-Nepean Dyspepsia Index questionnaire.*

Group	Mean (±SEM) Baseline	Mean (±SEM) Post intervention	↑ /* ↓+	Size of change*
Group A	26 (±3)	24 (±4)	↓	**2**
Group B	35 (±4).	33 (±4)	↓	**2**
Difference*	**9**	**9**		**-**
Group A+B	30 (±2)	28 (±3)	↓	**2**
Group a+b	28 (±3)	28 (±4).	**-**	**-**
Difference***	**2**	-		**2**

* ↑= increase compared to baseline ↓=decrease compared to baseline
↓+ indicate that a *increase* is associated with an *improvement* in symptoms
* size of change *within the same group*
* difference between *group A and B*
* group A is the 12 & 15 month parameter; group B is the 6 & 10 month parameter

3.5.2 Subjective psychological health

For psychological health mean score was 7 for group A+B, whilst for group a+b the mean score was 6 (Figure 10).

In group A+B, 5 of 20 participants reported their psychological health to be very good and gave it the highest score possible 10 (bimodal). Another 5 graded it to be at level 8 (bimodal). The lowest score given was 3, and 2 participants reported this score (Figure 10).

In group a+b, 4 participants of 13 reported their health as 8 (the mode) and 1 participant gave it the top score of 10, whilst the lowest was a 3 and 1 participant reported this (Figure 10).

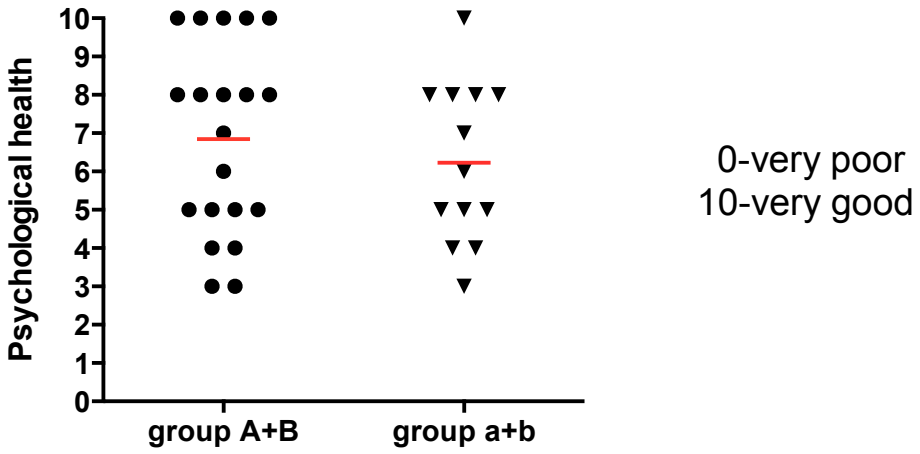

Figure 10. *Subjective psychological health level for group A+B (N20) and a+b (n13) at post intervention (approximately 15 months after for group A and a, and 10 months after for group B and b). The mean was 7 for group A+B, and the mean was 6 for group a+b. Data are expressed as each individual participants. Group A is the 12 & 15 month parameter; group B is the 6 & 10 month parameter; group a and b represent those in A and B on the FODMAP diet. Based on Clinical Picture questionnaire.*

3.5.3 Subjective quality of life

The mean score for QOL for group A+B was 5. For group a+b the mean was also 5 (Figure 11).

In group A+B, 10 of 20 participants graded their level of QOL to be 5 or lower, and the remaining 10 graded it to be 6 or higher. Five participants graded their OOL as high as 8, and two participants gave their QOL the lowest level possible. Five participants reported their QOL as 8 (the mode) (Figure 11).

In group a+b, 3 of 13 participants reported their quality of life to be a 3 (the mode). Three was also the lowest grading given. One participant graded the QOL to be 10 (Figure 11).

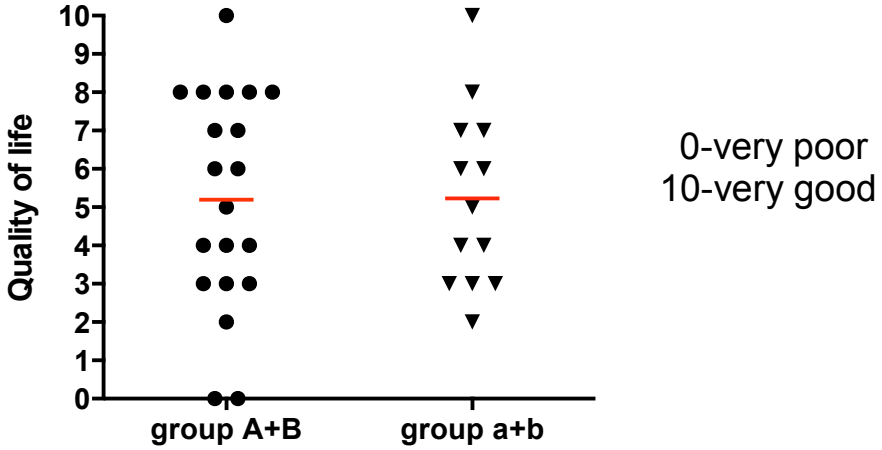

Figure 11. *Subjective everyday quality of life level for group A+B (N20) and a+b (n13) at post intervention (approximately 15 months after for group A and a, and 10 months after for group B and b). The mean was 5 for group A+B, and the mean was also 5 for group a+b. The mean was 5 for both group A+B and a+b. Data are expressed as each individual participant. Group A is the 12 & 15 month parameter; group B is the 6 & 10 month parameter; group a and b represent those in A and B on the FODMAP diet. Based on Clinical Picture questionnaire.*

3.5.4 Subjective everyday stress level

The mean score was 5 for group A+B N20, and for group a+b n13 the mean score was 5.5.

In group A+B, 8 of 20 participants graded their everyday stress level as 5 (the mode), 1 participant graded it the lowest possible, whilst 2 participants graded it the highest (Figure 12).

In group a+b 5 of 13 participants graded their everyday stress level as 5 (the mode), 1 participants graded it as 0 and 1 graded it as 10 (Figure 12).

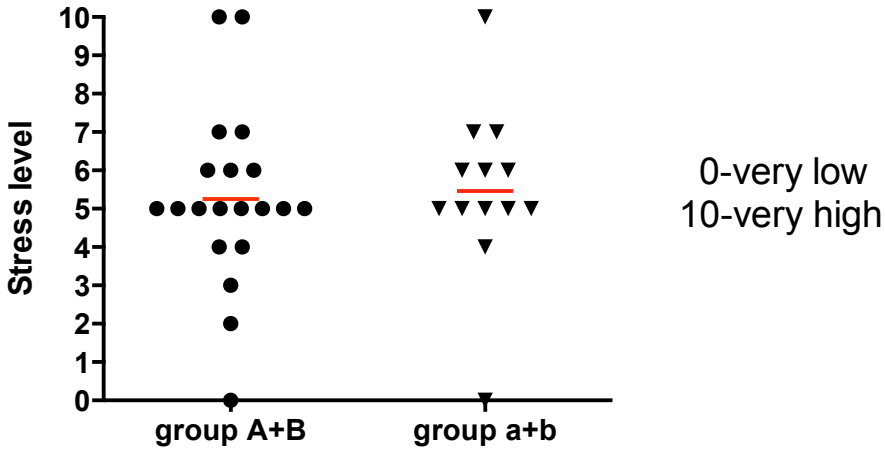

Figure 12. *Subjective every day stress level for group A+B (N20) and a+b (n13) at post intervention (approximately 15 months after for group A and a, and 10 months after for group B and b). The mean was 5 for group A+B, and the mean was 5.5 for group a+b. Data are expressed as each individual participants. Group A is the 12 & 15 month parameter; group B is the 6 & 10 month parameter; group a and b represent those in A and B on the FODMAP diet. Based on Clinical Picture questionnaire.*

3.6 Nutrition analysis

3.6.1 BMI before and after intervention

We found no significant change in BMI from baseline to post intervention neither in group A (P=0.688) nor group B (P= 0.813) *(Figure 13)*.

In group A, 3 participants had a stable BMI from baseline to post intervention. Five had an increase, and 2 had a decrease *(Figure 13)*.

In group B, also 3 participants had a stable BMI from baseline to post intervention. Four had an increase, and 3 had a decrease *(Figure 13)*.

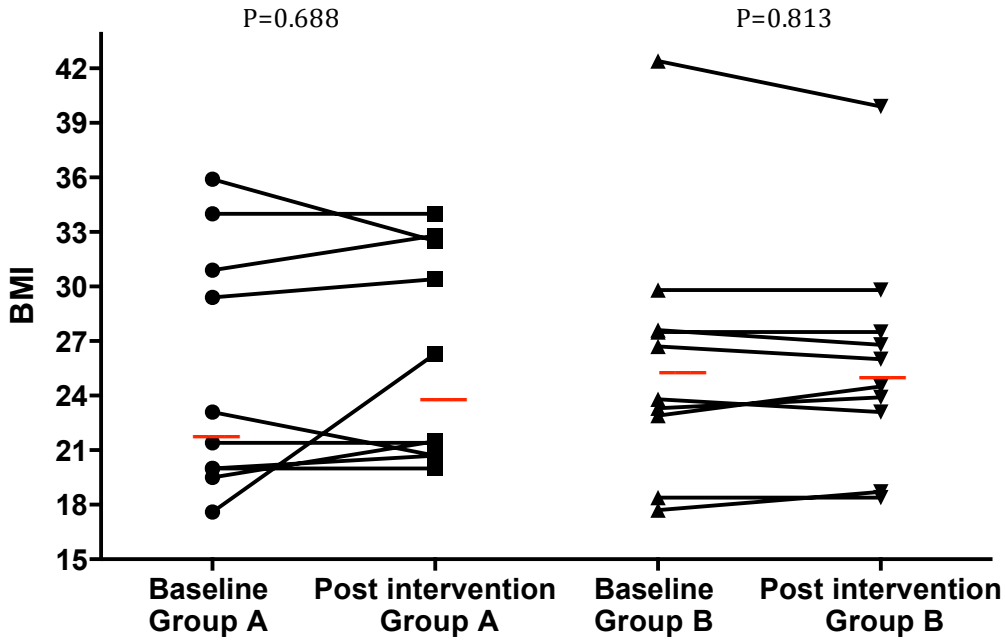

Figure 13*. BMI in group A (n10) and group B (n10) at baseline and post intervention (approximately 15 months after for group A and 10 months for group B). For group A the median was 22 at baseline versus 24 at post intervention, for group B the median was 25 both at baseline and at post intervention (in red). Data are expressed as each individual participant. Group A is the 12 month parameter; group B is the 6 month parameter. Based on anthropometry questionnaire.*

Neither when considering the groups collectively did we find a significant difference. Group A+B (P=0.726) and group a+b (P=0.999) (*Figure 14)*.

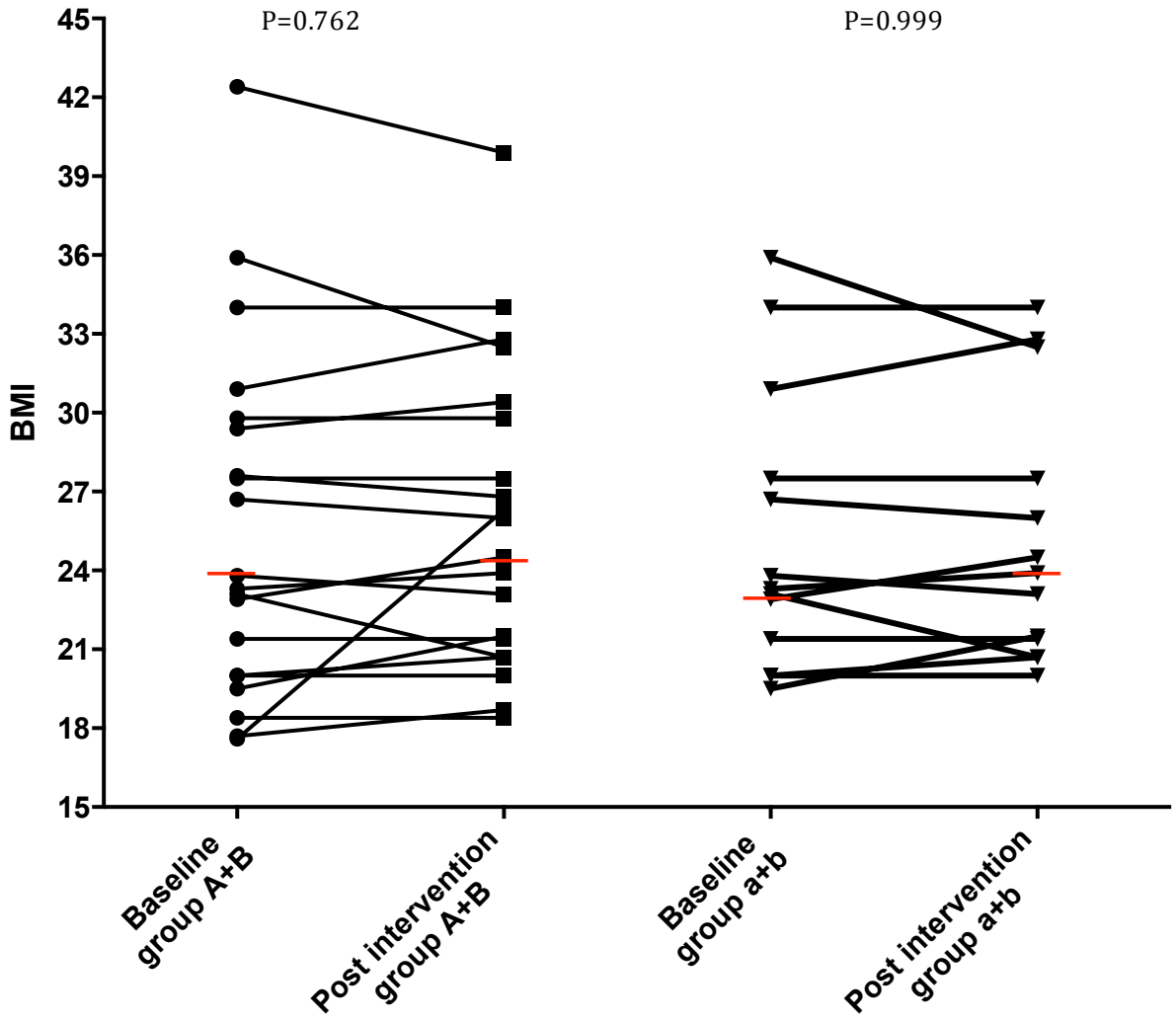

Figure 14. *BMI in group A+B (N20) and group a+b (n13) at baseline and post intervention (approximately 15 months after for group A/a and 10 months for group B/b). For group A+B the median was* 24 *at baseline and 25 at post intervention, for group a+b the median was 23 both and 24 at post intervention (in red). Data are expressed as each individual participant. Group A/a is the 12 month parameter; group B/b is the 6 & month parameter. Group a and b represent those in A and B on the FODMAP diet. Based on anthropometry questionnaire.*

Median difference

Both group A and B is within the normal median BMI range both at baseline and post intervention. Group A had a 2 points increase from baseline to post intervention whilst group B was stable (Table 10).

Considered collectively both group A+B and a+b were also within the normal median BMI range both at baseline and post intervention. Both groups had a one point increase from baseline to post intervention (Table 10).

