

THE EFFECT OF HOMOEOPATHIC SIMILLIMUM TREATMENT ON
IRRITABLE BOWEL SYNDROME SUFFERERS.

by

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I, Wim Marius Rademan, declare that this dissertation represents my own
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I DEDICATE THIS STUDY TO MY PARENTS

*THANK YOU FOR ALL THE LOVE AND SUPPORT YOU HAVE SHOWN ME DURING
MY LIFE AND ESPECIALLY DURING MY STUDIES.*

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ABSTRACTS

The aim of the study was to determine the effectiveness of Homoeopathic Simillimum treatment in Irritable Bowel Syndrome sufferers in terms of patient response to treatment. It was hypothesized that the homoeopathic simillimum treatment would result in a substantial improvement in all the clinical aspects of Irritable Bowel Syndrome sufferers, and that it could be used as an alternative to “conventional” treatment in many cases.

The study was a clinical trial, in which a placebo control group was compared with an experimental group. Convenience sampling was used to draw patients into the trial. Volunteers responded to advertisements that had been placed in various advertising media.

A minimum of 30 participants was assessed and if they complied with the diagnostic- and Manning criteria they were accepted into the study. The participants were randomly divided into a double – blind study that lasted 3 months. During this period half of the patients received placebo treatment while the other half received homoeopathic simillimum treatment. Neither the researcher nor the participants knew what type of treatment they received until the end of the research. The participants that fell into the placebo group was given the opportunity after the study was over to be treated with homoeopathic simillimum treatment.

All the data obtained by the researcher through the questionnaires was interpreted by

means of non-parametric statistical tests, since the sample size of the study was small.

The two major non-parametric tests are 1. The Mann-Whitney test (for 2 independent or unpaired groups) and; 2. The Wilcoxon's signed rank test (used within a group). A Statgraphics plus (version 6) computer program was used to statistically analyze this data.

The data used was the clinical findings and the Manning Criteria, which was obtained in the case history (includes age and sex) and physical examination performed by the researcher. Data found before and after the treatment period was compared using Frequency distribution and Bar charts.

Using the Mann – Whitney U test it was shown that there was no significant difference at the start of the research between the treatment and placebo groups at a 5 % level of significance. At the end of the trial period there was a significant difference between the treatment and placebo groups at a 5 % level of significance.

With the Wilcoxon's signed rank test it was found that there was a significant improvement in the treatment group between the beginning and end of the research findings at a 5 % level of significance. The placebo group did not show a significant improvement between the beginning and end of the research findings at a 5 % level of significance.

From the results, it was apparent that Homoeopathic Simillimum Treatment is effective

in decreasing the symptoms of Irritable Bowel Syndrome sufferers, and that it consequently improves the overall clinical picture. Therefore Homoeopathic Simillimum Treatment can be used as an alternative treatment, or as reinforcing treatment in other cases.

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DEFINITION OF TERMS

1. **Placebo:** This is an inactive substance or preparation given to patients in controlled studies to determine the efficacy of medicinal substances (Anderson 1989: 471).
2. **Simillimum:** A homoeopathic remedy specifically chosen from the entire range of homoeopathic remedies, and the pathogenetic action matches the symptom picture of the patient (Jouanny 1991: 91).
3. **Manning Criteria:** Six cardinal symptoms of Irritable Bowel Syndrome (IBS) used for diagnostic purposes of the syndrome (Talley et al. 1990).

CHAPTER ONE

INTRODUCTOIN

Irritable Bowel Syndrome (IBS) represents one of the commonest conditions encountered by gastroenterologists, internists and general practitioners. In the general population, symptoms consistent with IBS are reported by 10 - 20 % of persons, and accounts for 20% - 50% of referrals to gastroenterology clinics. Extrapolating to the white population of US, the cost were more than \$8 billion for IBS yearly, thus making it a costly disorder in the community. (Talley et al. 1995.)

Essence of Irritable Bowel Syndrome (IBS.): Intermittent diarrhea, abdominal colic relieved by bowel action and 'bloated' feeling -due to altered gut motility. The disease is one of negatives: there is no accepted definition and no structural pathology. (Hope et al. 1993: 518.)

Irritable Bowel Syndrome varies in severity from trivial to incapacitating. The pathophysiology and epidemiology are gradually being unraveled and it is becoming more apparent how poor the quality of life of these patients is. Nowadays its no longer acceptable practice to diagnose the condition and to discharge the patients on high fiber diets, particularly because it makes the situation worse. (Francis and Whorwell. 1997.)

Irritable Bowel Syndrome consists of a group of symptoms that suggest that there is a dysfunctional gut for which there is *no cure* as there is no known organic cause. The best lines of defense up to now have been a number of treatments that provides symptomatic relief of the symptoms of IBS. (Zietsman 1997.)

The Manning criteria are widely used for diagnosis and to observe the major symptoms in irritable bowel syndrome. They have a sensitivity and specificity of 67% and 70% respectively if three or more symptoms are positive (Jeong et al. 1993).

All six individual symptoms used in the Manning criteria were found to be reliable.

These key symptoms are (i) visible abdominal distention, (ii) pain relieved by a bowel action, (iii) more frequent stools with the onset of pain, (iv) looser stools with the onset of pain, (v) rectal passage of mucus, and (vi) a sensation of incomplete evacuation. Based on a logistic regression analysis of the discriminatory value of Manning criteria it was found that as the number of positive criteria increased, so did the predicted probability of IBS. (Talley et al. 1990.)

IBS is a motility disorder that involves the entire hollow gastrointestinal tract, creating a symptom complex with both upper and lower gastrointestinal symptoms. Predominant symptoms include variable degrees of abdominal pain, constipation or diarrhea, and postprandial distention. The symptoms nearly always occur in the waking state and are usually triggered by stress or the indigestion of food. There are two types of IBS grouped according to the signs and symptoms: The first is the spastic colon type where bowel movements are variable. Most patients have pain of colonic origin over one or more areas of the colon associated with periodic constipation or diarrhea. The second group of IBS patients primarily manifest painless diarrhea, usually urgent, precipitous diarrhoea that occurs immediately upon rising or, more typically, during or immediately after a meal. (Berkow 1992: 842.)

It seems adverse reaction to food is proposed to be a high causative factor in patients suffering from irritable bowel syndrome. Thus a diet that eliminates the offending foods is the obvious treatment for such adverse reactions. Compliance with a dietetic regimen is often poor and sometimes not completely free from risks. (Stefanini et al. 1995.)

Research has shown that the people suffering from IBS felt that it affected all aspects of their lives: work, leisure, travel and relationships. Sufferers indicated that they felt they would have coped better if they had been provided with more information about IBS, its possible causes and treatment, and greater sensitivity from members of the medical profession in dealing with them. (Dancey and Backhouse, 1993.)

A control group (n = 46 patients), a group of patients with irritable bowel syndrome (IBS) (n = 70) and a group of patients with major depression (MDE) (n = 60) were interviewed and compared concerning their family history of psychiatric disorders. The results showed that both IBS and MDE groups had a similar, higher prevalence of relatives with psychiatric illness than controls, i. e. there was a higher prevalence of anxiety and depressive disorder in the relatives. (Sullivan et al. 1995.)

In treating the Irritable Bowel Syndrome both the patient and the physician must realize that the condition is chronic, and that while it may be alleviated, it cannot be cured. There should also be an emphasis on the relationship between psychological stress and the onset of severe symptoms. Drug treatment is aimed at relieving the disease. With constipation, an increase in dietary bulk and psyllium bulk laxatives is used. Troublesome diarrhea

may respond to diphenoxylate or loperamide. Mild sedation with tranquilizers may be indicated, and anticholinergic drugs such, as dicyclomine is useful in some patients. Unfortunately, no specific drug (orthodox) or dietary regimen affords good relief and thus several therapeutic maneuvers need to be tried. (Isselbacher et al. 1994: 1421.)

There has been no specific research on the effect of Homoeopathy on the Irritable Bowel Syndrome but it seems from clinical experience that Homoeopathic treatment may be effective at addressing bowel disorders including psychiatric related bowel disorders (Vickers 1993: 188).

Therefore the aim of the study was to evaluate the efficacy of Homoeopathic Simillimum treatment in Irritable Bowel Syndrome sufferers in terms of the patient's perception and clinical findings by the researcher to determine what role the homocopathic simillimum treatment plays in the management of spastic colon.

CHAPTER TWO

REVIEW OF THE RELATED LITERATURE

2.1 Introduction

Irritable Bowel Syndrome is one of the commonest disorders in gastroenterology with a symptom complex that includes diarrhea, constipation, pain and bloating (Bonis and Norton 1996). Although IBS is one of the commonest conditions encountered in clinical practice, it is also one of the least understood conditions (Kelley 1997: 708).

Most individuals do not seek medical attention for their symptoms, and those that do require limited medical therapy and assurance (Almounajed and Drossman 1996). This disease is one of negatives: thus there is no accepted definition and no structural pathology (Hope et al. 1993: 518).

In a recent study it was shown that the majority of nurses in 18 London hospitals hold a very negative attitude towards IBS sufferers, which can be very detrimental to the treatment of such patients (Letson and Dancey. 1996).

