IMPACT EVALUATION OF FODMAP FOOD EDUCATION TO IRRITABLE BOWEL SYNDROME PATIENTS SELECTED FROM URBAN VADODARA ON RELIEF FROM SYMPTOMS AND IMPROVEMENT IN IBS QUALITY OF LIFE.

DEPARTMENT OF FOODS AND NUTRITION FACULTY OF FAMILY AND COMMUNITY SCIENCES

THE AHARAJA SAYAJIRAO UNIVERSITY OF BARODA

VADODARA- 390-002 – INDIA

June-2021

JAHNAVI DEO

B.Sc (F.C. Sc) (Honors)

Dietetics

CERTIFICATE

This is to certify that the contents of the thesis entitled **"impact evaluation of FODMAP food education to IBS patients selected from urban Vadodara on relief from symptoms and improvement in IBS quality of life."** submitted for degree of master of science (M.Sc) in foods and nutrition (dietetics) during the period of July-2020 to June-2021 by Miss Jahnavi Deo, has been carried out independently and represents her original work.

Prof. Dr Mini sheth

(Guide)

Prof. Dr Meenakshi Mehan

(Head)

THE MAHARAJA SAYAJIRAO UNIVERSITY OF BARODA

सत्यं शिवं सुन्दरम्

Department of Foods and Nutrition Faculty of Family and Community Sciences The Maharaja Sayajirao University of Baroda

VADODARA, GUJARAT INDIA.

ACKNOWLEDGEMENT

As I write this section, I feel eternally grateful to be able to carry out this study based on irritable bowel syndrome under the able supervision and immense efforts of my guide, Prof. (Dr). Mini Sheth who has been patient, calm, and cooperative throughout the study. I am more than grateful to be able to learn important life lessons like discipline, honesty, hard work and dedication from her. Her sincere and dedicated efforts have resulted in the successful completion of the study.

I would also like to thank Dr Meenakshi Bakshi Mehan, Professor and head, Department of foods and nutrition, MS university of Baroda for providing us with all the necessary facilities required for carrying out the study especially during these difficult times of this pandemic.

I extend my heartfelt thanks to the non- teaching staff of our department who have been working continuously and supporting us extensively during our study.

Lastly, I would like to thank my beloved parents (Ujjwala Deo and Late Vivek Deo) and my brother Bhargav Deo and my grandfather Gopal Prabhune for being my pillars of strength and supporting me throughout the thesis in every possible way. Thanks, are also due to my extended family, my friends who've been a constant source of motivation to me. I feel eternally grateful to almighty for all he has bestowed upon me.

-Jahnavi Vivek Deo.

CONTENTS

LIST OF TABLES

LIST OF FIGURES		
Figure no.	**Title**	**Page no.**

ABSTRACT

The first case of IBS was described in 1950. It was described in the Rocky Mountain Medical journal by William Osler. Back then, he used this term to refer it to a group of people who experienced bowel disturbances like abdominal pain, cramps, diarrhoea etc. with no potential source of infection. Later, it was called irritable bowel syndrome, how it is known today. IBS is known to affect about 9-15% of the global population. Today, there is an increasing prevalence of IBS globally. With an increasing prevalence, scientists and researches have now been working on finding scientifically sound evidences that may open newer perspectives towards the understanding of the disease.

The prevalence of IBS is greater in females than in males, which steadily decreases with advancing age. As of today, there is n definitive cure for the disease. It essentially includes a combination of lifestyle and dietary modifications. There is thus a dire need for greater researches that provide scientific evidences for provision of a better quality of life in IBS patients.

The present study entitled, **"impact evaluation of FODMAP food education to IBS patients selected from urban Vadodara on relief from symptoms and improvement in IBS quality of life."** Was planned and executed using the following objectives

- To enrol subjects (15-70 years) from free living population of urban Vadodara using the Rome-IV criteria and screen them for signs and symptoms of IBS.
- Distribution of list of low, moderate and high FODMAP foods to the subjects.
- Collection of baseline data of selected screened subjects with regard to general information, medication and medical history, anthropometry, depression status, symptom profile and quality of life parameters and frequency of consumption of high FODMAP foods.
- After seeking consent for intervention phase, subjects were asked to avoid the top 5 most frequently consumed high FODMAP foods for a period of 4 weeks.
- Post data was collected depression status, IBS symptom profile and IBS quality of life parameters.

- To study the effectiveness of intervention by comparison of pre and post data variables of symptom score, quality of life and depression status in selected subjects.

Data collection was done using purposive sampling. Data was collected from subjects of free living population of Urban Vadodara. A total of 200 samples were screened and administered with a questionnaire of Rome-IV criteria.out of this, 45 subjects qualified this criteria and were selected for the next phase of the study. Out of these, 37 subjects agreed to participate in the intervention phase. Post data collection was done on parameters similar to those of the baseline data after a period of 4 weeks (intervention period).

Results from the study after a 4-week intervention showed that there was a significant decline in the symptom score, depression status and an improvement in quality of life after a 4-week avoidance of the top 5 most frequently consumed high FODMAP foods. Thus, this study shows a positive effect of FODMAP avoidance on various health dimensions and other parameters like quality of life .

CHAPTER-1

INTRODUCTION.

IBS or irritable bowel syndrome is a gastrointestinal (GI) disorder characterized by altered bowel moments associated with abdominal pain, cramping, altered episodes of diarrhoea and/or constipation, bloating, urgency to defecate etc. presently, there has been no concrete evidence suggesting and explaining the pathological and physiological pathways governing the occurrence and progression of the disease. However, several mechanisms from different body systems have been identified and assumed to influence the severity of the disease. There has been a substantial evidence however, that IBS subjects tend to suffer from disturbances and impairments in their quality of life, usually associated with frequent flare-ups of IBS related symptoms and episodes of food intolerances that happen. Lot of researches, documentation and concrete clinical evidences are required in order to achieve a better understanding of the disease. (Lekha saha,2014).

The pathophysiology of IBS is yet unclear. However, several mechanisms and conditions have been identified as potential causal factors. Immune activation altered intestinal permeability and low- grade mucosal inflammation caused by consumption of triggering foods has been identified to cause inflammation of the gut, leading to worsening of IBS. Infections like gastroenteritis and food poisoning and GI diseases like GERD, bile malabsorption, bacterial overgrowth, dysbiosis etc. have also been found to be associated with what is referred to as post- infectious IBS (PI-IBS). Genetic inheritances and mutations (like that of the SCN5A gene) have shown to have positive

corelations with IBS. Other mechanisms like the gut- brain axis have shown positive relationship with IBS. (Gerald.J. Hottman,2016).

The prevalence of IBS has shown to be growing across the globe. With increasing awareness, people have started to know more about the disease and thus seek clinical correlation for the same. The National prevalence of IBS in India lies between 11-14% (Rahman et. al , 2017). There have been studies which show that the prevalence of IBS is greater in developed countries. Studies suggest that economically developed countries have a greater proportion of population living sedentarily, causing them to make unhealthy lifestyle choices (Rebecca M Lovell, Alexander C Ford, 2012). IBS is more prevalent in females than in males and affects people more below the age of 50 years. People above the age of 50 years are less likely to be affected by IBS. Pooled data from several researches showed that prevalence of IBS was lower in rural areas than those in urban areas. It was attributed to poorer lifestyle, greater sedentarism, lower physical activity and greater psychological stress in urban subjects due to their lifestyles (Ghoshal UC, Singh R,2017).

Diagnostic and clinical correlations of IBS have been evolving through the years. The first diagnostic criteria was developed by Manning.et.al in 1979. Rome criterion viz.; Rome I, II, III and IV have also been developed as non- invasive methods for diagnosis of IBS. They take a brief account of recurrent abdominal pain (once in a week at least for the past three months) and defecation profile. There is no standard diagnostic test for IBS. Clinicians usually use a combination of biochemical and clinical parameters for diagnosing IBS and ruling out other possibilities. Some imaging tests like CT-scan, MRI etc can also be used for diagnosing IBS. (Lekha Saha,2014).

IBS can affect an individual in very many ways. It can have an impact on physical, mental and emotional health aspects. Research has shown that IBS and related symptoms have a great impact on a person's mental health. IBS and depression and cognitive changes are interrelated. Many parts of the brain are involved in the pathways that cause and manipulate symptoms of IBS. The HPA axis for example is a pathway has a direct effect on the GIT. The paraventricular nucleus (PVN) of the hypothalamus produces neuropeptide hormone corticotropin releasing hormone (CRF). CRF is produced by the PVN in response to stress. High CRF levels are linked to Alzheimer's disease and MDD (major depressive disorder). CRF receptors are involved in the sensation of pain and stress. Hyperstimulation of CRF enhances pain sensation among IBS subjects. Elevated CRF levels cause inflammation and promote the production of stress hormones like glucocorticoids, cortisol etc, in turn promoting inflammation, stress and immunosuppression in the body. This becomes a cyclic process and causes what is known as chronic stress and inflammation. This causes a drastic reduction in the process of neuron formation/neurogenesis in the hippocampus. Reduced neurogenesis is known to cause impaired cognitive behaviours, poor memory and recall and atrophy. This in turn triggers depressive behaviours in patients. Chronic inflammation is also known to manipulate the immune system. It is known to cause imbalances between the ratios of inflammatory cytokines, especially (interleukins) IL-6 & IL-10 which are important immune modulators. The imbalances in the key modulators cause generalized immune activation causing intestinal inflammation. Localized inflammation of the intestine is known to alter the composition of the gut microbiota and intestinal permeability. The gut brain communication is an established theory that studies the connection and bi-directional communication between the gut

and the brain. The gut brain association is an important pathway which establishes an association between the gut microbiome imbalance and psychological disorders that affect the quality of life in IBS subjects. These factors contribute to the symptoms and severity of IBS. Thus, IBS subjects are most likely to have psychological disorders such as anxiety, depression etc. (Tatenda A Mudyanazdo,2018).

Food choices and diets have a great impact on severity of IBS. They've been used as therapies for the treatment of IBS. Scientists have found out sets of foods that cause worsening of IBS symptoms. These foods grouped together are called FODMAP foods, abbreviated fermentable oligosaccharides, disaccharides, monosaccharides and polyols. The FODMAP diet was first developed by the Monash University by Dr Peter Gibson and Dr Susan shepherd. The FODMAP diet has gained a lot of attention in the past years. Many researches have been done to find the efficacy of low FODMAP diet in IBS subjects. Researchers have reported a 75% efficacy rate of a low FOAMAP diet.

FODMAP's are short chain carbohydrates or sugars which are poorly absorbed in the small intestine. As a result, the undigested carbohydrate segments are acted upon by the gut microbes. They ferment the carbohydrate fragments and produce gasses like methane and hydrogen, producing symptoms of flatulence and wind. Upon reaching the large intestine, these carbohydrates attract excess water in the large intestine. This exerts an excess of osmotic load on the intestines, causing the stool to become watery. This in turn may cause symptoms like diarrhoea and faecal urgency. The excess gas production and high osmotic load may also alter the pH of gut, affecting the composition of the gut flora. There have been several other researches but scant of data and documentation have led to a limited understanding of the disease and its association

with FODMAP foods. Another research has shown that, ingestion of high FODMAP diet may cause excess production of short chain fatty acids (SCFA). Excess SCFA production may stimulate the release of 5-hydroxytryptamine or serotonin and histamine, which quite explains the missing link between food allergies and IBS. (Anusha Thomas, Eamonn M M Quiggley , 2015) Histamine production and mast cell activation may trigger an inflammatory and immune response in the gut and cause detrimental changes in the mobility, motility, sensitivity, permeability. It may also alter gut secretion, causing worsening of IBS symptoms. (Monia E Werlang, 2015).

The FODMAP diet regime is divided into three phases which include: The Restriction/elimination phase, the reintroduction or rechallenge phase and The maintenance or personalized phase. The low FODMAP diet is essentially a 4–6-week regime which is essentially followed to identify specific triggering foods. In the first phase, all the high FOAMAP foods are avoided. The second phase includes gradual reintroduction of high FOAMAP foods and identification of food specific symptoms of IBS. Any food that triggers a symptom flare-up is noted in this phase. This phase may last for several weeks as it includes minute observations of specific triggering ingredients of foods. After careful noting of the well-tolerated and non-tolerated food groups, the patient is made to proceed into the third phase or the maintenance phase. This phase includes continuation of foods that are well tolerated after reintroduction. Patients can start to consume these foods regularly. In the later stages, the patient may try to reintroduce the intolerable foods again, keeping a check on symptoms. This is essentially the dietary therapy given to IBS patients. There are several studies that have validated the use and efficiency of low FODMAP diet. (Erin Dwyer,2015 Monash University).

FODMAP diets are a convenient and feasible way to prevent worsening of symptoms. Patients find it better than other clinical therapies focussing on frequent use of medications, given the amount of side effects they have on the body. Thus, dietary approach may be a first line therapy for treatment of IBS.

Thus, the present study entitled "**impact evaluation of FODMAP food education to IBS patients selected from urban Vadodara on relief from symptoms and improvement in IBS quality of life."** was undertaken with the following objectives:

- To enrol subjects (15-70 years) from free living population of urban Vadodara using the Rome-IV criteria and screen them for signs and symptoms of IBS.
- Distribution of list of low, moderate and high FODMAP foods to the subjects.
- Collection of baseline data of selected screened subjects with regard to general information, medication and medical history, anthropometry, depression status, symptom profile and quality of life parameters and frequency of consumption of high FODMAP foods.
- After seeking consent for intervention phase, subjects were asked to avoid the top 5 most frequently consumed high FODMAP foods for a period of 4 weeks.
- Post data was collected on parameters like depression status, IBS symptom profile and IBS quality of life parameters.
- To study the effectiveness of intervention by comparison of pre and post data variables of symptom score, quality of life and depression status in selected subjects.

CHAPTER-2

REVIEW OF LITERATURE

Gastrointestinal disorders or functional bowel disorders are common disorders that affect a patients' quality of life. IBS or irritable bowel syndrome is one such GID which has posed as a challenge for healthcare providers essentially because of its unknown origin and lack of medical therapies available. IBS is a chronic disorder which is not fatal but affects a persons' life in many ways. The pathways governing disease progression are still unclear and a lot of research and documentation still remain to be done for a better understanding of the disease.

However, in recent years, dietary interventions have sought a significant role in the line of treatment. The low FODMAP diet has come into spotlight as an effective and harmless first line therapy for the treatment of IBS. FODMAP, abbreviated as fermentable oligosaccharides, disaccharides, monosaccharides and polyols are a group of short chain carbohydrates that are present in certain foods. These short chain carbohydrates remain unabsorbed in the small intestine. As a result, these carbohydrate fragments get fermented in the small intestine and produce gas and flatulence causing worsening of IBS symptoms. In recent years, extensive research has been done on the efficacy of low FODMAP diet in IBS. These have proven that 3 out of 4 IBS patients benefit from consumption of a low FODMAP diet.

In relation to the present study titled "**Impact evaluation of nutrition intervention on IBS subjects and its effectiveness in terms of relief of symptoms and improvement in IBS quality of life in selected samples from urban Vadodara.",** this study assembles the available literature and is divided into the following sections:

2.1 Global prevalence of IBS

2.2 National prevalence of IBS

2.3 History of IBS

2.4 Synopsis of IBS:

2.4.1 symptoms

2.4.2 Causes

2.4.2.1 Gut-brain axis

2.4.2.2 Genetics

2.4.2.3 Infection

2.4.2.4 Inflammation and immune activation

2.4.2.5 Serotonin dysregulation

2.4.2.6 Bacterial overgrowth

2.4.3 Risk factors

2.4.4 Diagnosis

2.4.5 Treatment

2.4.5.1 Pharmacological

2.4.5.2 Non- pharmacological

2.5 Depression and IBS

2.6 QoL and IBS

2.7 FODMAP and IBS

2.1 GLOBAL PREVALENCE OF IBS.

The prevalence of IBS is highly heterogeneous for different geographical regions. Most prevalence studies are community surveys done through telephonic interviews, online questionnaires or door to door surveillance. A meta - analysis of sever research papers from Europe, Southeast Asia, and North America showed that the global prevalence of IBS withing the community is somewhere around 10%- 25%. It reported that international prevalence was around 11.2% (95%CI), with geographical variations. This study found that among the selected countries, the lowest prevalence was in South Asia (7%) and the highest was recorded in South America (21%). (Canavan, C., West, J., & Card, T. (2014).

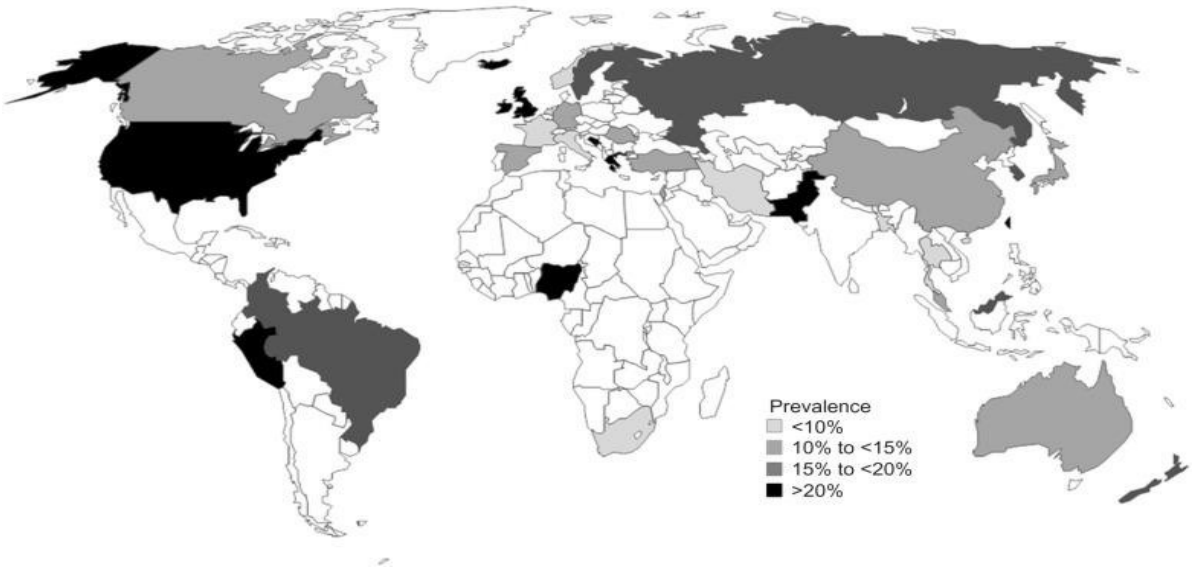


Figure- 2.1 (worldwide prevalence of irritable bowel syndrome)

Source: Canavan, C., West, J., & Card, T. (2014). The epidemiology of irritable bowel syndrome. *Clinical epidemiology*, *6*, 71–80. https://doi.org/10.2147/CLEP.S40245

In 2015, a meta-analysis was conducted that aimed to study the prevalence of IBS in children and adolescents from Asia. It identified 16 cross sectional studies from china, Japan, Korea,

Iran, Sri Lanka, & Saudi Arabia, with a sum total of population being 38,076. They extracted data on prevalence, pooled prevalence, sex differences subtypes etc. the study found the prevalence to be between 2.8% to 25.7%, while the pooled prevalence (95%CI.) was 12.41%. the risk ratio for girls: boys was calculated to be about 1.39, which meant that females were more prone to develop IBS than boys. However, there was no concrete conclusion drawn about the most prevalent subtype as, it was diverse and variable between studies. The highest prevalence (25.7%) was from south Korea, and the lowest (2.8%) being in Sri Lanka. (Devnarayana et. al, 2015, epidemiology of IBS in children and adolescents of Asia).

A meta - analysis reported that, about 10-20% of adults from the western countries have symptoms related to IBS. A similar prevalence was reported by Lovell and Ford estimated a 11.2% prevalence at 95% CI. However, the study found out that prevalence rates of countries were highly dependent on the diagnostic techniques used to find the prevalence. For example, in a study published in the same journal, Keshteli et. al found that, in Iranian adults, modified Rome-2 criteria reported a prevalence of 21.5% whereas, the actual prevalence in Iran was only 9%. Thus, the diagnostic criteria being used is of utmost importance when prevalence rates are concerned. **(*Endo, Y., Shoji, T., & Fukudo, S. ,2015)***

In a meta-analysis that aimed to look at the prevalence of IBS based of Rome-III &IV criteria, 184 studies were picked out of which, 57 were eligible for analysis. It took into account 4,23,362 subjects from 38 countries. Pooled prevalence using Rome-III of about 3,95,385 subjects was found to be 9.2% with IBS-M was predominant (in 33.8% patients). Pooled prevalence with Rome-IV criteria of about 82,476 subjects was found to be 3.8% with IBS-D being predominant (in 31.5% subjects). Gender based prevalence was seen to be greater in

females than males, with an odds ratio of 1.4. However, prevalence between countries was highly variable and thus no conclusion could be drawn**. (oka et.al., 2020)**

2.2 NATIONAL PREVALENCE OF IBS

A study in India which aimed to study the prevalence of IBS in urban slums of Mumbai. Prevalence of IBS in the Indian community varies between 10-20%. Out of which, only 20% seek medical attention. A cross sectional study was conducted in urban slums using systematic random sampling with a pre-tested and semi structured questionnaire.it concluded that, prevalence was about 12.27% out of which, 56% were males and 44% were females. With majority aged between 25-44 years (66%) and married (64%). The most common symptoms observed were relief from pain after bowel movement (68%), change in stool frequency (65%). It was found that, IBS-D subtype was predominant (51.52%). With $p < 0.01\%$, they found that, psychiatric disorders, sexual dysfunction, pelvic pain and decrease in QOL were significantly associated with IBS. While, gender, age and religion found no association with IBS. **(Nagaonkar et al, 2018).**

A study was conducted to understand the prevalence of IBS in Northern India. It was conducted in the rural community of Ballabgarh, Haryana. A questionnaire based on Rome-3 criterion module was administered and subjects were classified based on IBS subtypes (IBS-constipation, diarrhoea, mixed and unspecified). A total of 4,767 participants were enrolled with 555 having IBS-C, and 823 having IBS-D. the overall prevalence was found to be 4% and prevalence according to subtypes was as follows: IBS-C=0.3%, IBS-D=1.5%, IBS-M=1.7% & IBS-U=0.5%. Gender based prevalence showed that, prevalence was greater in females (4.8%) than males (3.2%), which increased with age. **(Makharia et. al, 2011)**.