Table 10. *BMI and the corresponding size of the difference in group A (n10), B (n10), A+B (N20), a+b (n13) at baseline and post intervention (approximately 15 months for group A/a and 10 months for group B/b). Data are presented as the median (25,75 percentile). Based on anthropometry questionnaires. *groups*

Group	**Median** (25,75percentile) **Baseline**	**Median** (25,75percentile) **Post intervention**	↑ /* ↓	**Size of change****
Group A	22 (20,32)	24 (21,33)	↑	**2**
Group B	25 (22,28)	25 (22,28)	-	**-**
Difference***	**3**	**1**	**-**	**2**
Group A+B	24(20,30)	25(21,30)	↑	**1**
Group a+b	23(21,29	24(21,30)	↑	**1**
Difference***	**1**	**1**		**-**

* ↑= increase compared to baseline ↓=decrease compared to baseline
* size of change *within the same group*
* difference between *group A and B*
* group A is the 12 & 15 month parameter, group B is the 6 & 10 month parameter
group A+B are all participants considered collectively, group a+b are those in group A and B on the FODMAP diet

3.6.2 Energy intake before and after intervention

We found no statistically significant change in percent kcal of the reccomended ditary intake (RDI) achieved from baseline to post intervention interval I in group B (P=0.999) nor in group b (P=0.438)(Figure 15).

In group B, 1 participants covered the kcal requirements at baseline versus 2 at post intervention. In group b, 1 participant covered the kcal requirement at baseline and post intervention (Figure 15).

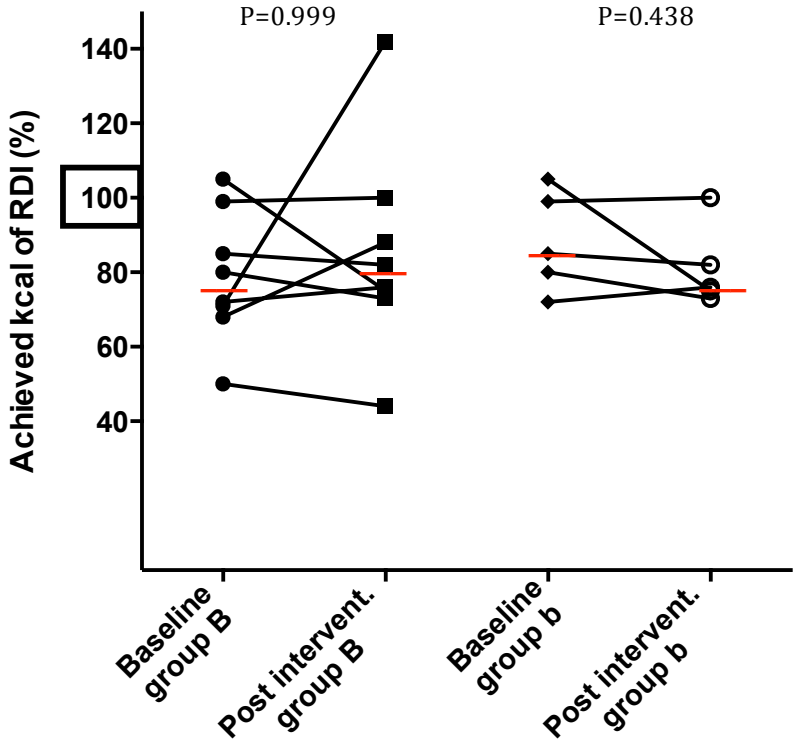

Figure 15. *Achieved percent of kcal of RDI in group B (n8) and b (n5) at baseline and post intervention (approximately 6 months). For group B the median was 76 % coverage at baseline versus 79 % at post intervention, for group b the median was 85 % at baseline versus 76% at post intervention (in red). Data are presented as each individual participant. Group B/b is the 6 month parameter. Group b represent those in B on the FODMAP diet. Based on 3-day food diaries (hence only group B/b representable).*

Median difference

For group B the achieved percent of kcal was slighlty higher at post intervention compared to baseline. For group b the achieved percent of kcal was lower at post intervention (Table 11).

Table 11. *The achieved per cent of kcal of RDI and the corresponding size of the difference in group B (n8) and b(n5) at baseline and post intervention (approximately 6 months) Data are expressed as the median (25,75 percentile). Based on 3-day food diary (hence therefore only group B/b representable).*groups*

Group	**Median** (25,75percentile) **Baseline**	**Median** (25,75percentile) **Post intervention**	↑ /* ↓	**Size of change****
Group B	76 (69,96)	79 (74,97)	↑	**3**
Group b	85 (76,102)	76 (74,91)	↓	**9**
Difference*	**9**	**3**		**6**

* ↑= increase compared to baseline ↓=decrease compared to baseline
* size of change *within the same group*
* difference between *group A and B*
* group A is the 12 & 15 month parameter, group B is the 6 & 10 month parameter group A+B are all participants considered collectively

Considered collectively, group A+B and a+b we saw similar trends in terms of kcal coverage of kcal at post intervention interval II compared to interval I (Figure 16).

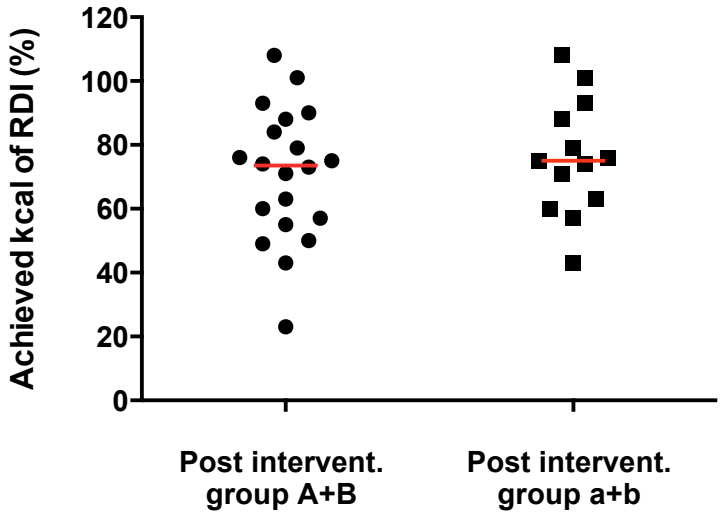

Figure 16. *Achieved per cent of kcal of RDI in group A+B (N20) and a+b (n13) at post intervention (approximately 15 months after for group A and a and 10 months after group B and b). The median was 74 % coverage for group A+B and 75 % for group a+b. Data are expressed as each individual participant and the median and 25,75 percentile. Group A is the 12 & 15 month parameter; group B is the 6 & 10 month parameter; group a and b represent those in A and B on the FODMAP diet. Based on 24hrR.*

3.6.3 Fibre intake before and after intervention

We found no statistically significant difference in fibre intake from baseline to post intervention interval I in group B (P=0.844) nor group b (P=0.750) (Figure 17).

In group B, 3 participants covered their intake of fibre at baseline and at post intervention. In group b the same 3 participants covered their intake at baseline and n at post intervention (Figure 17).

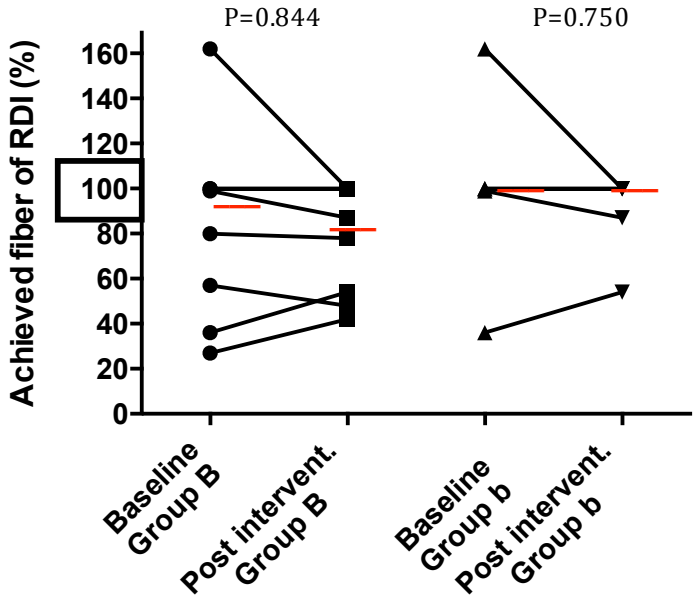

Figure 17. *Achieved per cent of fibre of RDI in Group B (n8) and group b (n5) at baseline and post intervention (approximately 6 months). For group B the median was 90 % coverage at baseline versus 83 % at post intervention, for group b the median was 100 % both at baseline and post intervention (in red). Data are expressed as each individual participant. Group B/b is the 6 month parameter. Group b represent those in group B on the FODMAP diet. Based on 3-day food diaries (hence only group B/b representable).*

Median difference

Group B had a decrease in achived percent of fiber of the RDI from baseline to post intervention, but for group b it was stable (Table 12).

Table 12. *Achieved per cent of fibre of RDI and the corresponding size of the difference in group B (n8) and b (n5) at baseline and post intervention (approximately 6 months). Data are expressed as median (25,75 percentile). Based on 3-day food diaries (hence therefore only group B/b representable). *groups*

Group	**Median** (25,75percentile) **Baseline**	**Median** (25,75percentile) **Post intervention**	**↑ /* ↓**	**Size of change****
Group B	90 (41,100)	83 (50,100)	↓	**5**
Group b	100 (68,131)	100 (71, 100)	-	**-**
Difference***	**10**	**17**	**-**	**5**

* ↑= increase compared to baseline ↓=decrease compared to baseline
* size of change *within the same group*
* difference between *group A and B*
* group B is the 6 & 10 month parameter, group b are those participants in group B on the FODMAP diet

Considered collectively, group A+B and a+b we saw similar trends in terms of fibre coverage of kcal at post intervention interval II compared to interval I (Figure 18).

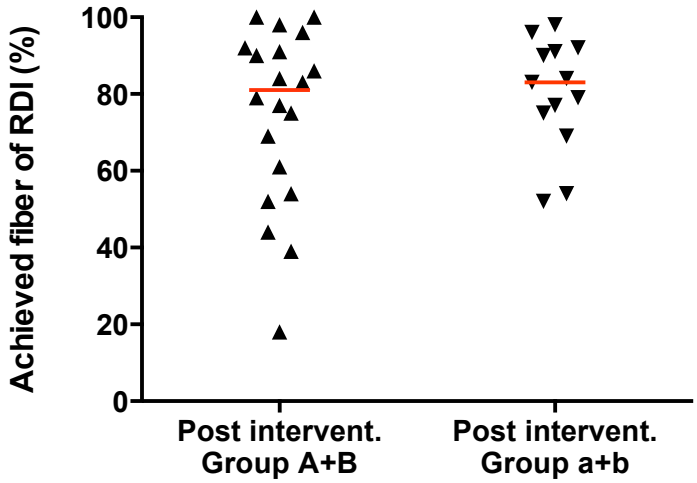

Figure 18*. Achieved per cent of fibre of RDI in Group A+B (N20) and a+b (n13) at baseline and post intervention (approximately 15 months for group A and a, and 10 months for group B and b). The median was 81 % coverage for group A+B and the median was 80 % coverage for group a+b. Data are expressed as each individual participant and the median (25,75) percentile. Group A is the 12 & 15 month parameter; group B is the 6 & 10 month parameter; group a and b represent those in A and B on the FODMAP diet. Based on 24hrRs.*

3.6.4 Macronutrient distribution before and after intervention

We found no statistically significant difference in median macronutrient distribution from baseline to post intervention for group B (protein P=0.250), cho (P=0.718), fat (P=0.563) nor in group b (protein P=0.635), cho (P=0.750), fat (P=0.750).

The median values for both group B and b for all macronutrients are within the reccomendations both at baseline and post intervention, except for saturated fat which is slightly above the reccomendations for both group B and b (Table 13).

Table 13. *Macro nutrient distribution and the associated p-values for group B (n8) and b(n5) at baseline and post intervention (approximately 6 months). Data are expressed as median (25 and 75 percentile). Based on 3- day food-diaries (hence therefore only group B/b representable). *groups*

Macro Nutr.	Baseline group B	Post group B	P-value	Baseline group b	Post group b	P-value	Guide-line
Protein	18(16-21)	21(18-24)	**0.250**	19(17-25)	21(19-26)	**0.625**	10-20
CHO tot	45(39-52)	44(37-54)	**0.718**	42(40-51)	41(35-51)	**0.750**	45-60
Added sugar	8(2-12)	6(2-14)	**0.999**	7(2-10)	2(2-15)	**0.999**	<10E
Fat tot	34(32-41)	35(29-42)	**0.563**	33(32-40)	37(31-41)	**0.750**	25-40
SAT	13(11-16)	12(11-15)	**0.500**	12(10-16)	12(11-15)	**0.999**	<10E
MUFA	10(10-12)	11(9-13)	**0.656**	10(10-12)	11(10-12)	**0.813**	10-20
PUFA	7(4-10)	6(4-10)	**0.999**	9(7-10)	7(6-12)	**0.999**	5-10

Wilcoxon matched- pairs signed rank test Nutritional supplements not included
Significant P≤0.05
* group B is the 6 & 10 month parameter, group b are those participants in B on the FODMAP diet

Considered collectively, group A+B at post intervention interval II, the median protein distribution was slightly above the recommendation, but this was not case for group a+b (n13).

In regards to median total carbohydrate both group A+B and a+b were slightly lower than recommended. The median saturated fat distribution was slightly high for both groups. The other macronutrients were within the guidelines (Table 14).

Table14. *Macro nutrient distribution in group A+B (N20) and a+b (n13) at post intervention (approximately 15 months after for group A and a, and 10 months after for group B and b). Data are expressed as median (25 and 75 percentile). Group A is the 12 & 15 month parameter; group B is the 6 & 10 month parameter; group a and b represent those in A and B on the FODMAP diet. Based on 24hrRs. *groups*

Macro nutrient	Post group A+B	Post group a+b	Guide-line
Protein	24(20-28)	21(20-29)	10-20
CHO tot	38(30-43)	34(28-41)	45-60
Sugar added	2(0-5)	2(0-4)	<10
Fat tot	38(33-42)	40(37-48)	25-40
SAT	14(12-18)	16(12-18)	<10
MUFA	12(10-13)	13(11-14)	10-20
PUFA	7(5-10)	10(6-11)	5-10

* group A is the 12 & 15 month parameter, group B is the 6 & 10 month parameter
group A+B are all participants considered collectively , group a+b are those participants in group A and B on the FODMAP diet
Nutritional supplements not included

3.6.5 Food frequency intake of specific foodstuff

In both group A+B 70 per cent of the participants reported having 2 or more serves of fruit daily and in regards to 3 or more severes of vegetables there was a 85 per cent coverage in the group. In group a+b the trends were similar (Table 15).

The intake of meat products was high across both groups, especially in group a+b where fish was consumed at least once a week in all participants (Table 15).

In terms of milk products for drinking beverage, the lactose free variant was most prevalent across both groups (Table 15).

Sixty per cent of all participants reported use of gluten free products and the prevalence was higher amongst group a+b (77 per cent) (Table 15).

All participants but one reported taking one or several nutritional supplements either daily or on a weekly basis (Table 15).

