THE EFFICACY OF A HOMOEOPATHIC COMPLEX *(CARBO VEGETABILIS* D9, *LYCOPODIUM CLAVATUM* D9, *NUX VOMICA* D9 AND *ROBINIA PSEUDOACACIA* D9) IN THE TREATMENT OF FUNCTIONAL DYSPEPSIA.

By:

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I, Erosha Surjoodeen, declare that this dissertation represents my own work in both conception and execution.

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AUM

SARASWATI NAMASTUBHYUM, VARADE KAMARUPINI

VIDYA RAMBHAM KARISHYAMI SIDDHIR BHAVATU ME SADA

MY SALUTATIONS TO YOU, MOTHER SARASWATI, THE GIVER OF BOONS ASSUMING DIFFERENT FORMS. BY YOUR WILL, I BEGIN THE PROCESS OF LEARNING. LET MY EFFORTS BE CROWNED WITH SUCCESS.

DEDICATION

I DEDICATE THIS DISSERTATION TO THE MOST INCREDIBLE WOMAN I KNOW, MY MOTHER, KAMLA.

THANK YOU FOR ALWAYS BELIEVING IN ME.

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ABSTRACT

The purpose of this placebo controlled study was to evaluate the efficacy of a homoeopathic complex (*Carbo Vegetabilis* D9, *Lycopodium clavatum* D9, *Nux Vomica* D9 and *Robinia Pseudoacacia* D9) in the treatment of patients suffering from functional dyspepsia; in terms of the patient's perception of the treatment. It was hypothesized that the patients treated with the complex would respond favorably in terms of the symptoms associated with dyspepsia.

In this experimental study the single variable design was used for its 'before and after with control'. Thirty patients with functional dyspepsia were selected after been screened according to diagnostic criteria identified by the researcher. These patients were divided into two groups according to simple random sampling. Data was collected at the Homoeopathic Day Clinic at the Durban University of Technology.

Group one received the homoeopathic complex and group two received a placebo complex. Patients received treatment over a period of six weeks (three consultations).

The patients, during each consultation, in the presence of the researcher, completed the Patient Perception Questionnaire.

Results were statistically analysed using the FriedmansTest (inter group comparison) and The Wilcoxon signed Rank Test (intra group comparison). When the three questionnaires for each patient were compared it was found that neither the placebo group, nor the experimental group yielded significant improvement. Therefore the results of this clinical trial demonstrated that this homoeopathic complex is not effective in the treatment of functional dyspepsia, when compared to placebo, in terms of patient perception.

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DEFINITION OF TERMS

Allopathic: A term, loosely applied to the practice of mainstream (orthodox) Medicine (Gaier,1991).

Barrett's oesophagus: Often associated in patients with recurrent reflux. This causes a change in the oesophageal epithelium from squamous to columnar histology. In 2-5% of cases this leads to the development of adenocarcinoma (McPhee,Ganong, 2006).

Centesimal scale (C): A method of potentising based on the principal that the first potency should contain one-hundredth part of the base drug and each succeeding potency should contain one-hundredth of the one immediately preceding. Centesimal potencies are denoted by suffixing "C" to the numerals denoting the deconcentration stage of the drug (Gaier, 1991).

Decimal scale (D): A method of potentising based on the principal that the first potency should contain one-tenth part of the base drug and each succeeding potency should contain one-tenth part of the one immediately preceding. Decimal potencies are denoted by suffixing"D" to the numerals denoting the deconcentration stage of the drug (Gaier, 1991).

Duodenal ulcers: Lesions in the duodeum, often caused by *Helicobacter pylori* infection (McPhee,Ganong, 2006).

Dyspepsia: This can be defined as a pain or discomfort in the upper abdomen and chest and is often described as having gas, a feeling of fullness or a gnawing or burning pain. It is also referred to as indigestion or heartburn and is accompanied by symptoms which include nausea, regurgitation, vomiting, prolonged abdominal fullness or bloating after a meal (Berkow, Beers, 1999).

Dysphagia: Difficulty in swallowing (Dorland's, 1998).

Dyskinesia: Impairment of power of voluntary movement, resulting in fragmentary or incomplete movements (Dorland's, 1998).

Heartburn: A burning, retrosternal discomfort that is related to meals, lying down, stooping and straining, and is relieved by antacids (Longmore et al, 2001).

Homoeopathy: The medical art and science developed by Samuel Hahnemann, which is based upon the cure of the totality of symptoms in disease by means of medicines and treatments capable of producing symptoms in a healthy individual which are similar to those of the disease itself (O'Reilly, 1996).

Homoeopathic Complex: A homeopathic preparation containing more than one medicinal substance (Gaier, 1991).

Gastrin: A poypeptide hormone released from G cells in the gastric antrum during digestion. Gastrin binds to Cholescystokinin Type B receptors on parietal cells to stimulate H^+ (hydrogen) ion secretion (McPhee,Ganong, 2006).

Gastritis: Inflammation of the mucosal layers of the stomach lining (McPhee, Ganong, 2006).

Gastric ulcers: Lesions penetrating through the mucosal layers of the stomach which usually occurs on the lesser curvature of the stomach (McPhee,Ganong, 2006).

Haematemesis: The vomiting of blood (Dorland's, 1998).

Helicobacter pylori: An organism which colonises the human acid-secreting stomach. It is the causative agent in gastric and duodenal ulcers, gastritis and has been linked to gastric cancer (McPhee,Ganong, 2006).

Hypergastrineamia: The presence of excess gastrin in the blood (Dorland's, 1998).

Materia Medica: Contents of a reference book containing all the necessary information on the proper use of medicines. Deals with the origin, composition properties, and also the classification and reference source of medicinal agents. These properties also include physical, chemical and biological, where appropriate, and toxicological characters of a drug as well as its reactive propensity as a homoeopathic therapeutic agent (Gaier, 1991).

Meleana: The passage of dark, pitchy, and grumous stools stained with blood pigments or with altered blood (Dorland's, 1998).

Non-steroidal anti-inflammatory: A group of drugs often implicated in the cause of dyspepsia, gastric ulceration and gastritis (McPhee, Ganong, 2006).

Odynophagia: Pain on swallowing (Dorland's, 1998).

Placebo: refers to a medical treatment, which has no specific medicinal activity and is just a dummy (Drake, 2004).

Potency: The word "potency" has the connotation of power. The nearest analogy would be "strength." Potency in many ways is the homoeopathic equivalent to dosage (Leckridge, 1997).

Potentisation: A multi-step process (involving dilution and succession or trituration) by which the inner medicinal power of a crude substance is released (O'Reilly, 1996).

Prokinetic drugs: a group of drugs commonly used in the treatment of gastro-esophageal reflux disease and dyspepsia. Examples include metaclopromide and cisapride (Snyman, Pope, 1998).