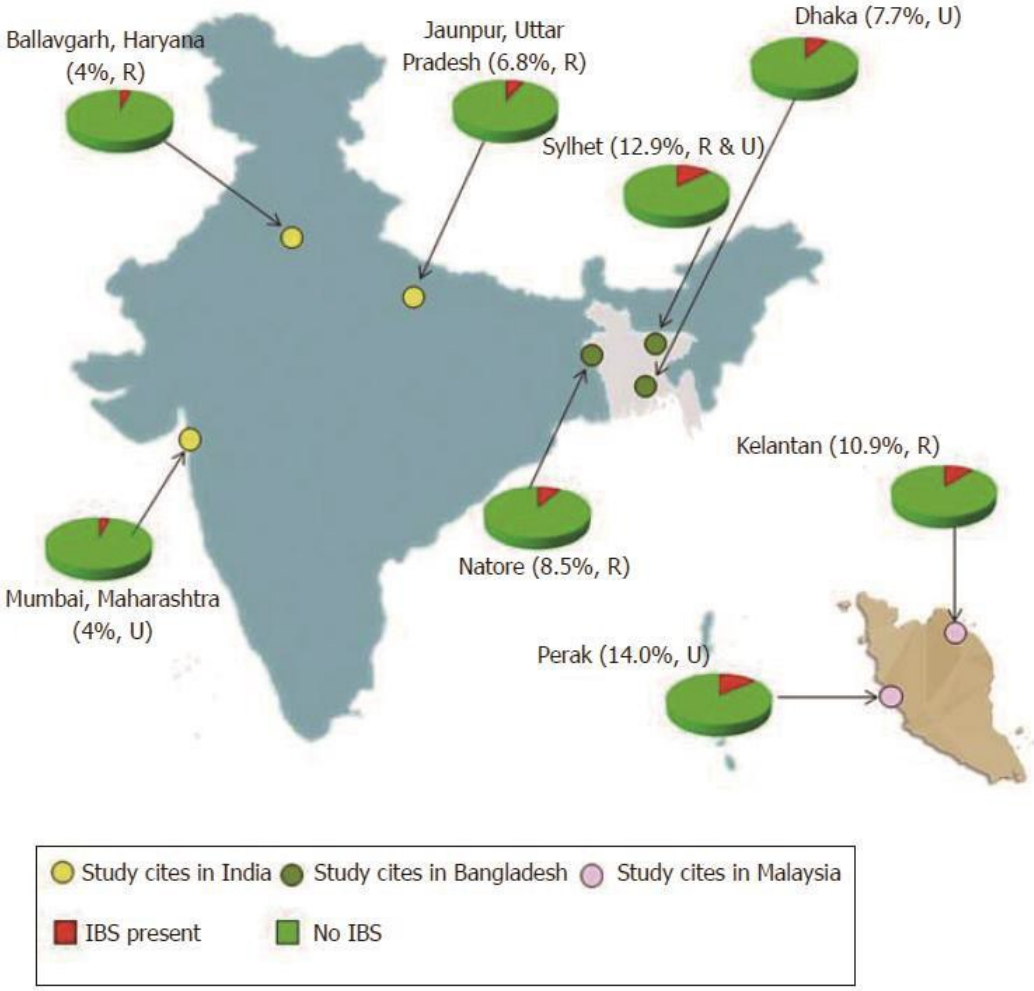


Figure- 2.2 National prevalence of IBS.

Source: Ghoshal UC, Abraham P, Bhatt C, Choudhuri G, Bhatia SJ, Shenoy KT, Banka NH, Bose.K, Bohidar NP, Chakravartty K. . 2008.

Rahman MM, Mahadeva S, Ghoshal UC. Epidemiological and clinical perspectives on irritable bowel syndrome in India, Bangladesh and Malaysia: A review. *World J Gastroenterol* 2017; 23(37): 6788-6801 [PMID: 29085223 DOI: 10.3748/wjg.v23.i37.6788]

2.3 HISTORY OF IBS

The history of IBS dates back to 1892, as reported by Osler. He characterized this disorder as "mucus colitis". This disorder was then characterized as tubular casts of colon consisting of

mucus (mucorrhoea), cell debris, and intestinal sand. Osler reported these patients to have normal colonic epithelium but reported that many patients were hysterical, hypochondriac, depressed and suffered from colicky abdominal pain. This disease was also described by Hurst but it seemed to disappear from texts by late 1920's. by 1928, it re-appeared in the texts as "colonic spasm". The term irritable colon first appeared in 1929in a research by Jordan and kiefer. They described the condition as Musculo neural disturbances present in 30% of the gastroenterology outpatients. ***(Maxwell et.al, 1997).***

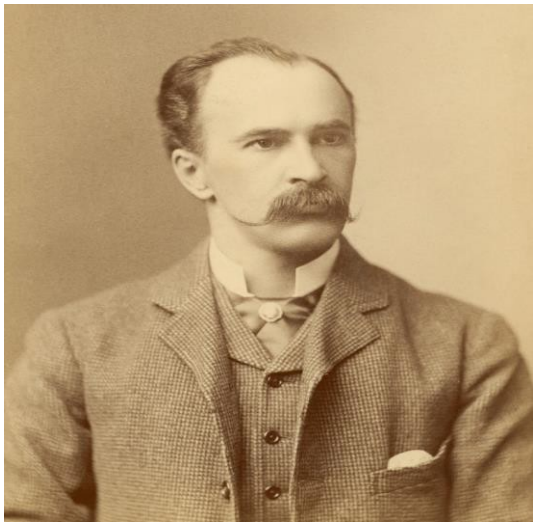


Fig-2.3 William Osler (1849-1919).

2.4 SYNOPSIS OF IBS:

Irritable bowel syndrome or IBS is a chronic gastrointestinal disorder that affects about 11-12% of the world's population. (Canavan et. Al, 2014). Globally, there has been a peak in the prevalence of IBS cases. This is primarily because of the drastic changes in the living conditions. These include increased sedentarism, reduced physical activity, increased consumption of processed foods, and other factors like pollution, genetics, presence of other infections, predisposition to GI diseases etc. A lot of research has gone into finding out the

exact causes of IBS. However, only a little is known about the disease. IBS is a chronic disease which does not usually end up being fatal. However, the disease has no permanent cure. It usually subsides down with appropriate and targeted therapies but may cause frequent flare – ups if appropriate therapies are not given. **(weaver et. al ,2017)**

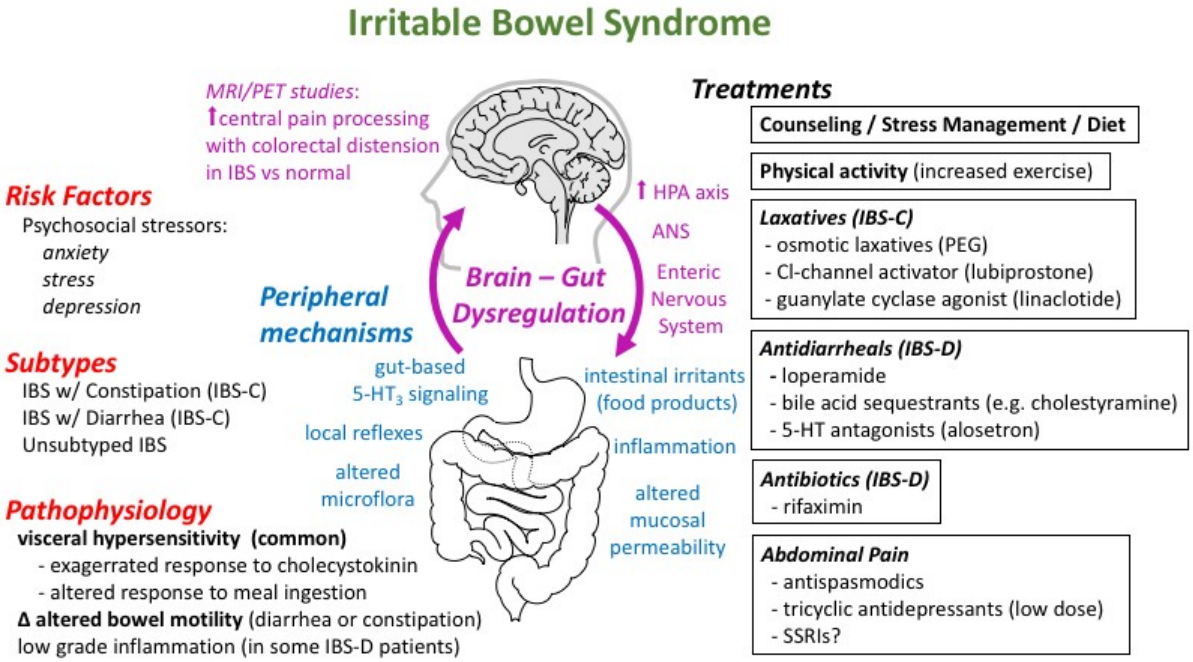


Figure 2.4 : an overview of irritable bowel syndrome

Source: https://tmedweb.tulane.edu/pharmwiki/doku.php/irritable_bowel_syndrome_ibs

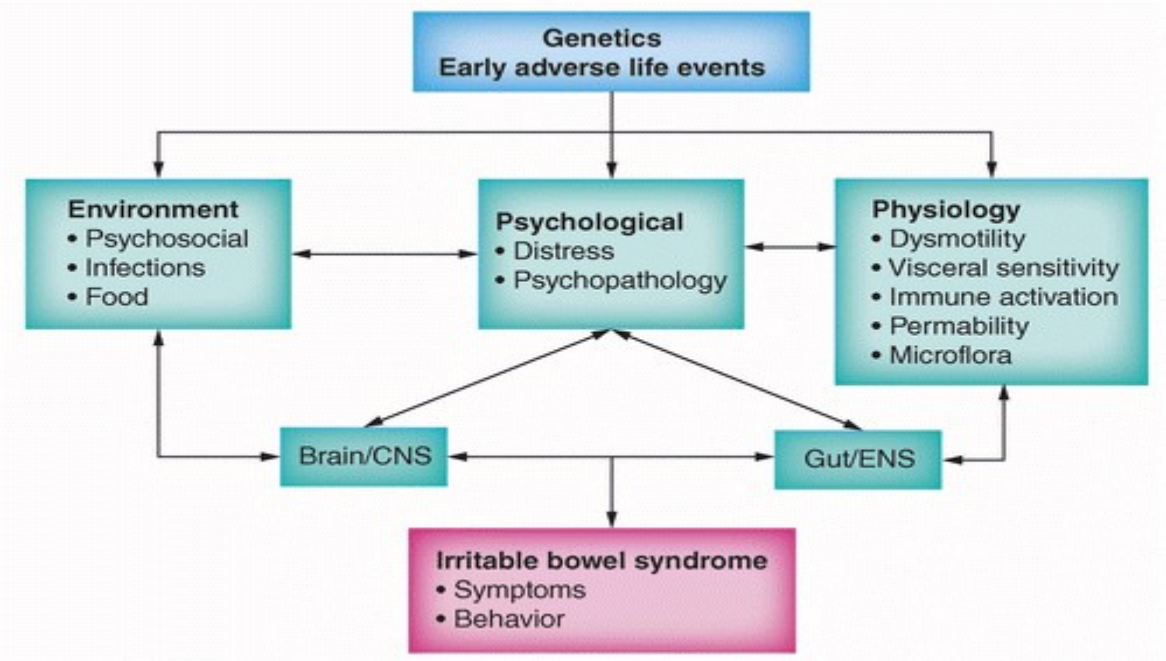


Figure -2.5: synopsis of IBS

Source: (Cristina Almansa & Lesley A Houghton, 2013)

2.4.1: SYMPTOMS:

Symptom in IBS usually include symptom affecting the gastrointestinal tract and extraintestinal manifestations. It usually includes chronic abdominal pain and altered bowel habits as the primary symptom. It also includes symptoms other than the GI tract, including sexual dysfunction, dysmenorrhea, dyspareunia, etc. IBS subjects are most likely to suffer from hypertension. Abdominal symptoms may include diarrhoea, constipation, or both. Based on this, IBS has been subtyped into three broad categories based on bowel symptoms. These include IBS-C(constipation predominant), IBS-D(diarrhoea predominant) and IBS-M(mixed). The prevalence of each subtype greatly varies between population groups according to various factors such as age, geographical location, gender, diet etc. **(Vahedi et.al,2010).**

2.4.2 CAUSES OF IBS.

A lot of theories and pathways have been found and believed to be associated with IBS. Several researches have revealed and identified plausible pathways and causes responsible for the disease progression.

2.4.2.1 Gut- Brain Axis:

IBS is a gastrointestinal disorder. However, the symptoms are not just limited to the GI tract. Investigators have found that, IBS also involves the brain. It was discovered that, the symptoms and severity of IBS is associated with the communication between gut and the brain. This pathway is called the gut brain axis. With advances in studies and concrete evidence, it is now clear from three prospective studies from 2 countries that, in about half of the enrolled subjects who were IBS patients, gastrointestinal symptoms arise first post which, there is development of mood disorders and other psychological disturbances. These have suggested that, the mood disorder and other psychological disturbances maybe an underlying cause of the gut disorders. Another independent study was done to associate ad find the link between IBS and psychiatric

disorders. This study made use of structured interviews for the same. This study revealed that, 40% of the subjects with mood disorders and 23% of patients with anxiety developed these diagnoses after IBS first appeared/was diagnosed. This shows that the symptoms relating to the gut appear prior to those of brain.

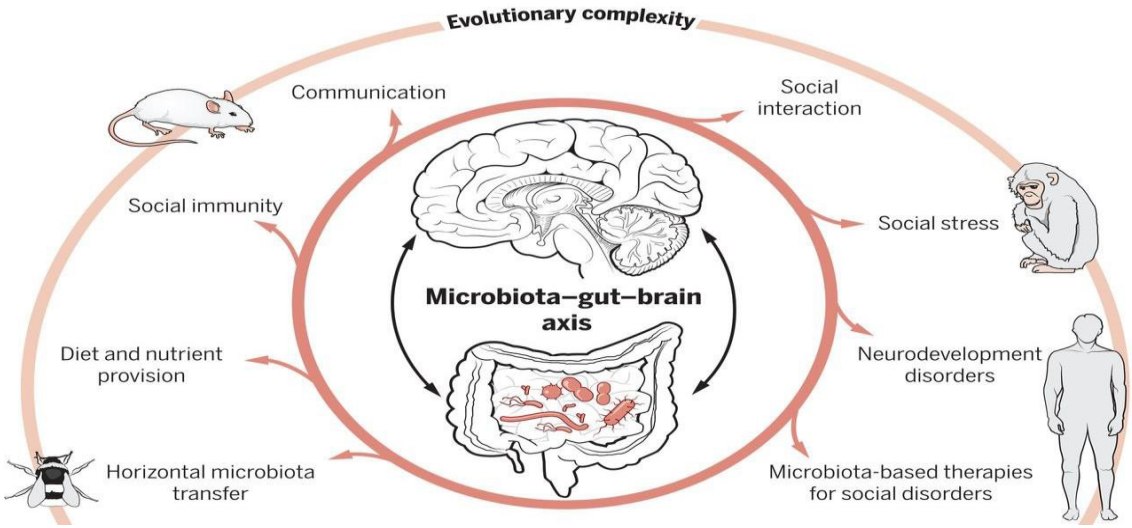


Figure 2.6 Gut brain Axis

Source- https://science.sciencemag.org/content/366/6465/eaar2016/tab-figures-data.

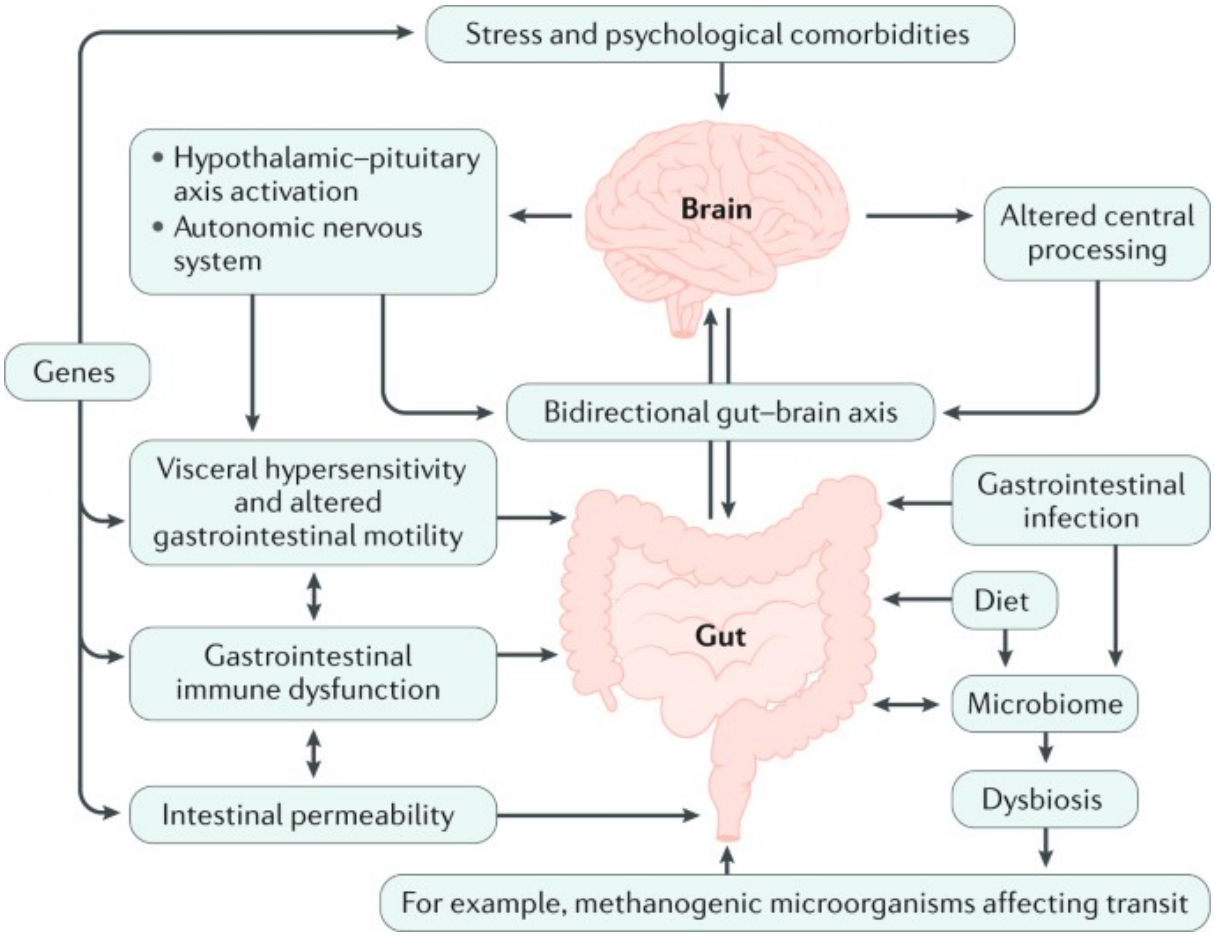


Fig- 2.7 : consequences of the gut brain axis.

Source- https://www.nature.com/articles/s41575-020-0286-8?proof=t#Bib1.

2.4.2.2 Genetics:

For a long time, scientists have seen the occurrence of IBS to be a consequence of genetics. One such investigation is the mutation of SCN5A gene. Some investigators have concluded that, IBS aggregates greater in monozygotic twins than in dizygotic twins. Mutations in the SCN5A gene voltage gated channel (type-5) have known to be associated with congenital QT syndrome. This syndrome is known to be associated with abdominal pain. This voltage gated

channel is also found in cajal and circular smooth muscle cells of the intestine. In a pilot study which aimed to find a link between gene mutation and IBS, 49 subjects having IBS with moderate to severe abdominal pain were studied. The study results showed that, there was a loss of these gated channels chiefly due to mutation of the SCN5A gene in one patient out of the 49 subjects. This loss of gated channel was absent in 1500 healthy controls that were compared against the case**. (Saito YA, Petersen GM, Larson JJ, et al. 2010).**

Another study was done to associate the genome with IBS. This study enrolled 580 IBS subjects with 1380 healthy controls. These enrolled subjects were replicated in 4 independent cohorts. Genomic testing showed SCN5A mutation in 2% subjects. most subjects with the mutation met the criteria for IBS subtype C (IBS-C) than D (IBS-D). **(Beyder A, Mazzone A, Strege PR, et al. 2014).**

Another study by Swan and colleagues showed assessed and studied the role of single nucleotide proteins (SNP's) in genes whose expression is affected by acute enteric infection by obtaining rectal biopsy samples of subjects with IBS-d or C and patients with *campylobacter jejuni* infection before six months. These cases were then compared to healthy controls. Investigators found that, SNPs in the tumour necrosis factor (TNF) superfamily 15; TNFSF15 and genes coding for TNF alpha (TNF-α) were known to predispose an individual to IBD associated with diarrhoea and post-infection IBS. However, the results from the study contrasted from other study results which showed that, TNFSF15 were associated with constipation**. (Swan C, Duroudier NP, Campbell E, et al. 2013).**

Chronic stress is a strong modulator of motor and sensory function. Stress modulates these functions through the corticotropin releasing hormone and signalling through catecholamines. A study was undertaken, and investigators enrolled 111 IBS subjects and 142 healthy controls.