Table 15. *Daily or weekly food frequency intake of specific foodstuff in group A+B (N20) and a+b (n13) at post intervention (approximately 15 months after for group A and a, and 10 months for group B and b). Data are presented as the number of participants and the corresponding percentage. Based on Food frequency questionnaires. *groups*

FOODSTUFF	Group A+B N20 (%)	Group a+b n13 (%)
2 serves of fruit daily	**14 (70)**	**10 (77)**
3 serves of vegetables daily	**17 (85)**	**12 (92)**
Milk products normal daily	7 (35)	4 (31)
Milk products lactose reduced daily	4 (20)	2 (16)
Milk products lactose free daily	11 (55)	**11(85)**
Hard cheeses daily/weekly	15 (75)	10 (77)
Gluten containing grains daily	8 (40)	5 (38)
Gluten free grains daily	**12 (60)**	**10 (77)**
Red meat weekly	15 (75)	11 (85)
Chicken weekly	12 (60)	9 (69)
Fish weekly	**16 (80)**	**13 (100)**
Nutritional supplements daily/weekly	**19 (95)**	**12 (92)**

* group A is the 12 & 15 month parameter, group B is the 6 & 10 month parameter
group A+B are all participants considered collectively , group a+b are those participants in group A and B on the FODMAP diet

4 Discussion

We conducted a quality assessment study of the long-term impact of the IBS intervention provided at LMS/HUS.

We hypothesised that the IBS intervention is associated with reduced IBS symptoms, improved quality of life and nutritional intake from baseline to post intervention.

A study of this kind is of large importance as IBS is a very prevalent disorder and the adequacy of group education requires critical evaluation.

We found no significant change in neither of the assessed parameters apart from the Visceral Sensitivity Index parameter in one group.

A study published in April 2015 has showed that dietician-led FODMAP education is clinically effective. They looked at before and after parameters regarding global symptom questions, symptom prevalence and stool output in 364 patients. The researchers recommend that group FODMAP training is considered as routine clinical care for IBS patients (76).

Furthermore, a systematic review from 2010 concluded that many self-management support interventions appear to benefit the IBS patient. Nevertheless, the authors acknowledged methodological flaws and encouraged well-designed clinical trials(77).

The results, study design and future aspects involving the current study will now be subject to critical discussion.

4.1 Discussion of results

4.1.1 Symptom control strategy implementations

We found that many participants had implemented many of the provided IBS symptom control strategies. However, details on the manners of implementation are largely unknown. Furthermore, participants may have implemented management strategies already at baseline. For example, participants may have already been on the FODMAP.

Information obtained through the FODMAP diet questionnaire (appendix 13) demonstrated that the majority of the participants executed the diet inappropriately. We identified that several participants did not perform systematic liberation of the strict low FODMAP diet. Very few had obtained a close to symptom-free state both before commencing elimination, and in between testing eliminated foods. Close to all participants did not test foods that they on previous occasions had found problematic. Most participants did not report to compensate for excluded foods.

The vast majority of the participants reported that personalised guidance on the diet would have been preferable. Our study has essentially confirmed the hypothetical comparisons, laid out by Shepherd and her team, regarding the potential differences between dieticians delivered FODMAP education versus no dietetic involvement (Table 16)(78).

Table 16. *A hypothetical comparison of education in the low FODMAP diet as delivered by a trained dietician compared with that as a self-taught option via instruction sheets, books over the internet. Disclaimer; the table is not original to this paper (78).*

	Dietician delivered	**Self-taught**
Structure of education	Complex, requires detailed explanation	Haphazard unchecked access to information
Suitability of foods explained comprehensively	Focus on suitable foods not just problematic foods	Potential misinformation-lists on internet, out-of-date information
Risk of unnecessary over-restriction	Minimises risk	Increases risk (e.g. failure to rechallenge)
Ability to attain nutritional adequacy	Ensure nutritional adequacy	Not monitored for nutritional adequacy
Personalised advice	individualised	Not individualised

* Referance: Shepherd, Lomer and Gibson: Short Chain Carbohydrates and Functional Gastrointestinal Disorders. The American Journal of Gastroenterology, March 2013.

4.1.2 Gastro intestinal symptoms

We found a statistically significant difference in the visceral sensitivity score in group A+B, but not in any of the other groups. We found a P-value close to significant in group A. In group B and a+b the trend was less compared to group A. It may be that the significant change in group A+B occurred due to the effects of collaborative comparisons.

We found no statistically significant difference in IBS symptom severity score in neither of the groups. It may appear so, however, that group A had an overall better symptom severity score reduction compared to group B (similar trends as seen with the visceral sensitivity).

The findings may correspond with the fact that 80 per cent of the participants in group A reported being on the FODMAP diet compared to 50 per cent in group B. This may indicate that the decision to implement the diet requires time (as a greater percentage in group A had implemented that diet).

Nevertheless, those on the FODMAP diet do not seem to vary much in symptom severity score compared to the group as a whole, and this may reflect the overall poor manners of execution of the FODMAP diet as previously discussed.

One should notice, however, that the mean IBS symptom severity score is relatively high in both groups (although particularly in group B) and this may indicate that our study participants represent relatively complex cases of IBS.

It must be emphasized that the IBS Symptom Severity Score questionnaire is a tool developed for monitoring the GI process. In our study we only measured at baseline and post intervention (once) and consequently our level of monitoring is questionable. Ideally the questionnaires should have been used at several interval points.

Furthermore, it may be argued that we should have dedicated more attention to the change in severity category distributions (mild, moderate, severe) rather than individual

differences, though, due to concerns on consistency and the relatively low number of participants we chose not to. One participant (in group A) scored less than 75 points at post intervention and this may indicate a state of remission. Upon questioning, the participant largely contributed the positive trends to the FODMAP diet. The participant revealed that it was challenging to be on the FODMAP and the participant had made use of other resources for management than those obtained at the IBS intervention.

In group B, no participant scored less than 75 points at baseline or post intervention. In group A, we had a decrease in the number of participants in the moderate category, whilst we had an increase in group B. We saw that the number of severe cases did not change in group A, whilst group B had a slight decrease. This may indicate that for group A we saw a greater positive trend compared to group B. See (appendix 19) for the distribution for all participants at baseline and post intervention.

4.1.3 Quality of life

Quality of life in patients with IBS is often reported to be low (35, 57). Although we found no statistically significant difference in the Short Form Nepean Dyspepsia Index questionnaires, it does appear that both groups resembled positive trends in terms of quality of life.

Interestingly, Group B showed the greatest change for the SF-NDI but the smallest change in IBS symptom severity score as discussed earlier (i.e. opposing trends). Nevertheless, the smallest change was seen in group a+b. Again, the magnitude of the association might be poor, but this may indicate that quality of life can be adversely affected from being on the FODMAP diet (especially if gastro intestinal relief is minimal).

One should notice that the SF-NDI questionnaires had a very low response rate, and many of those who didn't return the questionnaires in complete form were in fact on the FODMAP diet (further decreasing the magnitude of the association).

Subjective psychological health, quality of life and everyday stress level

We asked the participants (at interval II) to grade their psychological health, quality of life and everyday stress level using the visual analogue scale system (0-10 grading) and we were relatively surprised when relatively many participants graded their quality of life to be relatively high (the mode being 8 in group A+B). Does this mean that that visual analogue scale contradicts the SF-NDI scores where we saw no change? It may very well mean that the quality of life was already relative high at baseline and therefore we saw no change.

We also considered the subjective level of psychological health to be relatively high in all groups, although interestingly slightly lower in those on the FODMAP diet. Those on the FODMAP diet may have exhibited a slightly higher stress level compared to the group as a whole. Stress is commonly reported in IBS patients(20, 24).

4.1.4 Nutrition analysis

BMI

We found no significant change in BMI in neither of the groups. The median BMI was within the normal ranges both at baseline and post intervention. Interestingly, we saw a median increase in all groups. This may indicate that participants were relatively ill at the time of the intervention with a consequent lower weight status. Other studies have also found IBS patients to be in the normal BMI weight category, or borderline overweight (36). It is also evident that weight reduction upon implementation of the FODMAP diet may occur (if energy intake does not meet requirements), however, it does not appear to have occurred in our study.

Energy intake

We found no statistically significant difference in neither of the groups in terms of energy intake. Those on the FODMAP diet had a median reduction in energy intake and this may be due to the challenges of being on the diet. In our study, however, most

participants (regardless of being on the diet or not) did not cover their energy needs. There may be reason to suspect underreporting contributing to these results. The suspicion may be underbuilt by the stability in BMI as previously reported. Furthermore, one must take note of the high proportion of woman in our study, and women are particularly prone to underreporting(79).

Fibre intake

Regarding the fibre intake we found no statistically significant change of coverage of the median RDI in neither of the groups. Group B, however, did have a slight median reduction in fibre intake. It is known that the FODMAP diet may reduce total intake of fibre (57). Interestingly, in our study, group b (those on the FODMAP diet) had no median change in fibre intake. In fact, group b had a median coverage of RDI of one hundred per cent both before and after intervention. Keep in mind, though, that group b had a very small number of participants and outliers undoubtedly have coloured the result. Ideally we should have looked at the balance between insoluble and soluble fibre. An over abundance of fibre in general (especially if insoluble fibre is the predominant type) may have adverse effects on gastro intestinal health for IBS(23).

The 24hrR also showed a relatively high coverage of fibre, although the median coverage was slightly lower compared to the results from the 3-day food diary. However, this may very well resemble the discrepancies between the two methods rather than actual difference in intake.

Macronutrient distribution

We found no statistically significant change in median macro nutrient distribution from baseline to post intervention for neither of the groups. All distributions were within the recommendations, apart from saturated fat, which was slightly above the recommendations.

We found a borderline adequate coverage of carbohydrate distribution. This could be explained by the fact that many IBS patients report to adversely react to carbohydrate

containing foods(42, 51). Furthermore, many IBS patients in our reported that the gluten free products were less appealing than the gluten-containing products, and this may have impacted the intake. Data from the 24hrR confirmed these trends, as we found a slightly inadequate total carbohydrate distribution.

Furthermore, the 24hrR confirmed the trends observed from the 3-day food diaries regarding the slightly elevated saturated fat distribution.

Food frequency intake of specific foodstuffs

At post intervention (interval II) we investigated the food frequency intake of specific foodstuffs. We saw that the majority of all participants covered their daily fruit and vegetable requirements (2 serves of fruit and 3 serves of vegetables). As previously discussed, it may appear that the recruited participants for this study seem to be interested in aspects of a healthy diet. Other studies have found that carbohydrate rich foods such as fruit and vegetables may cause adverse affects in those with IBS and consequently these food choices can be consumed less frequently(42, 51, 80).

The participants may not have been sufficiently aware of the framework of the investigation, for example, it may be that participants have included potatoes when counting serves of vegetables. In regards to the daily fruit intake, we saw also saw a high the intake, however, slightly lower than the vegetable intake. This may correspond with exclusion due to potential fructose mal-absorption (53), however, several participants in our study also revealed that media driven adverse controversies on fructose consumption influenced their fruit intake.

We found that the majority of the participants eat gluten free grain products. Several individuals in our study claimed attributes resembling that of non-coeliac gluten intolerance. The majority of the participants reported spelt flour as a good alternative. The way of processing the spelt flour affects the final FODMAP content, and the Low FODMAP smart phone app considers correctly prepared sour dough spelt bread in restricted amounts as low FODMAP. Otherwise, it appeared that several participants in our study mistakenly considered spelt to be gluten free.

It is important for IBS sufferers to be aware that a total exclusion of gluten (or fructans) is not necessary for the health of the intestines (as it is in coeliac disease) (81). As an example, several participants in our study made use of rinsed oats and gluten free liver pate.

We found the lactose free product to be the most frequently consumed milk product. The lactose-reduced milk was hardly consumed at all. It appeared that several assumed that lactose had to be completely excluded from the diet.

All but one participant reported intake of one or several nutritional supplements either daily or weekly. Consequently we investigated nutritional adequacy (achieved percentage of the recommended dietary intake) both for the macro and micronutrients *excluding the nutritional supplements* in the analysis. We found an overall satisfactory median nutritional adequacy where many micronutrients exceeded the recommended dietary intake. For instance, we found a median coverage of vitamin b12 of 400 % and vitamin A with a150 % coverage (appendix 20). Therefore, due to the heavy reliance on nutritional supplements amongst our participants (95 per cent), there may be reason to suspect that many of our participants may exceed their RDIs for varying micronutrients (depending on the supplements used).

Furthermore, at the individual level, we estimated a total coverage of magnesium exceeds the RDI by over 2000 per cent. Interestingly, many of the IBS associated symptoms that this participant reported corresponded with general symptoms of excessive intake of magnesium. Interestingly, this particular participant reported initiation of the IBS symptoms approximately at the same time as implementing use of different supplements. It is very difficult to discuss cause and effect in such matters; however, the participant was informed about the coincidence and consequently omitted use of specific supplements. The participant has since reported improvement in symptoms.

It is interesting that many IBS patients have identified at least one food that causes adverse effect(82),however, the level of suspicion towards nutritional supplements

seem to be less prevalent. It can therefore be argued that the adequacy of nutritional supplements should be routinely assessed in consultations with IBS patients. More data on specific types and amounts used of the different nutritional supplements should have been collected.

Although the overall diet seemed healthy in our study participants, many had a relatively restricted and monotonous food intake (although many reported dietary liberation after commencing the FODMAP diet). Other studies have found that many IBS patients exclude foodstuff important for health (36).

4.2 Discussion of methods

4.2.1 Study design

We found it challenging to perform a quality assessment study for many reasons. The process can easily become a very large and tedious perhaps due to the somewhat diffuse study design framework. Furthermore, it may be difficult to pin point what variables are being measured. It is difficult to measure cause and effect and confounders are widely present. We may observe a gastro intestinal change after an IBS intervention attendance, however, for obvious reason it is difficult to suggest a definitive reasoning as to why we may have made these observations. Maki et al. have highlighted the critical importance of observational data in dietary research, however, the researchers also pin pointed the many limitations in need of acknowledgment (for example how chance, bias, confounding and lack of randomisation colouring the associations)(83).

The vast majority of all our participants reported having gastrointestinal impact of varying severity. This is not uncommon for individuals with IBS(24). Consequently, this may have impacted our results, as the gastro intestinal status at the time of answering the questionnaires has not been recognised. Several reported to have a ´rough run lately´ at the time of answering the questionnaires at post intervention.

We identified that 65 per cent (13 participants) used painkillers either regularly or occasionally. Two participants reported using laxatives and four participants reported using antidiarrheal such as Imodium.

It may be that important aspects and effects of the IBS intervention may *not* have been presented simply due to the methodology of the study. Did the aims correspond with the methods? Can one really propose (on the basis of the results of this study) that the IBS intervention at HUS cannot be associated with reduced IBS symptoms, improved QOL and nutritional intake?

Upon consideration of the IBS intervention evaluation feedback form (appendix 21) currently used at LMS, it becomes evident that approximately 90 per cent of the November, March and April participants (n45; i.e. including participants not recruited for this study) found the performance of the gastroenterologist, physiotherapist, clinical dietician and psychiatrist to be beneficial to them.

The IBS intervention at LMS adapts to participant feedback and also other input that may appear (for example new research). For instance, participants have expressed a need for more hands on practical skills for implementation of the FODMAP diet. Consequently, the IBS intervention programme conformed to this and is therefore slightly different to the programme presented in appendix 22 (from November 2013).

LMS also work on establishing the best methods for evaluation of the IBS intervention, and currently it is debated how to best address the variables of quality of life. It may be suggested that the visual analogue scale would be a suitable method.