2.1.1 Definition: "Irritable Bowel Syndrome is a combination of chronic recurrent symptoms of abdominal pain and disturbed defecation not explained by structural or biochemical abnormalities of the bowel wall. It is a localized manifestation of functional gastrointestinal disorders". (Hurst 1996: 1532.) According to the "Rome criteria" IBS can be defined as chronic abdominal pain for at least 3 months and present for several days a week (Louvel et al. 1996).

2.2 Epidemiology

In the general population, symptoms consistent with IBS are reported by 15% to 20 % of patients. 75 % of patients seen by physicians with IBS in Western countries are female. Male patients predominate in countries such as India and Sri Lanka. (Rakel 1996: 347.) Although very common in early adulthood, it can also have an onset after the age of 45 (Bennett and Plum 1996: 686). In the medical practice, 25 to 50 % of referrals to gastroenterologists are patients suffering from IBS (Hurst 1996: 1534). The prevalence of IBS is much higher in females, primarily because of a higher prevalence of constipation – predominant IBS. Females also have a higher number of Manning's symptom criteria. (Talley et al. 1995.)

2.3 Aetiology

No anatomical aetiology has been found up to now. Factors like emotions, diet, drugs, and hormones can precipitate and aggravate GI motility. Patients with IBS are more neurotic, anxious, and depressed than patients in a similar age group. Stressful and emotional conflict may result in the onset and recurrence of the syndrome. Some psychosocial precipitating symptoms involve marital discord, anxiety related to children, loss of a loved one, and obsessional worries over trivial everyday problem. (Berkow 1995: 842.)

There are several theories about the aetiology of IBS. Firstly, it is possible that there may be a generalized alteration of the visceral receptors throughout the gut. Secondly, there may be an increased perception due to altered central processing. Lastly, there may be

an imbalanced autonomic nervous system. (Hurst 1996: 1532.)

The latest beliefs are that the main causes of IBS are stress, poor eating habits, a lack of exercise, gut smooth muscle spasms and hiatus hernia (Zietsman 1997).

2.4 Pathophysiology

Patients with IBS have certain motility and sensory abnormalities, which distinguish them:

- Stimuli like stress, meals, and peptides alter colonic and small intestinal motor response.
- Pain symptoms in patients with IBS are due to hyperactivity of gut muscle.
- IBS patients also have reduced sensory thresholds for stimuli such as rectal and ileal Distention. (Rakel. 1996: 347.)
- Small bowel and sigmoid colon circular and longitudinal muscles are particularly susceptible to motor abnormalities. Pain of IBS is either due to abnormally strong contraction of the intestinal smooth muscle or to undue sensitivity of the intestine to distention. Hypersensitivity to the hormones gastrin and cholecystokinin may also be present. (Berkow 1992: 842.)

Investigations have failed to detect any histological, microbiological, or biochemical abnormalities but have suggested abnormal myoelectric and motor activity in the gut. Measuring myoelectric activity as well as slow wave and spike potentials it was found that patients with IBS have a 3 cycles per minute (cpm) motor activity in contrast with the 6 cpm found in normal control subjects. Emotional stress alters colonic motility with

inhibition of motility with depression, whilst stimulation occurs with hostility and anger. IBS patients also show selective hypersensitivity of internal mechanosensitive pathways associated with a nonspecific and central dysfunction of viscerosomatic referral. (Kelley 1997: 709.)

Neuropeptides like motilin and cholecystokinin are partly responsible for initiating intestinal dysmotility in IBS patients due to disrupted motilin and cholecystokinin release in the system. Motilin has been proposed to initiate the peristaltic reflex in the small intestine and cholecystokinin the gastrocolic reflex. (Sjolund et al. 1996.)

Patients with IBS show a deviation from normal brain activity patterns both during noxious rectal distention and during anticipation of rectal pain (Silverman et al. 1997). Repetitive sigmoid contractions may induce rectosigmoid hyperalgesia in patients with IBS, i. e. if the sigmoid splanchnic afferents get repetitive stimulated, central sensitization develops which is manifested as hyperalgesia and increased viserosomatic referral during rectal distention and spontaneous rectosigmoidal hyperalgesia in the absence of applied stimuli. (Munakata et al. 1997.)

Motor abnormalities in all parts of the gastrointestinal tract have been found, viz. esophageal, gastric, upper small bowel, ileac and colonic (Kumar and Gustavsson 1988: 402).

2.5 Clinical Manifestation

Dysregulated intestinal motor function, sensory functions and central nervous system functions are currently believed to be the basis for IBS (Dalton and Drossman 1997). And the hallmarks of IBS are cramping abdominal pain of colonic origin and an altered bowel habit. Symptoms are intermittent with variable periods of remission. (Bennett and Plum 1996: 686.)

The most predominant symptoms are a history of chronic constipation, diarrhea, or both occurring intermittently for months or years. The diarrhoea is worse in the morning or after breakfast. There are usually three to four bouts of loose stools then the patient will start feeling better for the remainder of the day. Some describe the stools to be "pencil-like" pasty stools rather than diarrhea. In rare cases some patients may develop a severe, painless diarrhea in which a watery bowel movement is present every day.

Chronic abdominal pain with constipation or with alternating constipation and diarrhea is another presentation in patients with IBS. These patients have bouts of intermittent crampy lower abdominal pain, often over the sigmoid colon, which is usually relieved by passage of flatus or stool. Abdominal bloating is also commonly found in patients with IBS. (Isselbacher et al. 1994: 1421.)

Continuous recurrent symptoms will be present for at least 3 months which consist of abdominal pain relieved by defecation or associated with changes in frequency or consistency of stools. Defecation is disturbed and involves altered stool characteristics with a feeling of bloating and abdominal distention. (Kelley 1997: 708.)

IBS is often accompanied by passage of an excessive amount of mucus, which might be interpreted as pus or as a worm by some patients. Other presentations of IBS include epigastric fullness, abdominal discomfort after a meal, nausea, and occasional bilious vomiting. These patients frequently complain of bloating, distention, and pain in the upper abdomen. (Bouchier et al. 1993: 270.)

Symptoms may occur for several years before patients seek medical advice. Precipitating factors that can set off an acute attack include (1) acute illness, (2) increased work demands and stress, (3) severe financial pressure, (4) loss of a job, (5) family crises, and (6) death of a close friend or loved one. (Cohen and Soloway 1987: 71.)

Patients with short symptom duration and fewer psychological symptoms have a better prognosis than patients with long histories of IBS and related psychological distress (Lembo et al. 1996). Some new findings have indicated that IBS is extremely prevalent in patients seeking treatment for dysthymia and is often undiagnosed and untreated (Masand et al. 1997).

A high prevalence rate of major depression, current panic disorders, and childhood sexual abuse is found in patients with IBS. It was also found that patients with IBS have a significant number of medically unexplained physical symptoms and disability ratings which are equal or higher than those of patients with severe organic gastrointestinal disease. (Walker et al. 1995.) When posttraumatic stress disorder was investigated in relation to IBS a high prevalence was found. These findings suggest that IBS is often

associated with psychiatric disorders, indicating that assessment and treatment of psychiatric disorders may be important in the treatment of IBS. (Irwin et al. 1996.)

Clinical Findings:

- In the most patients with IBS the physical examination is generally normal.
- Physical examination may reveal tenderness in the area of the colon.
- The majority of patients with IBS are between the ages of 20 and 50.
- IBS patients have a past history of multiple illnesses such allergies, headaches, kidney disease, joint symptoms, and in women dyspareunia. (Rakel. 1996: 347.)

2.6 Diagnosis and Physical Examination

Laboratory studies are generally all negative in IBS. The diagnoses should be suspected based on the patient's symptoms picture and by excluding organic disease. A minimal evaluation of complete blood count, stool sample and urinalysis must be obtained. Sigmoidoscopy is normal (Rakel 1996: 347.) Unless symptoms change, it will not be necessary to undergo the laboratory tests again (Rees and Willey 1993: 332).

Clinical features supportive of the diagnosis of IBS: (1) lower abdominal pain that recurs with altered bowel habits over a period of time without progressive deterioration, (2) symptom onset during periods of stress or emotional upset, (3) absence of fever or loss of weight, (4) small volume stools without any evidence of blood (Kelley 1997: 709).

The Manning criteria is widely used for diagnosing patients with IBS related symptoms

because the six cardinal symptoms used in this criteria were found to be very reliable. These key symptoms are: pain relieved with defecation, (2) onset of pain associated with more frequent defecation, (3) onset of pain associated with looser stools, (4) visible distention of the abdomen, (5) a feeling of incomplete evacuation, (6) and the passage of mucus per rectum. The more of these symptoms present in a patient the more likely it is that they have irritable bowel syndrome. IBS can be diagnosed if a patient presents with abdominal pain and any three of these six symptoms. (Talley et al. 1990.)

All six Manning symptoms were rigorously tested for their diagnostic value at the Mayo clinic in a large study and were found to be reliable (Pounder 1992: 51). Most patients show no abnormalities on their physical examination and laboratory tests with a case history suggestive of IBS (Levine 1992: 346). A combination of two or more symptoms of the Manning criteria may lead to a positive diagnosis for IBS, obviating the requirement for invasive investigations (Barrison et al. 1992: 7.3).