The study aimed to study genes encoding corticotropin- releasing hormone. Two genes viz.; rs28364015 and rs6472258 coding for corticotropin-releasing hormone and gene rs10474485 coding for corticotropin releasing binding protein were studied using sequencing techniques and polymerase chain reaction along with assessment of emotional status using questionnaires. However, there was no concrete conclusion in SNPs of healthy subjects. It was found that, in IBS-D predominant subjects without gene rs10474485A allele had significantly higher levels of emotional arousal in comparison to those without the allele. This study outcome was suggestive of the effect of genes and polymorphisms on the severity of emotional disorders in IBS subjects. This study thus established a link between the association of genetic changes in IBS subjects and their influence on the severity of emotional disturbances**. (Sasaki A, Sato N, Suzuki N, et al 2016).**

There have been other studies which have examined the role of genetics in immune regulation, epithelial barrier function, bile acid synthesis and cannabinoid receptors. However, these study results could not conclude anything because of limitations of sample size.

2.4.2.3 Infection:

A great deal of studies have reviewed the association between GI infections and their association on IBS and how infections can be a secondary cause of IBS.

Another study was done in rat models in which mucosal inflammation was chemically induced in rats. The observations made were conclusive of the link between severity of visceral hypersensitivity and severity of IBS. This link maybe seen as a mechanism for the prognosis

of IBS. Another major finding from this study was that, psychological stress in rats affects the visceral hypersensitivity in the rats.

In line of the above study, Wouters and his colleagues undertook a study to examine the risk factors for IBS. 19,000 were enrolled in a cohort study which aimed to study IBS after contracting other GI diseases pertaining to consumption of contaminated water containing norovirus, Giardia Lambia, and C Jejuni. The study found that subjects with pre-existing anxiety were more prone to developing IBS. The study results also showed that, there is an inverse relationship between anxiety scores pre- exposure and CD4 positive T cells expressing IL-2. there was also an association between development of PI-IBS and T-helper cells cytokine phenotype suggestive that development of IBS after an infection, essentially acute enteric infection was due to the switching of T-helper-2 immune cell response. (**Wouters MM, Van Wanrooy S, Nguyen A, et al 2016).**

Similar conclusions were made from the Millennium cohort study which collected data from individuals from active- military services. This study assessed anxiety and depression among soldiers and their link with the contraction of acute gastroenteritis and subsequent causing of PI-IBS. This study helped to establish a link between psychological stress and IBS. **(Riddle MS, Welsh M, Porter CK, et al. 2016).**

Another study was done which included 13 patients with PI-IBS, 19 patients with IBS unrelated to enteric infection and 16 healthy controls. A faecal microbiota analysis showed a significant difference between faecal samples of subjects with PI-IBS and healthy controls. It was concluded that, there was a reduced diversity of microbiota both, in mucosal and in the stool in PI-IBS. Reduced diversity was related with increased cell numbers of CD-8 and CD4RA positive intraepithelial lymphocytes. This also resulted in psychological symptoms like mood disturbances etc measured by hospital anxiety and depression score. Similar results

have reported dysbiosis or imbalances in gut microbiota in IBS patients, especially IBS-D**. (Carroll IM, Ringel-Kulka T, Siddle JP, Ringel Y, 2012).**

2.4.2.4: Inflammation and immune activation:

Persistent low grade inflammation is a potential cause of IBS.

The intestinal mucosa is richly embedded with the dense network of blood supply and immune cells. The intestinal or enteric immune system is frequently in contact with a variety of pathogens that enter the body through food. There is thus a constant activation of the immune system in the intestine. This frequent activation may result in a persistent low-grade inflammation of the mucosa. The persistent inflammation can trigger the inflammatory cascade and cause worsening of IBS symptoms. IBS subjects have been found to have increased lamina propria immune cells compared to healthy controls. This also resulted in oleoylethanolamide; a fatty acid amide and PARα agonist. These cells are known for their anti- inflammatory properties. This research finding is suggestive of the link between low grade inflammation and IBS. (**Ng, Q. X., Soh, A., Loke, W., Lim, D. Y., & Yeo, W. S. (2018.)**

The current research is thus suggestive of a positive corelation between inflammation, immune activation and IBS. Increasing evidences are suggestive of the microscopic changes that follow inflammation and IBS. This inflammatory response triggers the inflammatory cascade and attracts immune cells to the location of inflammation. These immune cells alter the mucosal permeability and sensitivity, thus causing damage and worsening of IBS symptoms**. (O'Sullivan , Clayton N, Breslin NP, et al. 2000).**

2.4.2.5 SEROTONIN DYSREGULATION

Serotonin, a hormone responsible for mood stability and well- being. Serotonin (5-HT) acts at receptors 5-HT3 and 5-HT4. Serotonin plays an important role in the maintenance of gut motility, stability, sensitivity and secretion. It is known to affect the functioning of the gut. It is usually seen that there is a reduced secretion of plasma 5-HT in IBS subjects with constipation. Whereas, the levels of plasma 5-HT are elevated in IBS-D. this shows a link between serotonin secretion, mood stability and gut motility in IBS subjects. This is conclusive of the hormonal regulation through the blood- brain barrier and affect on the gut related symptoms of IBS. **(Derbyshire SW. 2003).**

2.4.2.6 BACTERIAL OVERGROWTH:

Small intestinal bacterial overgrowth (SIBO) refers to a condition in which there is abnormal growth of gut microbiota in parts of the GI tract other than the gut. This is usually a result of abnormalities in the gut or due to the presence of infections etc. SIBO may also occur as a result of intolerances causing excess hydrogen gas production etc. there is an increased prevalence of SIBO among IBS patients. Although there is no clear effect- cause relationship between IBS and SIBO, investigators have been trying o find a link between the two. Some studies are conclusive of a negative correlation between IBS and SIBO.

2.4.3 RISK FACTORS FOR IBS:

In a review article by chitkara et al, various risk factors for IBS were summarised.it was found that many factors, external and internal and modifiable and non - modifiable were responsible for contributing in the prognosis of IBS. At different stages of life of life, different life events

and consequences play a role in the prognosis of IBS. Some factors like socioeconomic status, early manifestations GI symptoms. other factors such as trauma; in any developmental stage of live may also induce symptoms of IBS. Taking into consideration these factors, clinicians and other medical practitioners should be aware about management and prevention techniques to prevent or at least slow the prognosis of IBS. Clinicians should browse through the various therapies available for IBS and choose the one which best suits the patient. **(Chitkara, D. K., van Tilburg, M. A., Blois-Martin, N., & Whitehead, W. E. 2008).**

2.4.4 DIAGNOSIS:

Manning (1978)[12]	Rome I (1989)[13]	Rome II (1999)[14]	Rome III (2006)[4]
2 or more of the following symptoms: Abdominal distension Pain relief with defecation Frequent stools with pain Looser stools with pain Passage of mucus Sensation of incomplete evacuation	At least 3 months of continuous or recurrent abdominal pain: Relieved with defecation or Associated with change in stool consistency With at least 2 of the following on at least 25% of days: Altered stool frequency Altered stool form Altered stool passage Passage of mucus Bloating or abdominal distension	At least 12 weeks in past 12 months of continuous or recurrent abdominal pain or discomfort With at least 2 of the following: Relief with defecation Altered stool frequency Altered stool form Onset of symptoms more than 12 months before diagnosis	At least 3 days per month in past 12 weeks of continuous or recurrent abdominal pain or discomfort With at least 2 of the following: Relief with defecation Altered stool frequency Altered stool form Onset of symptoms more than 6 months before diagnosis

Figure- 2.8 comparison of diagnostic criterion for IBS.

Source- Canavan, C., West, J., & Card, T. (2014). The epidemiology of irritable bowel syndrome. *Clinical epidemiology*, *6*, 71–80. https://doi.org/10.2147/CLEP.S40245

Manning criteria: The first developed criteria for screening of IBS subjects was the Manning criteria (1978). This criterion identifies subjects with symptoms of IBS without any specified duration of symptoms. there is no specific cut-off score but a minimum of three symptoms viz.;

abdominal pain relieved by defecation, more frequent stools with onset of pain, Looser stools with onset of pain, passage of mucus from rectum, feeling of incomplete emptying, patient-reported visible abdominal distension etc.

Kruis criteria: this criterion was developed in 1984. This screening criteria takes into account symptoms like abdominal pain, flatulence, bowel irregularity etc for a duration of more than two (2) years. Signs that exclude IBS (each determined by the physician): Abnormal physical findings and/or history pathognomonic for any diagnosis other than IBS Erythrocyte sedimentation rate > 20 mm/2 h Leucocytosis > 10000/cc Anaemia (Haemoglobin < 12 for women or < 14 for men) Impression by the physician that the patient has rectal bleeding.

Rome criterion: Rome criterion viz.; I.II.III & IV were developed in the years 1990.1999 and 2006. Newer versions included corrections and improvements. Presently, the Rome criterion is used. It assesses patients based on presence of abdominal pain at least 1(one) day per week for last 3 (three) months. The second question is about the association of abdominal pain with any of the following viz.; related to defecation, associated with changes in stool frequency or associated with form (appearance) of the stool. The stool appearance is usually studied using the Bristol stool chart which classifies stool appearances based on the scale. A picture of the chart is attached below.

Figure- 2.9 - Bristol Stool chart.

2.4.5- TREATMENT:

Various treatment options for IBS have been made available. Clinicians have a lot of options including pharmacological as well as pharmacological and lifestyle therapies.

2.4.5.1 NON-PHARMACOLOGICAL TREATMENTS:

- **Natural and herbal remedies (such as peppermint oil) :** peppermint oil is one of the most widely researched remedy for reliving the symptoms of IBS. It is known to relive and calm the smooth muscles of the gut. This relaxation causes easing of symptoms of IBS. However, choosing the right medication for peppermint oil is important. Enteric coated pills are most commonly preferred as they reduce the chances of gastric reflux.
- **Nutritional supplements (fibre and probiotics**): fibre is an essential part of the food. However, the right amount and type of fibre is important to balance and normalize the bowel. Too much and too less fibre can cause adverse symptoms. A diet adequate in

fibre is essential for both IBS-C and IBS-D. A diet containing 25-30g of dietary fibre every day is recommended.

Probiotics are also beneficial for people suffering from IBS. Patients on antibiotics are prescribed probiotics which enhance and improve the quality and quantity of the gut bacteria. Symbiotics (mixture of prebiotic and probiotics) are beneficial. However, it is important to start probiotic therapy after consultation with a clinician.

- **Physical activity (such as yoga):** physical activity, especially yoga has shown to be beneficial for reliving symptoms of IBS. There have been several researches that have shown the positive correlation of yoga and IBS. It is essentially because yoga poses help to relax muscles and calm the gut. Also, yoga helps one to reduce stress and anxiety in individuals.
- **Psychological therapies (such cognitive behavioural therapy and hypnotherapy):** there is enough evidence from several researches that, individuals with stress anxiety and depression are more prone to developing IBS and vice-versa. Also, there has been evidence that, people with traumatic events in the past are more susceptible to develop IBS. Clearly, there is a major role of mental health in the prognosis of IBS. Therapies like CBT (cognitive behavioural therapy) and gut directed hypnotherapy have been gaining recognition in recent times. CBT helps an individual to assess his/her thoughts and identify thought processes which are more likely to cause aggravation of IBS related symptoms. on the other hand, gut directed hypnotherapy is a hypnotherapy which makes one to sit and imagine of a pill that he or she has had swallowed. Further, he/ she is asked to imagine and assume that the pill is working to relive the symptoms of IBS. A hypnotherapist makes the patient to slip into a state of altered

unconsciousness or that of a trance. The gut directed hypnotherapy is known to be beneficial in 70% of IBS patients. **(*chey WD, Kurlander J, Eswaran S. 2015).***

- **Diet:** dietary habits have an important role in the progression of the disease. Certain classes of foods, referred to as fermentable oligosaccharides, disaccharides, monosaccharides and polyols (FODMAP) are high in short chain carbohydrates which escape absorption and get fermented in the gut causing flatulence and other symptom of IBS. Research has shown that avoidance of foods with high FODMAP content helps to relive symptoms of IBS
- **2.4.5.2 PHARMACOLOGICAL TREATMENTS:**

Medications and pharmaceutical products such as anti-depressants, anti-spasmodic, anti-diarrhoea etc are used to treat GI symptom pertaining to the brain and GI tract.

1- **Anti- depressants** such as tricyclic antidepressants and selective serotonin-reuptake inhibitors (or SSRIs) are the most commonly prescribed drugs for symptoms of IBS relating to the brain such as depression, anxiety, mood disorders etc. Tricyclic antidepressants cause side effects of constipation and thus are more frequently used in patients with diarrhoea. SSRI's on the other hand are medications which are more beneficial in subjects with severe depression and IBS-D.

2- **Anti- spasmodic medications**- these medications were prescribed based on the belief that, irregular muscle contractions and spasms are the cause of abdominal pain in IBS patients. These medications work by relaxing smooth muscles and relieving spasms. However, their effect is short term. Side effects include xerostomia, constipation, fatigue etc.

3- **Antibiotics**: for those IBS subjects suffering with symptoms of bacterial overgrowth, antibiotics may be beneficial. In most cases, Rifaxamin is the most commonly prescribed antibiotic in IBS patients. A 4-week treatment with Rifaxamin is prone to benefit most IBS subjects globally and improve symptoms.

4- **Laxatives**- IBS results in changes in the form of stools. In such cases, laxatives are prescribed to patients for reliving symptoms. Two broad categories of laxatives are used viz.; IBS – osmotic and stimulant laxatives. Osmotic laxatives work by drawing water from the intestine and making the stool bulkier. These are used in patients with constipation. Commonly used osmotic laxatives include polyethylene glycol (PEG), milk of magnesia and lactulose. PEG is often recommended to patients with IBS-C.

   Stimulant laxatives work my causing contractions of the muscles in the intestines, causing passage of stools. Some examples of the mot commonly prescribed stimulant laxatives include senna, bisacodyl, castor oil, cascara, rhubarb, and aloe etc. however, there is still a dearth of proper evidence in the efficacy of these laxatives.

5- **Anti- diarrhoeal medications-** these medications are used to slow down bowel movements and curb diarrhoea.

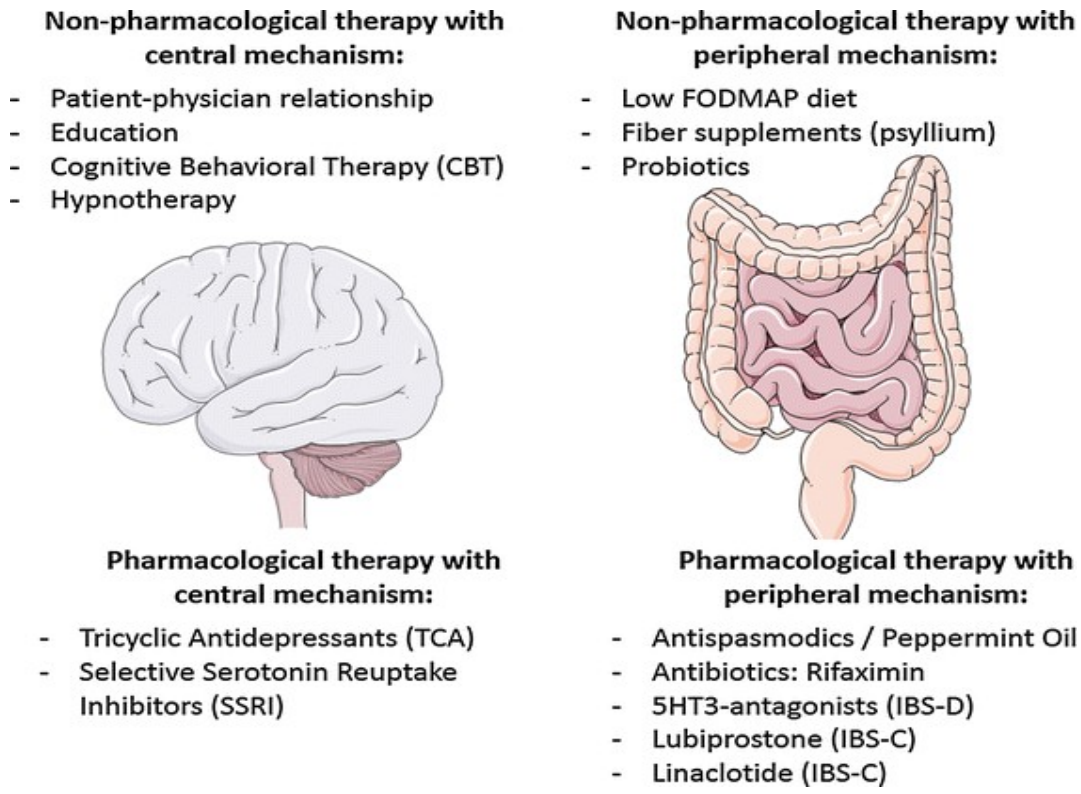


Figure-2.10 Treatments for IBS

Source- (Vanuytsel, T., Tack, J.F. & Boeckxstaens,2014)

2.5 DEPRESSION AND IBS:

A review article by Fond et al included pooled data from several research papers relating to depress and IBS. This meta-analysis was conclusive that psychological illnesses such as depression, anxiety and mood disorders were present in majority of IBS subjects. Case control studies studying the cause- effect relationship was studied A total of ten (10) studies were taken. These studies were basically case control studies which assessed psychological illnesses in cases and healthy controls. The outcome of the study was measured using standard mean difference (SMD). The prime finding oof the study was that there was a significant association of IBS and depression i.e., the mean anxiety and depression levels in IBS subjects were significantly higher than in healthy controls. **(Fond, G., Loundou, A., Hamdani, N. *et al* ,2014).**

Another study included 73 papers. The prevalence rates of anxiety and other psychological disorders was 39.1% and 23% respectively. The odds ratios for anxiety symptoms and disorders in IBS patients were 3.11 and 2.55 respectively at 95% CI. Also, the prevalence rates of depression related symptoms and disorders were 28.8% and 23.3% at 95% CI. The odds for depressive symptoms in IBS subjects compared to healthy subjects were three folds. **(Zamani, M, Alizadeh-Tabari,S, Zamani,V. 2019).**

2.6 QUALITY OF LIFE (QoL) and IBS:

There have been several studies that have studied domains of IBS relating to health. Over the years, scientists have thoroughly researched the different dimensions of health in IBS. IBS takes a toll on a patient's quality of life. It affects ones mental physical and emotional health thus worsening their quality of life. Quality of life has been one of the

In a study which aimed to determine the relationship between IBS and QoL, 87 IBS subjects and 56 healthy controls were enrolled to undertake a case control study on IBS and QoL. Following the enrolment, subjects were asked to fill questionnaires on IBS specific QoL and Depression inventory. The outcomes from the study revealed that the prevalence of depression was greater in IBS subjects. Also, the IBS-QoL scores revealed that, IBS-QoL scores in cases was significantly lower as compared to healthy subjects. This is predictive of the association of IBS and related symptoms with reduction in quality of life. There are 6(six) domains of QoL which are as follows dysphoria, interference with activity, health worry, food avoidance, sexual issues and relationship issues. The study also found that females had greater percentages of impairment of the domain of body image than males. (**Kopczyńska, M., Mokros, Ł., Pietras, T., & Małecka-Panas, E, 2018)**

2.7 FODMAP AND IBS:

In the recent years, FODMAP foods; abbreviated as fermentable oligosaccharides, disaccharides, monosaccharides and polyols have come into light after it was found that foods high in FODMAP's have been associated with symptoms of IBS pertaining to the gut. Consumption of diet rich in FODMAP'S have been known to create osmotic and functional imbalances and disturbances in the gut. This in turn causes changes in gut motility, permeability and sensitivity. Fermentation of these short fragments of carbohydrates leads to excess production of gasses which have been associated with flatulence and wind. FODMAP diets are an essential therapy that may be the easiest and the most feasible way to ease the symptoms of IBS. The FODMAP dietary regime includes three phases viz:

The Restriction/elimination phase, The reintroduction or rechallenge phase and The maintenance or personalized phase. The low FODMAP diet is essentially a 4–6-week regime which is essentially followed to identify specific triggering foods. In the first phase, all the high FOAMAP foods are avoided. The second phase includes gradual reintroduction of high FOAMAP foods and identification of food specific symptoms of IBS. Any food that triggers a symptom flare-up is noted in this phase. This phase may last for several weeks as it includes minute observations of specific triggering ingredients of foods. After careful noting of the well-tolerated and non-tolerated food groups, the patient is made to proceed into the third phase or the maintenance phase. This phase includes continuation of foods that are well tolerated after reintroduction.