Furthermore, according to the IBS intervention feedback questionnaire (appendix 15) 16 of 20 participants (80 per cent) reported that the course *did provide* necessary resources to improve their everyday quality of life. Sixty five per cent reported that their everyday quality of life *had improved* after the IBS intervention.

Nevertheless, eleven participants (55%) replied that further assistance for management of their IBS would be desirable. In terms of implementing the FODMAP diet, however, it

is worth noticing that the vast majority of the participants expressed some level of uncertainty in term of how to execute the FODMAP diet. Others have also identified challenges of the FODMAP without professional guidance(24).

Awareness of such information makes our study conclusion largely inappropriate (we found no difference in our parameters).

However, the IBS intervention does not satisfy the need for addressing nutritional adequacy- this may not be plausible for a group setting. However, strategies for enabling correct execution of phase II on the FODMAP diet should be developed. Many participants suggested an IBS Part II Intervention (for those having completed phase 1).

4.2.2 Participant recruitment

We had a very low recruitment rate, as we only recruited 20 out 73 possible participants (27 per cent).

One must question at what extent these participants represent the general IBS population. Voluntary participation may bias the level of random sampling. For instance, it may be likely that the recruited participants exhibit special interest in nutrition. Furthermore, continued contact with IBS professionals may have been considered beneficial due to the nature of the condition. In other words, we may have recruited extra complex cases (especially group B exhibited relatively complex variants of IBS).

The patient recruitment could have been enhanced in several ways.
Firstly, many participants did not bring the necessary questionnaires at baseline and therefore could not be included. In order to improve recruitment rate, the baseline questionnaires could have been filled out during IBS intervention. Secondly, participant recruitment could have been further enhanced if personal contact, and hence interest in the project, had been established prior to shipment of the repeated measure questionnaires.

In the process of recruiting patients for this study, we found that eighteen per cent of the included participants had received a different diagnosis after the IBS intervention and consequently these were not included. We have no knowledge on the current diagnosis of the recruited participants (and they may have received a different diagnosis after our point of contact).

It is alarming that such a high percentage of IBS participants participated in the IBS intervention, when in fact they should not have. Interestingly enough, all participants (including those 18 per cent who did not have IBS) fulfilled the Rome III criteria for IBS. Several researchers have highlighted the risks of misdiagnosing IBS(24, 41).

For obvious reasons, it is very important that those who participate in the IBS intervention in fact rightfully have been diagnosed with IBS.

4.2.3 Participant grouping

The time factor (12 months versus 6 months) and the implementation of the FODMAP diet were both considered important variables in need of differentiation. In retrospect, it has become evident that the chosen grouping methods may over emphasized the results. Ideally, we should have segregated those on the FODMAP diet versus those not on the FODMAP diet (rather than combining all participants in group A+B and then extracting those on the FODMAP diet in group a+b). However, the current methods were chosen due to the low number of participants.

Furthermore, IBS gastro intestinal impairment severity should have been further differentiated and investigated, as well as the IBS predominant diarrhoea versus IBS predominant constipation.

4.2.4 Data collection

We named our questionnaires for data collection *´repeat´* and ´single´ measure questionnaires. We are aware that this may easily be confused with the very different *repeated* measures data collection.

It may be argued that other questionnaires could have been better suited for representation of IBS gastro intestinal severity, quality of life and nutritional status.

Mixed methods of data collection may have biased the data. For instance, baseline data may have been obtained through mail, whilst post intervention data may have occurred through telephone interviews.

Furthermore, the post intervention measure questionnaires developed by Norene Grytten Kjøsnes exhibit qualities demonstrating inexperience in the field. For instance, in hindsight, it has become evident that certain aspects of the questionnaires may have been unclear to the participants.

Although the weighed 3-day food diary is considered a good tool for estimating nutritional intake(74)its practical limitations became evident in our study. We found the 3-day food diary very limiting both due to the very low response rate, but also the content. For instance had very few incorporated weekdays in their diary.

It may be argued that other methods for obtaining dietary data could have been utilised. The 24hrR has been criticised for its unlikely overall representation of daily intake(74). However, the majority of our participants claimed that the 24hrR presented was highly representative of their overall everyday eating regime. Many reported it to resemble at least 5 days a week. Therefore we would like to suggest that the 24hrR might be a suitable method for assessing nutritional intake in the IBS patients.
The majority of the data collection was reliant on participant knowledge, recollection skills and subjective opinions. Disclosing personal diet related information to nutrition postgraduates might involve bias(74).

4.2.5 Data processing and statistical analysis

It was challenging to decipher whether to run parametric or non-parametric tests. In fact, we ran both tests for all data in case of discrepancy. Reassuringly, the results were relatively similar (appendix 23).

Nevertheless, we highlight that the overall statistical power in this study is limited and therefore the significance of the p-values presented should not be heavily emphasised.

In particular, the accuracy of the nutrition data has several limitations. A major limitation is the low number of available 3-day food diaries (n8). Further, the participants may inaccurately report the actual food intake. Second, the investigator may inaccurately interpret the actual food intake. Further, the software programme used may inaccurately resemble the actual nutritional value due to for example geographical differences.

We chose to present the median for the nutrition data and the mean for the remaining data. In small data sets, data are easily coloured by outliers and this must be incorporated upon interpretation of our(83). It may be that we should have presented the median and range for all data.

Furthermore, it may be that the size of the change should have been further highlighted. For instance, for the visceral sensitivity measurements we saw that 50 per cent had 5 or less than 5 point change from baseline to post intervention. For size in change in all groups consult appendix 24.

4.3 Future aspects

Further assess adequacy of IBS education

The researchers of this paper have been in contact with several institutions in Norway, and it appears that several institutions are either running or are planning to run group education for IBS patients.

Future studies should aim to further ass the quality and adequacy of group based IBS interventions, arguably with more solid frameworks than those of the current study. Importantly, future research should take precaution upon recruitment of participants to ensure overall satisfying representation of the general IBS patient.

Evaluate efficacy of symptom control strategies

Until IBS pathophysiology has been confirmed, high quality studies should continue to investigate the strategies available for symptom relief. As of today it is reasonable to suggest that health experts should focus on the strategies with the strongest efficacy, such as the FODMAP diet.

Although the FODMAP is considered the best symptom control management strategy(52), the long-term health implications of the diet are unknown. The FODMAP reduction may affect intestinal microbiota and restriction in dietary intake may affect nutritional status(52).

Furthermore, researchers of the current study would like to encourage future research to investigate whether a potential down-regulation of the lactase enzyme is induced by a prolonged lactose restriction (as seen in the FODMAP diet phase 1). This is especially relevant as we found that most participants did not undertake proper liberalisation of the diet (phase 2). This could be of special interest in countries such as Norway where the prevalence of lactose intolerance is relatively low(46).

As per understood by the researchers of the current study, the majority of the high quality FODMAP diet studies originate in Australia and England. There is a need for good quality studies to occur also outside Australia and England, recollecting that the majority of fair skinned Australians are descendants from Europe.

Further investigate nutritional adequacy

We found that many of our participants had a monotonous food intake. Furthermore, prolonged gastrointestinal disturbances such as diarrhoea may indeed alter enteric nutrient availability. It may also be important to research use of nutritional supplements and effects on health and bowel health.

Much research has targeted means for minimising gastro intestinal impact in the IBS patients, and strategies such as the FODMAP diet has emerged. We would like to emphasize the importance of also addressing nutritional adequacy in the IBS patient group.

In order to enable practitioners to address both GI symptoms and nutritional adequacy there is a need for development of specific and efficient assessment and counselling tools.

Ensure best practice in health practitioners

The NICE guidelines state that only health care professionals with expertise in dietary management should manage IBS dietary treatment(23). Furthermore, we found that many of our IBS intervention participants had one or more additional diagnosis, for example heart disease. This further underpins that individual consultancy by clinical dieticians may be appropriate.

Health practitioners must be sufficiently informed and familiar with the many aspects of IBS and practice best quality approach within the frame works of their profession. As we have previously discussed, it can be argued that the level of knowledge on IBS may be unsatisfactory amongst many health professional(84, 85). Kings College in London offer

regular FODMAP training sessions for registered dieticians(86). This may be a reflexion on both the complexity and demand of the diet. One can argue that organised training of health practitioners is in order also in countries such as Norway.

Investigate IBS aetiology and consequent pathophysiology

Much attention within IBS research has been directed toward management strategies. Until IBS pathophysiology has been determined it will be difficult to provide potential treatment strategies.

Interestingly, 3 of 20 participants in our study (15 per cent) reported being diagnosed with hemochromatosis (type not specified). This prevalence was randomly observed when investigating prevalence of anaemia (reported present in only two participants). It is worth noticing that most cases of hemochromatosis are discovered by chance. Several commonalities are present between IBS and hemochromatosis, for instance chronic fatigue, depression, sexual disorders, abdominal pain and joint pain. It may be of potential interest for future research to investigate the prevalence of hemochromatosis in IBS patients.

5 Conclusion

We conducted a quality assurance study of the IBS intervention offered at Haukeland University Hospital.

We saw that 65 per cent of the participants had implemented the FODMAP diet at post intervention. However, many participants executed the diet inadequately.

We looked gastrointestinal symptoms and found found a significant difference in the visceral sensitivity index in group A+B, but not in any of the other groups. We found no significant difference in IBS symptom severity score.

We looked at quality of life and found no significant difference in the Short Form Nepean Dyspepsia Index.

We looked at nutritional adequacy and found no significant change in BMI, energy intake, and fibre intake or macronutrient distribution.

We do not that have sufficient evidence to conclude that gastro- intestinal symptoms, quality of life and nutritional adequacy will improve after the HUS associated IBS group intervention.

This study only recruited 20 IBS participants and generalisation is likely to be inappropriate.

Several interesting aspects have been highlighted and there is a need for future research addressing these.

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List of Appendix

Appendix 1. IBS intervention programme

Program

IBS – En bedre hverdag for pasienter med irritabel tarm syndrom

Kursleder: Marthe Jansen ved Nasjonalt Kompetansesenter for funksjonelle tarmsykdommer

1.kursdag: mandag 27.april 2015

08:45 – 09:00	Registrering
09:00 – 09:15	Velkommen, v/Marthe Jansen, Anne Britt Frantzen og LMS
09:15 – 09:45	Brukers historie, v/[redacted]
09:45 – 12:00	IBS – Sykdom og behandling, v/ Trygve Hausken, Professor
12:00 – 13:00	Lunsj
13:00 – 14:00	Leve med IBS, v/ Tor Jacob Moe, Psykiater
14:00 – 14:15	Pause
14:15 – 15:00	Oppsummering

2.krusdag: tirsdag 28. april 2015

09:00 – 11:00	FODMAP, v/ Synne Ystad, Klinisk Ernæringsfysiolog
11:00 – 12: 00	LavFODMAP - en praktisk tilnærming og mestring av IBS, v/Cecilie Hauge Ågotnes
12:00 – 13:00	Lunsj
13:00 – 14:00	Fysioterapeutiske betraktninger ved IBS, v/Eirik Østvold, Fysioterapeut
14:00 – 14:15	Pause
14:15 – 15:00	Refleksjon, oppsummering og evaluering av kurs v/Marthe Jansen

Appendix 2. Thesis suggestion.

Forslag til masteroppgave. Hus

Oppgavetittel	Effekt av intervensjon ved IBS
Hovedveileder	Mette Helvik Morken
Forskningsgruppe/ seksjon/ institutt	Avdeling for klinisk ernæring, HUS/K1, UiB
Biveileder/ seksjon/ institutt*	Trygve Hausken, K1, UiB
Evt. krav til/ønske om forkunnskap	Student ved masterstudiet i klinisk ernæring, UiB
Antall studenter	1
Oppstartstidspunkt og progresjonsplan (anslått tidsbruk til ulike deler av prosjektet)	Så snart som mulig, litteratursøk og protokoll våren 2014 Data-innsamling/-bearbeiding høst 2014/vår 2015 Ferdigstille masteroppgaven vår 2015
Ernæringsrelevans faglig/metodisk (spesifiseres)	Vurdering av effekt av blant annet kostholdsintervensjon på symptomer og matinntak ved IBS.
Oppgavebeskrivelse (Hva studenten skal gjøre, kort beskrivelse av forskningsgruppe/ fagmiljø, presisering av hvilke metoder studenten skal anvende)	En stor andel av befolkningen i Norge, og i resten av den vestlige verden, lider av mage-tarm symptomer relatert til diagnosen irritabel tarm (IBS). Høsten 2012 startet Lærings og mestringssenteret (LMS) ved Haukeland universitetssykehus (HUS), et kursopplegg over to dager for denne pasientgruppen. I kursopplegget inngår tre timers opplæring i FODMAP redusert kosthold ved klinisk ernæringsfysiolog. Ved kursstart får deltakerne utdelt flere typer spørreskjema. Disse skjemaene inkluderer: 1. SF-NDI (Spørreskjema om livskvalitet) 2. VSI (Visceral Sensitivity Index) 3. IBS. SSS (Gradering av mageplager) Vi ønsker å måle effekt av kursopplegget ved at kursdeltakerne fyller ut skjemaene igjen etter 6 og 12 mnd, i tillegg til et spørreskjema om eventuelle varige endringer i kostholdet. Kostintervju (24 timers recall) vil kunne si noe om næringsinntak i gruppen generelt, 6 og 12 mnd etter opplæring. Forslag til hypotese: Intervensjon i form av to dagers opplæring ved LMS/HUS er assosiert med bedret livskvalitet, mindre symptomer og bedret næringsinntak.

(klinisk ernæring) 2014-2015

* Angis hvis forskjellig fra hovedveileder. Minst en veileder må ha tilknytning til Det medisinsk-odontologiske fakultet.

Appendix 3. Gradering av mageplager. IBS-SSS questionnaire.

GRADERING AV MAGEPLAGER

(Aliment Pharmacol Ther 1997; 11: 395-402)

Ikke fyll ut feltene under:

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

Sett kryss over Ja eller Nei

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

0% — **100%**

Ingen smerte	Mindre alvorlig	Ganske alvorlig	Alvorlig	Svært alvorlig

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)

0% — **100%**

Ingen oppblåsthet	Mindre alvorlig	Ganske alvorlig	Alvorlig	Svært alvorlig

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

0% — **100%**

Svært fornøyd	Ganske fornøyd	Lite fornøyd	Svært lite fornøyd

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

0% — **100%**

Ikke i det hele tatt	Ikke særlig mye	Ganske mye	Fullstendig

☐ ***Sum***

Appendix 4. VSI spørsmåskjema. VSI questionnaire.