Proving: A controlled experiment, in which a medicine is administered to a healthy individual to ascertain what changes (signs, symptoms and behaviour) the medicine induces in the body and mind (O'Reilly, 1996).

Simillimum: the single homoeopathic medicine, or the drug picture of which most nearly approaches the total symptom complex of the patient, which will certainly cure that patient, if that patient's condition is within reversible limits (Gaier, 1991).

Trendelenberg's position: A position in which the patient is supine on the table or bed, the head of which is tilted downward 30 to 40 degrees, and the table or bed angulated (Bates, 2006).

LIST OF ABBREVIATIONS

CCK 1: Cholescystokinin 1 receptor

CCK 2: Cholescystokinin 2 receptor

Cl^{-} ions: Chloride ions

ESR: Erythrocyte sedimentation rate

H^{+} ions: Hydrogen ions

H.pylori*: Helicobacter pylori*

H-K ATPase: Hydrogen – potassium adenosinetriphosphatase

H-2 Receptors: Histamine 2 receptors

K^{+} ions: Potassium ions

NSAIDS: Non-steroidal anti- inflammatories

CHAPTER 1

INTRODUCTION

Dyspepsia can be defined as a pain or discomfort in the upper abdomen and chest and is often described as having gas, a feeling of fullness or a gnawing or burning pain (Mcphee, Ganong, 2006).

Although dyspepsia is often associated with organic disease of the upper alimentary tract such as peptic ulcer disease, oesophagitis and gastric carcinoma there remains a large group of patients who suffer from dyspepsia for which no cause can be found. Such patients are considered to have functional or non-ulcer dyspepsia (Haslett et al, 2002).

As the incidence of both gastric cancer and peptic ulcer disease have declined, that of gastro-oesophageal reflux and non ulcer or functional dyspepsia has become increasingly common, hence giving rise to the need for further research into this phenomenon (Richter, Talley, 2007).

Even though drugs can be used to a certain extent to control symptoms, most have serious side effects and dangers, which must be taken into consideration before prescribing them. Antacids are sometimes helpful, but side effects are

numerous and include constipation, dry mouth, blurry vision and gastro-intestinal disturbances (Borton, 2007).

Prokinetic drugs such as metaclopromide, domperidone are useful. However metaclopromide may induce extra-pyramidal side effects including tardive dyskinesia in younger subjects (Haslett et al, 2002).

A study conducted at the Durban Institute of Technology (formerly Technikon Natal) by Hall (1998) compared the efficacy of homoeopathic simillimum with placebo in the treatment of heartburn in gastro-oesophageal reflux disease. The trial concluded that homoeopathic simillimum is indeed effective in treating heartburn.

In an attempt to expand on the above mentioned results this trial placed emphasis on the treatment of functional dyspepsia and not simply heartburn caused by gastro-oesophageal reflux disease. This trial investigated the efficacy of a homoeopathic complex, which consisted of *Carbo Vegetabilis* (D9), *Lycopodium Clavatum* (D9), *Nux Vomica (*D9) and *Robinia Pseudeacacia* (D9) in the treatment of functional dyspepsia.

Successful homoeopathic treatment should stimulate the body's own defense mechanism to give systemic support to this 'self-healing' effort. As stated by Hahnemann in Aphorism 2 of the Homoeopathic Organon (O'Reilly, 1996), "The

highest ideal of cure is rapid, gentle and permanent restoration of health or the removal and annihilation of the disease in its whole extent, in the shortest, most reliable and most harmless way.

Homoeopathy provides a safe alternative to current trends in the treatment of various medical conditions. There are no harmful side effects and it is a much more economical approach to health care (British Homoeopathic Association, 2006).

The purpose of this placebo controlled study was to determine the efficacy of a homoeopathic complex in the treatment of functional dyspepsia in terms of the patient's perception to treatment with regard to intensity, frequency and duration of the attacks of dyspepsia.

The desired outcome of this clinical trial was for patients in the treatment group to have experienced significant relief from the symptoms of this condition when compared to the placebo group, across all three consultations.

If the treatment group produced results within the hypothesis, then the complex would have indeed been considered successful in the treatment of functional dyspepsia. However, a null hypothesis would have had to be accepted if no significant improvement was noted between the consultations.

CHAPTER 2

REVIEW OF THE RELATED LITERATURE

2.1 INTRODUCTION

It is vital to distinguish between heartburn and functional dyspepsia. Functional dyspepsia can be defined as a pain or discomfort in the upper abdomen and chest and is often described as having gas, a feeling of fullness or a gnawing or burning pain. It is accompanied by symptoms which include nausea, regurgitation, vomiting, prolonged abdominal fullness or bloating after a meal, for all of which no particular cause can be ascertained (Mcphee, Ganong, 2006). Heartburn is defined as a burning, retrosternal discomfort that is related to meals, lying down, stooping and straining, and is relieved by antacids (Longmore et al, 2001).

Dyspepsia is a common complaint affecting all population groups. Frequent doctors visits, expensive diagnostic procedures and unnecessary operations provide a financial drain, often without any long term relief from the symptoms (Richter, Talley, 2007).

As the incidence of both gastric cancer and peptic ulcer disease have declined, that of gastro-oesophageal reflux and non ulcer or functional dyspepsia has

reached epidemic proportions (Richter, Talley 2005). Functional dyspepsia seems to be on the incline in society today, possibly due to lifestyle factors, such as the consumption of highly processed foods, improper dietary habits and alcohol abuse (Sillberg, Sullivan, 2002).

Although dyspepsia can afflict men and women from all walks of life, it is most common in women ranging in the age from 16-60 years.
A woman is more likely to suffer dyspepsia during her child bearing years (Moayyedi et al, 2006). Women are more susceptible to dyspepsia due to pregnancy, poor eating habits and stress (Richter, Talley, 2001).

Sadly enough, the media have tended to trivialise dyspepsia, and patients and their doctors, may not readily seek the origin of such symptoms because they are indeed common – and because they may be interpreted as indicating some perceived misbehaviour on the part of the patient, such as overeating, smoking or being too corpulent (Parker, 2007).

The use of acid suppressive medication, such as histamine type 2 receptor antagonists and proton pump inhibitors, increased dramatically over the past decade. This increase represents a significant cost burden to the health care industry. In South Africa, approximately R460 000 – R540 000 is spent per annum on these medications, alone (van Heerden, 2008). The rapid growth of acid suppression therapy justifies scrutiny of the use of these medications to

ensure appropriate use. Investigators have found that 26% of patients failed to experience relief of symptoms despite chronic therapy (Richter, Talley, 2003).

Acid suppressive therapy, while largely effective, is often required indefinitely as symptoms recur once therapy is discontinued. A proportion of patients' persuing pharmacological treatment will experience intolerable side effects or persistant acidic regurgitation (Bernstein, 2002). This is due to an increase in gastric acid production so often noticed in patients on acid suppressive medication (Wolters, 2005).