2.7 Differential Diagnosis

In making an accurate differential: quality, location, and timing of pain must be considered which will be very helpful for the diagnosis. IBS in the epigastric region: biliary tract disease, peptic ulcer, intestinal ischemia, and carcinoma of the stomach or pancreas. Pain mainly in the lower abdomen: diverticular disease, inflammatory bowel disease, and carcinoma of colon. Postprandial pain accompanied by bloating, nausea, and vomiting suggest gastroparesis or partial obstruction. If diarrhea is the major complaint: lactose deficiency, laxative abuse, malabsorption, hyperthyroidism, inflammatory bowel

disease, and infectious diarrhea. Constipation as the main complaint: side effects of many different drugs such as anticholinergic, antihypertensive, and antidepressants.

Endocrinopathies must also be considered. (Kelley 1997: 710.)

2.8 Allopathic treatment

IBS is a very hard disease to treat but worthwhile responses can be achieved by carefully targeting the therapy to the many different facets of the disorder (Francis and Whorwell. 1997). Drugs are unproved in the global treatment of IBS, but certain drugs will certainly benefit specific symptoms of the syndrome (Thompson and Gick. 1996). Loperamide is such a drug and has shown beneficial in some cases of IBS with these symptoms but there was an increase of pain during the night (Efsskind et al. 1996). The use of placebo can be used advantageously for some patients (Thompson and Gick. 1996).

The treatment of IBS must be individualized due to fact that it has a multifactorial aetiology (Efsskind et al. 1996). The goal is to modify the factors that caused the exacerbation of symptoms and the patient's response to them. Lots of reassurance must be given to the patient because it is not a life threatening disease and cure is not likely. The first line of control is a dietary approach in which food allergies and intolerance to certain foods must be considered. (Hurst 1996: 1533.)

The next step is to introduce drugs for the different problems related to syndrome. Drugs such as anticholinergic agents, antispasmodic agents, antidiarrheal agents, antifatulence therapy, antidepressant and anxiolytic agents, and antiafferent agents are used. (Kelley

1997: 710.)

The newest therapies are based on reducing high – amplitude GI contractions with nonselective muscarinic antagonists, but due to the typical muscarinic side effects and its failure to relieve pain their efficacy is limited (Mitch et al. 1997). Other new aspects of treatment for IBS are a biopsychosocial approach with attention to the doctor – patient relationship as being the basis of the treatment (Almounajed and Drossman 1996).

Hypnotherapy has shown that in addition to relieving the symptoms of IBS it is capable of profoundly improving the patient's quality of life and reduced absenteeism from work. Although it is relatively expensive to provide it might be a good long – term investment. (Houghton et al. 1996.)

2.9 Homoeopathic Treatment

2.9.1 Introduction

Homoeopathy is a therapy based solely upon stimulating the human being and the human organism reacts to stress by producing the best possible response of which it is capable at that moment (Vithoulkas 1983: 87). Homoeopathy can be defined as 'a therapeutic method which clinically applies the law of similars and which uses medicinal substances in weak or infinitesimal doses' (Jouanny 1991: 11).

2.9.2 Principles

Doctor Samuel Hahnemann (1755 – 1843) was the founder of homoeopathy and

developed the first law of healing which he called "similia similibus curentur" which means 'let like be cured by like'. Hahnemann developed the word 'Homoeopathy' which was derived from the Greek word homoios (similar) and pathos (suffering or disease). (Castro 1990: 5.)

The first law is also called the law of similars, which indicates that there is a similarity in action between the toxicological action of a substance and its therapeutic action. Every patient display a set of symptoms which are characteristic of their disease. The disappearance of these symptoms which indicate cure can be obtained by prescribing to a patient weak or infinitesimal doses of a substance which, when administered to a healthy person, causes symptoms similar to those exhibited by the ill patient. Homoeopathic therapeutics acts in conjunction with the body's reactions and stimulates the defense mechanism of the organism. Homocopathic therapeutics is reactive, thus making it an individualized form of treatment. (Jouanny 1991: 12.)

Hahnemann also stated, in order to cure disease, the originating cause must be found and removed to allow any indisposition to clear on its own (Hahnemann 1986: 12).

2.9.3 Remedies

Homoeopathic remedies are non - toxic due to successive dilution's. These remedies do not act chemically but according to a particular physical state and have the capacity of making the ill patient react to his disease. (Jouanny 1991: 91.)

Some commonly used remedies for IBS and indications for them:

- *Argentum Nitricum*: One of its main functions is on the nervous system: it is a remedy that work on anxiety and fear of a patient.
GIT: Lots of frequent and loud eructations, Abdominal distention that may or may not be relieved by eructations.
Marked flatus, which is passed with or without relief, Diarrhea is one of the leading symptoms and can usually due to panic attacks or anticipation. Clinically well indicated for Irritable Bowel Syndrome. (Morrison 1993: 35.)
- *Colocynthis*: This remedy must always be considered if there is lots of colic present. The pains are severe and cramping, relieved by strong pressure. These pains are made worse by anger and excitement.
Abdominal pain is worse before diarrhoea whereas diarrhoea and colic is made worse by eating. Also indicated in IBS.
(Morrison 1993: 139.)
- *Lycopodium*: Lycopodium is the remedy of choice when digestive disturbance is the main problem (Boericke 1991: 411). Bloating abdomen, amelioration by eructation and flatus, patients feeling worse after eating even small amounts of food.
Lots of pyrosis with sour eructations. Alternation between constipation and diarrhoea and the stool can begin hard and

then turns soft and liquid. Clinically well indicated for IBS.
(Morrison 1993: 230.)

- *Nux Vomica:* This remedies pathology largely centered around the gastrointestinal tract which makes it a good remedy for IBS. Cramping and sharp pain in the abdomen, which gets aggravated by eating, tight clothes, and is made better by warmth, or warm drinks. Constipated with constant ineffectual urging for stool, small round stools passed which gives temporary relief. Incomplete sensation in the rectum with constipation alternating with diarrhoea. (Morrison 1993: 274.)
- *Pulsatilla:* The hallmark of this remedy is that symptoms are always changing, thus one day a patient can have constipation and next he can have a bout of diarrhoea , which is often the case in IBS. Pain and discomfort in the abdomen after eating with flatulence. Bloating of the abdomen with loud rumbling. No two stools are the same, thus it can alternate between constipation and diarrhca. (Boericke 1991: 517.)
- *Sepia:* The patient in need of this remedy tends to be depressed and very irritable. There is an empty feeling in the abdomen. Usually constipated without urging and there is a rectal

dissatisfaction, it feels as if there is a lump in the rectum. This remedy is well indicated for a female over the age of forty and who starting to have menopausal problems. (Morrison 1993: 345.)

It is vital that there is a good doctor – patient relationship for any treatment to be successful and effective and especially in IBS (Dalton and Drossman 1997).

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study Design

The study was a clinical trial, in which a placebo control group was compared with a treatment group, in order to evaluate the efficacy of Homoeopathic Simillimum Treatment on Irritable Bowel Syndrome Sufferers.

A total of 32 participants were each treated for 3 months over a period of 8 months. Sixteen participants received the Homoeopathic Simillimum Treatment and sixteen placebo treatment.

Advertisements were placed at the start of the study in a daily KwaZulu – Natal newspaper by the Homoeopathic department, Technikon Natal, regarding free treatment for volunteer participants. Posters were also displayed on noticeboards in local shopping centers, gyms and health shops. Participants from Dr. Cary's practice also responded to posters put up in his rooms.

Consultations took place at the Homoeopathic Day Clinic, Technikon Natal and at Dr. Cary's practice. All the cases was repertorised using a Murphy's Homoeopathic Medical Repertory (1993) and the treatment was then checked at the Homoeopathic Day Clinic by qualified clinicians and the medicine was dispensed from the premises. The initial consultation with the respondents to the advertisements was utilized to determine their eligibility in terms of the criteria for admissibility to the study. Criteria for admissibility will be discussed section 3.2.

Each participant was asked to complete an informed consent document (Appendix A) stating that they were participating in the study of their own free will and could withdraw at any time, without obligation. Participants were informed that it was a voluntary study and that it won't cost them anything.

During the initial consultation a full case history (Appendix B) and physical examination was performed. Participants were also requested to complete questionnaires under the researcher's supervision. There were three questionnaires (Appendix C, D, and E) that had to be completed and queries regarding the questions were clarified as the questionnaires were answered. (Questionnaires were completed at the beginning and at the end of the study). Appendix C: the Manning Criteria were only used for diagnostic purposes.

The participants were informed that they would be divided by a random list and that the study was a double – blind study in which an independent party would divide them into a placebo or Homoeopathic Simillimum treatment group.

Creation of the Random List: Each patient received a number on their first visit which corresponded to a number on the random list set up by the independent party. Each of the numbers on the list had a corresponding envelope containing a note that indicated if the patient was to received homocopathic simillimum treatment or placebo treatment. The only person who had access to these envelopes was the independent party. The independent party placed the notes into the envelopes before numbering to ensure that

even they didn't have the knowledge of which patient received which type of treatment.

It was made clear to the participants that they could receive placebo or Homoeopathic Simillimum treatment and that neither they nor the researcher would know which treatment group they were in until the end of the study.

Participants were seen once a month for three months after the first consultation. During the follow-up consultations the researcher would determine if there was an improvement or not and prescribe more medicine for the following month.

At the end of the three months following the start of the treatment all the data for each group was statistically analyzed.

3.2 Subjects

All participants in the study came from advertisements in the daily newspaper and from Dr. Cary's practice. Thirty-six people were accepted to participate in the trial. However only thirty-two completed the study. Since four withdrew during the trial period.