A lot of research has gone into evaluation of the efficacy of the FODMAP diet. One such review article analysed data pooled from various studies which compare the FODMAP diet with other dietary regimes. It was found that a FODMAP diet works well for almost 50-80% of IBS subjects in comparison to a habitual diet. Another study compared FODMAP diet to

NICE and modified NICE diets. However, subject groups following FODMAP diets showed significant improvement in symptoms related to bloating and abdominal pain compared to the other two groups. **(Werlang, M. E., Palmer, W. C., & Lacy, B. E. 2019)**

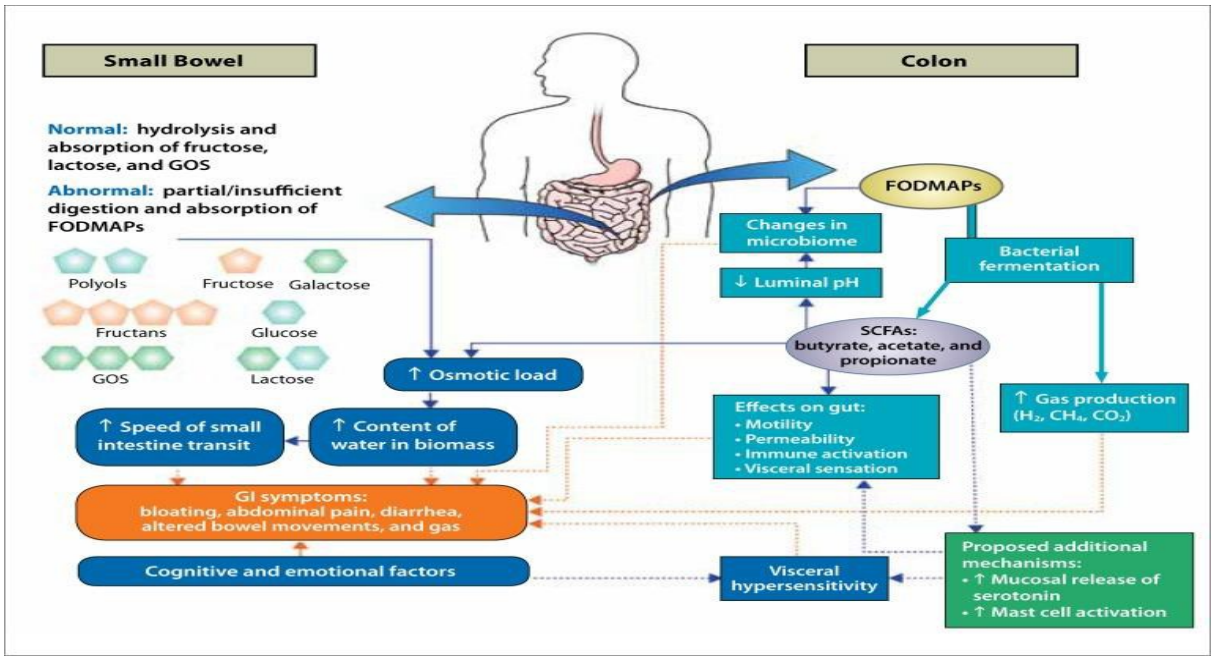


Figure – 2.11 : visual representation of how FODMAP foods affect the gut.(Werlang, M. E., Palmer, W. C., & Lacy, B. E. 2019)

CHAPTER- 3

SCOPE OF INVESTIGATION.

The study was undertaken with the aim to test the impact evaluation of FODMAP food education to IBS patients selected from urban Vadodara on relief from symptoms and improvement in IBS quality of life. The study was undertaken with the following working hypothesis:

- There will be an effect of the nutrition intervention in terms of relief from symptoms and improvement in quality of life in IBS patients.

To authenticate the above hypothesis, the study was undertaken with the following objectives:

- To enrol subjects (15-70 years) from free living population of urban Vadodara using the Rome-IV criteria and screen them for signs and symptoms of IBS.
- Distribution of list of low, moderate and high FODMAP foods to the subjects.
- Collection of baseline data of selected screened subjects with regard to general information, medication and medical history, anthropometry, depression status, symptom profile and quality of life parameters and frequency of consumption of high FODMAP foods.
- After seeking consent for intervention phase, subjects were asked to avoid the top 5 most frequently consumed high FODMAP foods for a period of 4 weeks.
- Post data was collected on parameters like depression status, IBS symptom profile and IBS quality of life parameters.
- To study the effectiveness of intervention by comparison of pre and post data variables of symptom score, quality of life and depression status in selected subjects.

CHAPTER-4

METHODS AND MATERIALS.

IBS or irritable bowel syndrome is a disease with growing prevalence. It has witnessed a surge in the past years. IBS has a significant disease and health burden accounting a prevalence of about 11% of the global population. The pathophysiology and aetiology is still unclear because of the multiple screening and diagnostic criterion available. But, after several decades of research, IBS is now looked at beyond its clinical aspects. IBS is known to affect an individual beyond the dimension of physical health. It is a disease that affects a person mentally and emotionally. It takes a toll on one's quality of life. (Caroline Canavan, 2014).

Dietary approaches to treat and ease IBS have been gaining popularity as first line therapies for the treatment of IBS. The low FODMAP diet has been extensively researched and has shown positive results. Clinicians and gastroenterologists have found dietary approaches as more feasible and easier alternatives to cure symptoms of IBS. (Aziz et. al, 2018).

The current study was undertaken with the aim to study the association of high FODMAP food restriction and symptom improvement. It was titled as:

"Impact evaluation of FODMAP food education to IBS patients selected from urban Vadodara on relief from symptoms and improvement in IBS quality of life."

The materials and methods chapter of the present study will proceed on the following outline:

4.1 Location of the study.

4.2 Study design.

4.3 Screening of the subjects.

4.3.1 Rome-IV criteria

4.4Physical questionnaire (Baseline/General information.)

4.4.1 Anthropometry

4.4.1.1 Height

4.4.1.2 Weight

4.4.1.3 BMI

4.4.2 Personal history

4.4.2.1 History of lifestyle habits

4.4.2.2 History of allergies and intolerances.

4.4.2.3 History of GI disorders and NCD's in the family

4.4.3 Dietary history

4.4.3.1 Type of diet

4.4.3.2 Meals consumed per day

4.4.3.3 Breakfast pattern

4.4.4 Medical ad medication history

4.4.4.1 Morbidity profile

4.4.4.2 medication history

4.4.4.3 History of illness and/or surgery

4.4.5 History of gastrointestinal disorder(s)

4.4.5.1 Subtyping of GI disorder

4.4.5.2 Frequency of occurrence

4.4.5.3 Symptom tracking

4.4.5.4 Presence of symptoms of lactose intolerance

4.4.5.5 Self - identification and avoidance of triggering foods.

4.5 Structured questionnaires.

4.5.1 Beck's depression inventory

4.5.2 IBS QoL domains

4.5.3 Food frequency questionnaire for high FODMAP foods.

4.6 Statistical analysis

4.7 Statutory clearances

4.8 Experimental group

4.9 Inclusion and exclusion Criteria

4.10 Intervention trail for FODMAP restriction

4.11 Supervision and compliance

4.12 Collection of post data

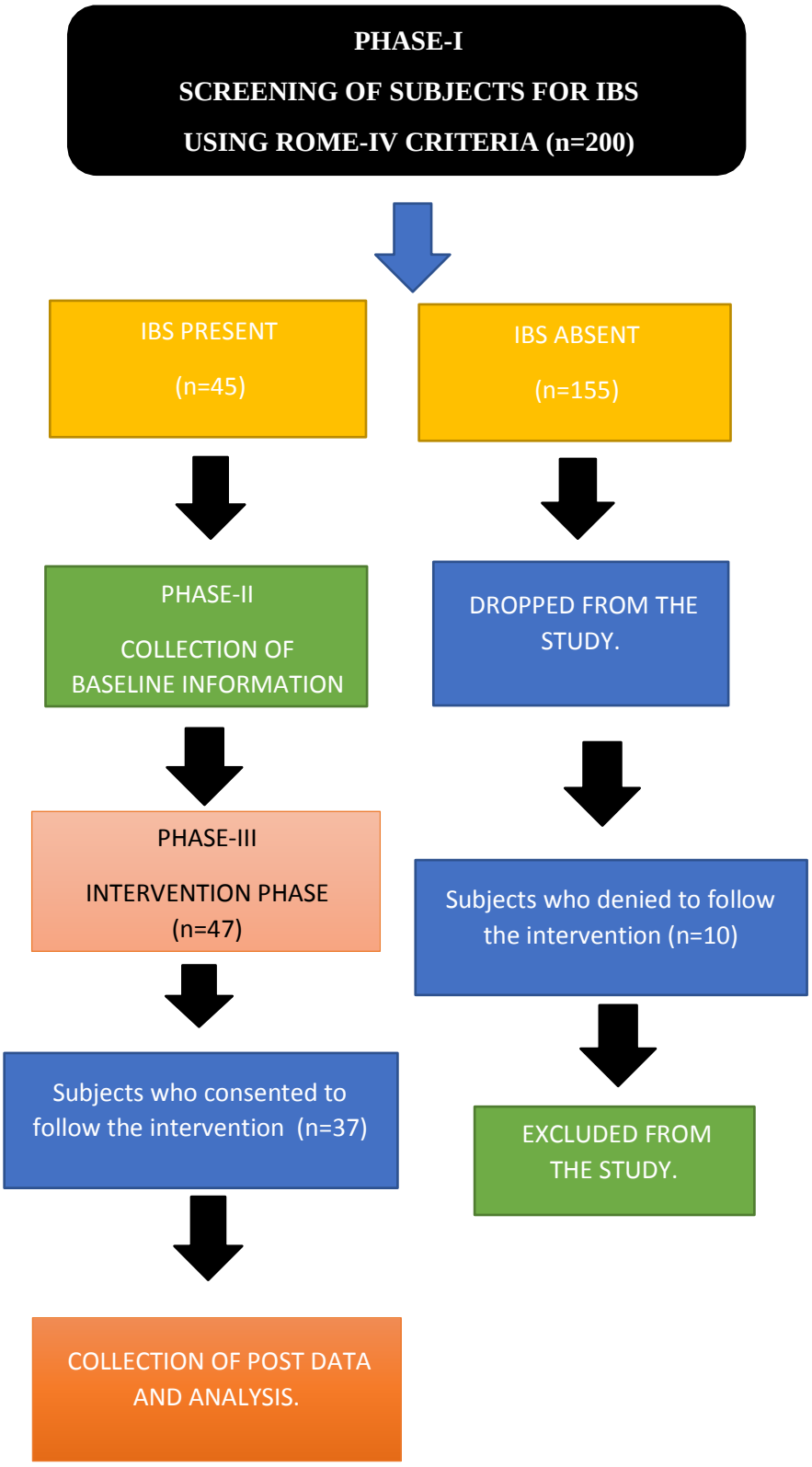
4.13 Statistical analysis

4.1 LOCATION OF THE STUDY:

Using purposive sampling, subjects aged between 15-70 years were screened from free living population of urban Vadodara for presence of symptoms of IBS using the Rome-IV diagnostic criteria. Subjects were screened through google forms and a brief account of the disease and the intervention was given. Subjects were enrolled after they consented to participate in the screening. (Appendix)

Fig. 4.1- Location of the study area.

4.2 STUDY DESIGN:



4.3 SCREENING OF THE SUBJECTS

Subjects were selected from free living population of urban Vadodara through purposive sampling (15-70 years). Subjects were given a consent form prior to filling the questionnaire. Selected subjects received a google form on Rome-IV criteria which included questions on abdominal pain at least once a week for the past three months and its relation to stool form, appearance or with defecation. Other background data related to age, contact information and gender was also collected. Those subjects who met the inclusion criteria and showed symptoms of IBS as those mentioned in the Rome-IV criteria, were enrolled for the next phase of the study.

4.4 PHYSICAL QUESTIONNAIRE (BASELINE/GENERAL INFORMATION)

After enrolment of subjects (n=47) after initial screening, a physical questionnaire was handed out to the selected subjects which contained general information regarding Name, age, gender, contact information, occupation etc as attached in Appendix-II.

4.4.1 Anthropometry

Anthropometry is a way to obtain measurements of the human body. It is a widely used technique used to get a quick overview of the human health. It is non -invasive, inexpensive, feasible and fast with very little instruments required. This essentially includes height, weight, BMI, waist and hip circumference etc.

4.4.1.1 Weight: it is the measure of body's relative body mass. A bathroom scale is usually used to measure weight of adults. The scale should be calibrated and standardised before use. The zero of the scale should be checked to avoid errors in weight measurements.

4.4.1.2 Height: It is a vertical measurement of the body taken using a flexible, non – stretchable fibre glass tape. Participants are required to stand against a wall bare- foot with the heels touching the wall and head kept straight. He/ she should remove any excess clothing and ornaments.

4.4.1.3 BMI (body mass index): is a simple index of weight -for- height that is commonly used to classify underweight, overweight, obesity in adults. It is defined as weight in kilograms divided by the square of height in meters (kg/m2).

4.4.2 PERSONAL HISTORY

4.4.2.1 History of lifestyle habits

This includes history taking of habits like alcohol intake, tobacco intake etc.

4.4.2.2 History of allergies and intolerances.

This section takes into account the presence of any history of allergies or food intolerances the subject has. The noted food intolerances may either be self – observed or clinically confirmed with lab tests.

4.4.2.3 History of GI disorders and NCD's in the family

This includes subject's family history of gastrointestinal diseases, GI cancers and other non – communicable diseases.

4.4.3 DIETARY HISTORY

4.4.3.1 Type of diet: Questions include the type of dietary regime followed by the subject (vegetarian, non- vegetarian, veganism, ovo- vegetarianism etc.

4.4.3.2 Meals consumed per day: Includes questions of number of meals consumed per day by the subject.

4.4.3.3 Breakfast pattern: whether or not the subject has breakfast every day, occasionally or never.

4.4.4 MEDICAL AND MEDICATION HISTORY

This includes questions pertaining to the medical and medication history of the subjects. It also includes the morbidity profile of the enrolled subjects. It also covers history of any illness or surgery in the recent past. This helps to decide whether or not the subject is eligible to be included in the study based on his/her health indicators.

4.4.5 History of gastrointestinal disorder(s)

Gastrointestinal disorders are very common in IBS; however, the frequency type and symptoms may vary. this allows a better understanding of the predominant GI disorder of a subject and subtyping of IBS. It also tracks down the symptoms and scores subjects on the number of symptoms they experience and the frequency of symptoms. IBS subjects also suffer from major food intolerances like lactose and gluten intolerance. This section asks if a subject has had lactose intolerance symptoms either self - observed or clinically confirmed. It also inquires about any triggering foods that have been identified by the subject and if he/she resorts to avoid them.

4.5 STRUCTURED QUESTIONNAIRES:

Some standardised, pre- formed questionnaires were used in the study. These questionnaires have been widely used and extensively tested over time and have been proven effective in determination of results. The explanation and use od each questionnaire has been discussed at length in the points that follow.

4.5.1 Beck's depression inventory

The Becks depression inventory is a structured questionnaire developed by Aron. T. Beck. It is a self – scoring depression scale that finds use in various settings. It is one of the most widely used tool in clinical settings for psychometric tests and measuring the scale of depression. This scale consists of 21 multiple choice questions on how a patient feels. Each question contains four options namely 0,1,2 and 3, representative of the individual scores each question gets (0,1,2,3). The subject is required to tick the option that best describes how he/she feels. The highest score for the scale sums up to 63 if one has chosen option 3 for all the questions. At the end of the questionnaire, the total score is calculated and compared with a standard pre-determined scale which is as follows (The Becks depression inventory is attached in

Appendix- III)

SCORE	**INTERPREATION**
1-10	These ups and downs are normal
11-16	Mild mood disturbance
17-20	Borderline clinical depression
21-30	Moderate depression
31-40	Severe depression
Over 40	Extreme depression

(Table -4.1: interpretation of Becks depression scale values).

4.5.2 IBS QoL domains:

Quality of life according to Britannica is the degree to which an individual is healthy, comfortable and able to participate in or enjoy life events. The Dormans quality of life index was used to assess QoL of the enrolled subjects. It includes six (6) domains of quality of life namely dysphoria, interference with activity, food avoidance, health worry, sexual issues and relationship issues. Subjects are asked to tick the QoL domains which are impaired. Each domain is given a score of one (1) and the total impaired domains are summed up to reach a QoL score. The greater the score, more impaired is the QoL. (The questionnaire for QoL is attached in Appendix- IV)

4.5.3 Food frequency questionnaire for high FODMAP foods.

FFQ CODE	FREQUENCY OF CONSUMPTION
0	Never
1	Seasonally
2	Occasionally
3	Monthly
4	Fortnightly
5	Weekly
6	2-3 times a week
7	Daily

Table 4.2 – interpretation of values of frequency for FFQ.

Food frequency questionnaire is an index for measuring the frequency of consumption of a food. A list of high FODMAP foods was procured from the FODMAP foods chart by Lauren Relund, adopted from Monash University. The list was placed against food frequencies namely daily, 2-3 times a week, weekly, fortnightly, monthly, occasionally, seasonally and never. These frequencies were scored from 0 (zero) for never and 7(seven) for daily. Each food was coded for individual participant and the final scores were summed up for individual subject and for individual food item.

4.6 Statistical analysis

Data from administered questionnaires was recorded and entered in excel spreadsheets in the form of coded data. The data was polished and revised before analysis. Analysis was done in excel spreadsheets which included functions like chi square tests, mean, mode, averages, paired t tests, ANNOVA, standard deviation etc. where ever applicable. These functions were performed using Microsoft Excel,2010 and Microsoft Word,2010.

4.7 Statutory clearances

The study design and protocol was approved by the Medical ethics committee of the Foods and Nutrition department of the Maharaja Sayajirao University of Baroda and the Institutional Ethics Committee for Human Research (IECHR). The study was allotted ethical approval number **IECHR/FCSC/2020/42** (Appendix-VI)**.** Informed consent was obtained from subjects prior to baseline data collection and enrolment for the intervention for a period of 4 weeks (Appendix-I)

4.8 Experimental group

Subjects from free living population who qualify the screening criteria for IBS were selected as the experimental group (n=47).

4.9 Inclusion and exclusion Criteria

The inclusion criteria involves selection of subjects aged 15-75 years, who are not on medications pertaining to GI disorders, laxatives, pain killers or medications like non-steroidal anti- inflammatory drugs (NSAID's), proton pump inhibitors etc. the enrolled subjects should not be taking any alternative treatments for GI disordes. People suffering from any major illnesses like cancer, HIV/AIDS, hepatitis etc or who have undergone any major surgeries in the past 3 months were excluded.

4.10 Intervention trail for FODMAP restriction

The subjects from phase-2 who gave their consent to undergo the intervention were enrolled for the study. The subjects were asked to avoid their 5 most frequently consumed high FODMAP foods (frequency includes daily, 2-3 times a week, weekly, and fortnightly) from the high FODMAP food list for a period of 4 weeks. The choices of these 5 foods was left to the subjects according to their feasibility to eliminate foods from their diets.

4.11 Supervision and compliance

A compliance sheet was circulated among all the subjects to check their adherence to the intervention**,** as attached in Appendix-V.

4.12 Collection of post data

Post data collection for all the 37 subjects was done on completion of the intervention phase. Data was collected on three (3) parameters, namely depression score, QoL parameters and symptom score.

4.13 Statistical analysis

Data from post intervention questionnaires was recorded and entered in excel spreadsheets in the form of coded data. The data was polished and revised before analysis. Analysis was done in excel spreadsheets which included functions like chi square tests, mean, mode, averages, paired t tests, ANNOVA, standard deviation etc. wherever applicable correlation tables were made and pre and post data analysis was done with functions like percentages, paired t tests, chi square tests to check the significance of differences between pre and post data on parameters like depression scores, symptom scores and QoL parameters. These functions were performed using Microsoft Excel,2010 and Microsoft Word,2010 and SPSS software.

STUDY PROTOCOL:

A total of forty - seven (47) subjects from phase-1 were selected for phase-2. They were then administered with questionnaires and after consent, data parameters including demographic details, occupation, dietary history, medication and medical history, symptom profile, depression scores, quality of life index and food frequency questionnaires were studied.

An informed consent was given to the subjects for enrolling in the third phase of the study i.e. the intervention phase. Those subjects who enrol for intervention were

instructed to restrict 5 foods most frequently consumed from the food frequency questionnaire. The choice of 5 foods was left to the subjects and were avoided for 4 weeks. After 4 weeks, subjects were asked to re- fill data for parameters like depression, quality of life and symptom scores. Data was recorded and difference between pre and post data was recorded and analysed for statistical significance in the same.

CHAPTER-5

RESULTS AND DISCUSSION

FODMAP (fermentable oligosaccharides, disaccharides, monosaccharides and polyols) foods have come into recognition in the recent years as a first line therapy for the treatment of IBS patients. There is a significant amount of evidence which supports the fact that a diet low in FODMAP helps to improve the symptoms of IBS. According to the Monash university, 3 out of 4 people are known to benefit from consumption of a low FODMAP diet. Hence, this study was undertaken to assess the effects of a low FODMAP diet in subjects with IBS in terms of improvement in quality of life and relief from symptoms.

The results of the present study, entitled **"impact evaluation of FODMAP food education to IBS patients selected from urban Vadodara on relief from symptoms and improvement in IBS quality of life"** are presented, discussed, and analysed in the following section. The results are presented under the following sections:

5.1: PHASE-1: Screening of subjects using Rome-IV criteria.

5.1.1 Presence of abdominal pain

5.1.2 Association of abdominal pain with defecation profile.

5.2: PHASE-2: Collection of baseline information

5.2.1 General information

Gender distribution

Employment status

Age distribution

BMI distribution**.**

5.2.2 Medical History

Co-morbidity profile

Family history of GID

5.2.3 Dietary and Gastrointestinal profile

Type of diet

Meals consumed per day.

Breakfast pattern

IBS subtype

Symptom score

Lactose intolerance among subjects

Depression scores

QoL scores.

Scores for frequency of consumption of high FODMAP foods.

5.3: PHASE-3: Intervention phase

Impact of nutrition intervention and FODMAP education on IBS subjects

Number of people avoiding high FODMAP foods.

Differences in mean scores of QoL, depression and symptoms pre and post intervention

Changes in scores of QoL, depression status and symptom before and after FODMAP avoidance.

5.1: PHASE-1: Screening of subjects using Rome-IV criteria:

Of the total 200 subjects screened from urban Vadodara, presence of abdominal pain once a week for the past 3 months was reported by 22% of the subjects (figure-5.1)

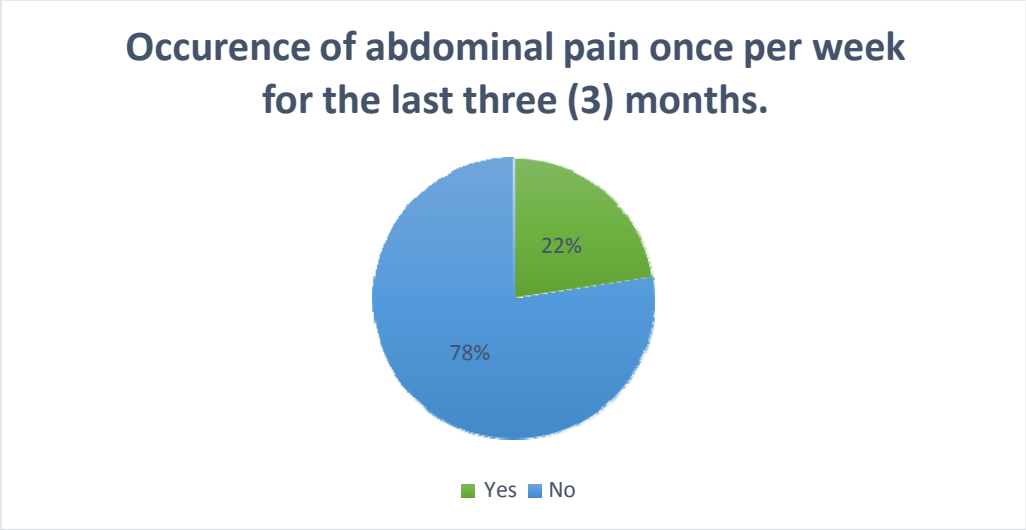


Figure- 5.1- occurrence of abdominal pain once a week for the past three months.