If dyspepsia occurs too frequently, it can interfere with the patient's way of life, particularly work involving lying or bending, and pleasure including gardening and sexual intercourse (Richter, Talley 2005).

2.2 AETIOLOGY OF FUNCTIONAL DYSPEPSIA

This study is based on the treatment of functional dyspepsia and excludes dyspepsia caused by gastric cancer, peptic ulcer disease and dyspepsia as a side effect of certain drugs.

Gastro-intestinal disease may be limited to the gastro-intestinal tract (e.g. reflux oesophagitis, peptic ulcers or delayed gastric emptying) or a manifestation of a systemic disorder (e.g. diverticular disease) or present as a systemic disease resulting from a primary gastro-intestinal pathologic process (e.g. vitamin

deficiencies resulting from malabsorption). Different parts of the gastro-intestinal tract are specialised for certain functions, therefore the most prominent causes, consequences and manifestations differ from one anatomical site to another (McPhee, Ganong, 2006).

Helicobacter pylori infection is responsible for almost all cases of gastric disorder, including dyspepsia and gastric ulcers that are not caused by medications, e.g. aspirin like drugs including heparin and warfarin and more commonly non-steroidal anti- inflammatories (Parker, 2007).

Forty percent of all individuals are infected with *helicobacter pylori*. In most cases gastritis is mild and not detectable. In some cases, the gastritis causes inflammation and ulceration (McPhee, Ganong, 2006).

T- Cells actively participate in the immune response to *helicobacter pylori*, hence limiting the immune mediated pathology. This may explain why certain patients do not present with clinical features, despite having a life long presence of the *helicobacter pylori* in the gastric mucosa (Blaser, Atherton, 2004). Bacterial survival may represent a “compromise” achieved by the host with the microbe and may reflect the excellent adaptation of *helicobacter pylori* to humans over thousands of years of co-evolution (Ghose, Perez, 2002).

Enhanced visceral sensitivity refers to increased sensitivity to pain—or a lower threshold for pain—due to stretching or enlargement (distension) of the stomach. Studies have consistently demonstrated visceral hypersensitivity in patients with functional dyspepsia (Longstreth, 2007).

The specific underlying processes that produce the symptoms and signs of functional dyspepsia are unclear. However, researchers have focused on several factors that may have some association with the condition. These include psychological, social, neurological and gut peptide factors (Longstreth, 2007).

Some reports indicate that patients with functional dyspepsia may be affected by certain mood disturbances, such as anxiety or depression, more frequently than those without functional dyspepsia. However, the psychological profile and the tendency to seek medical attention of patients with functional dyspepsia differ among various cultures and geographic regions (Taylor, 2006).

Gut Peptide factors that often contribute to functional dyspepsia are the family of hormones that regulate the gastric epithelial organisation and function which influence the response to food ingestion, via a negative feedback mechanism. Hence any disorder in the gut peptide chain can result in the development of gastric pathology (Silberg, Sullivan, 2002).

CCK1 (cholescystokinin 1) receptors and CCK2 (cholescystokinin 2) receptors located in the hypothalamic nuclei are important factors responsible for proper gastric function. If function of these receptors is inhibited in any way it could lead to the development of functional dyspepsia, and other gastric disease (Spiller, 2006).

2.3 CLINICAL FEATURES

The term dyspepsia includes a wide range of signs and symptoms. Included in the definition is upper abdominal pain which may or may not be related to food, gastro-oesophageal regurgitation and heartburn, anorexia, nausea and vomiting. When vomiting does occur, it does not provide relief from abdominal pain which distinguishes functional dyspepsia from peptic ulcers. Pain from peptic ulcers is often only experienced after meals. This is in combination with early repletion or satiety after meals, abdominal distention or bloating, flatulence (burping, belching) and colonic dysmotility (pellet like stools or a sense of incomplete rectal evacuation) (Sifrim, 2005).

Abdominal pain usually occurs daily, lasts for a significant amount of time and remains unaffected by antacids. Food may cause pain in the abdomen which can very often refer to sites such as the neck and chest. Pain from ulcer dyspepsia is usually more localised and may be relieved by antacids (Haslett et al, 2002).

Gastric and duodenal ulcers cause the same type of pain as functional dyspepsia but the pain is usually localised to the xiphoid and high substernal region. However, the pain is episodic whereas the pain experienced in functional dyspepsia is continous. Therefore it is important to eliminate stomach ulcers as aetiology in such a patient by conducting an endoscopy (Longstreth, 2007).

2.4 PATHOGENESIS

The mechanisms by which parietal cells secrete hydrochloric acid into the stomach have been extensively studied because of the importance of acid secretion in digestion and in disease states. The cell membranes of parietal cells express H-K ATPase (hydrogen-chloride adenosinetriphosphatase), a primary active transporter responsible for the secretion of hydrochloric acid. This H-K ATPase transporter pumps hydrogen ions in exchange for potassium ions across the cell membrane. Hydrochloric acid is then formed when the hydrogen ions combine with chloride ions present in the lumen. Proton pump inhibitors act on this H-K ATPase pump to block the hypersecretion of acid which is responsible for the symptoms of dyspepsia (McPhee, Ganong, 2006).

Gastrin, histamine and acetylcholine are hormones which simulate hydrogen ion secretion thereby increasing the secretion of hydrochloric acid (Longmore, Wilkinson and Torok, 2001).

In addition to the direct mechanisms which these three hormones stimulate hydrochloric acid secretion from parietal cells, acetylcholine and gastrin also indirectly stimulate secretion by acting on enterochromaffin like cells to promote the release of histamine, which then stimulates the parietal cells. Thus an over production of any of these hormones can result in hypersecretion of gastric acid (McPhee, Ganong, 2006).

Helicobacter pylori are an organism that lives in the mucus layer of the stomach. The mucus layer secretes urease which converts urea to carbon dioxide and ammonia. Ammonia buffers the surrounding fluid and protects the organism from acid. *Helicobacter pylori* also secrete proteins which trigger immune responses that damage the mucosa, resulting in gastritis which is responsible for dyspepsia and peptic ulcer disease (Gisalasen, 2007).

Increased sensitivity of the large bowel itself may be responsible for dyspepsia, as demonstrated by upper gastro-intestinal symptoms evoked by colonic distention (Richter, Talley, 2005).

2.5 CLINICAL DIAGNOSIS OF FUNCTIONAL DYSPEPSIA

2.5.1 Diagnostic Techniques

2.5.1.1 History and physical examination

Because there are no definitive tests for functional dyspepsia, the diagnosis is based upon a complete patient history and clinical evaluation. Excluding disorders that can produce similar symptoms is important (Longstreth, 2007).