All the participants satisfied the criteria for admissibility to the study, viz. participants had to comply with the *diagnostic criteria*, which consists of clinical findings (obtained by a case history and physical examination) and the Manning Criteria (Talley *et al.* 1990). With the Manning criteria, a participant required a minimum of three symptoms to be accepted.

3.3 Intervention

3.3.1 Homoeopathic Simillimum Treatment

The medicine that was utilized for this group came from a complete homoeopathic dispensary at the Homoeopathic Day Clinic, Technikon Natal. It was prepared in a Laminar flow room under strict control measures by people qualified in homoeopharmaceutics. These medicines were prescribed in granule or pill form, and were taken via the oral route and had to be chewed. These medicines were dispensed as hard lactose granules or pills and were impregnated at a rate of 2% with the chosen Homoeopathic Simillimum remedy.

A research technician according to the prescription set out by the researcher for each participant dispensed each participant's medicine. The research technician was the only person that was allowed to work with the medicine and was the only one that had access to which patient received placebo or homoeopathic simillimum treatment.

Participants were instructed to take the medication as prescribed by the researcher on the bottles of medicine. There was no standardization on potency or time allocation for medicine to be taken as it varied for each individual patient. Times for medicine to be taken varied from once a day, every second day, once or twice per week. Participants had to take the research medication exclusively whilst in the program and were not to alter their lifestyles.

Each participant was given one month's supply of his or her medicine at the start of the

treatment. Participants received more medicine at the follow – up consultations once a month. Participants were only given one-month supply of medicine at a time.

3.3.2 Placebo Treatment

The medicine in this group will look the same as the medicine in the homoeopathic simillimum group with the exception that there are no active ingredients in this medicine. The research technician prepared the placebo medicine in the same way as she prepared the real medicine according to the prescription set out by the researcher but instead of containing the patient's real medicine it contained placebo medicine.

The placebo medicine was in the form of neutral powders, granules or pills, which was prepared from saccharum lactis. All placebos were taken via the oral route. The participants in the same manner took the placebo medicine as with the homoeopathic simillimum treatment. Participants that received the placebo treatment received the correct homoeopathic simillimum treatment at the end of the treatment trial.

3.4 Measurements and Observations

Each participant was supplied with copies of the questionnaires at the beginning and end of the trial for statistical measurements. These were completed in the presence of the researcher.

3.4.1 Short – Form McGill Pain Questionnaire (SF – MPQ)

Melzack developed this questionnaire in 1987 for the measurement of pain. The chief

function of this questionnaire in the research was to ascertain the severity of pain suffered by the participants and their Present Pain Intensities.

The SF – MPQ has 15 descriptors which is ranked on an intensity scale 0 = none, 1 = mild, 2 = moderate, 3 = severe. The sum of the 15 descriptors was taken on a scale from 0 to 45 where 0 = no pain and 45 = the most severe pain. The Present Pain Intensity index was ranked on a scale of 0 = No Pain, 1 = Mild, 2 = Discomforting, 3 = Distressing, 4 = Horrible. The figures from the values at the beginning and the end were compared to indicate the change that took place after trial.

3.4.2 Questionnaire on the Accompanying Symptoms of IBS

The researcher developed this questionnaire for some of the main descriptor symptoms of irritable bowel syndrome. Each of the 18 questions in this questionnaire was graded using a “Semantic Differential Scale” i.e. a scale consisting of five gradings, the highest (5) being the most severe/ negative and the lowest (1) being no symptoms/ positive.

This questionnaire was first pretested before it was completed by the participants at the beginning and the end of the research in the presence of the researcher. The figures from the values of these questionnaires were compared at the end to indicate the change that took place after the trial.

3.4.3 Questionnaire on Manning Criteria for Diagnosis of IBS

The Manning Criteria (consisting of the 6 cardinal symptoms of IBS) was only used for

diagnosing purposes at the start of the research to ascertain whether participants were accepted into the study or not. With these criteria, a participant required a minimum of three symptoms to be accepted into the trial as an IBS patient.

3.5 Statistical procedure

The data obtained from the various questionnaires and observations were statistically analyzed by means of non-parametric statistical tests. The two major non-parametric tests that were used were the: 1. The Mann-Whitney test and; 2. The Wilcoxon's signed rank test. A computer program Statgraphics plus Version 6 were used to statistically analyze the data. (Steyn et al. 1994.)

The Mann – Whitney U test was used to determine the statistical difference between the treatment and placebo groups. The Wilcoxon's signed rank test was used to determine the effectiveness of each group by comparing values from before and after the trial to determine if there was any improvement.

Both the Mann -- Whitney U test and the Wilcoxon's signed rank test was performed at 5 % ($\alpha = 0.05$) level of significance. The null hypothesis stated that there would be no significant difference between the two groups at the end of the study. If the statistical values exceeded 0.05, the null hypothesis was rejected and the alternative hypothesis was accepted (i.e., that a significant difference would exist between the two groups).

CHAPTER FOUR

THE RESULTS

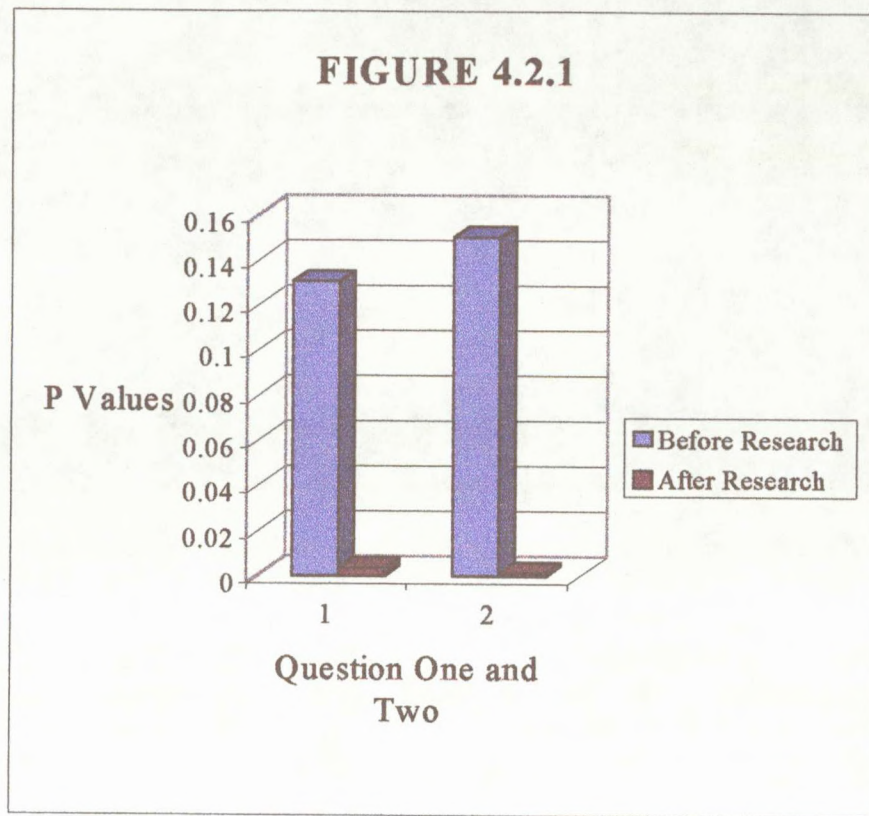
4.1 Introduction

All the data obtained from the case history and questionnaires were used. Two questionnaires were given to each participant to be completed in the presence of the researcher, a set at the beginning, and a set at the end of the research. The individuals were assessed at their first visit by the researcher and if they complied with the *diagnostic criteria*; which consists of clinical findings (obtained by a case history and physical examination) and the Manning Criteria (Talley *et al.* 1990) they were accepted into the study group. With the Manning criteria, a participant required a minimum of three symptoms to be accepted.

4.2 Short – Form McGill Pain Questionnaire (SF – MPQ)

In this questionnaire two questions were used for statistical analyzes at the beginning and end of the trial. Question one contained the 15 options of different pain, which was graded from no pain (nil) to worst possible pain (forty-five). The second question contained five different options of Present Pain Intensity. The lower each participant scored at the end of the study the better was the improvement.