Of the total screened subjects, majority of them (49%) associated recurrent abdominal pain with change in stool frequency, followed by 33% and 18% association with stool appearance and defecation respectively.

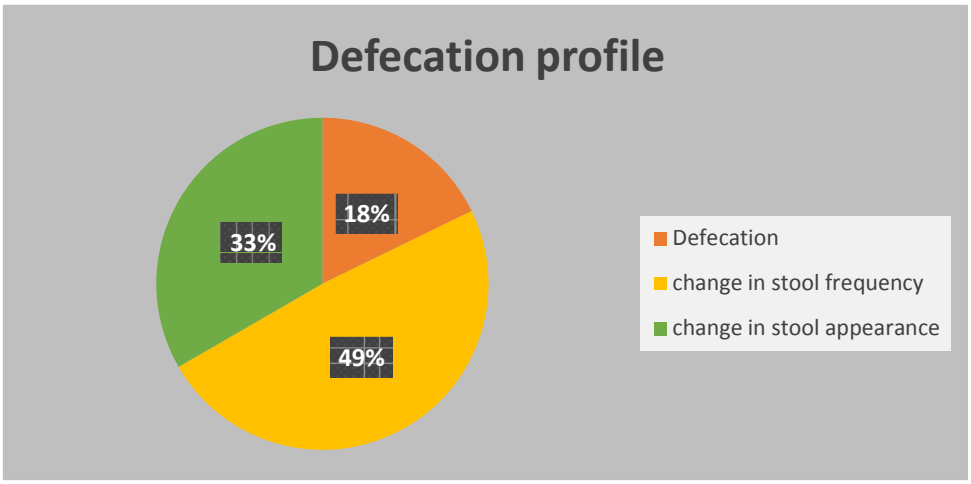


Figure-5.2: Association of abdominal pain with defecation profile.

5.2: PHASE-2: Collection of baseline data from enrolled subjects:

5.2.1 GENERAL INFORMATION:

As depicted in table- 5.1 and graphically presented in figure 5.3, majority of the enrolled IBS subjects were females (56.76%) followed by males (43.24%).

TABLE 5.1- Gender of IBS SUBJECTS-

GENDER	N	%
Male	16	43.24
Female	21	56.76
Other	0	0
TOTAL	37	100

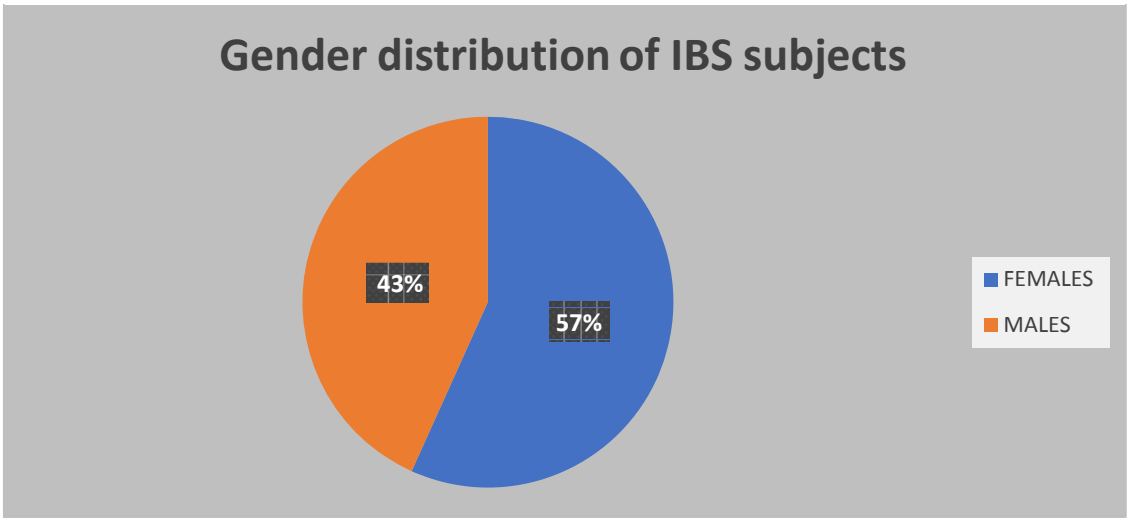


Figure- 5.3- Gender distribution of IBS subjects.

Among all the screened subjects, majority were students (43.243%), followed by service sector (18.918%), business & housewives accounted for 10.81% and self-employed and retired accounted for 8.108 % as presented in Table 5.3.

Table- 5.3: Employment status of IBS subjects:

OCCUPATION	N	%
Business	4	10.81
Self employed	3	8.108
Service	7	18.918
Unemployed	3	8.108
Housewife	4	10.81
Student	16	43.243
TOTAL	37	100

As presented in table 5.4 and graphically presented in figure- 5.4, amongst all the selected IBS subjects, 45.95% were between the age of 15-25 years, followed by 26-50 years (32.432%) and 51-70 years (21.621%).

TABLE 5.4 - Group wise age distribution of IBS subjects.

AGE (years)	N	%
15-25	17	45.945
26-50	12	32.432
51-70	8	21.621
TOTAL	37	100

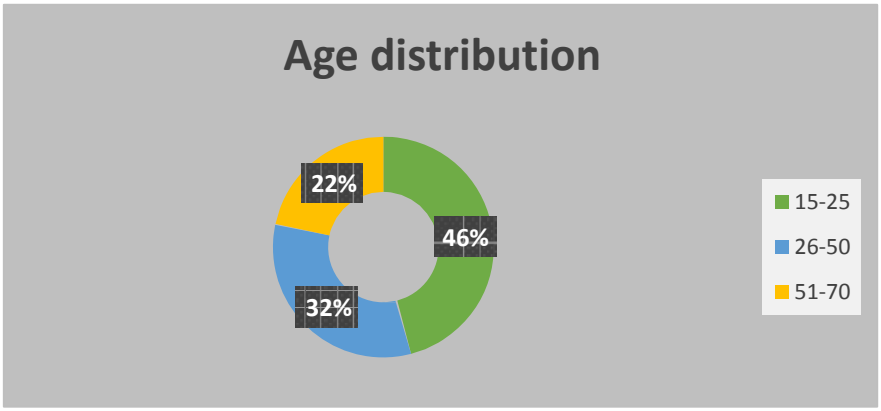


Figure- 5.4- Age distribution of IBS subjects.

Out of all the 37 subjects, most of the subjects (40.540%) were obese, followed by Normal (37.837%) and overweight (18.918%). Out of this, only 2.7% of the subjects were underweight as presented in Table 5.5 and graphically presented in Figure 5.5.

TABLE 5.5 – Body mass Index distribution of selected IBS subjects:

BMI (Kg/m2) *	N	%
<18.5 (underweight)	1	2.7
18.5-22.9 (normal)	14	37.837
23-26.9 (overweight)	7	18.918
>27 (obese)	15	40.540
TOTAL	37	100

*BMI distribution calculated based on Asia-Pacific classification

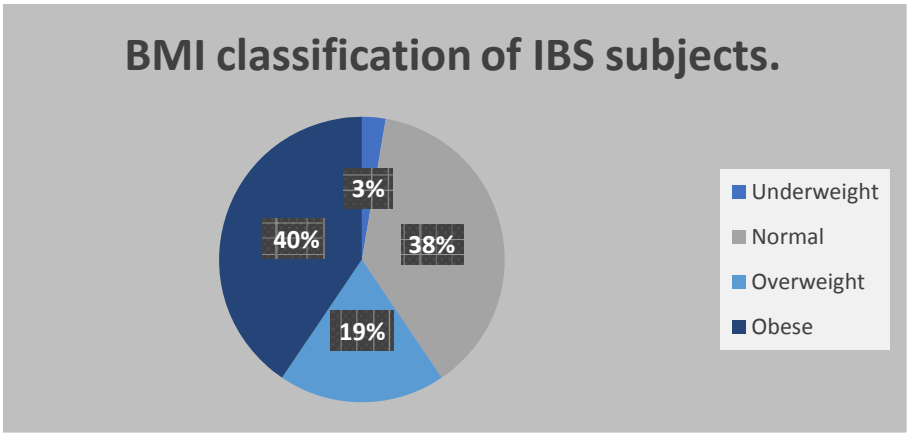


Figure- 5.5: BMI distribution of IBS subjects.

5.2.2 MEDICAL HISTORY

As shown in Table- 5.6, out of 37 subjects, 18 subjects had co-morbidity(s). Majority of the subjects had hypertension (38.89%), followed by diabetes (22.23%). Subjects with hypertension and diabetes were about 11.12% and those with different combinations of co-morbidities were 1% each**.**

TABLE 5.6 – Co-morbidity profile of selected IBS subjects.

Co-morbidity	**N**	**%**
DM	4	22.23
HTN	7	38.89
HTN+ EPI	1	5.5
THYROID	1	5.5
DM+ HTN+CVD	1	5.5
THYROID +HTN+CVD	1	5.5
DM+CVD	1	5.5
DM+HTN	2	11.12
TOTAL	18	100

(DM-diabetes mellitus, HTN- hypertension, EPI- epilepsy, CVD- cardiovascular disease)

Out of all the screened subjects, 43.243% subjects had family history of GI disorders, while 56.756% did not have any family history of irritable bowel syndrome, as presented in Table-5.7.

TABLE 5.7- Presence of family history of GI disorders in IBS subjects:

FAMILY HISTORY OF GI DISORDERS	N	%
PRESENT	16	43.243
ABSENT	21	56.756
TOTAL	37	100

***-GI disorders include irritable bowel syndrome, inflammatory bowel disease, GI cancer etc**.

5.2.3 DIETARY AND GASTROINTESTINAL HISTORY

Out of all the IBS subjects, majority of the subjects (56.756%) were vegetarians, followed by non-vegetarians and ovo-vegetarians 21.63% as presented in Table 5.8 and graphically represented in Figure- 5.6.

TABLE 5.8- Type of diet consumed by selected IBS subjects:

TYPE OF DIET CONSUMED	N	%
Vegetarian	21	56.756
Non-vegetarian	8	21.621
Ovo-vegetarian	8	21.621
TOTAL	37	100

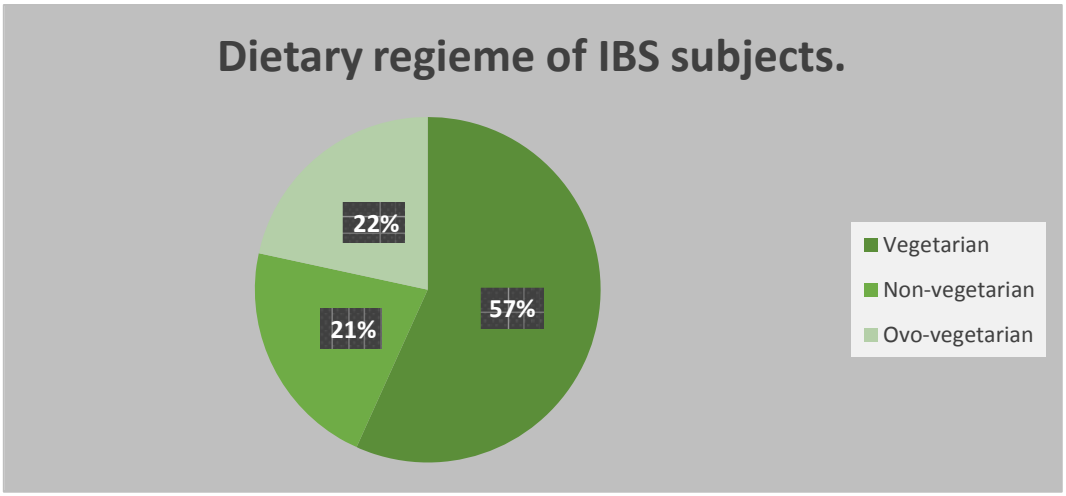


Figure- 5.6: Dietary regime of IBS subjects.

Out of the total screened IBS subjects, majority of the subjects (59.5%) consumed more than 4 meals per day, essentially including 2 major meals and 3 snacks. About 41% of the subjects consumed 3-4 meals as represented in Table 5.9 and graphically presented in Figure 5.7.

TABLE 5.9 – Number of meals consumed per day by IBS subjects.

NUMBER OF MEALS PER DAY	N	%
3-4	22	40.540
>4	15	59.46
TOTAL	37	100

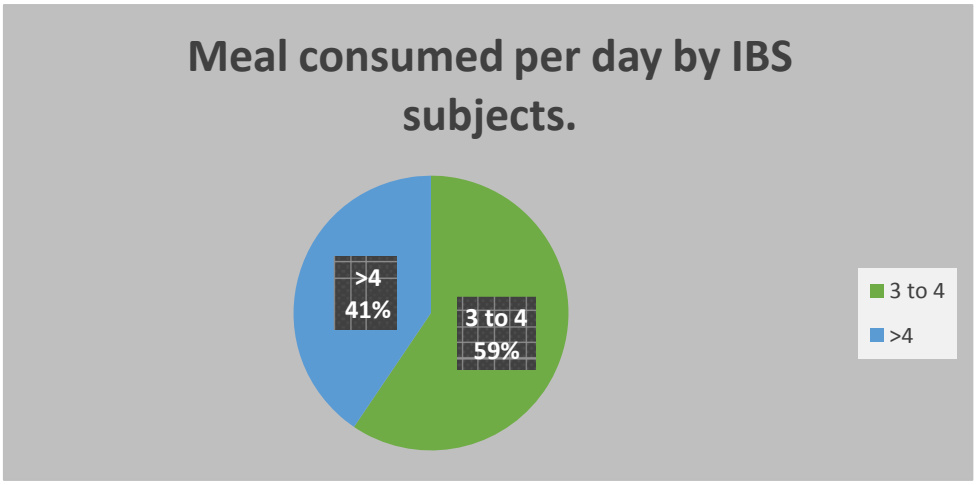


Figure- 5.7- Number of meals consumed per day.

Out of all the screened subjects, majority of them (78.4%) had breakfast every day, followed by 18.9% of the subjects who had breakfast sometimes. However, only about 2.7% subjects did not have a habit of having breakfast every day as represented in Table -5.10

TABLE 5.10- Breakfast pattern (regularity of having breakfast) in screened IBS subjects.

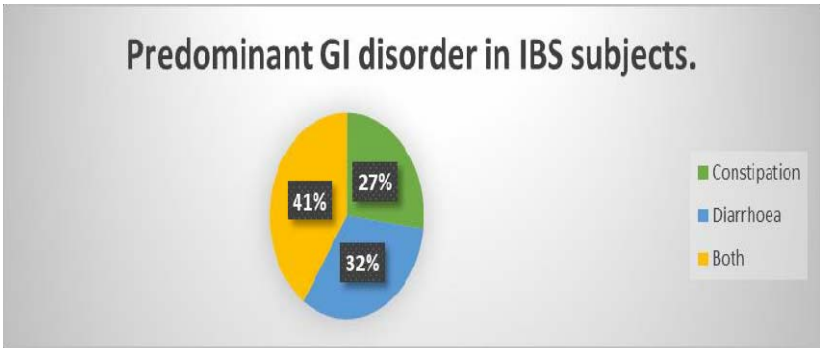
Number of IBS subjects consuming breakfast	N	%
Everyday	29	78.382
Never	1	2.7
Sometimes	7	18.918
TOTAL	37	100

Out of all the screened subjects, majority of them (40.54%) suffered from both (diarrhoea and/or constipation), followed by diarrhoea predominant subtype and constipation predominant subtype, 32.432% and 27.02% respectively as shown in Table 5.11 and graphically represented in Figure 5.8.

TABLE 5.11- Predominant subtype of gastrointestinal disorder (defecation profile) in IBS subjects.

Predominant GI problem	N	%TOTAL
Constipation	10	27.028
Diarrhoea	12	32.432
Both	15	40.540
TOTAL	37	100

Figure- 5.8 Predominant subtype of IBS.



As presented graphically in Figure 5.9 and Table- 5.12, 51.351% subjects experienced 2 symptoms followed by 29.728% who experienced 3 symptoms followed by 10.8% and 8.10% who have had a symptom score of 4 and 1 respectively.

Table- 5.12: Symptom score distribution of IBS subjects

NUMBER OF SYMPTOMS EXPERIENCED	N	%TOTAL
0	0	0
1	3	8.108
2	19	51.351
3	11	29.729
4	4	10.812
5	0	0
TOTAL	37	100

Note: Symptom score- each symptom (abdominal pain, abdominal cramps, bloating, gas, irregular bowel movements, discomfort) was scored All the symptoms were summed up and the total score was ranged from 0 (no symptoms) to 5 (all symptoms).

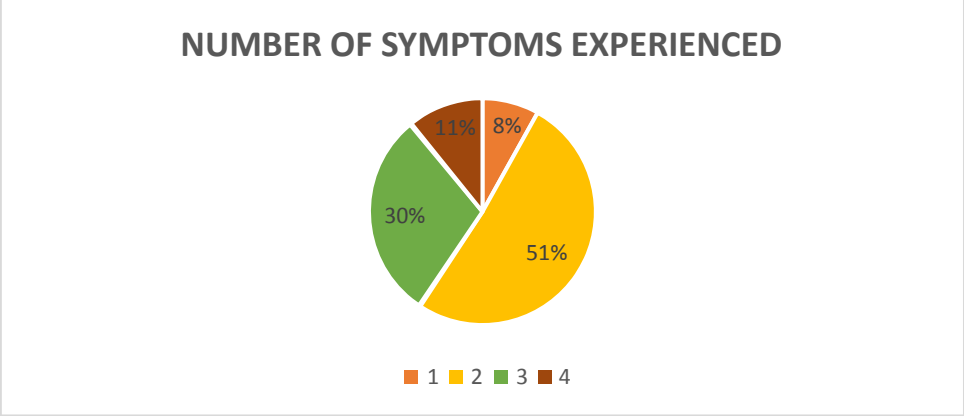


Figure- 5.9: Number of Symptoms experienced by IBS subjects.

As shown in Table 5.13, out of the selected subjects, 54% did not have any symptoms on consumption of milk and milk products while 32% had symptoms of lactose intolerance.

TABLE 5.13: Prevalence of GI symptoms upon consumption of milk and milk products in IBS subjects based on self-observation.

Occurrence of symptoms	N	%
Yes	12	32.432
No	20	54.05
Not sure	5	13.5
TOTAL	37	100

As presented in Table-5.14 and Figure 5.10, 54% had moderate depression, 32% were normal followed by severe depression (8.108%) and mild mood disturbance (5.405%).

TABLE 5.14- Depression scores of IBS subjects-

Depression Score	N	%
Normal	12	32.432
Mild mood disturbance	2	5.405
Moderate depression	20	54.05
Severe depression	3	8.108
TOTAL	37	100

Note: Depression score was calculated using the Beck's depression inventory. It includes a set of 21 questions. Scores are interpreted as follows1-10 (normal), 11-16 (mild mood disturbance), 17-20 (borderline clinical depression), 21-30 (moderate depression), 31-40 (severe depression), >40 (extreme depression)

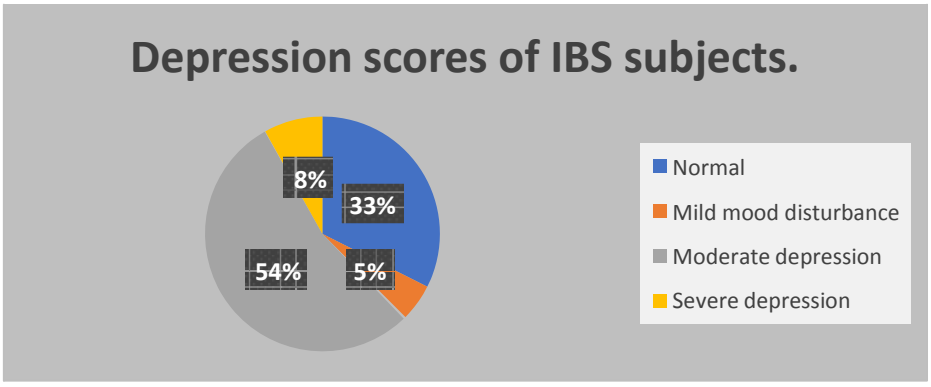


Figure- 5.10: Depression scores of IBS subjects.

Of the total screened IBS subjects, 48.64% reported a QOL score between 1-2 followed by 35.12% with a QOL score between 3-4 and 16.215% reported a score between 5-6, as depicted in Table 5.15 and Figure 5.11.

TABLE 5.15- Quality of life scores* of IBS patients-

QOL Scores	N	%
1-2	18	48.64
3-4	13	35.12
5-6	6	16.215
TOTAL	37	100

Note: Quality of life is calculated based on 6 domains of QoL Each parameter is scored 1 point. A total of QOL score is done and grouped as 1-2: Slight impairment in QoL,

3-4: Mild impairment and 5-6 : severe impairment in QoL.