There are no clear cut signs pointing to the diagnosis on clinical examination, however a physical examination of the patient may reveal epigastric tenderness on abdominal palpation. Some patients may appear anxious and distraught (Haslett et al, 2002).

To confirm a diagnosis of functional dyspepsia, distinguishing features must be recognised:

- pain or discomfort is not episodic but tends to occur daily for long periods of time
- pain may persist throughout the day from morning to night, unaffected by food, antacids or bowel movement; food might provoke pain
- pain is diffuse, described by sweeping movements of the hands over the abdomen, and may be referred to more than one site.
- night pain, waking the patient from sleep is rare
- when vomiting occurs, it brings no relief from pain and the patient cannot eat for hours afterwards (Haslett et al, 2002).

Patients with dyspepsia are often given treatment without performing any specialised investigations (e.g. endoscopy and colonoscopy). Also when these diagnostic procedures are performed, they frequently fail to identify abnormality in as many as 50% of cases (Larsen, 2004).

Because dyspepsia can be an early warning of a serious disease, like gastric cancer, diagnostic procedures are performed in certain cases. These tests will eliminate or confirm possible duodenal ulcers, duodenitis, gastric ulcers, gastric malignancy, gastro-oesophageal reflux disease, peptic ulcers or oesophagitis (Wolters, 2005).

If the dyspepsia continues for more than a few weeks, fails to respond to treatment or is accompanied by weight loss, anemia, vomiting and other unusual symptoms, specialised diagnostic investigations should be done. These tests include complete blood cell counts, tests for blood in stool, barium studies and endoscopy of the oesophagus, stomach and intestine (Talley, 2005).

2.5.1.2 Therapeutic trial

The treatment of a patient with acid suppressive agents and evaluating the response is the only way of confirming the diagnosis. If a patient's symptoms suggest functional dyspepsia, performing therapeutic trials before traditional testing may be more efficacious and more cost effective; primary health care physicians can help offset the cost of referral for majority of patients by learning how to perform a therapeutic trial (Longmore et al, 2001).

2.5.1.3 Barium swallows and X-Rays

X-rays taken with the patient in the trendelenburg position may show reflux of barium from the stomach into the oesophagus which will confirm gastro-oesophageal disease and eliminate the diagnosis of functional dyspepsia (Bates, 2006).

According to Richter, Talley (2007), barium studies have limited usefulness in the analysis of patients with functional dyspepsia.

2.5.1.4 Gastrointestinal Endoscopy

Endoscopy is a direct visual examination of the intestinal tract with a flexible tube containing light transmitting glass fibres or a video transmitter that returns a magnified image. The patient is appropriately positioned and the tip of the endoscope is placed in the hypopharynx. As the patient swallows, the scope is gently guided through the cricopharyngeal muscle (upper oesophageal sphincter) and then advanced under direct vision through the stomach and into the duodenum (Andrews, 2006).

Forgacs (2000) advise endoscopy as the most useful investigation in the majority of cases, especially if the patient's pattern of symptoms indicate that long term treatment may be necessary with any drug more potent than antacids or alignates.

2.5.1.5 Oesophageal Biopsy

Biopsy is an accurate indicator of gastro-oesophageal reflux, showing thinning of the squamous mucosal layer and basilar layer hyperplasia. These histologic changes may occur without evidence of gross oesophagitis by endoscopy. A positive biopsy correlates best with oesophageal symptoms of reflux regardless of endoscopic or x-ray findings. Endoscopic biopsy is also the only test that can consistently detect the columnar mucosal changes of Barrets's metaplasia (Bates, 2006).

2.5.1.6 Blood Tests

According to Longmore et al (2001), blood tests revealing

- Decreased heamoglobin ;
- Increased platelets;
- Raised ESR ;
- Increase in liver function enzymes

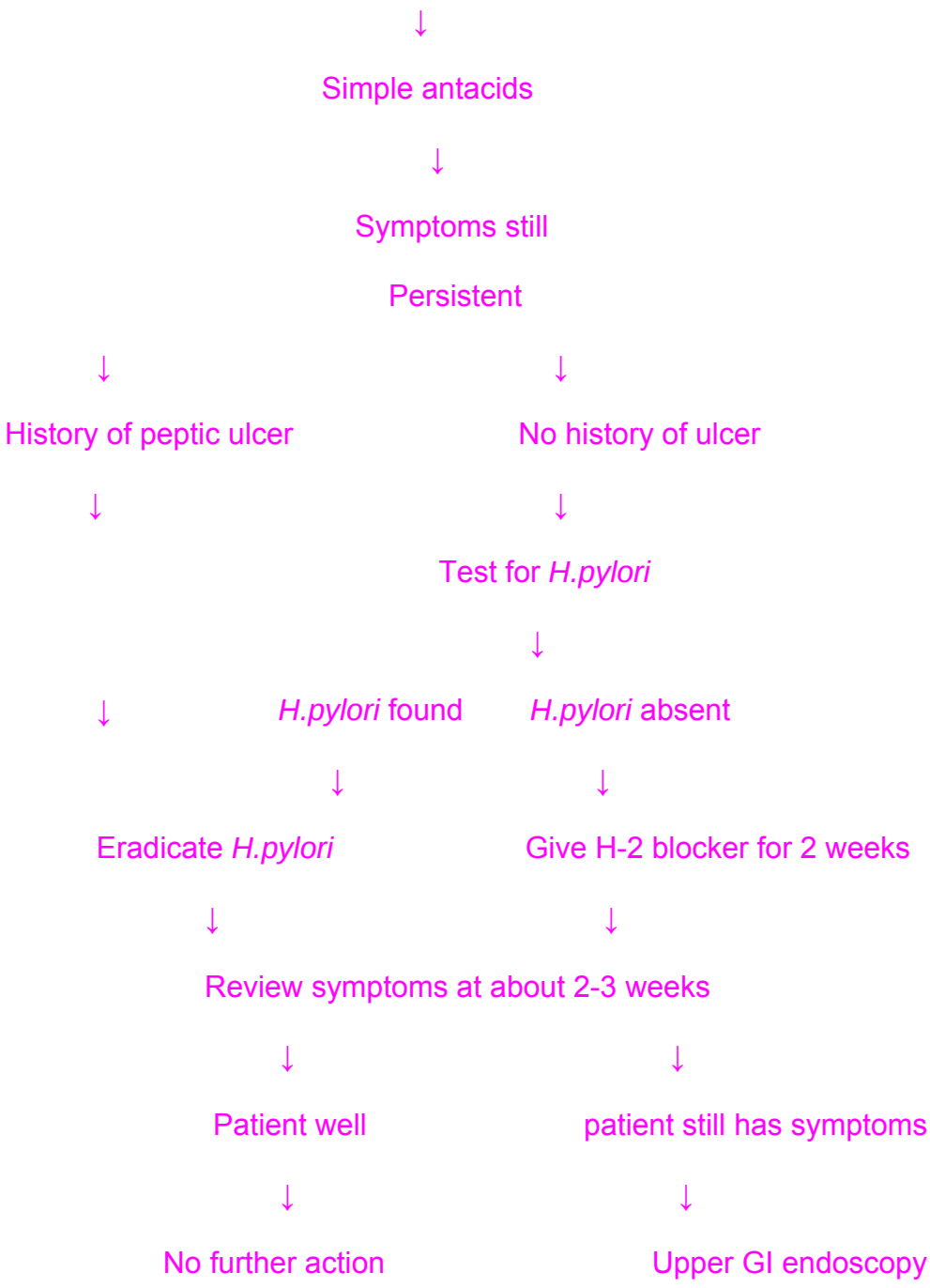
point to an organic cause in patients with dyspepsia and therefore further tests must be carried out to confirm functional dyspepsia.