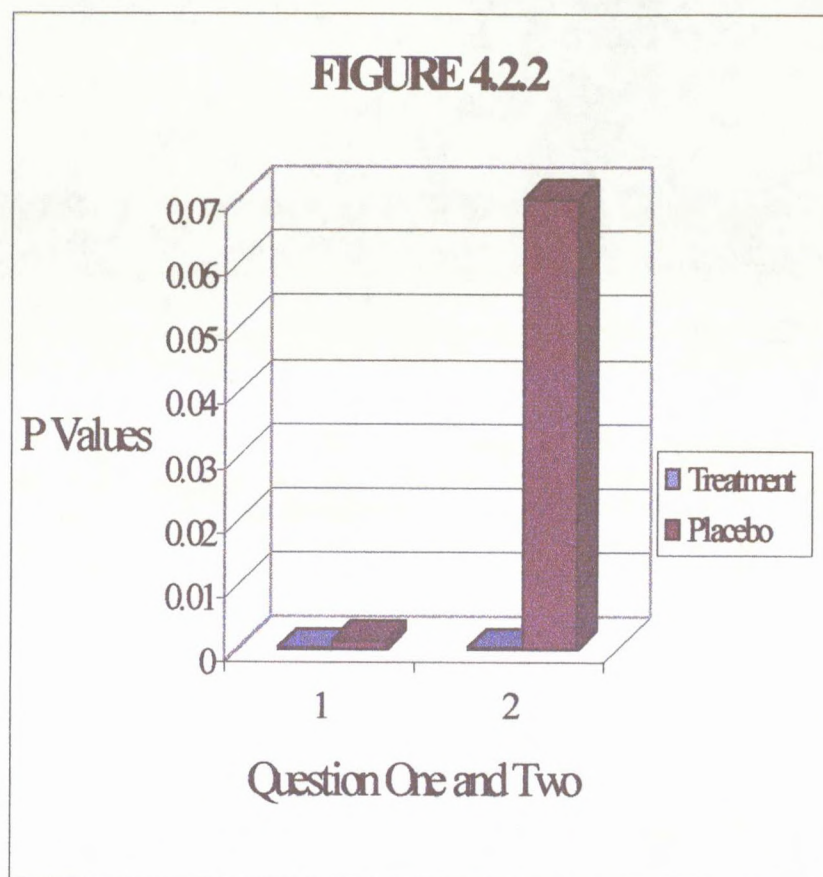
Figure 4.2.1: This figure shows the difference in P values between question ONE and TWO of the SF – MPQ at the beginning and end of the research trial, between the treatment and placebo groups.



On performing the Mann – Whitney Unpaired test (used for unrelated groups i.e. between treatment and placebo group), it was found that there was no significant difference between treatment and placebo groups before treatment commenced in question one and two at the 5 % level of significance. P values were 0.13 for question one and 0.15 for question two.

After the research trial it was found that there was a significant difference between the treatment and placebo groups for question one and two at the 5 % level of significance. P values were 0.003 for question one and 0.0007 for question two.

Figure 4.2.2: This figure shows the difference in P values between question ONE and TWO of the SF – MPQ at the beginning and end of the research trial within the groups.



On performing the Wilcoxon's signed rank test (used for two related groups i.e. within treatment or placebo group), it was found that there was a significant improvement between beginning and end in the research trial for the treatment group in question one and two at the 5 % level of significant. P values were 0.00015 for question one and 0.0002 for question two.

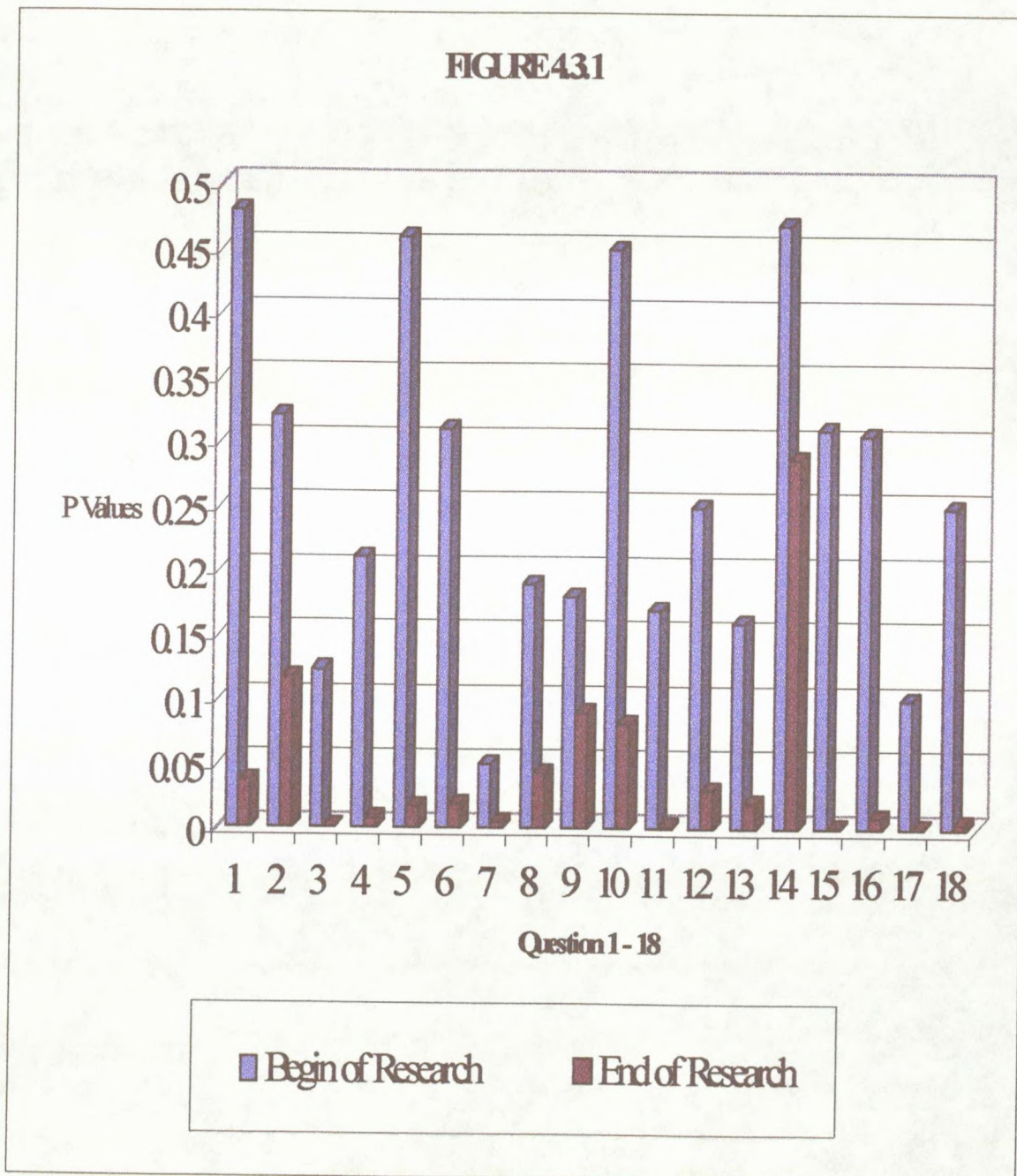
In the Placebo group the null hypothesis was rejected for question one and it was found that there was a significant improvement between beginning and end in the research trial at the 5 % level of significance. For question two the null hypothesis was accepted and it was found that there was no significant improvement between the beginning and end of the research trial at the 5 % level of significance. P values were 0.0013 for question one and 0.07 for question two.

Question one for this questionnaire dealt with the severity of pain each patient suffer with and was made up of the 15 different types of pain in which a level of pain was determined from a rank between 0 (no pain) to 45 (most severe pain). Question two was the present pain intensity of the patient's.

4. 3 Questionnaire on the Accompanying Symptoms of IBS.

This questionnaire was developed for some of the main descriptor symptoms of irritable bowel syndrome. Eighteen questions were used in this questionnaire and they were graded using a "Semantic Differential Scale" i.e. a scale consisting of five gradings, the highest (5) being the most severe/ negative and the lowest (1) being no symptoms/ positive.

Figure 4.3.1: This figure shows the difference in P values between question ONE to EIGHTEEN of the Accompanying Symptom Questionnaire at the beginning and end of the research trial, between the treatment and placebo groups.