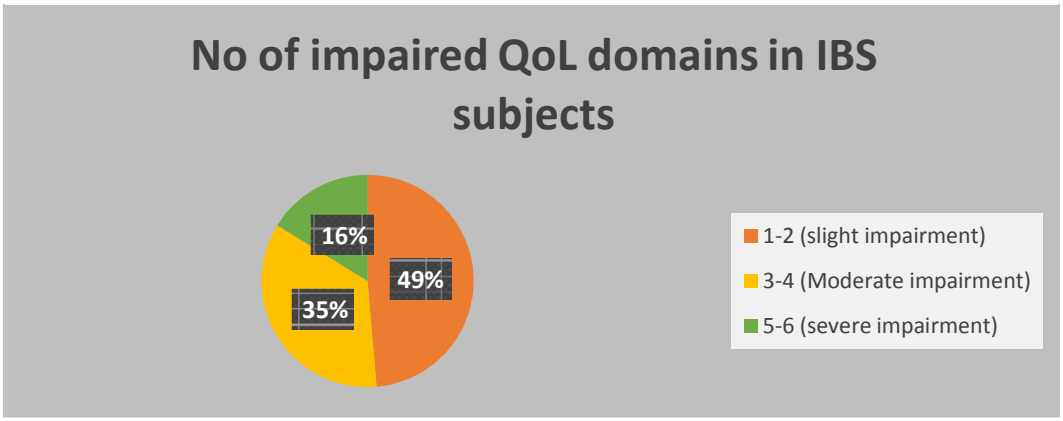


Figure 5.11- QoL scores of IBS subjects

Frequency of consumption of high FODMAP foods at baseline:

The following tables depict the food groupwise FODMAP scores of high FODMAP foods. The scores have been calculated using coded scores for frequencies which are as follows (Daily-7, 2-3 times a week -6, weekly-5, fortnightly-4, Monthly-3, occasionally- 2, seasonally-1, Never-0). The tables in the coming section show the scores of frequencies calculated cumulatively for all the 37 subjects, based on individual frequencies of consumption of a food item.

Table- 5.16 shows the frequency of consumption of grains, white roots and tubers and plantains. The most frequently consumed grain products were wheat based products, followed by whole wheat bread.

Table- 5.16: Scores for frequency of consumption of grains, white roots and tubers and plantains.

Grains, white roots and tubers and plantains (n=5)	**Score**
Barley based product	47
oat bread	65
spelt kernels/flakes	144
whole wheat bread	162
wheat based products(bran, cereal, couscous, germ)	241

Table 5.17 shows the frequency of consumption of pulses. The highest score was for beans followed by split peas(boiled).

Table- 5.17: Scores for frequency of consumption of pulses.

Pulses (n=5)	**Scores**
Beans (baked, black, broad, fava,kidney,soya)	193
Tofu/silken	13
Textured soy protein	56
Falafel	44
Split peas, boiled	135

Table 5.18 shows the frequency of consumption for nuts and oilseeds. It shows that there was a greater frequency of consumption of pistachios than cashews.

Table- 5.18 : Scores for frequency of consumption of for nut and oilseeds.

Nuts and oilseeds (n=2)	Scores
Pistachios	159
Cashews	140

Table 5.19 shows the frequency of consumption for dairy and alternatives. The most consumed food from this group was buttermilk.

Table- 5.19: Scores for frequency of consumption of dairy and alternatives.

DAIRY AND ALTERNATIVES (n=7)	Scores
Buttermilk	212
Cream cheese	38
Cream, regular	76
Cow & goat milk	103
Ice cream	129
Soy milk	08
Yogurt	54

Table 5.20, the shows the frequency of consumption of vegetables. This food group was the most frequently consumed food group among all other food groups**.** The most frequently consumed vegetable was peas followed by onions and garlic.

Table- 5.20: Scores for frequency of consumption of vegetables

VEGETABLES (n=10)	Scores
Bitter melon /karela	97
Cauliflower	193
Corn kernels, canned	112
Garlic	202
Green onion, white part	164
Mushroom	78
Onions	206
Onions, small pickled	55
Peas, green, thawed	207
Tomato sauce with added garlic	175

Table 5.21 shows the frequency of consumption of fruits. The most frequently consumed fruits were apples, followed by figs and apricots.

Table- 5.21: Scores for frequency of consumption of fruits

FRUITS (n=13)	Scores
Apples	196
Apricots	177
Blackberries	34
Cherries	57
other dried fruits	-
Figs	186
Guava, unripe	37
Lychee	23
Mango	31
Peaches	19
Pears	15
Plums	09
Watermelon	30

Table 5.22 shows the frequency of consumption of sweeteners. The most frequently consumed sweetener was Honey.

Table- 5.22: Scores for frequency of consumption of sweeteners

SWEETNERS (n=2)	**Scores**
Fruit juice concentrates	101
Honey	179

Table 5.23 shows the frequency of consumption of beverages. The most frequently consumed beverage was tea (chai), followed by malted drinks.

Table- 5.23: Scores for frequency of consumption of beverages

BEVERAGES (n=4)	**Scores**
Cordial (apple, orange, raspberry)	16
Malted drinks	151
Certain teas (oolong, fennel, chamomile)	144
strongly infused teas (chai, dandelion, herbal)	244

Association between various study parameters:

The table below shows correlations between various variables of the study. Correlation is a statistic measure which shows the degree of association between two variables. Correlation constant "r" shows the value for correlation. The value lies between -1 to 1. Negative value is indicative of negative and inverse correlation, positive value indicates positive correlation between two variables. The above table has been tested at CI of 95% (*) and 99% (**).

- There is a positive correlation between IBS subtype and family history of GI disorders (r =0.326*). Majority of the IBS subjects had IBS-M and had an absence of family history related to GI disorders. Thus, absence of family history and incidence of IBS-M are significantly associated.
- Occupation and BMI are negatively associated with each other (r= -0.421**). Most of the study population fell under the category of students and most of the students were obese according to the Asia- Pacific classification for BMI.
- Diet type and depression score were negatively correlated (r= -0.433**). Majority of the subjects suffered from moderate depression and majority of the subjects were vegetarian. This means that, subjects consuming a vegetarian diet had lesser depression scores (better mental health).
- There was a positive correlation between QoL scores and Depression scores (r= 0.420**). This means that impairment of quality of life affects depression scores. There is a proportional increase of depression scores along with impairment od QoL. Thus, with improvement in quality of life, there is improvement in depression status.
- Depression scores and occupation are positively correlated (r= 0.464**). Majority of the study population were students and majority of the subjects were moderately depressed. Thus, there is a greater incidence of depression among students.

Correlations

		Gender	Age (yrs)	fly.history	BMI	diettype	meals/day	breaKfast	QOL SCORE	Depression score	frequency	whiCh?	symptoms	miiK and miiK products	Occupation
Gender	Pearson Correlation		.146	-.009	-.007	-.139	.054	-.105	-.099	.000	.077	.213	.063	-.086	.114
	Sig. (2-tailed)		.387	958	.965	.413	.751	.537	.562	1.000	.649	.206	.709	.612	.502
	N	37	37	37	37	37	37	37	37	37	37	37	37	37	37
Age (yrs)	Pearson Correlation	.146	1	201	.157	.096	.116	-.234	-176	-.231	.155	.137	.213	-037	-.523**
	Sig. (2-tailed)	.387		233	354	.571	496	163	.297	169	.359	420	.205	.827	<.001
	N	37	37	37	37	37	37	37	37	37	37	37	37	37	37
ny.history	Pearson Correlation	-.009	.201	1	.063	.211	.279	.105	.099	-.147	.209	326'	.075	-.165	-.205
	Sig. (2-tailed)	.958	.233		.712	.210	094	.537	.562	.387	.215	.049	.660	.328	.224
	N	37	37	37	37	37	37	37	37	37	37	37	37	37	37
BMI	Pearson Correlation	-.007	.157	063	1	.322	.234	-.237	-.266	-.203	.127	.160	-.239	-.068	-.421**
	Sig. (2-tailed)	.965	.354	712		.052	.163	.157	.112	.229	.454	.344	.155	.688	.009
	N	37	37	37	37	37	37	37	37	37	37	37	37	37	37
diettype	Pearson correlation	-.139	.096	211	322	1	327"	068	-.020	-.433**	.176	095	042	-.001	• 542. .
	Sig. (2-tailed)	.413	.571	210	.052		.048	.691	.907	.007	.298	.574	.807	.993	<.001
	N	37	37	37	37	37	37	37	37	37	37	37	37	37	37
meals/day	**Pearson Correlation**	.054	.116	.279	.234	.327"	1	-.285	-.081	-.444**	.131	.338*	.105	-.267	-.320
	Sig. (2-tailed)	.751	.496	094	.163	.048		087	.634	006	.438	.041	.534	.110	.053
	N	37	37	37	37	37	37	37	37	37	37	37	37	37	37
breakfast	**Pearson Correlation**	-.105	-.234	105	-.237	068	-.285	1	314	185	-.218	084	022	150	029
	Sig. (2-tailed)	.537	.163	537	.157	.691	.087		.058	.274	.194	.623	.896	.376	.863
	N	37	37	37	37	37	37	37	37	37	37	37	37	37	37
QOL SCORE	Pearson Correlation	-.099	-.176	099	-.266	-.020	-.081	314	1	.420**	-.012	.005	-.045	-.018	.128
	Sig. (2-tailed)	.562	.297	562	.112	.907	634	058		010	.942	.979	.791	.915	449
	N	37	37	37	37	37	37	37	37	37	37	37	37	37	37
Depression score	**Pearson Correlation**	.000	-.231	-.147	-.203	-.433**	-.444**	185	.420	1	-.159	-.202	-.207	.167	
	N	37	37	37	37	37	37	37	37	37	37	37	37	37	37
frequency	**Pearson Correlation**	.077	.155	209	.127	.176	.131	-.218	-.012	-.159	1	.007	-.019	.089	-.090
	Sig. (2-tailed)	.649	.359	215	.454	.298	.438	.194	.942	.348		.967	.913	.599	.596
	N	37	37	37	37	37	37	37	37	37	37	37	37	37	37
whiCh?	Pearson Correlation	.213	.137	.326.	.160	.095	.338.	.084	.005	-.202	.007	1	.078	-.105	-.120
	Sig. (2-tailed)	.206	.420	049	344	.574	041	623	.979	232	.967		.648	.536	.479
	N	37	37	37	37	37	37	37	37	37	37	37	37	37	37
symptoms	Pearson correlation	.063	.213	075	-.239	.042	105	022	-.045	-.207	-.019	.078	1	-.051	.081
	Sig. (2-tailed)	.709	.205	.660	.155	.807	.534	.896	.791	.219	.913	.648		.764	.635
	N	37	37	37	37	37	37	37	37	37	37	37	37	37	37
miiK and miiK products	Pearson Correlation	-.086	-.037	-.165	-.068	-.001	-.267	150	-.018	167	.089	-.105	-.051	1	.071
	Sig. (2-tailed)	.612	.827	328	.688	.993	.110	.376	.915	.322	.599	.536	.764		.676
	N	37	37	37	37	37	37	37	37	37	37	37	37	37	37
Occupation	**Pearson Correlation**	.114	-.523 .	-.205	-.421	-.541 i	-.320	.029	.128	.464**	-.090	-.120	.081	.071	
	Sig. (2-tailed)	.502	<.001	224	.009	<.001	.053	.863	.449	.004	.596	.479	.635	.676	
	N	37	37	37	37	37	37	37	37	37	37	37	37	37	37

—. Correlation is significant at the 0.01 level (2-tailed)

•. Correlation is significant at the 0.051evel (2-tailed).

PHASE-III: Intervention phase

Impact of nutrition intervention and FODMAP education on IBS subjects:

Phase-3 of the study was the intervention phase wherein, the selected subjects were asked to avoid high FODMAP foods for a period of 4 weeks. However, the subjects were not ready to avoid all the high FODMAP foods because of various constraints. Thus, the participants were asked to choose any 5 most frequently consumed high FODMAP foods of their choice from the 48 high FODMAP foods from the list. This section shows the outcomes of the intervention phase.

Commonly avoided high FODMAP foods with number of subjects out of n= 37 avoiding the same.

As shown in figure 5.12, the most avoided FODMAP FOOD by majority of all subjects was honey, followed by tomato sauce, apples, cauliflower, beans and cashews.

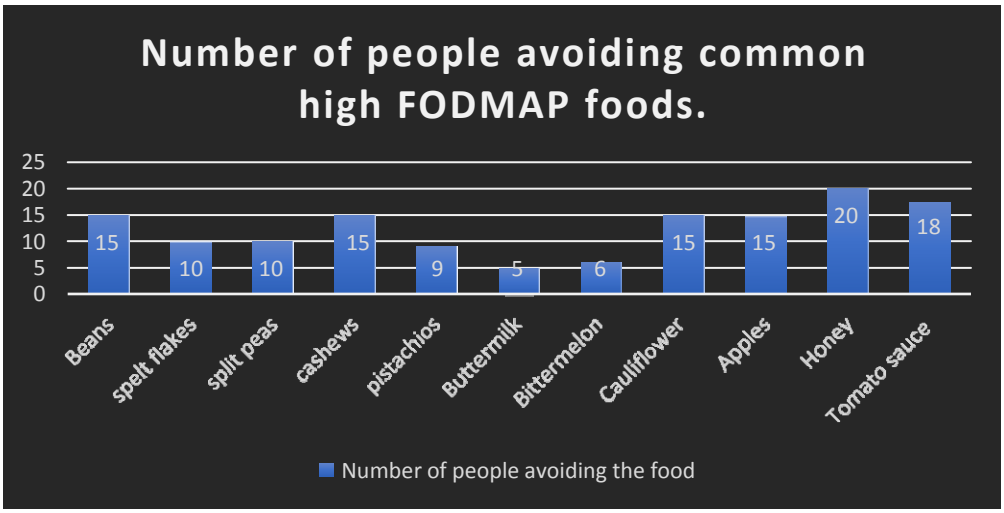


Figure- 5.12: Number of people avoiding the most frequently consumed high FODMAP foods.

The most avoided foods during the intervention (as chosen by the subjects were as follows:

- Beans
- Spelt kernels/flakes
- Split peas, boiled.
- Cashews
- Pistachios

- Buttermilk
- Bitter melon
- Cauliflower
- Tomato sauce with added garlic or onion
- Apples
- Cauliflower
- Honey.

❖ The most frequently consumed yet non avoidable FODMAP's were as follows
- Buttermilk
- Garlic
- Onion
- Tea
- Wheat based products.

❖ After 4 weeks avoidance of high FODMAP foods, the mean depression was reduced from 105 to 84.

❖ The mean score of QoL score of IBS subjects was reduced from 102 to 83.

❖ The mean symptom score of IBS subjects was reduced from 90 to 78.

Changes in scores of QoL, depression status and symptom before and after FODMAP avoidance

As presented in Table- 5.25, there was a significant improvement in the Quality of life and depression status of the IBS subjects post intervention. There was a statistically significant decrease in the symptoms (20.07%) and QoL scores (18.84%) after intervention. There was also a statistically significant improvement seen in the depression scores (20.07%) of subjects before and after intervention.

TABLE 5.25: Changes in mean values of symptoms, QoL score and Depression score before and after dietary intervention.

Parameters	Maximum value		values	(t critical value two tailed- 2.06). Paired-t test
Symptom score	5	Pre test	2.43	2.78*
		Post test	2.11	
		Difference	0.143↓	
		% Difference	20.07% ↓	
QoL score	6	Pre test	2.76	3.157*
		Post test	2.24	
		Difference	↓0.52	
		% Difference	↓18.84%	
Depression Score	5	Pre test	2.84	3.841*
		Post test	2.27	
		Difference	↓0.57	
		% Difference	↓20.07%	
*Significant at 0.05.				

DISCUSSION

IBS or irritable bowel syndrome is a functional gastrointestinal disorder which is characterised by irregular bowel movements consisting of symptoms typically affecting the bowel such as diarrhoea and/or constipation, wind, flatulence, abdominal pain and discomfort, urgency to defecate etc. IBS is known to affect more females than males and it is more commonly seen in smaller age groups as compared to younger age groups. The disease can progress from milder to more severe forms comprising of painful symptoms and worsening of the same. Currently, both pharmaceutical and non-pharmaceutical treatment options have been used by physicians and gastroenterologists to reduce the severity of IBS symptoms. This study comprises of a similar treatment which aims to assess the effect of a low FODMAP diet on the depression status, QoL score and symptom score of selected IBS subjects.

To evaluate the effect of this low FODMAP diet, the screened IBS subjects who consented to participate in the intervention phase of the study were asked to follow a low FODMAP diet which consisted of complete avoidance of top 5 most frequently consumed high FODMAP foods (daily, 2-3 times a week and weekly) for a period of 4 weeks.

According to research from Monash University, a low FODMAP diet is essentially prescribed to patients suffering from IBS. The low FODMAP diet consists of 4 phases. Avoidance is the first phase of the regime which includes complete exclusion of all high FODMAP foods. This phase helps in reliving symptoms of IBS. Studies have shown that a 4- week intervention on exclusion of FODMAP foods from the diet is effective in reliving symptoms of IBS. 3 out of 4 people benefit from exclusion of high FODMAP's from the diet. (https://www.monashfodmap.com/about-fodmap-and-ibs/).

There have been several studies which have evaluated the efficacy of the low FODMAP diet in patients suffering from IBS. A study was undertaken which evaluated the effect of low FODMAP diet in a long term. About 180 IBS patients were enrolled and followed up for a period of 16 months. Out of these, 86% subjects reported either partial or full efficacy of the low FODMAP diet in improvement from symptoms like bloating and abdominal pain. The study reported a statistically significant reduction in pain and discomfort associated with IBS in patients who followed a low FODMAP diet. Thus, it was conclusive that dietary therapy can be an effective therapy in the treatment of IBS. (Maagaard, L., Ankersen, D. V., Végh, Z., Burisch, J., Jensen, L., Pedersen, N., & Munkholm, P. (2016).

There are several studies that have examined the effect and relationship between IBS and obesity. Trends and results from studies suggest that rapidly changing lifestyle and eating habits such as increased consumption of fatty and processed foods, a low fibre diet and increasing sedentarism are all precursors to diseases such as IBS. It has also been found that obese and overweight subjects are more likely to experience worsening of symptoms related to IBS because of overeating and impaired satiety signalling. (Pickett-Blakely O. (2014). In the present study, majority of the enrolled subjects, about 40% were obese based on Asia Pacific classification of body mass index.

The present study had majority of the subjects who were students (43%), i.e., in the age group between 15-30 years. Majority of the screened subjects were females (56%) followed by males (44%). Out of this, majority of the subjects (56%) did not report any evidence of family history relating to any GI disorder such as cancer, IBS, IBD etc.

A review article by Fond et al included pooled data from several research papers relating to depress and IBS. This meta-analysis was conclusive that psychological illnesses such as

depression, anxiety and mood disorders were present in majority of IBS subjects. Case control studies studying the cause- effect relationship was studied A total of ten (10) studies were taken. These studies were basically case control studies which assessed psychological illnesses in cases and healthy controls. The outcome of the study was measured using standard mean difference (SMD). The prime finding oof the study was that there was a significant association of IBS and depression i.e., the mean anxiety and depression levels in IBS subjects were significantly higher than in healthy controls. (Fond, G., Loundou, A., Hamdani, N. *et al* ,2014).

In a study which aimed to determine the relationship between IBS and QoL, 87 IBS subjects and 56 healthy controls were enrolled to undertake a case control study on IBS and QoL. Following the enrolment, subjects were asked to fill questionnaires on IBS specific QoL and Depression inventory. The outcomes from the study revealed that the prevalence of depression was greater in IBS subjects. Also, the IBS-QoL scores revealed that, IBS-QoL scores in cases was significantly lower as compared to healthy subjects. This is predictive of the association of IBS and related symptoms with reduction in quality of life. There are 6(six) domains of QoL which are as follows dysphoria, interference with activity, health worry, food avoidance, sexual issues and relationship issues. The study also found that females had greater percentages of impairment of the domain of body image than males. (Kopczyńska, M., Mokros, Ł., Pietras, T., & Małecka-Panas, E, 2018).

CONCLUDING REMARKS:

It can hence be concluded, from the results of the study that, a 4 – week avoidance of the most frequently consumed FODMAP foods can cause a significant effect on depression status, quality of life and symptom severity and score. it is therefore evident from the study that, avoidance of high FODMAP foods can be used for IBS subjects to reduce symptom severity and improve depression and quality of life scores.

Correlation tables suggests that there is a greater incidence of depression among students. Moderate depression was seen in about 54 % of the study population, which was majoritily students (43%). A statistically significant correlation was seen between IBS subtype and family history of GI disorders (r =0.326*). Vegetarian diet reduces the chances of incidence of depression among subjects. There was a positive correlation between QoL scores and Depression scores (r= 0.420**). This means that impairment of quality of life affects depression scores. There is a proportional increase of depression scores along with impairment od QoL. Thus, with improvement in quality of life, there is improvement in depression status.

CHAPTER – 6

SUMMARY AND CONCLUSIONS

With advances in technology and adverse lifestyle practices, there has been a sharp rise in gastrointestinal disorders such as irritable bowel syndrome. It is a disease which has several implications on various dimensions of health. IBS does not affect one just physically, but also takes a toll on an individual's mental health. Thus, with increasing incidence of IBS round the globe, there is also a simultaneous increase in depressive disorders and other mental and psychological effects. Hence, there is a dire need to collect and put into practice scientifically sound evidences to help people with IBS live a better life with minimal side effects on health. Thus, the present study, "**impact evaluation of FODMAP education on IBS patients and its effectiveness in terms of relief from symptoms and improvement in IBS quality of life from selected samples of urban Vadodara."**

The study was carried out in three (3) phases, which included:

PHASE-I: This phase included screening of subjects aged between 15-75 years from free living population of urban Vadodara. Screening was done using the Rome-IV criteria. A total of 200 subjects were screened (n=200).

PHASE-II: subjects from phase-1 who qualified the Rome-IV criteria, were chosen for the second phase of the study. Phase-II essentially included collection of baseline information from the selected subjects after their consent. This information included dietary history, medical & medication history, personal and family history, anthropometry etc.