VSI Spørsmålsskjema

LES NØYE IGJENNOM DETTE FØR DU SVARER PÅ SPØRSMÅLENE:

Nedenfor finner du påstander som beskriver hvordan man kan oppleve symptom eller ubehag i magen eller i nedre del av buken. Forskjellige symptomer kan være *smerte, diaré, forstoppelse, oppblåsthet eller ett plutselig behov for å gå på toalettet.*

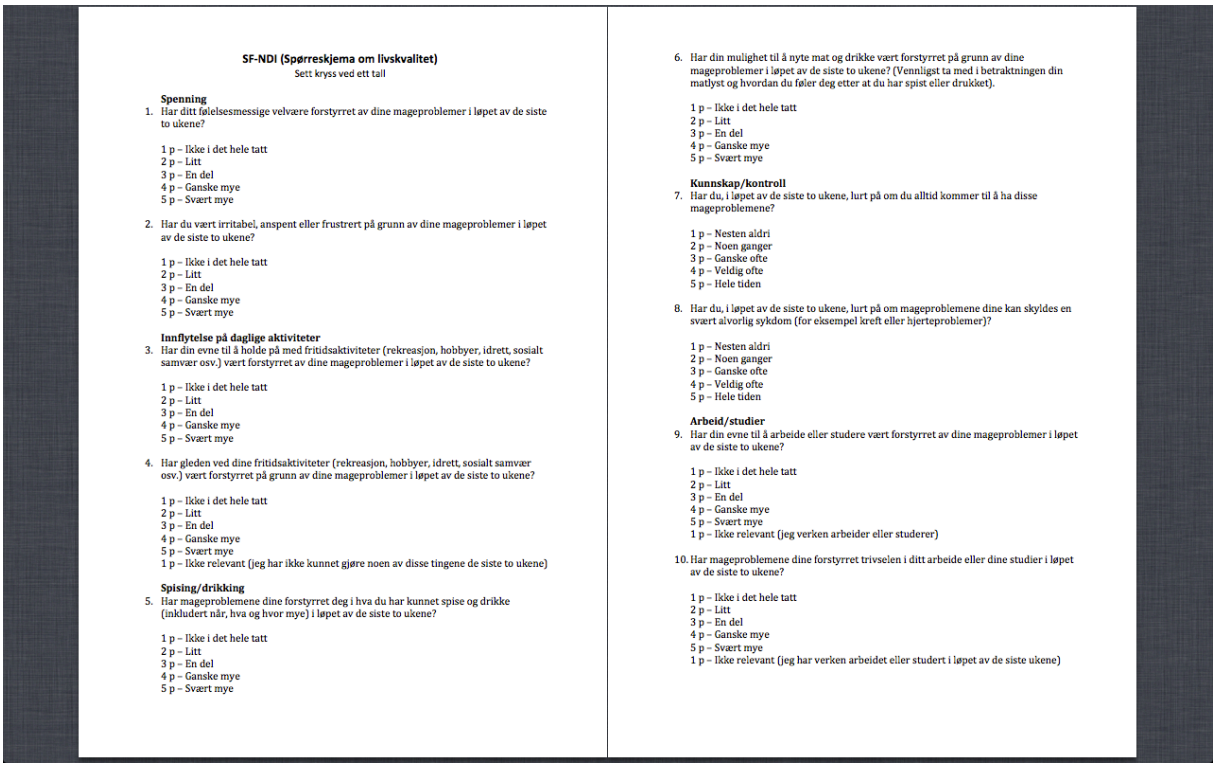
Svar på hvordan disse påstandene *stemmer for deg.* Svar på alle påstandene ved å sette en ring rundt **det sifferet som best beskriver hvordan DU kjenner deg**. Svar så ærlig som mulig.

Eksempel:

Stemmer veldig godt	Stemmer ganske godt	Stemmer noenlunde	Stemmer delvis	Stemmer ikke så godt	Stemmer ikke i det hele tatt
1	2	(3)	4	5	6

Påstand	**Stemmer veldig godt**	**Stemmer ganske godt**	**Stemmer noenlunde**	**Stemmer delvis**	**Stemmer ikke så godt**	**Stemmer ikke i det hele tatt**
1. Jeg uroer meg for at følelsen av oppblåsthet og oppsvulmet mage kommer til å bli verre, uansett når på dagen jeg spiser	1	2	3	4	5	6
2. Jeg kjenner meg urolig når jeg skal på en restaurant der jeg ikke har vært tidligere	1	2	3	4	5	6
3. Jeg uroer meg ofte over mine mageproblem	1	2	3	4	5	6
4.Jeg har vansker med å kople av og slappe av, ettersom jeg ikke kan slutte å tenke på ubehaget i magen	1	2	3	4	5	6
5. Jeg uroer meg ofte for at jeg ikke skal kunne ha normal tarmtømming	1	2	3	4	5	6
6. Jeg prøver sjelden ny mat, ettersom jeg er urolig for at den skal gi meg ubehag i magen	1	2	3	4	5	6
7. Uansett hva jeg spiser kommer jeg trolig til å kjenne ubehag	1	2	3	4	5	6
8. Så snart jeg kjenner ubehag i magen blir jeg engstelig og urolig	1	2	3	4	5	6
9.Det første jeg gjør når jeg kommer til ett sted jeg ikke har vært før er å finne ut hvor toalettet er	1	2	3	4	5	6
10. Jeg er hele tiden bevisst på hvordan det føles i magen	1	2	3	4	5	6
11. Jeg tror ofte at ubehag i magen kan være ett tegn på alvorlig sykdom	1	2	3	4	5	6
12. Så fort jeg våkner om morgenen uroer jeg meg for at jeg skal kjenne ubehag i magen utover dagen	1	2	3	4	5	6
13. Jeg blir urolig når jeg kjenner ubehag i magen	1	2	3	4	5	6
14. I stressete situasjoner får jeg store problem med magen	1	2	3	4	5	6
15. Jeg tenker hele tiden på hvordan det kjennes i magen	1	2	3	4	5	6

Appendix 5. SF-NDI questionnaire (spørreskjema om livskvalitet)



SF-NDI (Spørreskjema om livskvalitet)
Sett kryss ved ett tall

Spenning

1. Har ditt følelsesmessige velvære forstyrret av dine mageproblemer i løpet av de siste to ukene?

   1 p – Ikke i det hele tatt
   2 p – Litt
   3 p – En del
   4 p – Ganske mye
   5 p – Svært mye

2. Har du vært irritabel, anspent eller frustrert på grunn av dine mageproblemer i løpet av de siste to ukene?

   1 p – Ikke i det hele tatt
   2 p – Litt
   3 p – En del
   4 p – Ganske mye
   5 p – Svært mye

Innflytelse på daglige aktiviteter

3. Har din evne til å holde på med fritidsaktiviteter (rekreasjon, hobbyer, idrett, sosialt samvær osv.) vært forstyrret av dine mageproblemer i løpet av de siste to ukene?

   1 p – Ikke i det hele tatt
   2 p – Litt
   3 p – En del
   4 p – Ganske mye
   5 p – Svært mye

4. Har gleden ved dine fritidsaktiviteter (rekreasjon, hobbyer, idrett, sosialt samvær osv.) vært forstyrret på grunn av dine mageproblemer i løpet av de siste to ukene?

   1 p – Ikke i det hele tatt
   2 p – Litt
   3 p – En del
   4 p – Ganske mye
   5 p – Svært mye
   1 p – Ikke relevant (jeg har ikke kunnet gjøre noen av disse tingene de siste to ukene)

Spising/drikking

5. Har mageproblemene dine forstyrret deg i hva du har kunnet spise og drikke (inkludert når, hva og hvor mye) i løpet av de siste to ukene?

   1 p – Ikke i det hele tatt
   2 p – Litt
   3 p – En del
   4 p – Ganske mye
   5 p – Svært mye

6. Har din mulighet til å nyte mat og drikke vært forstyrret på grunn av dine mageproblemer i løpet av de siste to ukene? (Vennligst ta med i betraktningen din matlyst og hvordan du føler deg etter at du har spist eller drukket).

   1 p – Ikke i det hele tatt
   2 p – Litt
   3 p – En del
   4 p – Ganske mye
   5 p – Svært mye

Kunnskap/kontroll

7. Har du, i løpet av de siste to ukene, lurt på om du alltid kommer til å ha disse mageproblemene?

   1 p – Nesten aldri
   2 p – Noen ganger
   3 p – Ganske ofte
   4 p – Veldig ofte
   5 p – Hele tiden

8. Har du, i løpet av de siste to ukene, lurt på om mageproblemene dine kan skyldes en svært alvorlig sykdom (for eksempel kreft eller hjerteproblemer)?

   1 p – Nesten aldri
   2 p – Noen ganger
   3 p – Ganske ofte
   4 p – Veldig ofte
   5 p – Hele tiden

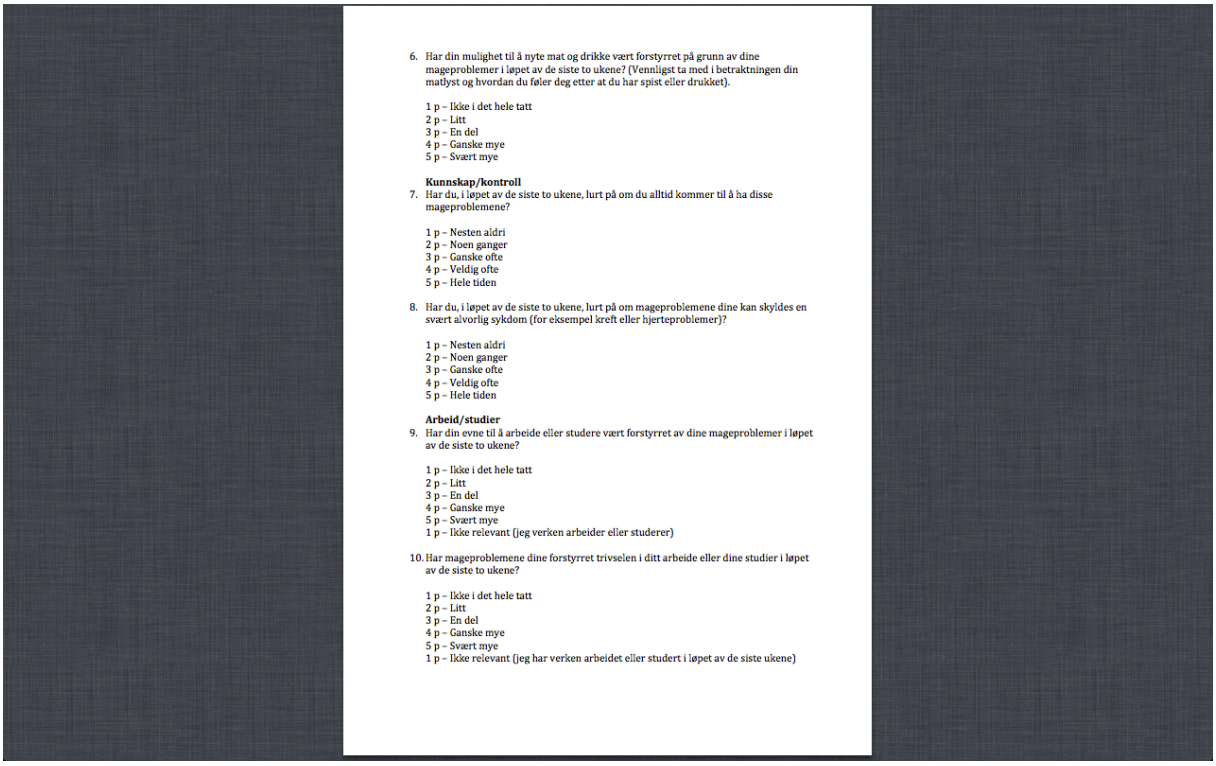
Arbeid/studier

9. Har din evne til å arbeide eller studere vært forstyrret av dine mageproblemer i løpet av de siste to ukene?

   1 p – Ikke i det hele tatt
   2 p – Litt
   3 p – En del
   4 p – Ganske mye
   5 p – Svært mye
   1 p – Ikke relevant (jeg verken arbeider eller studerer)

10. Har mageproblemene dine forstyrret trivselen i ditt arbeide eller dine studier i løpet av de siste to ukene?

    1 p – Ikke i det hele tatt
    2 p – Litt
    3 p – En del
    4 p – Ganske mye
    5 p – Svært mye
    1 p – Ikke relevant (jeg har verken arbeidet eller studert i løpet av de siste ukene)



6. Har din mulighet til å nyte mat og drikke vært forstyrret på grunn av dine mageproblemer i løpet av de siste to ukene? (Vennligst ta med i betraktningen din matlyst og hvordan du føler deg etter at du har spist eller drukket).

   1 p – Ikke i det hele tatt
   2 p – Litt
   3 p – En del
   4 p – Ganske mye
   5 p – Svært mye

Kunnskap/kontroll

7. Har du, i løpet av de siste to ukene, lurt på om du alltid kommer til å ha disse mageproblemene?

   1 p – Nesten aldri
   2 p – Noen ganger
   3 p – Ganske ofte
   4 p – Veldig ofte
   5 p – Hele tiden

8. Har du, i løpet av de siste to ukene, lurt på om mageproblemene dine kan skyldes en svært alvorlig sykdom (for eksempel kreft eller hjerteproblemer)?

   1 p – Nesten aldri
   2 p – Noen ganger
   3 p – Ganske ofte
   4 p – Veldig ofte
   5 p – Hele tiden

Arbeid/studier

9. Har din evne til å arbeide eller studere vært forstyrret av dine mageproblemer i løpet av de siste to ukene?

   1 p – Ikke i det hele tatt
   2 p – Litt
   3 p – En del
   4 p – Ganske mye
   5 p – Svært mye
   1 p – Ikke relevant (jeg verken arbeider eller studerer)

10. Har mageproblemene dine forstyrret trivselen i ditt arbeide eller dine studier i løpet av de siste to ukene?

    1 p – Ikke i det hele tatt
    2 p – Litt
    3 p – En del
    4 p – Ganske mye
    5 p – Svært mye
    1 p – Ikke relevant (jeg har verken arbeidet eller studert i løpet av de siste ukene)

Appendix 6. Kostregistering. 3-day food diary.

HELSE BERGEN - ALT HANDLAR OM MENNESKE
Haukeland universitetssjukehus

Irritabel tarm, LMS

KOSTREGISTRERING
3 dager før kursstart

NAVN _____

ADRESSE _____

_____

FØDSELSNR _____

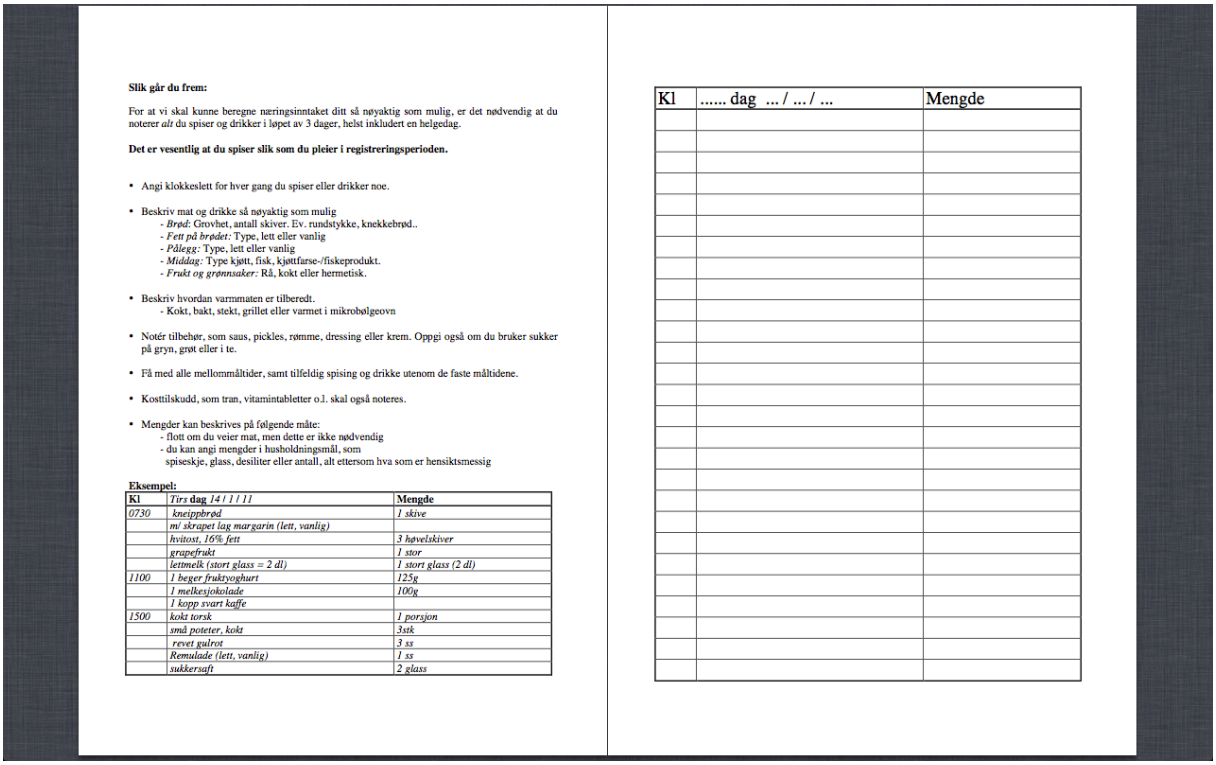
HØYDE _____

VEKT _____

Skjemaet returneres i utfylt stand første kursdag eller per post til:

Mette Helvik Morken
Avdeling for klinisk ernæring
Haukeland Universitetssykehus
5021 Bergen

Tlf. 55 97 38 32 / 900 46 947



Slik går du frem:

For at vi skal kunne beregne næringsinntaket ditt så nøyaktig som mulig, er det nødvendig at du noterer *alt* du spiser og drikker i løpet av 3 dager, helst inkludert en helgedag.