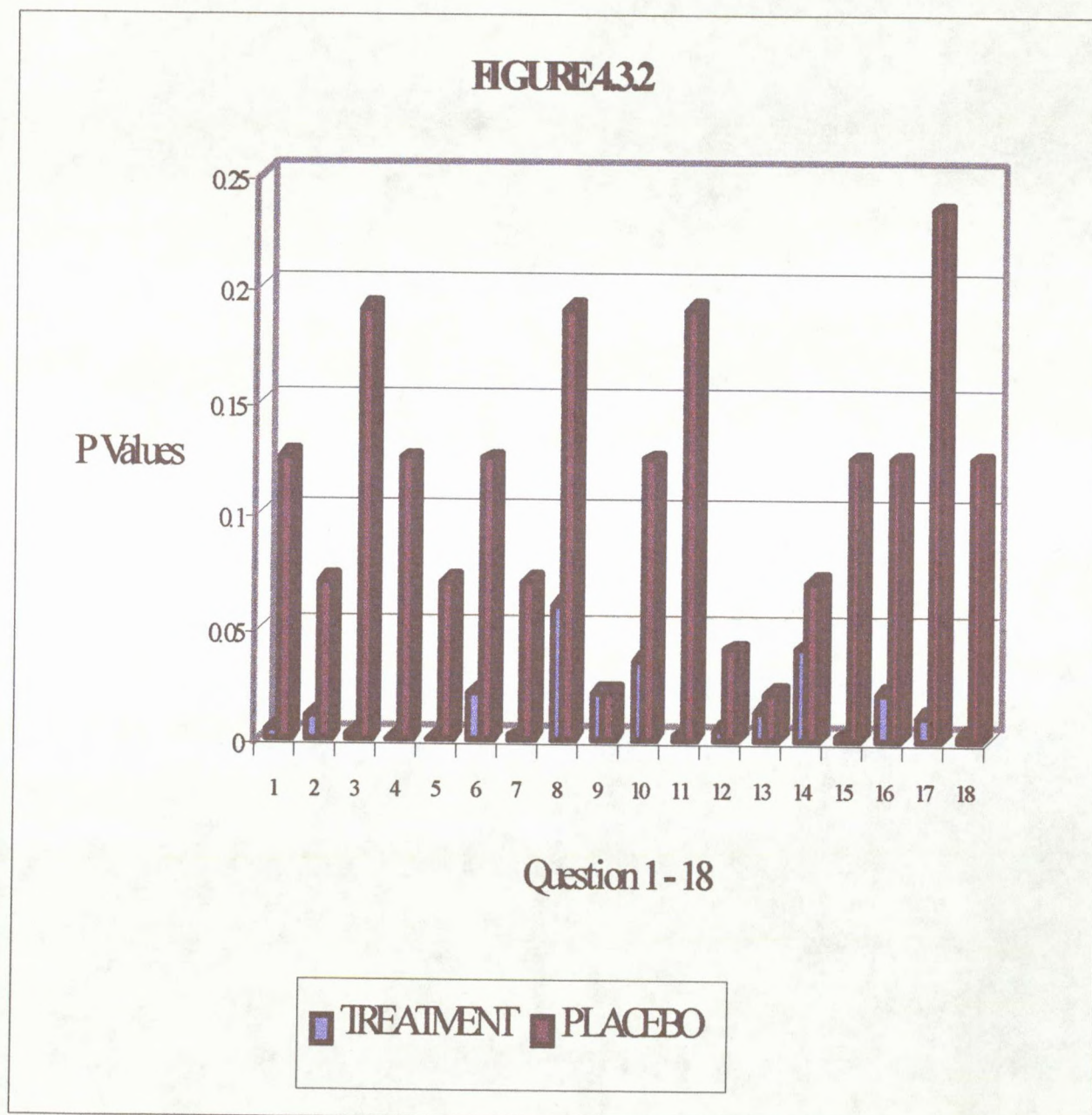


On performing the Mann – Whitney U test at the beginning of the research trial the null hypothesis was accepted for each of the questions of this questionnaire and it was found that there was no significant difference between treatment and placebo groups at the 5 % level of significance. All the P values were equal or higher than the 5 % level of significance. P values varied between 0.05 and 0.483.

After the research trial, with the majority of the questions the null hypothesis was rejected and it was found that there was a significant difference between the treatment and placebo groups at the 5 % level of significance. P values varied between 0.0009 and 0.043. With questions 2 ($P = 0.117$), 9 ($P = 0.09$), 10 ($P = 0.082$) and 14 ($P = 0.287$) the null hypothesis got accepted and it was found that there was no significant difference between the treatment and placebo groups at the 5 % level of significance.

Question two was concerned with if bowel movement was more frequent with onset of pain or not. Question nine dealt with sleeplessness due to abdominal pain. Question ten dealt with sleeplessness due to bowel motion. Question fourteen investigated if participant did experience any weight fluctuation. These question is not readily found in IBS, especially question 9, 10 and 14. The other questions can be found in appendix E at the end.

Figure 4.3.2: This figure shows the difference in P values between question ONE to EIGHTEEN of the Accompanying Symptom Questionnaire at the beginning and end of the research trial, within the groups.



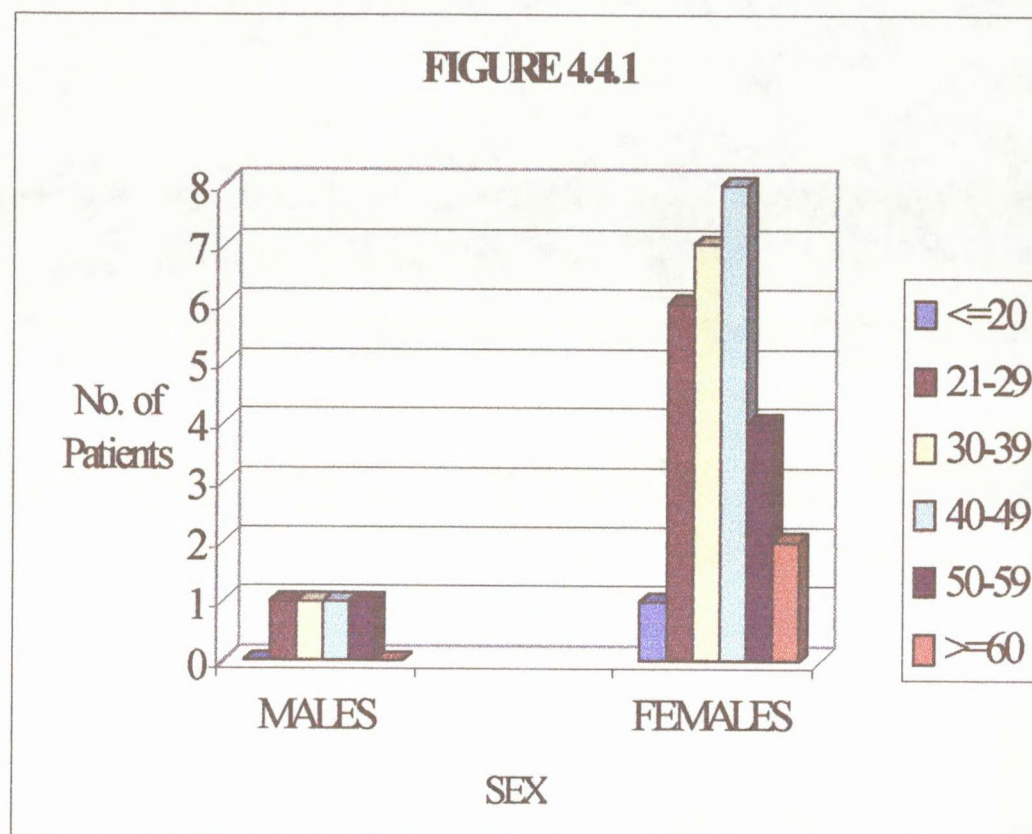
On performing the Wilcoxon's signed rank test it was found that there was a significant improvement between beginning and end in the research trial for the treatment group in question one to eighteen at the 5 % level of significant. P values varied between 0.00025 to 0.04. Only question 8 ($P = 0.06$) did not show a significant improvement at the end of the research trial at a 5 % level of significance. Question eight dealt with bowel motions before breakfast.

In the Placebo group the null hypothesis was accepted for the majority of questions and it was found that there was no significant improvement between beginning and end in the research trial at the 5 % level of significance. P values varied between 0.07 and 0.235. For question 9 ($P = 0.02$), 12 ($P = 0.04$) and 13 ($P = 0.02$) the null hypothesis got rejected and it was found that there was a significant improvement between the beginning and end of the research trail at the 5 % level of significance.

Question 9 dealt with sleeplessness due to abdominal pain, question 12 dealt with pain eased with flatus (passing gas) and question 13 dealt with stools being hard and small (pellet - like). The rest of the questions can be seen at end in appendix E.

4.4 Other Data collected during the study

Figure 4.4.1: This figure shows the sex and age differences within the research trial.



It was indicated through this figure that the majority of patients suffering from IBS is young to middle aged females. From the 32 participants the research 28 (87.5 %) was female and 4 (12.5 %) was male.

Table 4.4.1: This table summaries the patient profile including remedies

TABLE 4.4.1		
<u>Patient profile for Treatment and Placebo groups</u>		
<u>REMEDY</u>	<u>Treatment group</u>	<u>Placebo group</u>
Argentum Nitricum	1	2
Calcarea Carbonica	1	2
Carcinosin	0	1
Gelsemium	0	1
Graphites	1	0
Ignatia Amara	1	0
Lycopodium	3	2
Magnesia Phosphorica	1	0
Nux Vomica	2	1
Pulsatilla Nigra	1	2
Plumbum Metallicum	1	0
Sepia Officinalis	2	4
Silicea	1	0
Thuja Occidentalis	1	1

This patient profile indicate that the most popular remedies used was Lycopodium Calvatum (5 patients) and Sepia Officinalis (6 patients). Other remedies that was commonly coming up was Argentum Nitricum (3 patients), Calcarea Carbonica (3 patients) and Nux Vomica (3 patients).

Table 4.4.2: This is a summary of the summary statistics at the beginning of the treatment of question 1 and 2 of the SF – MPQ and of question 1 to 18 of the Accompanying Symptoms Questionnaire.