PHASE-III: this phase was the intervention phase wherein, subjects from phase-2 were asked to consent for their participation in phase-3. This phase included a 4-week complete avoidance

of most frequently consumed high FODMAP foods, derived from food frequency questionnaire.

SALIENT FINDINGS OF PHASE-I:

Outcomes derived from screening of subjects:

- Majority of the screened subjects were females, followed by males.
- From 200 screened subjects, 155 (77.5%) subjects did not have any symptoms related to IBS.
- 45 (22.5%) subjects had symptoms of IBS (abdominal pain once a week for 3 months) according to the Rome-IV criteria.
- Out of the 45 subjects, 18% subjects reported abdominal pain associated with defecation, 33% associated it with change in stool appearance and 49% associated it with change in stool frequency.

Results from phase-1 of the study show that, in the general population, there exist IBS like symptoms in about 22% of the subjects. These symptoms are more common in women than in men. However, the association of IBS symptoms, chiefly abdominal pain was made with three different parameters (defecation, changes in stool frequency and stool appearance). In this study, majority of the subjects associated their abdominal pain with a change in stool frequency. There is a decline of IBS incidence as the age increases, which means that IBS is commoner in the lower age groups.

SALIENT FINDINGS OF PHASE-II

- Majority of the enrolled and screened IBS subjects were females (56.76%) followed by males (43.24%).
- Among all the screened subjects, majority were students (43.243%), followed by service sector (18.918%), business & housewives accounted for 10.81% and self-employed and retired accounted for 8.108 %.
- Amongst all the selected IBS subjects, 45.95% were between the age of 15-25 years, followed by 26-50 years (32.432%) and 51-70 years (21.621%).
- Out of 37 subjects, 18 subjects had a co-morbidity history. Majority of the subjects had hypertension (38.89%), followed by diabetes (22.23%). Subjects with hypertension and diabetes were about 11.12% and those with different combinations of co-morbidities were 1% each.
- Out of all the screened subjects, 43.243% subjects had family history of GI disorders, while 56.756% did not have any family history of irritable bowel syndrome
- Out of all the 37 subjects, most of the subjects (40.540%) were obese, followed by Normal (37.837%) and overweight (18.918%). Out of this, only 2.7% of the subjects were underweight.
- Out of all the IBS subjects, majority of the subjects (56.756%) were vegetarians, followed by non-vegetarians and ovo-vegetarians 21.63%.
- Out of the total screened IBS subjects, majority of the subjects (59.5%) consumed more than 4 meals per day, essentially including 2 major meals and 3 snacks. About 41% of the subjects consumed 3-4 meals.
- Out of all the screened subjects, majority of them (78.4%) had breakfast every day, followed by 18.9% of the subjects who had breakfast sometimes. However, only about 2.7% subjects did not have a habit of having breakfast every day.

- Out of all the screened subjects, majority of them (40.54%) suffered from both (diarrhoea and/or constipation), followed by diarrhoea predominant subtype and constipation predominant subtype, 32.432% and 27.02% respectively.
- Of the total subjects, 51.351% subjects experienced 2 symptoms followed by 29.728% who experienced 3 symptoms followed by 10.8% and 8.10% who have had a symptom score of 4 and 1 respectively.
- From the above subjects, 54% had moderate depression, 32% were normal followed by severe depression (8.108%) and mild mood disturbance (5.405%).
- From the screened IBS subjects, 48% reported 1-2 impaired domains of QoL, 35.12% with 3-4 impaired domains and 16.215% reported 5-6 impaired domains of QoL.

The phase-2 of the study included collection of baseline information. Out of 45 subjects in the first phase, 37 subjects agreed to participate in phase 2. Results from this phase show that, majority of the subjects having IBS symptoms were females, out of which majority of the subjects were students aged between 15-30 years. Anthropometry revealed that, majority of the subjects were obese. Dietary information revealed that, majority of the subjects were vegetarians and had breakfast regularly with an average of more than 4 meals per day. Depression status showed that majority of the subjects were moderately depressed and 1-2 impaired QoL domains with a minimum of 2 symptoms related to IBS.

SALIENT FINDINGS OF PHASE-III

- The mean FODMAP score of the total enrolled subjects (n=37) was found to be139.37 with a maximum score of 160 and a minimum score of 120.
- The most frequently consumed high FODMAP foods were as follows:
    - Tea
    - Wheat based products.
    - Onions
    - Apples
    - Cauliflower.

. The most avoided foods during the intervention (as chosen by the subjects were as follows:

- Beans
- Spelt kernels/flakes
- Split peas, boiled.
- Cashews
- Pistachios
- Buttermilk
- Bitter melon
- Cauliflower
- Tomato sauce with added garlic or onion
- Apples
- Cauliflower
- Honey.

- The most frequently consumed yet non avoidable FODMAP's were as follows
    - Buttermilk

- Garlic
- Onion
- Tea
- Wheat based products.

- After 4 weeks avoidance of high FODMAP foods, the mean depression was reduced from 105 to 84.
- The mean score of QoL score of IBS subjects, was reduced from 102 to 83.
- The mean symptom score of IBS subjects, was reduced from 90 to 78.

CHAPTER-7

FUTURE SCOPE OF INVESTIGATION

- FODMAP foods are foods containing fermentable oligosaccharide, disaccharide, monosaccharides, and polyols. These are a class of sugars which escape digestion and as a result are acted upon by intestinal microbes. This produces gas and flatulence. The sugar fragments also attract water thus making stools bulkier and causing urgency to defecate, diarrhoea, cramping pain etc..
- It has been proven that avoidance of foods rich in FODMAP's is beneficial to control and improve IBS related symptoms.
- Clinical studies can be initiated to check the impact of FODMAP avoidance.
- Retrospective studies on clinically confirmed IBS subjects can be done to find the missing links and associations between the development of IBS.
- Ready reckoners like pamphlets, brochures, websites etc can be developed for helping IBS patients with their daily food choices and food alternatives.

CHAPTER-8

BIBLIOGRAPHY

1. Beyder A, Mazzone A, Strege PR, (2014). Loss-of-function of the voltage-gated sodium channel NaV1.5 (channelopathies) in patients with irritable bowel syndrome. Gastroenterology 146: 1659–68.)
2. Carroll IM, Ringel-Kulka T, Siddle JP, Ringel Y (2014) Alterations in composition and diversity of the intestinal microbiota in patients with diarrhoea-predominant irritable bowel syndrome. NeurogastroenterolMotil 24: 521–30.
3. Chitkara, D. K., van Tilburg, M. A., Blois-Martin, N. and Whitehead, W. E. (2008). Early life risk factors that contribute to irritable bowel syndrome in adults: a systematic review. The American journal of gastroenterology, *103*(3), 765–775. https://doi.org/10.1111/j.1572-0241.2007.01722.x)
4. MaxwellPR,,Mendall MA, Kumar D.(1997),Irritable bowel syndrome, The Lancet 350(9092),1691-1695, doi.org/10.1016/S0140/(6376(97) 05276-8
5. Canavan, C., West, J., and Card, T. (2014). The epidemiology of irritable bowel syndrome. *Clinical epidemiology*, *6*, 71–80. https://doi.org/10.2147/CLEP.S40245
6. Chey WD, Kurlander J, Eswaran S. (2015). Irritable bowel syndrome: a clinical review. JAMA.313(9):949-58.
7. Cristina Almansa&Lesley A Houghton, (2013), Irritable bowel syndrome: aetiology, pathogenesis andpathophysiologyFuturemedicine, https://doi.org/10.2217/ebo.13.545
8. De Oliveira EP, Burini RC. (2009). The impact of physical exercise on the gastrointestinal tract. CurrOpin Clin NutrMetab Care12(5):533-8.
9. Derbyshire SW. (2003). A systematic review of neuroimaging data during visceral stimulation. Am J Gastroenterol 98: 12-20 [PMID: 12526930 DOI: 10.1111/j.1572-0241.2003.07168.x
10. Endo, Y., Shoji, T., &Fukudo, S. (2015). Epidemiology of irritable bowel syndrome. *Annals of gastroenterology*, *28*(2), 158–159.
11. Fond, G., Loundou, A., Hamdani,N.(2014). Anxiety and depression comorbidities inirritable bowel syndrome (IBS): a systematic review and meta-analysis. *Eur ArchPsychiatry Clin Neuroscience* 264, 651–660. https://doi.org/10.1007/s00406-0140502-z
12. Ford AC, Quigley EM, Lacy BE, Lembo AJ, Saito YA, Schiller LR,(2014). Effect of antidepressants and psychological therapies, including hypnotherapy, in irritable bowel syndrome: systematic review and meta-analysis. Am J Gastroenterol. 109(9):1350-65.

13. Ghoshal UC, Abraham P, Bhatt C, Choudhuri G, Bhatia SJ, Shenoy KT, Banka NH, Bose K, Bohidar NP, ChakravarttyK.(2008). Epidemiological and clinical profile of irritable bowel syndrome in India: report of the Indian Society of Gastroenterology Task Force. Indian J.Gastroenterol., 27:22-28

14. Gerald J Holtmann, Alexander C Ford, Nicholas J Talley(2016), Pathophysiology of irritable bowel syndrome, Lancet gastroenterology and hepatology, volume-1, 133-146.

15. Johannesson E, Simren M, Strid H, Bajor A, SadikR. (2011). Physical activity improves symptoms in irritable bowel syndrome: a randomized controlled trial. *Am J Gastroenterol.*106(5):915-22.

16. Kopczyńska, M., Mokros, Ł., Pietras, T., and Małecka-Panas, E. (2018). Quality of life and depression in patients with irritable bowel syndrome.*Przeglad gastroenterologiczny*, *13*(2), 102–108. https://doi.org/10.5114/pg.2018.75819.

17. Kristen Ronn Weaver, Gail D'EramoMelkus, Rory Meyers, Wendy A Henderson, Am J Nurs, 117(6): 48–55. https://doi:10.1097/01.NAJ.0000520253.57459.01.

18. Lekhasaha, (2014), Irritable bowel syndrome, pathogenesis, diagnosis, treatment and evidence-based medicine, World journal of gastroenterology,20(22), 6759-6773.

19. Li J, Zhu W, Liu W, Wu Y, Wu B. (2016). Rifaximin for Irritable Bowel Syndrome: A Meta-Analysis of Randomized Placebo-Controlled Trials. Medicine. 95(4): e2534.

20. Lovell, R. M., & Ford, A. C. (2012). Global prevalence of and risk factors for irritable bowel syndrome: a meta-analysis. *Clinical gastroenterology and hepatology : the official clinical practice journal of the American Gastroenterological Association*, *10*(7), 712–721.e4. https://doi.org/10.1016/j.cgh.2012.02.029

21. Magge, S., &Lembo, A. (2012). Low-FODMAP Diet for Treatment of Irritable Bowel Syndrome. *Gastroenterology & hepatology*, *8*(11), 739–745.

22. Makharia et. Al, (2011),Prevalence of irritable bowel syndrome: a community based study from Northern India. Journal of neurogastroenterology& motility)

23. Mudyanadzo, Chandanbindya H, Oksana Y, Nalini Narayanan Architha , Hasan M. Ashqar(2018), Irritable bowel syndrome and depression: a shared pathogenesis, Cureus10(8), DOI/10.7759/Cureus 3178.

24. Nagaonkar, Vijaykumar S, Digambar Tulshiram Kangule,,Snehashree S (2018), A Study of Prevalence and Determinants of Irritable Bowel Syndrome in an Urban Slum Community in MumbaiJournal or Datta Meghe institute of medical sciences,13(2) .

25. Ng, Q. X., Soh, A., Loke, W., Lim, D. Y., & Yeo, W. S. (2018). The role of inflammation in irritable bowel syndrome (IBS). *Journal of inflammation research*, *11*, 345–349. https://doi.org/10.2147/JIR.S174982.

26. O'Sullivan , Clayton N, Breslin NP, (2000). Increased mast cells in the irritable bowel syndrome. Neurogastroenterology and Motility;12(5):449–457.

27. Oka. P, Parr H, Barberio B et. al (2020)Global prevalence of irritable bowel syndrome according to Rome-iii and Rome -Iv criteria- a systematic review and meta-analysis. The Lancet Gastroenterology and hepatology 2468- 1253.

28. Pickett-Blakely O. (2014). Obesity and irritable bowel syndrome: a comprehensive review. *Gastroenterology & hepatology*, *10*(7), 411–416.

29. Rahman M,Sanjiv M, Ghoshal C, (2017) ,Epidemiological and clinical perspectives on irritable bowel syndrome in India, Bangladesh and Malaysia: A review, World journal of gastroenterology, 23(37), 6788-6801.

30. Rahman MM, Mahadeva S, Ghoshal UC. Epidemiological and clinical perspectives on irritable bowel syndrome in India, Bangladesh and Malaysia: A review. *World J Gastroenterol* 2017; 23(37): 6788-6801 [DOI: 10.3748/wjg. v23.i37.6788]

31. Riddle MS, Welsh M, Porter CK. (2016) The epidemiology of irritable bowel syndrome in the US military: findings from the millennium cohort study. Am J Gastroenterol 2016; 111: 93–104.

32. Saito YA, Petersen GM, Larson JJ, (2010).Familial aggregation of irritable bowel syndrome: a family case-control study. Am J Gastroenterol; 105: 833–41.

33. Sasaki A, Sato N, Suzuki N. (2016) Associations between single-nucleotide polymorphisms in corticotropin-releasing hormone-related genes and irritable bowel syndrome. PLoS One 11: e0149322.

34. Schumann D, Langhorst J, Dobos G, Cramer H (2018). Randomised clinical trial: yoga vs a low-FODMAP diet in patients with irritable bowel syndrome. Aliment Pharmacol Therapy.;47(2):203-11.

35. Swan C, Duroudier NP, Campbell E,(2013). Identifying and testing candidate genetic polymorphisms in the irritable bowel syndrome (IBS): association with TNFSF15 and TNFα. Gut 2013; 62: 985–94.

36. Vahedi H, R Ansari, MM Mir-Nasseri and E Jafari. (2010). Irritable Bowel Syndrome- a review articles, Middle East journal of digestive disorders, 2(2), 66-77.

37. Vanuytsel, T., Tack, J.F. and Boeckxstaens G.E. (2014) Treatment of abdominal pain inirritable bowel syndrome. *J Gastroenterol*49,1193–1205 https://doi.org/10.1007/s00535-014-0966-7

38. Werlang, M. E., Palmer, W. C., & Lacy, B. E. (2019). Irritable Bowel Syndrome and Dietary Interventions. *Gastroenterology & hepatology*, *15*(1), 16–26.

39. Wouters MM, Van Wanrooy S, Nguyen A,(2016). Psychological comorbidity increases the risk for postinfectious IBS partly by enhanced susceptibility to develop infectious gastroenteritis. Gut. 65: 1279–88.

40. Maagaard, L., Ankersen, D. V., Végh, Z., Burisch, J., Jensen, L., Pedersen, N., &Munkholm, P. (2016). Follow-up of patients with functional bowel symptoms treated with a low FODMAP diet. *World journal of gastroenterology*, *22*(15), 4009–4019. https://doi.org/10.3748/wjg.v22.i15.4009

WEBLIOGRAPHY.

41. https://www.monashfodmap.com/about-fodmap-and-ibs/

CHAPTER-9

APPENDICES

APPENDIX-1

List of FODMAP foods (low, moderate, and high).

Foods	Low in FODMAPs	Moderate in FODMAPs	High in FODMAPs
Vegetables (Note: you can eat multiple green servings of vegetables per/meal snack)	• Alfalfa • Arugula • Bamboo shoots • Bean sprouts • Bell peppers, red • Bok choy (1 Cup/85g) • Broccoli (1 C/90g) • Cabbage, Chinese/wombok • Cabbage, red or green (1 C/90g) • Callaloo, tinned • Canned baby corn • Carrot • Celeriac • Chicory leaves (1/2 C/72g) • Chili, red/green (11cm/28g) • Choy sum & gai lan • Chrysanthemum greens (3 C/225g) • Collard greens • Cucumber • Daikon, white (1 C/140g) • Eggplant/Aubergine (1.5 C/80g) • Endive, leaves • Fennel bulb (1/2 C/48g) • Fennel leaves (2 C/48g) • Gai lan (3 C/200g) • Galangal • Ginger root • Green beans (12 beans/86g) • Green onion/chives, green parts only • Jicama (1 C/140g) • Kabocha/Japanese pumpkin • Kale • Kohlrabi (1 C/135g) • Leeks, leaves (2/3 C/54g) • Lettuce • Mushrooms, oyster type only • Okra (6 pods/60g) • Olives, black and green • Parsnip • Potatoes • Radish • Seaweed/nori • Snakebean/yardlong (1 C/90g) • Spinach (3 C/110g) • Spaghetti squash (1 C/155g) • Swede (2 C/130g) • Swiss chard • Tomatoes, cherry (8/136g) • Tomatoes, common • Tomatoes, roma (4/180g) • Tomatoes, canned (1/2 cup/92g) • Turnip/Rutabega (1 C/65g) • Water chesnuts • Witlof • Yam (1 C/164g) • Zucchini (1/3 cup/65g)	• Artichoke hearts, canned (1/8 cup/28g) • Beetroot (2 slices/20 g) • Beetroot, canned or pickled (1/2 C/60g) • Bell pepper, green (1/2 C/52g) • Broccolini (1/2 C/45g) • Brussel sprouts (2 sprouts/38g) • Butternut squash (1/4 C/30g) • Cassava/Yucca root (1/2 C/69g) • Cabbage, red fermented (1/2 C/70g) • Cabbage, savoy (1/2 C/35g) • Celery (1/4 stalk/12g) • Chayote/Choko (1/2 C/84g) • Cho cho (1/2 C/84g) • Corn, sweet (1/2 cob/43g) • Dulse flakes (2 tsp/10g) • Mushrooms, champignons, canned (1/2 cup/110g) • Mushrooms, shiitake dried (7g) • Mushrooms, porcini dried (1 tbsp/10g) • Onions, large pickled only (2/45g) • Peas, canned (1/2 C/42g) • Peas, snow (5 pods/17g) • Pumpkin, canned (1/4 C/60g) • Sauerkraut, white cabbage (1 Tbsp/20g) • Sweet potato (1/2 C/70g) • Sun-dried tomatoes (2 pieces/8g) • Taro (1/2 C/82g) • Tomato paste (2 Tbsp) • Tomato sauce (1/2 cup) (no onion/garlic) • Wakame flakes (1 tsp/5g)	• Artichokes • Asparagus • Bittermelon/Karela • Cauliflower • Corn kernels, canned • **Garlic** • Green onion, white parts only • Leek bulbs • Lotus root • Mushrooms (except oyster, canned champignons, dried porcini, and dried shiitake) • **Onions** • Onions, small pickled • Peas, green, thawed • Peas, sugar snap • Shallots • Tomato sauce with added garlic or onion

Check the Monash University App for the most up to date information. Eat a variety of low FODMAP foods.
The moderate FODMAP foods are safe to eat but only at the maximum serving size listed.
The serving size is per meal/snack, not per day. Avoid high FODMAP foods during elimination.