2.6 MEDICAL TREATMENT

2.6.1 Multiphasic Approach to Treatment

The following table on management of a patient with dyspepsia is adapted from Longmore et al (2001).

Managing dyspepsia in patients ≤45 years not on NSAIDS,with no weight loss, dysphagia, bleeding, repeated vomiting, aneamia, masses, or bowel habit change



The majority of patients with dyspepsia have mild to moderate symptoms, which are treated with the so called phase one measures, discussed below**.**

2.6.1.1 Lifestyle Modification

These simple measures can be an efficacious and cost effective component of management in patients with dyspepsia.

Treatment begins with dietary and lifestyle changes, in conjunction with antacid use. These modifications include things such as weight reduction, elevation of the bed (not just the use of extra pillows), avoidance of alcohol, caffeine, acidic, fatty or spicy foods; even chocolate and carminatives (spearmint and peppermint) because all these foods have adverse effects on lower esophageal sphincter pressure. Another simple but important precaution is to refrain from overeating and to eat dinner at least three hours before bedtime (Brewer, 2007).

2.6.1.2 Antacids

An estimated one in every two adults in the United States uses antacids, and more than one in four adults take them at least twice a month. The great majority of frequent antacid users treat themselves for symptoms of dyspepsia (Moayyedi et al, 2006).

Antacids act primarily by neutralising intragastric acidity and thus modifying the irritant nature of gastric material into the oesophagus (Richter, Talley, 2005).

The side effects of antacids are numerous and include diarrheoa, constipation, dry mouth, increased thirst, stomach cramps and blurry vision (Graham et al, 2004).

The irregular and uncontrolled use of antacids may cause bowel irregularities (constipation and diarrhoea) and aggravate kidney disorders. Prolonged use may actually cause an increase in the production of stomach acid if a person suddenly stops taking it – this is called acid rebound (Willacy, 2007).

2.6.2 Phase Two Therapy

Patients with moderate to severe symptoms or complications or both are candidates for phase two therapy or the use of Histamine-2 receptor antagonists. This class of medications inhibits the production of gastric acid, which, in combination with pepsin, is believed to be the most damaging component of refluxed material (Richter, Talley, 2005).

Cimetidine, Famotide, Nizatidine and Ranitidine, which are H-2 receptor blockers are most commonly used to treat functional dyspepsia (Spiller, 2006).

Histamine-2 antagonists appear to lose their efficacy over 28 days of therapy. This may explain the failure of H-2 antagonists to correct more serious grades of dyspepsia (Melzer, Rosch, 2004).

The proton pump inhibitors omeprazole, esomeprazole, lansoprazole, pantoprazole and rabeprazole cause a dose-dependent inhibition of gastric acid secretion by inhibiting the proton pump in actively secreting gastric parietal cells. They have a much greater efficacy and longer duration than H2-receptor antagonists and are used to treat more serious cases of dyspepsia (Tidy, 2007).

These drugs, however can decrease Vitamin B12 absorption in some patients. This may become a clinical issue in patients who receive proton pump inhibitors for very long periods of time, and B12 levels should be monitored in such cases. Gastrin levels also rise in some patients who receive proton pump inhibitors (Robinson 2000).

Use of an H-2 receptor antagonist and a proton pump inhibitor together may yield a slightly better response when used alone, but the additional cost of the combined therapy rarely justifies its use (Tidy, 2007).

All of the above mentioned regimens are expensive and require doses throughout the day (Marshall, 2000).

2.6.3 Over- the- counter Histamine 2 (H-2) Receptor Blockers

Over-the-counter formulations of prescription H-2 receptor antagonists are more readily available. Dyspepsia sufferers often know when they might become susceptible to an attack, so before consuming a large meal, they possibly take an

H-2 blocker as a precaution. However, not much is known on the efficacy of H-2 blockers at lower than prescription doses (Naidoo, 1999).

It has been suggested that the symptomatic relief provided by an over-the counter H-2 receptor blocker might deter patients from seeking medical attention for a serious underlying disorder. Consequently appropriate diagnosis and therapy would be delayed. Similar concerns should be expressed over the already massive use of antacids and prescription H-2 receptor antagonists (Richter, Talley, 2003).

2.6.4 Maintenance Therapy

When therapy is stopped or reduced, symptoms often tend to recur. Long term maintenance therapy therefore remains necessary because relapse rates are extremely high after cessation of therapy (Brewer, 2007).

Chronic treatment with profound acid suppressive therapy may have long term consequences. Omeprazole leads to a strong increase in corpus gastritis in especially *Helicobacter pylori* positive patients, which may explain the observed development of corpus atrophy in a substantial number of patients after several years of continued acid –suppressive treatment. Long term powerful acid suppression with proton pump inhibitors in patients with reflux disease led to a worsening of inflammation of the *Helicobacter pylori*-associated inflammation,

especially in the corpus, and to accelerated development of atrophy (Borton, 2007).

If *Helicobacter Pylori* is cured, proton pump inhibitors seemingly lose acid suppressive efficacy (possibly through loss of buffer or improved parietal cell function). The consequences of this finding may be far reaching (Haslett et al, 2002).

2.7 Homoeopathic Treatment

2.7.1 What is Homoeopathy ?

Homeopathy is individualized and the treatment is patient specific. A key premise is that every person has energy called a vital force or self-healing response. When this energy is disrupted or imbalanced, health problems develop. Homeopathy aims to fuel the body's own healing mechanisms. As a system of medicine it not only cures an array of acute and chronic diseases, but also strengthens the immunity of the patient (Hansen, 2001).

2.7.2 The Founder of Homoeopathy

Samuel Hahnemann, a German medical doctor formulated for the first time in the history of medicine the complete laws and principals governing health and disease, and proved them in actual clinical experience (Vithoulkas, 2000).