SUMMARY STATISTICS AT THE BEGINNING OF TREATMENT.										
<u>TREATMENT</u>						<u>PLACEBO</u>				
Ques. No.	Average	Median	Mode	Standard error	Coeff. Of Variation	Average	Median	Mode	Standard error	Coeff. Of Variation
1	10.75	7	7	1.8154	67.5514	14.94	15.5	7	2.3848	63.8606
2	2.69	3	2	0.1760	26.2010	2.38	2	2	0.2016	33.9463
1	2.63	3	3	0.3146	47.9355	2.75	2.5	1	0.4330	62.9837
2	2.56	3	3	0.2577	40.2254	2.5	2	1	0.4183	66.9328
3	2.94	3	3	0.3590	48.8899	3.56	3	3	0.3287	36.9116
4	4.06	4	5	0.2134	21.0194	3.5	3.5	5	0.3873	44.2626
5	3.88	3.5	3	0.2394	24.7077	3.69	4.5	5	0.3843	41.6825
6	1.81	1	1	0.3191	70.4214	2.06	1	1	0.3350	64.9793
7	3.31	3.5	4	0.2988	36.0899	3.88	4	4	0.3146	32.4724
8	1.94	1	1	0.3472	71.6875	2.31	2	1	0.3949	68.3166
9	1.81	1	1	0.2772	61.1684	2.13	2	1	0.2720	51.1911
10	1.56	1	1	0.2409	61.6917	1.44	1	1	0.1818	50.6044
11	2.56	2.5	2	0.2882	44.9910	3	3.5	4	0.3651	48.6865
12	2.75	2.5	2	0.3594	52.2760	3.13	3.5	4	0.3520	45.0659
13	2.06	1.5	1	0.3472	67.3428	2.56	2	1	0.3760	58.6990
14	1.63	1	1	0.2212	54.4653	2.69	1	1	0.2536	60.1172
15	3	3	1	0.3979	53.0548	3.31	4	4	0.3732	45.0729
16	2	1	1	0.3416	68.3130	2.19	2	1	0.3319	60.6899
17	1.75	1	1	0.2500	57.1429	2.25	2	1	0.2958	52.5874
18	3.75	4	4	0.2661	28.3888	3.94	4	5	0.3091	31.4056

Table 4.4.3: This is a summary of the summary statistics at the end of the treatment of question 1 and 2 of the SF – MPQ and of question 1 to 18 of the Accompanying Symptoms Questionnaire

<u>SUMMARY STATISTICS AT THE END OF TREATMENT.</u>										
<u>TREATMENT</u>						<u>PLACEBO</u>				
Ques. No.	Average	Median	Mode	Standard error	Coeff. Of Variation	Average	Median	Mode	Standard error	Coeff. Of Variation
1	2	0.5	0	0.6831	136.62	8.81	7	0	1.9983	90.7062
2	0.56	0	0	0.1818	129.32	1.88	2	2	0.2868	61.1979
1	1.5	1	1	0.2738	73.0297	2.38	1.5	1	0.4069	68.5424
2	1.45	1	1	0.2409	67.0562	2	1	1	0.3764	75.2773
3	1.56	1	1	0.3158	80.8488	3.19	3	3	0.3788	47.5357
4	1.69	1	1	0.2846	67.4576	3.06	3	5	0.4229	55.2455
5	1.81	1.5	1	0.2771	61.1684	3.25	3.5	5	0.4518	55.6120
6	1	1	1	0	0	1.63	1	1	0.3010	74.1021
7	1.88	1	1	0.3276	69.8782	3.38	4	4	0.386	45.7424
8	1.375	1	1	0.2719	79.1135	1.88	1	1	0.3400	72.5411
9	1.188	1	1	0.188	63.1579	1.38	1	1	0.1797	52.2760
10	1	1	1	0	0	1.18	1	1	0.1360	45.8025
11	1.38	1	1	0.2561	74.5232	2.75	3	1	0.3476	50.5615
12	1.69	1	1	0.3381	80.1461	2.63	3	1	0.375	57.1429
13	1.13	1	1	0.125	44.4444	1.81	1	1	0.3318	73.2464
14	1.13	1	1	0.125	44.4444	1.25	1	1	0.1707	54.6504
15	1.38	1	1	0.1797	52.2760	3	3.5	1	0.3979	53.0548
16	1.13	1	1	0.0854	30.3613	1.81	1.5	1	0.2453	54.1280
17	1.13	1	1	0.0854	30.3613	2.13	2	1	0.2719	51.1911
18	2.06	2	2	0.2321	45.0283	3.375	3.5	5	0.375	44.4444

CHAPTER FIVE

DISCUSSION

This study was designed to evaluate the efficacy of homoeopathic simillimum treatment in Irritable Bowel Syndrome patients in terms of patient perception and clinical findings.

IBS is seen as a chronic syndrome complex of sensory and motor disorders affecting the colon and other areas of the gastrointestinal system (Kelley 1997: 708). The questions in the two questionnaires covered the majority of the symptom complexes to indicate how poor the quality of life of these patients really are and the changes that occurred in the patients during the research trial.

Abdominal pain of colonic origin and an altered bowel habit are the hallmarks of this syndrome. Symptoms are intermittent with variable periods of remission. (Bennett and Plum 1996: 686.) Question one and two of the SF – MPQ concentrated on the type and severity of pain the participants suffered and it was found that there was no significant difference between the treatment and placebo groups at the beginning of treatment trial. At the end of the research trial it was clearly indicate that there was a significant difference between the treatment and placebo groups in these two questions.

At the end of the research trial there was a significant improvement within the treatment group when values was compared between the beginning and end. With question one of the SF – MPQ in the placebo group it was found that there was a significant improvement after the research trial. In question two of the SF – MPQ in the placebo group it was found that there was no significant improvement at the end of the research trial.

Looking at these changes that occurred in the SF – MPQ after the patients got treated with there respective Homoeopathic Simillimum treatment was it clear that there was a significant difference and improvement in the severity of pain in patients suffering from Irritable Bowel Syndrome.

The majority of patients continue to have persistent symptoms several years after the original diagnosis (Bonis and Norton 1996). These persistent symptoms include irregular patterns of defecation, altered stool characteristics and bloating with a feeling of abdominal distention (Rakel 1996: 247). Using a questionnaire for the Accompanying Symptoms of IBS, which covers the major symptoms it was possible to indicate the changes that can occur using homoeopathic treatment.

With question one to eighteen of the Accompanying Symptom Questionnaire it was found that there was no significant difference between the treatment and placebo groups at the beginning of treatment trial. At the end of the research trial it was found that with the majority of the question there was a significant difference between the treatment and placebo groups. Thus, from this was concluded that there was a significant difference in patients suffering from IBS if they got treated with homoeopathic simillimum treatment compared to the patients that received the placebo treatment.

When these eighteen question was tested within the treatment group all the question showed that there was a significant improvement after the research trial had ended except for one question in which no significant improvement was found. Thus indicating that

there was a significant improvement in patients suffering from IBS symptoms after they got treated with the correct homoeopathic simillimum treatment.

Testing these eighteen questions within the placebo group showed that there was no significant improvement after the research had ended except for three questions which are not commonly found in IBS. Except for two or three patients in this group the majority of patients showed no improvement in their suffering of IBS after they got treated with placebo treatment.

Drugs are unproved in the treatment of IBS, but certain agents may benefit specific symptoms and the use of placebo response can be an advantage (Thompson and Nick 1996). In the treatment group it was shown that there was a significant improvement from the beginning to the end of the research trial compared to the placebo group that did not show a significant improvement at the end.

The majority of the patients suffering with IBS are young or middle – aged adults. There is a 4: 1 ratio for female – to – male (Isselbacher et al. 1994: 1421). From the 32 participants in the research 28 (87.5 %) were female and 4 (12.5 %) were male (7: 1).

IBS is not a life – threatening illness but causes a great deal of distress to the individuals suffering with it, symptoms can vary from mild to incapacitating (Isselbacher et al. 1994: 1421). There is no cure for the disease but only a number of treatments that can relieve the symptoms (Zietsman 1997). In this study the homoeopathic simillimum treatment has

shown that it can make an significant change in the life's of patients suffering from IBS.

If the study was to be reproduced a larger group of participants must be considered and more attention must be put on dietary aggravations and food intolerance especially lactose intolerance. There is a high prevalence of lactose malabsorption in IBS due to fact that lactose malabsorption may induce abdominal symptoms indistinguishable from those of IBS. Thus a test for diagnosing lactose malabsorption must be included in the diagnostic workup for IBS. (Vernia et al. 1995.) It must also be suggested to the patients that they must seek psychological help if there are lots of emotional upset and grief.

6.1 Conclusion

IBS is usually a mild annoyance but for some people it can be disabling. It is this latter group that are too afraid to go to dinner parties, seek employment, or travel on public transport. (Rees and Willey 1993: 331.)

This research attempted to evaluate the efficacy of Homoeopathic Smillimum Treatment compared to placebo treatment in Irritable Bowel Syndrome patients in terms of the patient's perception and clinical findings by the researcher.

No significant differences were found at the start of the research between the treatment and placebo groups according to the questions from the two questionnaires on patient perception of the problem and clinical findings by the researcher.

A statistically significant improvement was observed at the end of the research trial when the homoeopathic treatment was compared to the placebo treatment with regard to patient's perception and clinical findings. With a reduction in severity of symptoms in the questionnaires in the treatment group between the beginning and end of the research trial suggested an improvement in IBS related suffering.

Thus the Homoeopathic Simillimum Treatment may be considered to be an effective method of treatment for the symptoms and problems related around IBS.

6.2 Recommendations

As it is difficult to avoid all aggravating factors in the modern life we live in it is necessary to try and determine these aggravating factors and try to avoid them or to learn to cope better with them. Since it is almost impossible to avoid everyday stress, emotional upset and food it is recommended that patient's learn what aggravates them and to try and avoid these factors.

It is recommended for future studies that food allergies and intolerance must be incorporated and treated accordingly and in conjunction with the recommended homoeopathic simillimum treatment. It can also be recommended that patients seek psychological advice and help if it is indicated especially if there is a long history of psychosocial stress and emotional upset.

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APPENDICES

APPENDIX A

INFORMED CONSENT FORM

(To be completed in duplicate by patient/subject*)

* Delete whichever is not applicable.