Det er vesentlig at du spiser slik som du pleier i registreringsperioden.

- Angi klokkeslett for hver gang du spiser eller drikker noe.
- Beskriv mat og drikke så nøyaktig som mulig
  - *Brød*: Grovhet, antall skiver. Ev. rundstykke, knekkebrød..
  - *Fett på brødet:* Type, lett eller vanlig
  - *Pålegg:* Type, lett eller vanlig
  - *Middag:* Type kjøtt, fisk, kjøttfarse-/fiskeprodukt.
  - *Frukt og grønnsaker:* Rå, kokt eller hermetisk.
- Beskriv hvordan varmmaten er tilberedt.
  - Kokt, bakt, stekt, grillet eller varmet i mikrobølgeovn
- Notér tilbehør, som saus, pickles, rømme, dressing eller krem. Oppgi også om du bruker sukker på gryn, grøt eller i te.
- Få med alle mellommåltider, samt tilfeldig spising og drikke utenom de faste måltidene.
- Kosttilskudd, som tran, vitamintabletter o.l. skal også noteres.
- Mengder kan beskrives på følgende måte:
  - flott om du veier mat, men dette er ikke nødvendig
  - du kan angi mengder i husholdningsmål, som spiseskje, glass, desiliter eller antall, alt ettersom hva som er hensiktsmessig

Eksempel:

Kl	*Tirs* **dag** *14 / 1 / 11*	**Mengde**
0730	*kneippbrød*	*1 skive*
	m/ skrapet lag margarin (lett, vanlig)	
	hvitost, 16% fett	*3 høvelskiver*
	grapefrukt	*1 stor*
	lettmelk (stort glass = 2 dl)	*1 stort glass (2 dl)*
1100	*1 beger fruktyoghurt*	*125g*
	1 melkesjokolade	*100g*
	1 kopp svart kaffe	
1500	*kokt torsk*	*1 porsjon*
	små poteter, kokt	*3stk*
	revet gulrot	*3 ss*
	Remulade (lett, vanlig)	*1 ss*
	sukkersaft	*2 glass*

Kl	..... dag ... / ... / ...	Mengde

Appendix 7. 24 Hour Recall

name:_____

Hvordan spiser du på en typisk god dag?

Hvor mange dager I uken vil du si at du spiser ca sånn?

Helgen annerledes?

Appendix 8. Anthropometry questionnaire**.**

Spørreskjema om personinformasjon og antropometri ID_____

Navn_____

Fødselsdato_____

Høyde_____

Vekt før kurs:_____
Vekt nå:_____
Vekt hx:_____

□stabil □ustabil □ jevnt synkende □jevnt stigende □raskt tap □raskt stigende

Fysisk aktvitetsnivå
□ **Lite aktiv** (mindre enn 60 min fysisk aktivitet hver dag)
□ **Aktiv** (60 min hver dag)
□ **Svært aktiv** (mer enn 60 min fysisk aktivitet hver dag)

Appendix 9. The knowledge base questionnaire

Spørreskjema om kunnskapsbase ID_____

Følger du en spesiell diett? □JA□NEI
Hvilken _____
Hvem rådet deg/hvor hørte du om den dietten? _____

Hvor har du hentet informasjon om dietten fra:
□Ibs-skolen
□Internett
□Faglitteratur
□Venner/kjente
□Aviser/ukeblad
□Utdanning
□Annet_____

Har du noen gang fått kostholdsveiledning (utenom IBS-skole) □JA □NEI
Hva gjaldt det_____
Hvilken proffesjon hadde veilederen _____
Var dette før eller etter IBS-skole □før □etter

Har du innhentet kostråd på egenhånd □JA □NEI
Var dette før eller etter IBS-skolen □JA □NEI

Appendix 10. The Roma III IBS questionnaire

Spørreskjema om Roma III kriterier ID_____

Pasienten har vert plaget med tilbakevendende magesmerter eller ubehag i over 6 mnd
□ **JA** □ **NEI**

Plagene har vert tilstede minst 3 dager i mnd de siste tre mnd □ **JA** □ **NEI**

Samtidig må også to av disse 3 punktene vere tilstede
Plagene lindres ved tarmtømming □ **JA** □ **NEI**
Forandring i avføringsfrekvens ved symptomer □ **JA** □ **NEI**
Forandring i avføringens konsistens ved symptomer □ **JA** □ **NEI**

Appendix 11. The clinical picture questionnaire

Spørreskjema om generelt sykdomsbilde og behandlingsforløp **ID**_____

#Hvor lenge IBS-syk _____

Oppstod IBS plagene dine plutselig **(ila dager/uker)** **□JA □NEI □KANSKJE**
Oppstod IBS plagene i forbindelse med matforgiftning/gastroenteritt **□ JA □NEI □KANSKJE**
IBS plagene har igrunn/muligens vert der hele livet **□JA □NEI □KANSKJE**

Andre diagnoser: □NEI □JA hvilken:_____

Påviste allergier? □ja hva da:_____ □nei
Hvem utførte denne testingen? □lege □alternativ terapeut

Jeg har som oftest daglige IBS symptomer ☐JA ☐NEI
Jeg er periodevis symptombelastet ☐JA☐NEI
Graden av symptomene varierer i perioder ☐JA ☐NEI

Bruker du:
□Stoppende midler (f.e Immodium) □daglig □ ofte □ sjelden □ aldri □ slutta
□lakserende middel □daglig □ofte □ sjelden □aldri □slutta
□Smertestillende □daglig □ofte □ sjelden □aldri □slutta
annet:_____ **hvor ofte**:_____

Hva har du mest av? □Diare □forstoppelse □om lag likt

Har du/har du hatt følgende plager/symptomer:
□Smerte/ubehag i mage/nedre mageregion
□Oppblåsthet med luft
□Oppblåsthet uten luft
□Ufullstendig tømming
□Slim i avføring

□Trett uopplagt
□Kvalme
□Muskelsmerte
□Hyppig trang til å tisse
□Jeg føler at jeg ikke får til å puste skikkelig
□Plager om natten
□Blod i avføring **□jeg har varslet helsepersonell**
☐ Stort vekttap som jeg ikke har noen forklaring på **□jeg har varslet helsepersonell**
☐Raskt vekttap som jeg ikke har noen forklaring på **□jeg har varselt helsepersonell**
□Anemi/blodmangel /lav blorprosent etc ☐vet ikke
□hoy blodprosent/jernlagre etc ☐vet ikke

Har du fått ekskludert cøliaki?
□Ja □nei □vet ikke □ikke ennå
□ med blodprøver □ med gastroskopi

Spiste du glutenfritt før cøliaki-undersøkelse?
□Ja □ nei □ vet ikke □ har ikke tatt gastroskopi □ har ikke tatt blodprøver

Har du fått ekskludert inflammatorisk tarmsykdom som Ulcerøs Colitt og Crohns sykdom?
□ Ja □ nei □ vet ikke □ tror det

Har du utført pustetester som f.e hydrogentesting
□ ja □ nei □ vet ikke □ tror det

Har du fått råd om å prøve laktosefritt kosthold fra helsepersonell uten videre undersøkelse
□ ja □ nei □ husker ikke

Har du blitt møtt med mistro av helsepersonell/f.e ´dette er bare psykisk´
□ ja □ nei □ja men mindre nå enn tidligere

Hvor ofte er du er borte fra jobb/skole grunnet ibs?
□ avogtil □ofte □sjelden □aldri □jeg går ikke på jobb/skole

Er du fornøyd med effektiviteten din på jobb/skole
□ ja □ nei □ som oftest □sjelden □jeg går ikke på jobb/skole

Jeg kjenner meg rystet rystet til å takle stress
□ja □nei

Hvordan vurderer du stressnivået til i hverdagen?
0 _____10
lavt kjempehøyt

Hvordan opplever du din psykiske helse?
0_____10
veldig dårlig veldig god

Hvordan graderer du livskvaliteten din?
0_____10
veldig dårlig veldig god

Appendix 12. The strategy implementation questionnaire

Spørreskjema for å kartlegge bruk av strategier ID_____

Jeg spiser generelt regelmessige måltider
□ ja □ nei□ som oftest □ som oftest ikke

Jeg spiser generelt små og hyppige måltider (ikke få og store)
□ ja □ nei □ som oftest □ som oftest ikke

Jeg spiser generelt sunt
□ ja □ nei □ som oftest □ som oftest ikke

Jeg spiser generelt variert
□ ja □ nei □ som oftest □ som oftest ikke

Jeg har generelt ro rundt måltidet
□ ja □ nei □ som oftest □ som oftest ikke

Jeg lever som oftest et regelmessig liv (balanse mellom aktivitet og hvile)
□ ja □ nei □ som oftest □ som oftest ikke

Jeg spiser syrnede melkeprodukter som youghurt eller surmelk
□ ja □ nei □ avogtil □ sjelden □ slutta

Jeg tar tilskudd av melkesyrebakterier (probiotika)
□ ja □ nei □ avogtil □ sjelden □ slutta

Jeg tar tilskudd av geldannende fiber (visiblin/fiberhusk/benefiber/oppefri/guargum)
□ ja □ nei □ avogtil □ sjelden □ slutta

Jeg spiser generelt veldig fet mat
□ ja □ nei □ avogtil □ sjelden □ slutta

Jeg spiser generelt stekt mat
□ ja □ nei □ avogtil □ sjelden □ slutta

Jeg spiser røkt mat
□ ja □ nei □ avogtil □ sjelden □ slutta

Jeg spiser sterkt krydret mat
□ ja □ nei □ avogtil □ sjelden □ slutta

Jeg drikker alkohol
□ ja □ nei □ avogtil □ sjelden □ slutta

Jeg drikker kaffe eller annen koffeinholdig drikke
□ ja □ nei □ avogtil □ sjelden □ slutta

Jeg bruker lavendelolje
□ ja □ nei □ avogtil □ sjelden □ slutta

Jeg bruker peppermynteolje/kapsler
□ ja □ nei □ avogtil □ sjelden □ slutta

Jeg bruker laktase tabletter når jeg spiser laktoseholdig mat
□ ja □ nei □ avogtil □ sjelden □ slutta

Jeg spiser generelt 2 eller mer porsjoner frukt/bær daglig
□daglig □ukentlig □avogtil □aldri □ sjelden □ slutta

Jeg spiser generelt 3 eller mer porsjoner med grønnsaker daglig
□ daglig □ ukentlig □ av og til □ aldri □ sjelden □ slutta

Middagstallerken min består av 1/3: grønnsaker, 1/3: potet/ris/pasta/brød 1/3:kjøtt/fisk
□ så godt som daglig □ av og til □ aldri □ mer grønnsaker□ mer potet/ris/pasta/brød □ mer kjøtt/fisk

Jeg er medlem av landsforeningen mot fordøyelsessykdommer
□ ja □ nei □ har tenkt til det

Jeg er bevist på pusteteknikken min
□ja □ nei □ av og til

Jeg er bevisst på sittestilling min
□ ja □ nei □ av og til □ som oftest

Jeg har skaffet meg bøker og eller annen informasjon om fodmap-dietten
□ ja □ nei □har tenkt til det

Jeg har lastet ned fodmap applikasjonen
□ ja □ nei □ har tenkt til det

Jeg har tatt i bruk/begynt å leve etter fodmap-dietten
□ ja □ nei □ delvis □ har tenkt til det

* *<u>OM POSITIVT SVAR GÅ VIDERE TIL SPØRRESKJEMA OM FODMAP</u>*

Appendix 13. The FODMAP diet questionnaire

Spørreskjema om utførelse av fodmap-dietten ID_____

Jeg mener at jeg har forstått hvordan man utfører fodmap dietten
□ja
□nei
□kanskje
□delvis
□jeg har ikke prøvd fodmap dietten

Jeg lever per dags utifra fodmap dietten
□ja
□nei
□delvis

Jeg har ikke prøvd fodmap dietten fordi *(*om aktuelt)*
□jeg har ikke hatt tid ennå
□den virker for krevende
□jeg forstår ikke helt konseptet
□jeg tror ikke at den kommer til å hjelpe meg
□Annet:_____

Jeg har utført eliminasjonsfasen (fase 1)
□ja
□nei
□holder på nå

Jeg spiste høy-fodmap-mat (avvik) i lav-fodmap-fasen (fase 1)
□ofte
□sjelden
□aldri

I fase 1, eliminasjonsfasen, hvor vanskelig var det å overholde lav-fodmap dietten? (unngå avvik etc)
0_____10
Kjempelett kjempevanskelig

Hvor fornøyd er du med lav- fodmap-diett som symptomlindring
0_____10
ingen symptomlinding full symptomlindring

Jeg står på lav fodmap- dietten permanent (altså streng variant)
□ja
□nei
□som oftest

Jeg har utført fase 2 (provokasjons/utprøvings/liberaliserings/test-fasen)
□ja
□nei
□holder på nå

Jeg var symptomfri når startet fase 2 (re-introdusering av matvarer)
□ja
□nei
□delvis

Jeg ventet til jeg var (så godt som)symptomfri mellom hver gang jeg reintroduserte nye matvarer
□ja
□nei
□delvis

Testet du hver matvare mer enn 1 gang og over flere dager?
□ja
□nei
□som oftest

Har du testet matvarer som du tidligere har identifisert som problematiske?
□ja, for jeg var ikke sikker på hvilken matvare som var synderen
□nei, for jeg er helt sikker på at jeg ikke toler disse

Når jeg testet matvarer og fikk symptomer
□kuttet jeg matvaren helt
□prøvde jeg mindre doser til jeg fant mitt toleransenivå
□kuttet jeg foreløpig, men jeg har jeg tenkt til å teste igjen senere

Jeg har testet meg frem til min toleranse-grense for ulike fodmap-grupper
□ja
□nei
□holder på endå