Hahnemann observed from his experiments with Cinchona bark, used as a treatment for Malaria, that the effects he experienced from ingesting the bark

were similar to the symptoms of malaria. He therefore reasoned that cure proceeds through similarity, and that treatments must be able to produce symptoms in healthy individuals similar to those of the disease being treated. Through further experiments with other substances, he developed many other homoeopathic remedies, which are widely used today (South African Faculty of Homoeopathy, 2007).

2.7.3 The Principals of Homoeopathy

2.7.3.1 Homoeopathic Simillimum Treatment

The law of similars or "like cures like" is the essence of homoeopathy. The "picture" of the person's illness is ascertained by a thorough examination and careful history taking, along with observation and physical examination. This enables the practitioner to make a clear diagnosis and also to be aware of specific features of the 'illness" in this particular individual. The practitioner then attempts to work out which medicinal substance has a "drug picture" which most closely resembles the "picture" of the "illness" of this patient (Leckridge, 1997).

2.7.3.2 The Concept of Simplex Treatment

In Aphorism 273, Hahnemann states, "in no case is it necessary to administer more than a single, simple medicinal substance at one time with a patient". By administering one remedy at a time, a practitioner will be able to distinguish its actions from the interfering effects of other substances (De Scheeper, 2001).

2.7.3.3 The Concept of Homoeopathic Complexes

According to Kayne (2002), some remedies can be mixed together and administered successfully as a complex despite it being in contradiction to the Hahnemanian principle of prescribing only single remedies. Certain French and German products contain as many as 20 different remedies in potencies ranging from 3X to 30CH. Interestingly, this complex approach to prescribing is being adopted in modern orthodox medicine as an element of care plans involving the treatment including, diabetes.

He also explains that complexes are used for three reasons:

1. The homoeopath may be unsure which remedy is appropriate and therefore if a complex is given, the chance of a correct prescription is increased.

2. Complexes are used when a patient is suffering from a condition, which has more than one symptom that needs to be treated or the patient has more than one complaint at one time.

3. The final reason is for the sake of convenience to save time and effort.

2.7.3.4 The concept of the minimum dose

Hahnemann experimented with diluting his remedies in an attempt to find that dose that would still be curative but would not produce unwanted side effects. He

used two scales of dilution. The one in ten known today as the D or X (D=decimal, X=ten) range of potencies, and the one in hundred, the C (centesimal) range (Wholistic Research Company, 2001).

The decimal scale was selected for use in this study as it is regarded in common homoeopathic practice as a lower potency scale. It can be administered more frequently to treat chronic conditions (De Scheeper, 2001).

2.7.3.5 The Concept of Potency

The word "potency" has the connotation of power. The nearest analogy would be "strength." Potency in many ways is the homoeopathic equivalent to dosage (Leckridge, 1997).

The remedies employed in this study, each have a low potency of D9. This low potency is indicated when one requires a homoeopathic drug to function only on the physical level of the body. Aggravations, often associated with administering high potencies are prevented (O'Reilly, 1996).

2.7.3.6 Herings law of cure

Hering stated that, "if cure is in progress, symptoms will manifest at levels which are progressively of less crucial importance to the individual to express fullness and creativity of life" (Vithoulkas, 2000).

This law states that cure takes place:

- From the top to the bottom of the body
- From the inside to the outside

- From the most important organs to the least important
- In reverse order of the onset of symptoms

Hence, mental symptoms (emotions) might be expected to improve before physical symptoms are resolved, and recent symptoms will subside before long standing, chronic symptoms (Kayne, 2002).

2.7.4 How is homoeopathy different from orthodox medicine ?

Orthodox medicine aims to provide symptomatic relief of an illness, whereas homoeopathic medicine is aimed toward treating the root cause of illness.
The patient is treated as an individual with emphasis on physical, mental and emotional symptoms and not simply the physical aspect of disease (Hansen, 2001).
Homoeopathy provides a safe alternative to current trends in the treatment of various medical conditions. There are no harmful side effects and it is a much more economical approach to health care (Lockie, 1998).

2.7.5 The Homoeopathic Treatment of Dyspepsia

Homoeopathy is a system of medical therapy that concentrates on treating the whole person. This means that the practitioner recognises that the patient is not just a physical entity, but also has emotional, mental and spiritual aspects – all or any of which may need treatment. It is also recognised that this complex individual does not live in isolation, but is in continual interaction with his or her

environment, and that this must also be taken into account in both assessing the problem and planning the treatment (Swayne, 1998).

Therefore, in the case of treating a patient with dyspepsia, the homoeopathic practitioner will consider not only the physical symptoms but the mental, emotional and general symptoms of the individual patient (Wholistic Research Company, 2001).

All these symptoms as well together with the findings from the physical examination (Munro, Campbell, 2000 -Appendix F) are then used to build up the patient's clinical picture. A comparison of this clinical picture with the remedy picture of different remedies in the Materia Medica will then give the remedy which is most appropriate for the specific individual (De Scheeper, 2001).

2.7.6 Materia Medica of Remedies Used in the Complex

The complex employed in this study consists of four remedies each indicated in the treatment of the symptoms associated with dyspepsia.

Carbo vegetabilis

The common name for this remedy is "activated charcoal". Charcoal is half burnt wood or artificial coal, a black amorphous (lacking a crystalline structure) form of carbon, made by heating wood in the absence of air. The homoeopathic preparation of this remedy is from the finest beech, which is stripped of bark and

cut into small pieces. These pieces are then heated until red hot and rapidly smothered in an earthern jar with a tightly fixed lid (Castro, 1995).

The gastric indications of *carbo vegetabilis* include:

-sour, putrid eructations after eating and drinking which bring temporary relief from belching

-waterbrash, nausea in the morning

-burning in stomach, extending to back and chest

-pain in stomach with distended abdomen and slow digestion

-sensitivity in the epigastric region

-excessive flatulence, violent almost constant eructations

-fatty foods, milk and meat aggravate (Vermeulen, 2000).

-crampy pains in stomach, causing patient to bend double

- distress comes on half an hour after eating

-digestion is slow, food putrefies before it digests

- sour rancid belching

-excessive discharge of foetid flatus

-cannot bear tight clothing around abdomen

-abdomen greatly distended, better for passing wind (Boericke, 1998).

-empty, bitter risings of food, especially fatty food

- pyrosis, hiccough after every movement

- nausea, especially after a meal

- vomiting of food, mixed with blood in the evening

- cramps of stomach, contractive, pressive, burning

- heaviness, fullness, tension of the stomach with accumulation of flatus

- colic with sensation of burning pressure, much sensitiveness and pressure in the pit of the stomach

- pain in the hypochondria, like that of a bruise

-shooting pains under the ribs

- pain in abdomen, as from lifting a weight

- borborygmi and movement in the abdomen (Clarke, 1991).