TITLE OF RESEARCH PROJECT

The effect of Homoeopathic Simillimum

Treatment on Irritable Bowel Syndrome Sufferers

NAME OF SUPERVISOR

Prof. A. E. Simjee

NAME OF RESEARCH STUDENT

Mr. W. M. Rademan

PLEASE CIRCLE THE APPROPRIATE ANSWER

1. Have you read the information sheet?
YES/NO
2. Have you had an opportunity to ask questions regarding this study? YES/NO
3. Have you received satisfactory answers to your questions? YES/NO
4. Have you had an opportunity to discuss this study? YES/NO
5. Have you received enough information about this study? YES/NO
6. Who have you spoken-to? _____
7. Do you understand the implication of your involvement in this study? YES/NO
8. Do you understand that you are free to withdraw from this study? YES/NO
 - a) at any time
 - b) without having to give a reason for withdrawing, and
 - c) without affecting your future health care.
9. Do you agree to voluntarily participate in this study? YES/NO

PATIENT/SUBJECT* Name _____
(in block letters)

Signature _____

PARENT/GUARDIAN* Name _____
(in block letters)

Signature _____

WITNESS Name _____
(in block letters)

Signature _____

RESEARCH STUDENT Name WIM RADEMAN
(in block letters)

Signature _____

APPENDIX B

PATIENT CASE HISTORY

GENERAL:

Name: _____ Date: _____

Address: _____

DOB: _____ Age: _____

Phone No.: (H) _____ (W) _____

Occupation: _____

PAST MEDICAL HISTORY:

1. Have you ever had any serious medical problems?
2. Have you ever been in hospital and for what?

CURRENT HEALTH STATES:

1. Do you suffer from any allergies?
2. Are you taking any medication at present?
3. Do you smoke?
4. Do you drink any form of alcohol?

FAMILY HISTORY:

1. Are your parents alive?
2. Did/ Do any of them have any medical problems?
3. Any medical problems in the rest of the family?
4. Do you have any children, and are they all healthy?

MAIN COMPLAINT:

Onset:

Duration:

Etiology:

Characters:

Modalities:

Previous diagnoses and When:

What was done to determine the diagnoses:

All features concerning the main complaint (Gastrointestinal tract) must be covered in this section and must not be dealt with in the systems review:

- Type of pain, location of pain, aggravating and relieving factors, and associated symptoms
- Bowel action: - Constipated

- Diarrhea
 - Alternation between Constipation and Diarrhea
- Stool character and quantity.
- Rectum: Passage of mucus
Incomplete evacuation
- Bloating (Distention) with winds or not.
- Are symptoms worse with periods of stress.
- What aggravates or relieves the symptoms of IBS.
- Diet (cravings and aversions).

SYSTEM REVIEW.

- General:
(Usual weight, Recent LOW, Weakness, Fatigue, Fever)
- Skin:
(Any eruption, rashes, growths or changes)
- Head:
(Headaches, Vertigo)
- Eyes:
(Any vision problems, pain, redness, cataracts)
- Ears:
(Hearing problems, Tinnitus, Discharge)
- Nose:
(Hayfever, Nose bleeds, Sinus troubles)
- Mouth and Throat:
(Frequent sore throat, Bleeding gums, Ulcers)
- Neck:
(Pain, Stiffness or swollen glands)
- Respiratory system:
(Asthma, Emphysema, Tuberculosis, Pneumonia, Wheezing, Cough, Sputum)
- Cardiac system:
(Chest pain, Heart problems, Hypertension, Rheumatic fever, Murmurs, Palpitations, Dyspnoea at times of day, Edema)
- Gastrointestinal system:
(Covered in M.C.)

- Kidney and Urinary system:
(Cystitis, Burning on urination, Polyuria, Nocturia, Haematuria, Incontinence, Pyelonephritis, Stones)
- Genitoreproduction system:
(Male: Strength of urine stream, Pain in testicles, Erection strength, Libido, History of venereal diseases)
(Female: Period duration, Discharges, PMT, Breast tenderness before period, Number of Children, Hysterectomy, Menopausal, History of venereal diseases)
- Peripheral vascular system:
(Leg cramps, Varicose veins, Intermittent claudication, Thrombophlebitis)
- Musculoskeletal system:
(Muscular and joint pain, stiffness, Arthritis, Gout, Backache)
- Neurological system:
(Fainting, Blackouts, Seizures, Weakness, Paralysis, Numbness, Tingling)
- Endocrine system:
(Thyroid trouble, Diabetes, or other)
- Psychiatric:
(Nervousness, Tension, Depression, Memory loss)

Additional Homoeopathic Questions:

- Mind:
(Sleep/Dreams, Fears, Anxiety, Memory)
- Emotions:
(Moods, Depression, Anger)
- Physical:
(Best times of day, Modalities: Cold/ Warmth, Inside/ Outside, Touch, Movement/ Rest, Humidity/ Dryness, Thirsty/ Not Thirsty, Seaside/ Inland, Consolation/ No Consolation, Morning upon waking, After meals, Winter/ Summer, Strong Pressure, Dark).

ON EXAMINATION:

Vital Signs:

Blood Pressure:

Pulse:

Respiration Rate:

Temperature:

Weight:

(Observe the patients posture, gait, dress, grooming, and personal hygiene. Facial expressions, reaction to things in the environment. Listen to patient's speech, note state of awareness and level of consciousness.)

Gastrointestinal Exam:

Do a complete and thorough examination on the entire GIT. (Inspection, Palpation, Percussion, Auscultation.)

General Examination:

Do a quick but thorough examination of all the systems of the body to make sure that there are no other abnormalities.

APPENDIX C

MANNING CRITERIA FOR DIAGNOSING IBS.

Patient's Name:

Date:

Symptoms:

YES NO

1. Is the pain relieved with defecation?
2. Is the onset of pain associated with more frequent defecation?
3. Is the onset of pain associated with looser stools?
4. Is there distention of the abdomen?
5. Is there rectal dissatisfaction (feeling of incomplete evacuation)?
6. Is there passage of mucus per rectum?

Total no. of yeas out of six /6

Total no. of no's out of six /6

APPENDIX D

SHORT-FORM McGill PAIN QUESTIONNAIRE
RONALD MELZACK

PATIENT NAME:

DATE:

	<u>None</u> (0)	<u>Mild</u> (1)	<u>Moderate</u> (2)	<u>Severe</u> (3)
1. THROBBING				
2. SHOOTING				
3. STABBING				
4. SHARP				
5. CRAMPING				
6. GNAWING				
7. HOT-BURNING				
8. ACHING				
9. HEAVY				
10. TENDER				
11. SPLITTING				
12. TIRING-EXHAUSTING				
13. SICKING				
14. FEARFUL				
15. PUNISHING-CRUEL				

NO PAIN | _____ | WORST POSSIBLE PAIN

PPI

- 0 No Pain -----
- 1 Mild -----
- 2 Discomforting -----
- 3 Distressing -----
- 4 Horrible -----
- 5 Excruciating -----

APPENDIX E

ACCOMPANYING SYMPTOM QUESTIONNAIRE.

Each question in this section is graded, using a "Semantic Differential Scale" i.e. a scale consisting of five gradings, the highest (5) being the most severe/negative.

Place a cross over the number that best describes how you feel.

- | | | | | | | | |
|--|--------|-------|-------|-------|-------|-------|--------|
| 1. Is the stool looser with onset of pain? | always | | | | | | never? |
| | | 5 | 4 | 3 | 2 | 1 | |
| 2. Is the bowel movement more frequent with onset of pain? | always | | | | | | never? |
| | | 5 | 4 | 3 | 2 | 1 | |
| 3. Is the pain eased after a bowel movement? | always | | | | | | never? |
| | | 5 | 4 | 3 | 2 | 1 | |
| 4. Do you experience visible distention of the abdomen? | always | | | | | | never? |
| | | 5 | 4 | 3 | 2 | 1 | |
| 5. Do you experience a feeling of distention? | always | | | | | | never? |
| | | 5 | 4 | 3 | 2 | 1 | |
| 6. Do you pass mucus per rectum? | always | | | | | | never? |
| | | 5 | 4 | 3 | 2 | 1 | |
| 7. Do you experience a feeling of incomplete emptying? | always | | | | | | never? |
| | | 5 | 4 | 3 | 2 | 1 | |
| 8. Is there bowel motion before breakfast? | always | | | | | | never? |
| | | 5 | 4 | 3 | 2 | 1 | |
| 9. Do the abdominal pain awake you? | always | | | | | | never? |
| | | 5 | 4 | 3 | 2 | 1 | |
| 10. Does the bowel motion awake you? | always | | | | | | never? |
| | | 5 | 4 | 3 | 2 | 1 | |
| 11. Do you experience urgency defecation? | always | | | | | | never? |
| | | 5 | 4 | 3 | 2 | 1 | |
| 12. Is the pain eased with flatus (passing gas)? | always | | | | | | never? |
| | | 5 | 4 | 3 | 2 | 1 | |
| 13. Is the stool hard and small (pellet-like)? | always | | | | | | never? |
| | | 5 | 4 | 3 | 2 | 1 | |
| 14. Do you experience any weight fluctuation? | always | | | | | | never? |
| | | 5 | 4 | 3 | 2 | 1 | |
| 15. Do you experience any constipation? | always | | | | | | never? |
| | | 5 | 4 | 3 | 2 | 1 | |

16. Do you experience
diarrhea?

always never?
5 4 3 2 1

17. Does your constipation
alternate with diarrhea?

always never?
5 4 3 2 1

18. Are your symptoms
worse with periods
of stress?

always never?
5 4 3 2 1