Har du funnet din toleransegrense for akseptabel symptombelastning
□ja
□nei
□jeg tester matvarer nå

Kompanserer du for matvarer du har ekskludert (altså ersatter matvarer som ekskluderes)
□ja
□nei
□som oftest

Jeg ser på lav-fodmap lister som "ja-lister"
□riktig
□galt
□delvis

Jeg ser på høy-fodmap lister som "nei-lister"
□riktig
□galt
□delvis

Ved hjelp av fodmap-dietten jobber jeg mot et kosthold med minst mulig restriksjoner
□riktig
□galt
□delvis

Har fodmap dietten påvirket variasjonen i kostholdet ditt
□uforandret
□økt
□innsnevret

Dietten har hjulpet meg til å finne ut hvilke matvarer jeg kan spise
□ja
□nei
□delvis

Fodmap dietten av hjulpet meg til å finne ut hvor store mengder jeg kan spise av problematiske matvare
□ja
□nei
□delvis

Hvor vanskelig var /er det å forstå prinsippene/konseptet bak fodmap-dietten?
0_____10
Kjempelett kjempevanskelig

Fra 1-10 hvor utfordrende var/er det å praktisk gjennomføre fodmap-ditten?
0 _____10
kjempelett kjempeutfordrende

Jeg kunne trengt mer individuell og tilrettelagt fodmap-veiledning
□ja
□nei
□kanskje

Appendix 14. The general diet questionnaire

Spørreskjema om generelt kosthold ID:_____

(NB*frukt og grønnsaker spurt om i annet skjema ***laktase tabletter** spurt om i annet skjema**)**

Spiser du vanlige melke-produkter?
□ ja □daglig □ukentlig □sjelden □slutta
□nei □ikke nå i fodmap-fase 1 □toler ikke funnet ut via fase 2 □mistenker at jeg ikke toler

Spiser du laktose-reduserte produkter
□ja □daglig □ukentlig □sjelden □slutta
□nei □ikke nå i fodmap-fase 1 □toler ikke funnet ut via fase 2 □mistenker at jeg ikke toler

Spiser du laktose-frie produkter?
□Ja □daglig □ukentlig □sjelden □slutta
□nei □ikke nå i fodmap-fase 1 □toler ikke funnet ut via fase 2 □mistenker at jeg ikke toler

Spiser du harde oster?
□ja
□nei
□avogtil
□sjelden
□slutta

Spiser du vanlige og grove gluten- holdige korn-produkter?
□ja □daglig □ukentlig □sjelden
□nei □slutta

Spiser du glutenfrie produkter?
□ja □daglig □ukentlig □sjelden
□nei □slutta

Erfarer du at speltmel er bedre for deg
□ja
□nei

Spiser du rødt kjøtt?
□ja □daglig □ukentlig □sjelden □aldri
□nei

Spiser du hvitt kjøtt; kylling?
□ja □daglig □ukentlig □sjelden □aldri
□nei

Spiser du fisk?
□ja □daglig □ukentlig □sjelden □aldri
□nei

Tar du kosttilskudd?
□ja □vit □min □multivit □multimin □tran □protein-tilskudd□fiber-tilskudd
□annet:_____
□nei

Jeg spiser som oftest bare mat
□som jeg vet hvordan er tilberedt □riktig □galt □tenker jeg ikke på
□som er ´rene ´uten tilsetningstoffer □ riktig □galt □tenker jeg ikke på

Appendix 15. The IBS intervention feedback questionnaire

Spørreskjema om generell kurs-feedback ID_____

(*nøytral vil si at dette har jeg ikke tenkt på/tatt stilling til/har jeg ikke noe formening om)

På ibs-skolen fikk jeg nyttig informasjon for å få en bedre hverdag
□ ja □ nei □ litt □ nøytral

Jeg føler at jeg har fått en bedre hverdag etter deltagelse på ibs- skole
□ ja □ nei □ litt □ nøytral

På ibs-skolen fikk jeg kunnskap som bidrar til økt trygghet og mestring i hverdagen
□ ja □nei □litt □nøytral

Jeg hadde hatt bruk for mer oppfølging i forbindelse med IBS
□riktig □galt □nøytral

*NB! DENNE INFORMASJONEN BØR SAMKJØRES MED LMS SITT EVALUERINGSSKJEMA

Appendix 16. Ethical considerations approval.

Vår ref.nr.: 2015/751

Viser til din forespørsel om fremleggingsplikt for prosjekt "Kvalitetssikring av IBS-skole".

Det som skal legges vurderes av REK er prosjekter som innebærer forskning på mennesker, humant biologisk materiale og helseopplysninger, dersom formålet er å fremskaffe ny kunnskap om helse og sykdom. Kvalitetssikring og evaluering (av etablert behandling) faller normalt utenfor.

Vi anser dette prosjektet som kvalitetssikring som faller utenfor helseforskningslovens virkeområde.

Vi vil presisere at denne vurderingen er å anse som veiledning etter forvaltningslovens § 11.

Med vennlig hilsen
Arne Salbu
rådgiver
post@helseforskning.etikkom.no
T: 55978498

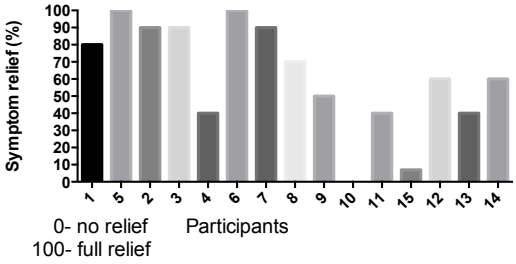
Regional komité for medisinsk og helsefaglig forskningsetikk REK vest-Norge (REK vest)
http://helseforskning.etikkom.no

Appendix 17. List of additional disorders.

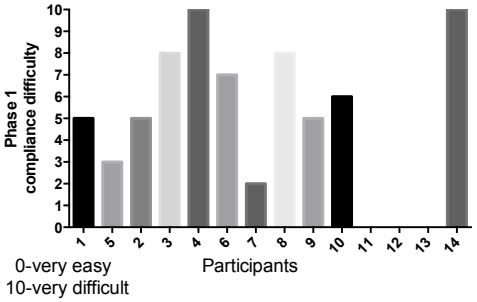
3 participants= haemochromatosis
3 participants= chronic migraine
2 participant= depression and anxiety
2 participants= chronic fatigue syndrome
2= hypothyroidism
2=hyperlipaemia
2=asthma
2=lumbar disc herniation
1=muscle myalgia
1=scoliosis
1=hypermobility joint syndrome
1=psoriatic arthritis
1=polycystic ovary syndrome
1=chronic kidney disease
1=diabetes type 1
1=breast cancer
1=overweight

Appendix 18. Symptom relief of, compliance to, difficulty understanding concept, practical difficulty of diet in practice

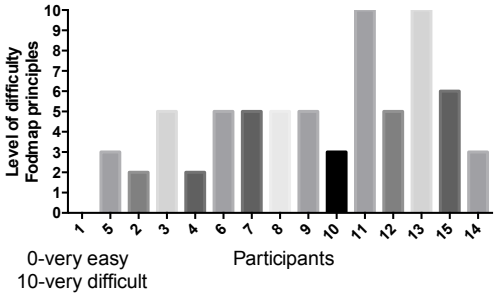
1. Hvordan graderer du symptom-lette av FODMAP dietten i fase 1?



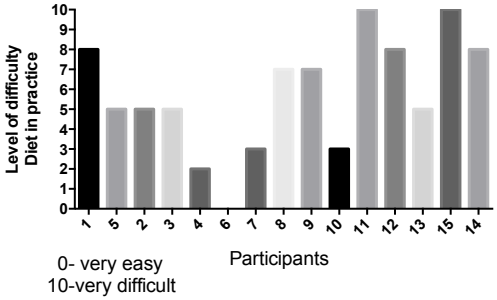
2. Hvor vanskelig var det å overholde dietten i fase 1?



3. Hvor vanskelig er det å forstå FODMAP dietten?



4. Hvor utfordrende er det å leve på dietten i praksis?



Appendix 19. Gastro intestinal progress, severity groupings (remission, mild cases, moderate, severe).

In group A 70 per cent of the participants were in the moderate category (175-300 points) at baseline compared to 50 per cent at post intervention. In group B we saw the opposite trend with an increase from 40 per cent to approximately 60 per cent for the moderate category.

Group b however had a reduction in prevalence of participants in the severe category (≥ 300 points) this was not the case for group A.

*IBS Symptom Severity Score prevalence before and after intervention (approximately 12 months for group A and 6 months for group B) in group A (n10), B (n10) and a+b (n13). Data are presented as number of participants and the corresponding percentage. Based on IBS Symptom Severity Score questionnaire. *groups*

Points *	Group A PRE n (%)	Group A POST n (%)	Group B PRE n (%)	Group B POST n (%)	Group a+b PRE n (%)	Group a+b POST n (%)
≤ 75	-	1(10)	-	-	-	1(8)
75-175	1(10)	2(20)	3(30)	1(10)	2(15)	1(8)
175-300	7(70)	5(50)	1(10)	4(40)	8(62)	7(54)
≥ 300	2(20)	2(20)	6(60)	5(50)	3(23)	4(31)

* ≤ 75 indicative of remission, 75-175 mild cases, 175-300 moderate, ≥ 300 severe (0=minimum score possible, 500=maximum)

* group A is the 12 & 15 month parameter, group B is the 6 & 10 month parameter
group A+B are all participants considered collectively , group a+b are those participants in group A and B on the fodmap diet

Appendix 20 . Nutrition data comparisons ; wilcoxon versus t-test and mean versus median

1. macro nutritent distribution
2. macro nutrient per cent achieved of RDI
3. micro nutrient per cent achieved of RDI

1. Macro nutrient distribution (3-day food diary)

Macro nutrient distribution in group B and B, showing results of paired t-tests in black and wilcoxon matched test in green. Paired t-tes show mean and standard devation, wilcoxon who median, 25-75 percentile. Values in per cent of achieved macro nutrient distribution (baseline and 6 months post intervention). Willcoxon results marked in green.

Macro nutrient	Baseline Group B	6months Group B	P-value	Baseline Group b	6months Group b	P-value	Guideline
Protein	19.0(±4.0) 17.5(16.3-20.5)	20.8(±3.5) 21.0(18.0-24.0)	0.226 0.250	20.2(±4.8) 19.0(16.5-24.5)	21.8(±3.9) 21.0(18.5-25.5)	0.491 0.625	**10-20**
CHO tot	44.1(±8.9) 44.5(38.8-51.8)	44.1(±8.8) 43.5(36.5-53.5)	0.999 0.718	44.4(±6.0) 42.0(39.5-50.5)	42.6(±9.0) 41.0(35.0-51.0)	0.597 0.750	**45-60**
Added sugar	7.6(±5.4) 7.5(2.0-11.5)	7.9(±7.2) 5.5(2.0-13.8)	0.763 0.999	6.0(±4.5) 7.0(1.5-10)	6.8(±8.0) 2.0(1.5-14.5)	0.818 0.999	**<10E**
Fat tot	36.8(±8.9) 34.0(31.5-40.3)	35.4(±6.9) 35.0(28.8-41.8)	0.504 0.563	35.2(±4.1) 33.0(32.0-39.5)	35.8(±5.6) 37.0(30.5-40.5)	0.717 0.750	**25-40**
SAT	14.6(±6.8) 13.0(11.0-16.3)	13.3(±3.6) 11.5(11.0-15.3)	0.396 0.500	12.4(±3.4) 12.0(9.5-15-5)	12.6(±2.1) 12.0(11.0-14.5)	0.909 0.999	**<10E**
MUFA	11.1(±2.6) 10.0(10-12.3)	10.9(±2.2) 10.5(9.3-12.6)	0.711 0.656	10.4(±1.5) 10.0(9.5-11.5)	10.8(±1.5) 11.0(9.5-12.0)	0.670 0.813	**10-20**
PUFA	6.8(±2.9) 7.0(3.5-10.0)	6.8(±3.2) 6.0(4.3-10.0)	0.999 0.999	8.4(±2.1) 9.0(6.5-10.0)	8.2(±3.3) 7.0(5.5-11-5)	0.871 0.999	**5-10**

1. Macro nutrient distribution (24hrR)

Macro nutrient distribution in group A+B and a+b at baseline and post intervention.Values are presented in per cent of achieved macro nutrient distribution. Mean and standard devation first, median, 25-75 percentile (for comparisons).

Macro nutrient	Group A and B	Group a and b	Guideline
Protein	23.3(±6.3) 23.5(19.5-28.3)	23.6(±5.1) 21.0(20.0-29.0)	10-20
CHO tot	38.45(±9.4) 37.5(30.3-43.0)	35.1 (±8.5) 34.0(28.0-40.5)	45-60
Sugar added	2.8(±3.2) 2.0(0.0-5.0)	2.0 (±2.1) 2.0(0.0-3.5)	<10
Fat tot	38.3(±8.1) 38.0(32.5-42.0)	41.3 (±7.4) 40.0(37.0-47.5)	25-40
SAT	14.3 (±3.9) 14.0(12.3-17.8)	15.6 (±4.3) 16.0(12.0-18.0)	<10
MUFA	12.1 (±3.3) 12.0(10.3-13.0)	12.9 (±2.9) 13.0(11.0-13.5)	10-20
PUFA	7.6 (±3.2) 7.0(5.0-10.0)	8.4 (±3.3) 10.0(5.5-11.0)	5-10

2. Macro nutrient intake (3-day food diary)

Macro nutrient per cent achieved of RDI in group B and b at baseline and post intervention. Showing results of paired t tests in black and wilcoxon matched test in green (for comparison). Paired t-tes show mean and standard devation, wilcoxon who median, 25-75 percentile.

Macro Nutrient	Baseline Group B	6months Group B	P-value	Baseline Group b	6months Group b	P-value
Protein	99.0(±7.7) 100.0(100.0-100.0)	103.9(±19.6) 100.0(100.0-101.5)	0.469 0.999	102.0(±4.5) 100.0(100.0-105.0)	100.4(±0.9) 100.0(100.0-101.0)	0.374 0.999
CHO	76.1(±22.0) 79.0(67.0-94.5)	76.8 (±26.9) 72.5(56.3-100.0)	0.941 0.999	84.2(±14.8) 85.0(69.5-98.5)	72.8(±17.6) 67.0(59.5-89.0)	0.243 0.250
Fat tot	96.3(±9.6) 100(90.5-100.0)	98.1 (±8.1) 100.0(97.5-100.0)	0.735 0.813	99.6(±7.1) 100.0(94.5-104.5)	99.8(±0.4) 100.0(99.5-100.0)	0.950 0.999
MUFA	83.9(±14.4) 82.5(70.3-99.8)	84.5 (±12.0) 86.5(74.8-94.8)	0.918 0.984	89.0(±15.4) 99.0(73.0-100.0)	87.4(±7.7) 91.0(79.5-93.5)	0.792 0.999
PUFA	83.6(±28.0) 100(57.8-100.0)	88.3 (±19.7) 96.0(85.5-100.0)	0.470 0.813	101.0(±2.2) 100.0(100.1-102.5)	97.0(±6.7) 100.0(92.5-100.0)	0.242 0.500

2. Macro nutrient intake (24hrR)

Achieved per cent of macro nutrient of RDI in group A+B and a+b at baseline and post intervention. Values are presented in per cent of achieved macro nutrient distribution. Mean and standard devation first, median and 25-75 percentile (for comparison).