Lauren Renlund MPH, RD
Registered Dietitian & Nutrition Coach

Foods	Low in FODMAPs		Moderate in FODMAPs	High in FODMAPs
Grains	Arrowroot (3/4 C/135g)	Popcorn	Amaranth, puffed (1/4 C/10g)	Sarnglut?n-free flours (amararrth, bean, coconut, einkorn, emmer,
Note: check all	Buckwheat grouts, cooked	Quinaa & quinaa flakes Pearl barley, sprouted	Almond meal (1/4 C/24g) Bulgar/Bourghal (1/4 C) Buckwheat kernels (1/8 C/27g)	non-seived spelt, soy) Barley-based products
	Corn tortill as (3/70g) Corn meal/Polenta	Rice, white/brown/		
ingredients lists		(1/2 C/100g) cracker'>/flake'>/noodles		garbanzo, kamut, lupin,
for high FODMAP ingredients,	Glut en-free bread s, cookies, (without add ed FODMAPs)	Rice bran (2 tbsp/16g)	Coconut flour (2 tbsp/12g) Cookie/ biscuit, wh eat (1small/12g)	Freekeh
inuli n/chicory particularly root extract in glut e n-free prod ucts	crackers, pasta, noodl es etc. Some gluten-free flours (buckwheat, cassa va, corn, green banana, millet, quinoa, rice, sieved spett,	Rice ca kes (2/28g) Rice, puffed (1/2 C/15g) Sam p, cook ed	Cornflakes, gluten-free (1C) Cornflakes (1/2 C/15g) Crackers, wheat (2 crackers/18g) Egg noodl es (1/2 C/40g) Oat bran (2 tbsp/22g) Pret zels (1/2 C)	Laska noodles Oat bread Rye-based products or kamut f lour Sourdough, ma de ....nth rye Whole wheat bfead
Note: same wh eat products (c racke rs, pasta, bread) have	sotg hum,teff, yam) Kelp noodles (1 C/113g) Konjac noodl es (150g)	(1C/148g) Sorghum Sourdough, t raditio nal	Pasta, wheat *or* spelt (1/2 C/74g) Rice cri sps (1/4 C/7g)	Spelt, kernels/flakes Wheat-based products "'Inulin/Chi cory root
small safe serving slzes, see mod erate column	Millet kemets, cooked (1C/125g) Millet bread (2 sltces/56g) Oats & oat flakes (1/2 C/ SOg)• Oat groat< (1/2 C/120g)	long ferm ent, no yeast, wheat or spelt flour (2 slices) Starches, com/potato/ taoioca	Spelt pasta (1/2 C/74g) Sourdough, short ferment time (1 slice) Wheat grain, sprouted (1/4 C/50g) White bread, wh eat (1ske/24g)	(bran, cerea l, couscous, germ) extract"*
Dairy&	Almond milk (1C) Butter Bri e/Cam embert cheese	Havarti cheese (54g) Hemp milk (1C) Lactose-free milk/yogurt	Chocolate (dark <30g; milk and white <15 g) Coconut milk, canned (1/3C) Coconut milk, drinking. UHT (1/2 C)	Buttermilk Cream cheese Cream, regular
Alternatives	(40g) Cheddar chee<e (4Dg)	a milk (1C) Macadami	Coconut yogurt (1/2 C)	Custard
Nate: ch eck all ingredients lists				

far high FODMAP	Colby cheese (40g)	Mozzarella (1/2C/60g) Pecorino (1/2C/60g)	Cottage cheese (1/4 C) Oat milk (1/8 C)	Cow's and goat's milk Ice cream
ingredients	Feta cheese (1/2C/125g) Goat cheese (1/2C/60g) Goats milk yogurt (170g) Haloumi cheese (2 slices/SOel	Quinoa milk (1C) SINiss cheese (54g) Soy milk, with soy protein Soy cheese (2 slices/40g)	Quark (4 tablespoons) Rice milk (3/4 C) Rtcotta cheese (2 tbsp/40g) Whipping cream, whipped (1/2 C}	Kefir Sour cream Soy milk, made with soy beans Yogurt

Foods	Low in FODMAPs		Moderate in FODMAPs	High in FODMAPs
Fruits Note: limit all fruits to 1 serving per meal or snack; serving size is 1 medium if not listed	Banana (common, unripe)(100g) Banana, dried (10 chips/20g) Bluebemes (1/4 Cheaped/40g) Breadfruit Cantaloupe melon (1/2 C/90g) clementine CumqJat (4frui t/76g) Dragon fruit Dcrian (2 segments/102g) Grapes (1cup/150g) Guava, ripe only Honeydew melon (1/2 C/90g) Kiwi (2 small/150g) Lemon juice Lime juice Mandarins (2 small/125g) Mangosteen Oranges, ravel Passionfruit Paw paw (1C/140g) Plartain, peeled Prickly pear Pineapple (1C/140g) Raspberries (30/60g) Rf<Jbarb (1C/130g) Star fruit /Carambola Strawberries (10/140g) Tamarind (4/8g) Tangelo Tangerine		Avocado (1/8 whole/3Dg) Banana, normal, ripe with brown spots (1/3 medium fruit/33g) Banana, ripe(1/2 banana/56g) Coconut milk (1/2 cup) Coconut, dried, shredded (1/4 cup/18g) Coconut, fresh (1/2 C/4Bg) Cranberries, dried (1Tbsp/13g) Currants (1 Tbsp/13g) Goji berries (1/2 Tbsp/6g) Grapefruit (1/3 C/B0g) Guava, tinned in syrup (1slice/27g) Longan (S/15g) Mixed peel, Citrus fruits (1/3 C/S0g) Persimmon (3/4 of one fruit/60g) Pomegranate (1/4 cup seeds/38g) Rambutan (2/31g) Raisins, regular (not sultanas)(1 Tbsp)	Apples Apricots Blackberries Boysenberries Cherries Other dried fruits fejjoa Figs Guava, unripe Lychee Mango Nectarines Peaches Pears (except prickly) Plums Tamarillo Watermelon
Meat& Alternatives (Legumes, Soy, etc.) Note: check all ingredients lists for high FODMAP ingredients	Meat/Poultry/Fish/Eggs Brazil nuts (10 nuts/40g) Chestnuts (10 nuts/64g) Chia seeds (2 tbsp/24g) Ed<mame (1qsog) Egusi seeds (2 tbsp/24g) Flaxseed (1 tbsp/15g) Macadcmia (20 nuts/40g} Mince, quorn (75g) Peanuts (32 nuts/28g); Peanut butter (2 tbsp/32g) Pecans (20 halves/40g) Pine nuts (1t bsp/14g) Poppy seeds (2 tbsp/24g) Pumpkin seeds (2 tbsp/23g) Sescme seeds (1tbsp/11g) Sunflower seeds (3 tbsp/30g) Tempeh, plan (100g) Tigernuts (20g) Tofu, firm (2/3 C/170g) Walnuts (20 halves/60g)		Almonds (10 nuts/12g); butter 1 tbsp Butter beans, canned (1/4 C/35g) Chana dahl & urid dahl (1/2 C/46g) Chickpeas, canned (1/4 C/42g) Hazelnuts (10 mts/15g) Lentils, canned (1/2 C/46g) Lentils, red/green, boiled (1/4 C/23g) Lima beans, boiled (1/4 C/39g) Mufe beans, boiled (1/4 C/53g) Mufe beans, sprouted (2/3 C/95g) Tal"inl (1tbsp/20g)	Beans (adzch baked, black, borlotti, broad, fava, haricot, navy, red kidney, soya) Cashews Falafel Split peas, boiled Pistachios Tofu, silken Textured soy protein/TVP

Foods	Low in FODMAPs	Moderate in FODMAPs	High in FODMAPs
Sweeteners Note: 10Vll" FODMAP sweeteners should still be consumed in moderation	• Artificial sweeteners EXCEPT polyols/sugar alcohols (a spartame,sucralose, stellia, etc.)(note: many stevia products have added polyols) • Candies made with low FOOMAP sugars/syrups • Glucose • Maple syrup • Ricemalt syrup • Regular corn syrup • Sugar/sucrose (brown, cane, invert, palm, raw, white)	• Coconut sugar (1 tsp) • Golden syrup (1/2 tbsp/7g) • Jaggery (1/2 tbsp/12g) • Molasses (1 tsp/Sg) • Treacle, coconut (1/2 tbsp/14g)	• Agave • Applesyr • Fn.x::tose • FrUt JUice concentrates • High fructose ca-n syrup (called glucosefructose in Canada) • Honey • Lactose • Pd yols/sugar alcohols (sorbitol, mannitol, xy!itol, maltitol, lactitd, and isomalt)
Beverages Note: alcohol and caffeine are stimulant s and may trigger symptoms; carbonated beverages may mer easegas	• Beer • *Coffee* • Decaffeinated *coffee* andespresso • Espresso • Pops/sodas, made withoLt high FOOMAP sweeteners & jUices • Certain teas (roobios/red, green, peppermint, white, buchu, and hrneybush) • Kvass (1C) • ProNourishNLtritional Drink by Nestle • Some spirits (gin, vocl<a, whisky) • Tomato jUce, withoLt added high FOOMAP juices (1C) • Water, regular/sparkling • Wheatgrass juice • White coffee, instart from powder • Wine, red/sparklin&fsweet/white	• Coconut water (100 ml) • Crartlerry juice, sweetened without added fructoseor polyols (1 C) • Hct chocolate (only if made with low FODMAP milk and max 2 tsp cocoa powder) • Kombucha (180mLXonly if made without hiFODMAP JUiCes) • Malted chocolate flavoured beverage base (1.5 tsp/lOg) • Malted chocolate flavoured drink, 3 in 1 (1/2 >achet/16g) • OrangeJuice(1/2 C) • Pomegranate juice(1/2 C) • Certain teas, weakly infused (t::(ack, dandeliot\ ard chai) • Chrysanthemum tea (180ml)	• Cordial (apple, orange, raspberry) • ..Uices made with high FOOlV\APfruits • Malted milk drink, a-iginal flavoor • Rum • Certain teas (oolong. fernel, chamomile) • Certain teas, strongly infused (chai, dardelion, and herbal containing chicory root) • Tequila (*note: untested twt lik∈to be high FODMAi'J* • Wine, only sticky/dessert type

Foods	Low in FODMAPs	Moderate in FODMAPs	High in FODMAPs
Ingredients Other Foods &	• Agorpg) • Brown rice protein powder (2 tbsp/40g) • Creamer powder (2 sachetsj6g)	• *Soy* sauce (2 Tbsp)* • Spirulina • mixes for garlic/onion,	• Barbeque sauce (2 Tbsp)" • Bay Le,.,es(lleof) • cacao powder \2 heaped tsp/Sg) • carob powder (1 heaped tsp/6g) • Choc ate (dark<30g; milk and white <15 g)	• *Inulin/ChicO()' root extract* (note: commonly added to processS{!d foods)
Note: check all for high	•		• Caviar dip	
	•		• Garlic powder	
	•		• OlUtney (1Tbsp)	
ingredients lists FODMAP ingredients;	• capers 11tbsp)	• Spices (check Spice especially chili		• Garlic/onion flavoured oils • Fruit bars
	•	•	•	
spices• and flavoursmay •natural include	• Eggplant dip • Egg re •rer(1tbsp/Gg) • Ginger root herkins in vinegar" • G	powders) • Sweet and sour sauce (2 Tbsp)'	• Cor"' powder (2 heilped tsp/Bg) • Jam, strawberry or marmalade, without • Coconut jam (1/2 tbsp) • high FDDMAP sweeteners (2 tbsp)	• Jam (blueberry, berry) • blackcurrent or mixed • Dnion powder • Pastasauce (if-am- based or containing
garlic/onion •read	•	• Tomato paste (2 Tbsp)•	•	
	• Herbs		• Ketchup (1Tbsp)' • Misop aste(12g)*	
	•	•	•	
ingredients lists for added garlic or onion	• Horseradish (2tbsp) • Fish sauce (1 tbsp) • Jello/instantjelly	• Tomato sauce (1/2 C)"	• Pesta, withtXIt garlic/MiPrl (1/2 Tbsp) • Oyster sauce (1Tbsp)	• Pesta (containing garlic/onion)
*f nnent<don during	• Kelp noodles (1C/113g)	• Vanilla bean pods & extract/essence process mg	• Rel;sh 11Tbsp)' • Tamarind paste (1/2Tbsp) lowff'ed • Licorice, black \4Sg)	• garlic/onion) • Tzatziki dip Mayonnaise [1]
	•	•	•	

Vinegar, apple cider(2 tbsp)

oligosaccharide content	Mint jelly & sauce (1tbsp) Mirin Mustard (1tbsp)" Nutritional yeast flakes 11tbsp/16g) Dils (avocado, coconut, olive, sunflower, vegetable, etc.) Pea protein powder (2 tbsp/40g) Peanut butter (2tbsp) Pickles"	Tahini (1Tbsp) Vegemite (1tsp) Vinegar, rice white(2 tbsp) Vinegar, white Wasabi paste (2 tbsp) Wasabi powder (1tsp) WOfcestershiresauce (2 Tbsp) Wheatgrass powder (1 tsp/3g) Xar1thamgum	Qumce poe (1/2Tbsp)	

APPENDIX-2
Consent form for enrollment in the study.

Department of Foods and Nutrition Faculty of Family and Community Sciences The Maharaja Sayajirao University of Baroda

CONSENT FORM

Research Topic: "**Impact evaluation of nutrition intervention on IBS subjects and its effectiveness in terms of relief of symptoms and improvement in IBS quality of life in selected samples from urban Vadodara**

Primary Investigator: Prof.(Dr.) Mini Sheth

Student: Ms. Jahnavi Deo

There is an increasing prevalence of irritable bowel syndrome (IBS) globally. It can be attributed to lifestyle changes, decreased physical activity and other internal and external factors. The disease may affect patients in terms of quality of life, work potential, mental and physical health etc. Accumulating evidence supports the view that a diet high in FODMAP foods causes worsening of GI symptoms and contributes to worsening of IBS.

Hence keeping this in mind I am conducting my Master's research to assess impact of FODMAP education on IBS patients in urban Vadodara and its effectiveness in terms of relief of symptoms and improvement in IBS quality of life.

For the same purpose, I require information about your general information, anthropometric data, medical and medication history (if any), socio-economic status and your willingness to follow a low FODMAP diet for the period of 4 weeks. I will also require information post intervention it will take less than 15-30mins at a sitting. The information you have shared with me will remain confidential and shall be used only for research purpose.

If you have any further queries regarding this study, you can contact us.

Prof. (Dr.) Mini Sheth: 9879359229

Ms. Jahnavi Deo

I _____give my free and informed consent to participate in the study. I have been explained the purpose of the study and informed that I can quit the study at any point without giving any explanation.

Contact number: _____

Signature: _____

General Information

1. Name of institution _____
2. Name of respondent: _____
3. sex : male/ female/ other
4. D.O.B. of respondent: ____dd/__mm/ ___yyyy_____
5. Age of respondent: ____ years
6. Contact no. :_____
7. Occupation _____
   a) Business
   b) Self- employed
   c) Service
   d) Unemployed/ retired
   e) Housewife
   f) Student

8. PAST HISTORY:

a. History of DM/ HTN /TB/ BA/ IHD/ CVA/ EPILEPSY
b. History of similar illness in the past: _____
c. History of surgery: _____

9. Personal history:
a. History of alcohol intake: _____
b. History of smoking: _____
c. History of psychiatric illness: _____

10. Family history:
a. History of GI cancers/ inflammatory bowel disease/ celiac disease/ NCDs/others _____

11. **Other relevant history**:
a. Relation to food: milk/ alcohol/ wheat etc.
b. Recent travel history: _____
c. Abnormal eating habits: _____
d. Allergy _____

12. **Medication history: _____**

13. Anthropometric measurements:

a. Ht: _____
b. Wt: _____
c. BMI: _____

14. DIETARY HISTORY:

14.1. Type of diet consumed?

a) Vegetarian
b) Non-vegetarian
c) Ovo vegetarian
d) Vegan
e) Other.

14.2 Do you follow any dietary regime?

a. Jainism
b. Swaminarayan
c. Gluten free diet
d. Intermittent fasting
e. Other _____

14.3 Number of meals per day

a. 1-2
b. 2-3
c. 3-4
d. >4

14.4 Do you have your breakfast every day?

a. Yes
b. No
c. sometimes

15. Physical activity pattern:

NAME	DURATION

16. Do you suffer from any gastrointestinal problems?

a. YES
b. NO

17. If yes, which of the following?
    a. Constipation
    b. Diarrhoea
    c. Both

18. What is the frequency of occurrence?
    a. Once a week
    b. Once a month
    c. More than once a week
    d. More than once a month
    e. Rarely
19. Tick against the symptoms you have.
    a. Abdominal pain
    b. Abdominal cramps
    c. Bloating
    d. Gas
    e. Irregular bowel moments
    f. Discomfort
20. Do you experience any symptoms on consumption of milk and milk products?
    a. Yes
    b. No
    c. Not sure.
21. Have you found out any specific tiggering food(s)?
    a. Yes
    b. No
    c. Somewhat.
22. Do you try to avoid these triggering foods?
    a. Yes
    b. No
    c. Somewhat.

Food Frequency Questionnaire

For High FODMAP Foods

Sr. No.	Food groups and items	Daily	2-3 times a week	Weekly	Fortnightly	Monthly	Occasionally	Seasonally	Never
1.	**Grains, white roots and tubers and plantains**								
	Barley-based product								
	Freekeh								
	Laska noodles								
	Oat bread								
	Rye-based product								
	Sourdough, made with rye or kamut flour								
	Spelt, kernels/flakes								
	Whole wheat bread								
	Wheat-based products (bran, cereal, couscous, germ)								
	Inulin/Chicory root extract*								

2.	PULSES								
	Beans (adzuki, baked, black, borlotti, broad, fava, haricot, navy, red kidney, soya								
	Tofu, silken								
	Textured soy protein/TVP								
	Falafel								
	Split peas, boiled								
3.	**Nuts and Oilseeds**								
	Cashews								
	Pistachio								
4.	**Dairy & Alternatives**								
	Buttermilk								
	Cream cheese								
	Cream,regular								
	Custard								
	Cow's and goat's milk								
	Ice cream								
	Kefir								
	Sour cream								
	Soy milk, made with soy beans								
	Yogurt								
5.	**vegetables**								
	Artichokes								
	Asparagus								
	Bittermelon/Karela								
	Cauliflower								
	Corn kernels, canned								
	Garlic								
	Green onion, white parts								

	only								
	Leek bulbs								
	Lotus roots								
	Mushrooms								
	Onions								
	Onions, small pickled								
	Peas, green, thawed								
	Peas, sugar snap								
	Shallots								
	Tomato sauce with added garlic or onion								
6.	**fruits**								
	Apples								
	Apricots								
	Blackberries								
	Boysenberries								
	Cherries								
	Other dried fruits								
	Feijoa								
	Figs								
	Guava, unripe								
	Lychee								
	Mango								
	Nectarines								
	Peaches								
	Pears (except prickly)								
	Plums								
	Tamarillo								
	Watermelon								
7.	**sweeteners**								
	Agave								
	Apple syrup								
	Fructose								
	Fruit juice concentrates								
	High fructose corn syrup (called glucose-fructose in Canada)								
	Honey								

	Lactose								
	Polyols/sugar alcohols (sorbitol, mannitol, xylitol, maltitol, lactitol, and isomalt)								
8.	**Beverages**								
	Cordial (apple, orange, raspberry)								
	Juices made with high FODMAP fruits								
	Malted milk drink, original flavour								
	Rum								
	Certain teas (oolong, fennel, chamomile)								
	Certain teas, strongly infused (chai, dandelion, and herbal containing chicory root)								
	Wine, only sticky/dessert type								

APPENDIX-3

Beck's depression scale

DEPRESSION SCALE:

Beck's Depression Beck's Depression Inventory

1.

0 I do not feel sad.

1 I feel sad

2 I am sad all the time and I can't snap out of it.

3 I am so sad and unhappy that I can't stand it.

2.

0 I am not particularly discouraged about the future.

1 I feel discouraged about the future.

2 I feel I have nothing to look forward to.

3 I feel the future is hopeless and that things cannot improve.

3.

0 I do not feel like a failure.

1 I feel I have failed more than the average person.

2 As I look back on my life, all I can see is a lot of failures.

3 I feel I am a complete failure as a person.

4.

0 I get as much satisfaction out of things as I used to.

1 I don't enjoy things the way I used to.

2 I don't get real satisfaction out of anything anymore.

3 I am dissatisfied or bored with everything.

5.

0 I don't feel particularly guilty

1 I feel guilty a good part of the time.

2 I feel quite guilty most of the time.

3 I feel guilty all of the time.

6.

0 I don't feel I am being punished.

1 I feel I may be punished.

2 I expect to be punished.

3 I feel I am being punished.

7.

0 I don't feel disappointed in myself.

1 I am disappointed in myself.

2 I am disgusted with myself.

3 I hate myself.

8.

0 I don't feel I am any worse than anybody else.

1 I am critical of myself for my weaknesses or mistakes.

2 I blame myself all the time for my faults.

3 I blame myself for everything bad that happens.

9.

0 I don't have any thoughts of killing myself.

1 I have thoughts of killing myself, but I would not carry them out.

2 I would like to kill myself.

3 I would kill myself if I had the chance.

10.

0 I don't cry any more than usual.

1 I cry more now than I used to.

2 I cry all the time now.

3 I used to be able to cry, but now I can't cry even though I want to.

11.

0 I am no more irritated by things than I ever was.

1 I am slightly more irritated now than usual.

2 I am quite annoyed or irritated a good deal of the time.

3 I feel irritated all the time.

12.

0 I have not lost interest in other people.

1 I am less interested in other people than I used to be.

2 I have lost most of my interest in other people.

3 I have lost all of my interest in other people.

13.

0 I make decisions about as well as I ever could.

1 I put off making decisions more than I used to.

2 I have greater difficulty in making decisions more than I used to.

3 I can't make decisions at all anymore.

14.

0 I don't feel that I look any worse than I used to.

1 I am worried that I am looking old or unattractive.

2 I feel there are permanent changes in my appearance that make me look unattractive

3 I believe that I look ugly.

15.

0 I can work about as well as before.

1 It takes an extra effort to get started at doing something.

2 I have to push myself very hard to do anything.

3 I can't do any work at all.

16.

0 I can sleep as well as usual.

1 I don't sleep as well as I used to.

2 I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.

3 I wake up several hours earlier than I used to and cannot get back to sleep.

17.

0 I don't get more tired than usual.

1 I get tired more easily than I used to.

2 I get tired from doing almost anything.

3 I am too tired to do anything.

18.

0 My appetite is no worse than usual.

1 My appetite is not as good as it used to be.

2 My appetite is much worse now.

3 I have no appetite at all anymore.

19.

0 I haven't lost much weight, if any, lately.

1 I have lost more than five pounds.

2 I have lost more than ten pounds.

3 I have lost more than fifteen pounds.

20.

0 I am no more worried about my health than usual.

1 I am worried about physical problems like aches, pains, upset stomach, or constipation.

2 I am very worried about physical problems and it's hard to think of much else.

3 I am so worried about my physical problems that I cannot think of anything else.

21.

0 I have not noticed any recent change in my interest in sex.

1 I am less interested in sex than I used to be.

2 I have almost no interest in sex.

3 I have lost interest in sex completely

APPENDIX-4

Questionnaire for Quality of life (QoL)

QoL domain	Tick against the impaired domain.
Dysphoria	
Interference with activity	
Food avoidance	
Health worry	
Sexual issues	
Relationship issues	

APPENDIX-5

Rome-IV criteria

1- I consent to participate in the following screening:
   - Yes
   - No
2- Contact information: _____
3- Name of respondent: _____
4- Age (in years): _____
5- Gender
   - Female
   - Male
   - Prefer not to say
6- Have you experienced recurrent abdominal 1 day per week for the past three months?
   - Yes
   - No
7- If yes, was the pain associated with any of the following? (multiple selection can be done)
   - Related to defecation
   - Associated with change in stool frequency
   - Associated with form (appearance) of stool.

APPENDIX- 6

Compliance sheet for FODMAP avoidance

Day of intervention	Intervention followed	Intervention not followed	Any adverse effects reported.
Day-1			
Day-2			
Day-3			
Day-4			
Day-5			
Day-6			
Day-7			
Day-8			
Day-9			
Day-10			
Day-11			
Day-12			
Day-13			
Day-14			
Day-15			
Day-16			
Day-17			
Day-18			
Day-19			
Day-20			
Day-21			
Day-22			
Day-23			

Day-24			
Day-25			
Day-26			
Day-27			
Day-28			
Day-29			
Day-30			