Lycopodium clavatum

The common name for this remedy is “wolfs claw” and it belongs to the plant family lycopodiaceae. It is an ever green trailing plant found on heaths, moores and pastures throughout Great Britain, Northern Europe and North America. The plants roots resemble a wolfs foot, hence its name. The spores of the plant contain a fine, yellow, odourless, tasteless pollen which is collected toward the end of summer. This powder is then potentised to produce the homoeopathic remedy (Castro, 1995).

The gastric indications of *lycopodium clavatum* include:

- dyspepsia due to farinaceous foods

- excessive sour erucatations and weak digestion

- great bloating and flatulence

- feels full after small meals

- incomplete burning eructations rise in pharynx and burn for hours

- stomach pain relieved by rubbing abdomen

- excessive hunger, sour taste in mouth (Vermeulen, 2000).

-pressure in stomach after eating with bitter taste in mouth

- hiccough

- pain shoots across abdomen from right to left

- constant sense of fermentation in the abdomen

- sinking sensation in stomach, worse at night

- wakes at night, feeling hungry

- sour and acrid eructations

- sour vomiting

- eating ever so little creates fullness (Boericke, 1998).

-incomplete eructations, burning, rising only into the pharynx where they cause burning

- sour eructations,with acid gnawing in the stomach

- nausea in a room which disappears in open air

- waterbrash, sometimes every second day

- vomiting of food and bile especially at night

-slow digestion

- contactive pains in the stomach
- swelling of epigastrum with sensitivity to touch
- stitches on left side of pit of stomach
- cramps in diaphragm, aggravated by stooping
- violent gall stone colic
- abdomen is bloated, full and distended immediately after light meals
- heaviness in abdomen
- flatulence cannot pass and causes pain
- much rumbling of wind in stomach (Clarke, 1991).

Nux vomica

The common name for this remedy is “poison nut” and it belongs to the family, Loganiaceae. *Nux vomica* seeds are produced by a large, ever green tree native to certain parts of India, Burma, Thailand and China. It produces orange coloured fruit about the size of an apple. Each fruit contains a soft, jelly like pulp and five seeds. These seeds are extremely bitter to taste, owing to the strychnine contained in them and are highly poisonous in nature. The seeds are powdered finely in a heated mortar and triturated with sugar of milk to produce the remedy (Castro,1995).

The gastric indications of *Nux vomica* are**:**

- nausea in morning and after meals
- disordered stomach from alcohol, drugs

- flatulence with difficult, sour bitter eructation

- bloated epigastrum

- ravenous hunger one day before attack of dyspepsia

- heartburn from eating acid and fat food

- feeling of stone in pit of stomach after eating fatty food

- hunger yet aversion to food (Vermeulen, 2000).

- sour taste in mouth with nausea in the morning

- flatulent pyrosis

- nausea and vomiting with much retching

- region of stomach very sensitive to pressure

- desire for stimulants

- dyspepsia from drinking strong coffee

- difficult belching of gas

- wants to vomit but cannot

- spasmodic colic

- bruised soreness of abdomen (Boerike, 1998).

- abortive risings with painful spasmodic constriction in oesophagus

- frequent bitter acid risings and regurgitiation

- belching of wind which is difficult

- continual nausea and inclination to vomit

- scraped sensation in pit of stomach with heartburn

- waterbrash, straining to vomit

- retching and violent vomiting of mucous, bile and sour matter

- pressure and tension in stomach accompanied by tension in between shoulder blades

- colic of coffee and brandy drinkers

- disordered stomach from over eating and high living

- great uneasiness in pre-cordial region as if heart would burst

- heat and burning as if parts were raw, pain as from bruised abdomen

- jerking and twitching of abdominal muscles (Clarke,1991).

Robinia pseudoacacia

This remedy belongs to the plant family leguminosae. Commonly known as the "black locust" or false acacia, it is a thorny tree originally from North America but can also be found in Europe. The bark is used to prepare the mother tincture. The active principles contained in the bark are tannins, toxalbumins and syringin (Demarque et al, 1997).

The gastric indications of *Robinia pseudoacacia* are:

-dull, heavy aching of stomach

-nausea and sour eructations

-great distention of stomach and bowels

-flatulent colic and indigestion

-acrid and acidic eructations

- aggravated at night

-burning pain in stomach and shoulders

- profuse vomiting of intensely sour fluid (Vermeulen, 2000).

- acid dyspepsia

- pyrosis

- gastro-oesophageal reflux

- hiatal hernia

- nocturnal acid gastralgia

- reflux of liquid due to gastric acid hypersecretion

- profuse acid vomiting, “setting teeth on edge”

- frontal headache accompanies gastric symptoms (Demarque et al, 1997).

- thirst, with constant eructations of sour fliud

- heartburn and acidity of stomach at night and when lying down

- regurgitation of acid and bitter substances, everything turns to acid

- nausea for three hours followed by vomiting of intensely sour food

- nausea and attempts to vomit when sitting

- vomiting of ropy mucous, tinged with blood

- dull heavy pain in stomach

- very severe deep sharp pain in stomach all day and night

- constant dullness in epigastric region with cutting pain in stomach and bowels, accompanied by rumbling

- burning distress in stomach and region of gall bladder

- bowels greatly distended with flatulence, seems to fill up the whole abdomen

- soreness in bowels when moving (Clarke, 1991).

2.7.7 Other homoeopathic remedies used in the treatment of dyspepsia

Arsenicum album

- dyspepsia from vinegar, acids, ice water, ice cream

-stomach feels raw, as if torn

-constant desire to drink water but only sips

- cutting pains in abdomen and stomach, rolls about in pain

- long lasting eructations

-gulping up of acid which excoriates the throat

-dyspepsia accompanied by icy coldness, great exhaustion (Vermeulen, 2000).

Pulsatilla pratensis

-dyspepsia and great tightness after a meal, must loosen clothing

- perceptible pulsation in pit of stomach

- aversion to fat food, butter, pork and bread

- stitching pains aggravated by walking

- hunger with rancid nausea

- scraping sensation in stomach and throat

-vomitting of food eaten long before (Boericke, 1998).

Ipecacuahna

-nausea from the smell of food, improved by eating

-empty eructations with excessive salivation - gastritis, not even a drop of food will stay down

- rumbling in the abdomen, accompanied by distention

- cutting, gripping pains especially around umbilicus

- after vomitting must sleep (Vermeulen, 2000).

2.8 The Placebo Enigma

Placebo refers to a medical treatment, which has no specific medicinal activity and is just a dummy. Placebo effect dates back to Hippocrates who observed that certain gravely ill patients seemed to recover through sheer “contentment”. Placebo accounts for much of the benefit people get from anti- depressants and all the benefit from anti-biotics taken for viral infections which are not affected by the drugs (Grady, 2004).

It is often considered as a classic example of body- mind relation that depends on largely sub-conscious interactions between the doctor, the treatment process and the patient. Evidence will be adduced that it depends on the patient’s belief or expectation that treatment is effective; it often operates without deliberate intention, and, it affects physiological and psychological processes (Linde, 2006).