Macro nutrient	Group A and B	Group a and b
Protein	98.0(±19.7) 100.0(100.0-100.0)	102.0(±4.5) 100.0(100.0-102.0)
CHO	59.2(±19.4) 62.5(42.3-78.0)	59.7(±19.3) 61.0(47.0-77-0)
Fat tot	90.6(±24.9) 100.0(76.5-100.0)	100.2(±17.2) 100.0(89.5-103.5)
MUFA	74.9(±23.4) 77.5(60.8-98.3)	83.1(±15.9) 85.0(65.0-100.0)
PUFA	83.3(±26.1) 96.0(62.3-100.0)	88.9(±19.3) 100.0(70.0-100.0)

Data are represented as mean (±SD)
Nutritional supplements not included

3. Micro nutrient intake (3 day food diary)

Micro nutrient per cent achievement of RDI at in group B and b at baseline and post intervention. Paired t-test show mean and standard devation, wilcoxon who median, 25-75 percentile. Wilcoxon in green. And the associated p-values.

Micro nutrient	Baseline Group B	6months Group B	P-value	Baseline Group b	6months Group b	P-value
Vit A	111.0(±76.6) 90.5(49.3-190.8)	148.4(±92.9) 155.5(48.5-237.0)	0.288 0.547	136.2(±86.3) 109.0(59.5-226.5)	207.8 (±00.0) 214.0(155.5-257.0)	0.191 0.188
Vit D	35.3(±26.6) 38.5(9.5-46.3)	56.4(±22.9) 49.5(39.5-69.3)	0.064 0.063	46.4(±25.5) 41.0(28.0-67.5)	67.2(±22.5) 64.0(49.0-87.0)	0.215 0.188
Vit E	133.3(±107.1) 106.0(80.8-127.0)	134.1(±63.7) 121.0(101.3-162.8)	0.965 0.383	169.0(±124.2) 118.0(103.5-260.0)	162.2(±63.0) 141.0(117.0-218.0)	0.836 0.813
Thia	113.0(±47.7) 119.5(74.0-137.0)	129.5(±41.9) 125.5(105.3-165.5)	0.441 0.641	134.4(±43.1) 134.0(101.0-168.0)	134.2(±25.3) 127.0(115.0-157.0)	0.993 0.999
Ribo	119.4(±39.4) 119.5(95.5-140.0)	141.8(±46.9) 153.0(115.0-173.0)	0.197 0.250	138.3(±30.9) 131.0(114.5-166.0)	142.6(±26.2) 148.0(116.0-166.5)	0.744 0.813
Vit B6	119.6(±55.8) 111.5(102.0-140.8)	149.5(±51.2) 144.5(123.3-194.8)	**0.044*** **0.023***	142.0(±53.4) 113.0(107.5-191.0)	159.2(±41.1) 153.0(125.5-196.0)	0.173 0.188
Folate	77.1(±40.4) 71.5(50.0-98.0)	78.5(±33.8) 74.5(54.3-105.0)	0.764 0.602	96.2(±38.3) 89.0(67.0-129.0)	94.6(±30.2) 96.0(68.0-120.5)	0.818 0.999
Vit B12	361.9(±321.4) 280.0(196.3-368.8)	388.1(±177.5) 330.0(265.0-531.3)	0.733 0.484	480.0(±363.4) 335.0(280.0-752.5)	446.0(±185.4) 365.0(295.0-637.5)	0.768 0.999
Vit C	175.1(±143.8) 143.0(66.0-331.0)	170.0(±135.4) 114.0(75.0-303.0)	0.668 0.641	219.2(±164.0) 157.0(75.0-394.5)	219.8(±150.9) 171.0(86.0-378.0)	0.972 0.999
Calcium	96.9(±38.4) 89.5(66.0-133.5)	115.8(±42.4) 114.0(95.8-158.5)	0.360 0.383	111.4(±42.8) 96.0(76.0-154.5)	118.8(±30.6) 110.0(97.5-144.5)	0.782 0.813
Iron	78.3(±50.4) 60.0(45.5-119.3)	81.8(±40.2) 81.0(51.8-103.5)	0.682 0.999	101.8(±50.3) 84.0(60.0-152.5)	97.6(±39.5) 83.0(68.0-134.5)	0.694 0.625
Potass	107.9(±44.6) 103.5(85.3-123.5)	110.5(±34.9) 113.5(99.0-130.0)	0.861 0.978	128.4(±40.9) 107.0(103.5-164.0)	113.0(±14.2) 110.0(101.0-126.5)	0.314 0.438
Magnes	124.1(±77.1) 114.0(84.0-127.5)	122.0(±47.4) 112.0(107.5-146.5)	0.899 0.945	156.2(±81.3) 123.0(114.0-215.0)	134.4(±43.5) 113.0(108.0-171.5)	0.312 0.438
Zinc	153.4(±51.6) 147.5(105.8-195.8)	157.6(±53.9) 152.0(125.3-169.0)	0.874 0.813	182.4(±42.0) 180.0(147.5-218.5)	154.8(±18.6) 167.0(134.5-169.0)	0.274 0.313
Selenium	134.0(±142.0) 102.0(63.0-113.5)	162.1(±122.3) 129.0(95.0-207.3)	0.108 0.148	181.6(±165.9) 112.0(102.0-296.0)	213.0(±130.4) 145.0(129.0-331.0)	0.279 0.438
Copper	165.0(±93.3) 153.0(96.5-243.0)	154.3 (±65.2) 148.5(109.5-206.3)	0.411 0.844	215.8(±77.9) 180.0(153.0-296.5)	191.4(±46.6) 192.0(148.5-234.0)	0.221 0.313
Phosph	258.4(±107.0) 244.5(183.8-319.8)	265.9(±75.4) 269.5(239.0-332.5)	0.812 0.945	314.2(±93.5) 319.0(240.5-385.5)	282.2(±44.7) 268.0(243.0-328.5)	0.331 0.438
Iodine	40.5(±21.7) 33.5(19.8-64.8)	48.9(±31.3) 39.0(24.0-81.0)	0.091 0.102	43.6(±22.9) 34.0(24.5-67.5)	51.2(±26.8) 42.0(28.0-79.0)	**0.023*** **0.063***

3. Micro nutrient intake (24hrR)

Per cent of achieved micro nutrients of RDI in group A+B and a+b at baseline and ost intervention. Values are presented in per cent of achieved macro nutrient distribution. Mean and standard devation first, median and 25-75 percentile (for comparison).

Micro nutrient	Group A and B	Grou a and b
Vit A	111.7 (±109.9) **91.5(44.3-122.5)**	106.1(±58.3) 104.0(62.0-120.0)
Vit D	110.0(±107.8) 57.5(21.3-204.8)	145.8(±108.3) 154.0(55.0-213.0)
Vit E	107.3 (±46.1) 115.0(75.3-130.5)	123.9(±38.6) 124.0(93.0-133.0)
Thiamine	120.9(±47.6) 114.5(86.3-153.9)	117.8(±34.6) 108.0(88.5-146.0)
Riboflavine	101.1(±38.2) 103.0(73.3-127.0)	105.1(±35.0) 100.0(76.5-136.5)
VitB6	153.7(±60.6) 154.4(122.8-166.5)	147.9(±20.9) 156.0(128.0-166.0)
Folate	66.2(±27.5) 64.0(44.0-92.8)	70.9(±21.5) 74.0(47.5-91.5)
Vit B12	440.5(±388.4) 265.0(170.0-641.3)	500.4(±305.7) 455.0(245.0-662.5)
VitC	125.6(±78.7) 106.5(68.3-188.0)	142.4(±81.2) 113.0(78.5-218.8)
Calcium	89.9(±46.9) 81.0(51.3-136.3)	107.5(±43.1) 108.0(76.5-142.0)
Iron	72.4(±39.9) 65.0(42.0-94.8)	72.0(±34.7) 63.0(45.5-84.5)
Potassium	94.2(±31.4) 100.5(80.8-105.0)	96.2(±18.6) 101.0(93.0-105.0)
Magnesium	103.8(±31.8) 109.0(85.0-121.0)	110.9(±20.1) 111.0(100.5-121.0)
Zinc	129.4(±47.2) 125.0(108.5-164.3)	136.9(±39.7) 127.0(112.0-169.5)
Selenium	143.0(±81.2) 145.0(67.5-206.0)	171.8(±74.6) 178.0(113.0-216.0)
Copper	123.8(±45.9) 124.0(100.0-156.8)	129.6(±36.3) 128.0(111.0-151.5)
Phosphorus	268.5(±86.2) 262.0(228.8-329.5)	279.7(±68.8) 267.0(238.5-327.0)
Iodine	34.9 (±28.0) 27.5(18.0-37.5)	40.2(±31.2) 27.0(23.5-50.0)

Appendix 21. Result of LMS feedback form.

LMS sitt evaluerings-skjema;

Totalt deltager repons kombinert nov 13, mars 14, april 14 (20+12+13) = n45

	Svært nyttig /nyttig n(%)
Ervfaringer v/bruker innlegg	15+7+4 =26(58)
Sykdom og behandling v/gastroenterolog	17+12+13=42(93)
Aktivitet ved IBS v/fysioterapeut	16+12+14=42(93)
Kostråd ved IBS v/KEF	17+12+11=40(89)
Stress og IBS v/psykiater	14+12+13=39(87)

Appendix 22. Current LMS evaluation form.

Evaluering
IBS-En bedre hverdag for pasienter med irritable tarm syndrom
25 og 26 november 2013

antall innleverte skjema:_____ antall deltagerer:_____

1. Hvor nyttig var temaene for deg og din situasjon:

		Svært nyttig	Nyttig	Noe nyttig	Lite nyttig	Ikke nyttig	Ikke tema på kurset
Bruker innlegg	Erfaringer						
Faglige innlegg	Sykdom og behandling						
Faglige innlegg	Fysikalske betrakninger						
Faglige innlegg	Rettigheter						
Faglige innlegg	Kostråd						
Faglige innlegg	Stress						
Bruker organisasjoner	Informasjon om likemansarbeid og andre tilbud						

2.Hvor nyttige var disse læringsmetodene for deg og din situasjon?

	Svært nyttig	nyttig	Noe nyttig	Lite nyttig	Ikke nyttig	Ikke aktuelt på kurset
Dialog med fagpersoner						
Samtaler I gruppe/gruppearbeid						
Lage egen handlingsplan						
Praktiske øvelser						
Høre andres erfaringer						
Dele mine erfaringer						
Få tips og gode råd						

3. Jeg er
(sett ring) bruker/pasient pårørende kvinne mann alder____

4. Hvordan/fra hvem fikk du vite om læringstilbdudet?

4. Var det noe du savnet? (bruk eventuelt baksiden)

5. Andre kommentarer? (bruk eventuelt baksiden)

Takk for at du hjelpe oss å forbedre våre tilbud!

Appendix 23. P values for VSI, IBS-SSS, SF-DNI tests,
both for parametric and non parametric data (for comparison).

IBS-SSS

Grouping	Paired t-test P- value	Wilcoxon P-value
Group A	0.204	O.160
Group B	0.949	0.922
Group A + B	0.233	0.189
Group a	0.369	0.313
Group b	0.682	0.625
Group a + b	0.301	0.217

SF-NDI

Grouping	Paired t-test P- value	Wilcoxon P-value
Group A	0.598	0.641
Group B	0.347	0.250
Group A + B	0.359	0.319
Group a	0.836	0.813
Group b	0.070	NA
Group a + b	0.918	0.797

VSI

Grouping	Paired t-test P- value	Wilcoxon P-value
Group A	0.069	**0.051**
Group B	0.252	0.406
Group A + B	**0.027***	**0.033***
Group a	0.159	>0.999
Group b	0.679	>0.999
Group a + b	0.133	0.231

Appendix 24. Size of change in point scores for potential elimination of those with minimal changes.

1. IBS-SSS
2. VSI
3. SF-NDI

1. IBS-SSS 10 point change

In group A+B 60 per cent had a 10 or more IBS Symptom Severity Score reduction from baseline to post intervention, whilst 15 per cent had an increase.

In group a+b also 60 per cent had a 10 or more point IBS Symptom Severity Score reduction from baseline to post intervention, whilst 40 per cent had an increase.

This means that in group A+B, 25 per cent had 10 or less than 10 points difference from baseline to post intervention, and perhaps should have been displayed better in the result section of this paper.

For group a+b the equivalent per cent was 0. I.e those on the FODMAP diet exhibited *greater* size of change.

*The number of participants in group A+B (N20) and a+b (n13) who had a more than a 10 or more point decrease/increase in IBS-Symptom Severity Score from baseline to post intervention. Data are presented as number of participants and the corresponding percentage. Based on the IBS Symptom Severity score questionnaire. *groups*

Group	10≥ points ↓ +* n (%)	10 ≥ ↑ n (%)
A+B N20	n12 (60)	n3 (15)
a+b n13	n8 (60)	n5 (40)

↓+ indicate that a decrease is associated with an improvement in symptom

** group A is the 12 & 15 month parameter, group B is the 6 & 10 month parameter*

group A+B are all participants considered collectively , group a+b are those participants in group A and B on the fodmap diet

2. VSI 5 point change

In group A+B 35 per cent had a 5 or more Visceral Sensitivity Index point increase from baseline to post intervention, and 15 per cent had a decrease.

In group a+b 33 per cent had an increase and 25 per cent had a decrease.

This means that in group A+B, 50 per cent had 5 or less than 5 points difference from baseline to post intervention, and perhaps should have been displayed better in the results section of this paper.

For group a+b the equivalent per cent 58. I.e. for VSI the difference in being on the FODMAP diet and not was *similar.*

The number of participants in group A+B (n19) and a+b (n12) who had a 5 or more point increase and decrease in the Visceral Sensitivity Index Score from baseline to post intervention. Data are expressed as number of participants and the corresponding percentage. Based on Visceral Sensitivity Index questionnaire. *groups

Group	5≥ points ↑+* n (%)	5≥ ↓ n (%)
A+B	n7 (35)	n3 (15)
a+b	n4 (33)	n3 (25)

↑+ indicate that a *increase* is associated with an *improvement* in symptoms

* group A is the 12 & 15 month parameter, group B is the 6 & 10 month parameter
group A+B are all participants considered collectively , group a+b are those participants in group A and B on the fodmap diet

3. SF-NDI 5 point change

In group A+B 45 per cent had a 5 or more point decrease decrease in Short-Form Nepean Dyspepsia Index point score whilst 20 per cent had an increase.

In group a+b 22 per cent had a decrease and 33 per cent had an increase.

This means that in group A+B, 35 per cent had 5 or less than 5 point change from baseline to post intervention, and perhaps should have been displayed better in the results section of this paper.

For group a+b the equivalent per cent was 55, I.e. it seems that being on the FODMAP diet produced **lesser** change than the group as a whole.

*The number of participants in group A+B (n15) and a+b (n10) who had a more than a 5 point decrease and increase in the Short-Form Nepean Dyspepsia Index point score from baseline to post intervention (approximately 12 months for group A and a, and 10 months for group B and b). Data are presented as number of participants and the corresponding percentage. Based on the Short-Form Nepean Dyspepsia Index questionnaire. *groups*

Group	5≥ points ↓+* n(%)	5≥ points ↑ n(%)
A+B n15	7(45)	3(20)
a+b n9	2(22)	3(33)

* ↓+ indicate that a *increase* is associated with an *improvement* in symptoms

* group A is the 12 & 15 month parameter, group B is the 6 & 10 month parameter group A+B are all participants considered collectively