2.8.1 The Clinical Spectrum of Placebo Reaction

It is a complex response affecting not only subjective pain and many other symptoms, but also objective signs of pathology and physiology. The only thing learned from a placebo trial is whether or not the patient is placebo positive (Pearce, 1995).

2.8.2 What Treatments Act as Placebos?

The type of placebo agent is varied. Perceived clinical interest, caring, sympathy in the attending physician, similarly have considerable therapeutic impact, irrespective of the material nature of the treatment. Placebo effects play a role in: drugs, homoeopathic medicines, acupuncture, psychotherapy, biofeedback and transcutaneous nerve stimulators. The benefit of placebo is transient but not always short-lived (Grady, 2004).

Pharmacologically inert substances like, lactose granules or powders, alcohol and cane sugar tablets are often used as homoeopathic placebos (Linde, 2006).

2.8.3 The Use and Exploitation of Placebo

Individuals are not consistent in their placebo responses and we cannot accurately predict the placebo- responder. Independently, evaluated, randomized controlled trials are essential in prospective trials of drugs, and physical treatments. In most instances, they must include a placebo component. The placebo effect is therefore a very controversial topic, and much less has been written on it in the past (Grady, 2004).

For the purpose of this trial, placebo was used as a control group to determine the effectiveness of the treatment group. However, patients in the placebo group did yield significantly positive results and this is discussed further in Chapter 5.

CHAPTER 3

3.1 MATERIALS AND METHODS

3.1. Objectives

The objective of this study was to determine the efficacy of a homoeopathic complex (*Carbo vegetabilis* D9, *Lycopoduim clavatum* D9, *Nux vomica* D9 and *Robinia pseudoacacia* D9) in the treatment of functional dyspepsia with regards to clinical symptoms.

3.2 Sample size

A minimum of thirty participants were required for the study, but provision was made for thirty- five patients, to allow for drop outs. A diagnosis of functional dyspepsia was previously made by the patients own medical health practitioner or by the researcher and confirmed by the clinician on duty. Diagnostic procedures included a thorough medical history focused on the distinguishing features of functional dyspepsia

A physical examination was carried out to determine the presence of epigastric tenderness on abdominal palpation (Haslett et al, 2002). Prior to selection participants were given the participant information sheet (Appendix B) and given a full explanation of the procedure. Once the patient agreed to participate, they were provided with the consent form (Appendix D) to sign. As the researcher is not fluent in Zulu, the consultations were carried out in English; however consent forms and information sheets were available in Zulu. (Appendix C and E).

3.3 Selection of participants

Patients were recruited via advertisements in local newspapers and posters and pamphlets were distributed in local health shops and notice boards. Patient participation was on a voluntary basis and they were selected via convenience sampling. A group of thirty patients were selected according to the following inclusion and exclusion criteria:

3.3.1. Inclusion Criteria

- Patient's had to be between the ages of 18 years to 55 years of age.
- Both sexes were accepted.
- All race groups were accepted.
- Patients had to have a history of dyspepsia and exhibit classical symptoms such as, upper abdominal pain which may or may not be related to food, gastro-esophageal regurgitation and heartburn, anorexia, nausea and vomiting. This is in combination with early repletion or satiety after meals, abdominal distention or bloating, flatulence (burping, belching) and colonic dysmotility, pellet like stools or a sense of incomplete rectal evacuation (Sifrim, 2005).
- Patients on current unrelated medication including, anti-hypertensives or other chronic medication, were accepted as participants on the condition that the medication remained unchanged for the duration of the trial.

3.3.2 Exclusion Criteria

- Patients on current dyspepsia medication (homoeopathic, allopathic or otherwise were not accepted as participants.
- Patients on non-steroidal anti-inflammatories or any other drug commonly known to produce the symptoms of dyspepsia were not included in this trial (Longmore et al, 2001).
- Patients with a history of gastric or any other malignancy and peptic ulcer disease were excluded from the trial (Haslett et al, 2002).
- Pregnant females were not included in this trial.
- Alcohol or drug abuse or any condition e.g. mental illness or dementia, associated with poor compliance.

3.4 Randomisation and Blinding

This was a double-blind placebo controlled study, which means that neither the patient nor the researcher were aware of which treatment the patient was on until the research was unblinded at the end of the trial. Both the homoeopathic complex and placebo complex and their corresponding packaging were indistinguishable to both the researcher and the patient.

The thirty patients were split into two groups of fifteen, using a process of simple randomisation. A randomisation sheet (Appendix I) was drawn up by the research supervisor, Dr C.M Hall. As the patient arrived for an appointment they were allocated a number on the randomisation sheet by the clinic receptionist.

The medication dispensed to the patient corresponded to the allocated number on the randomisation sheet. Dispensing was done by the clinic technician.

3.5 Ethical issues

The experimental complex was compared to placebo in order to determine whether the homoeopathic complex was more effective than placebo in the treatment of functional dyspepsia. Apart from the fact, that 50% of patients received placebo and the other 50% received the homoeopathic complex, all patients were treated equally in all other respects, therefore any improvement in the condition could be attributed to the homoeopathic complex alone.

A placebo is made of a medically inactive substance. It is allegedly inert and harmless. It is therefore used to illustrate the effects of a presumed active drug (Berkow and Beers, 1999).

The researcher explained the nature of the study to all the participants. Each participant was given the Patient Information Sheet (Appendix B) to read. This sheet explained the need for the use of the placebo to make the study scientifically acceptable. The sheet also informed the patient that there was a fifty percent chance that they would receive the placebo complex and if unblinding of the study revealed that they were in fact on placebo, free treatment would be offered to them at the end of the trial. Patients were assured that any information shared with the researcher would be treated in strictest confidence and they were free to withdraw from the study at any time. Patients were also informed that

they would be required to attend an initial consultation, followed by two subsequent consultations over a four week period. Informed consent was then obtained upon the completion of the Informed Consent form (Appendix D).

Functional dyspepsia, although not without complications, is not considered a life threatening condition. Patients were therefore, not placed at serious risk by receiving placebo medication. The placebo complex was visibly indistinguishable from the active complex.

3.6 Location of the Study

The study was conducted at The Homoeopathic Day Clinic which is based at The Durban University of Technology, Steve Biko Campus in Ritson Road, Berea.

3.7 The Treatment

The complex was prepared by Natura Homoeopathic Laboratories, Pretoria, South Africa, according to German Homoeopathic Pharmacopoeia standards. Each of the four remedies were prepared individually to produce D9 liquid potency banks. The four remedies were then mixed in equal parts in a 20% ethanol based solution in a volume to volume ratio. The placebo complex was prepared in 20% ethanol and appeared identical but did not contain any active ingredients. Preparations were done accurately in sterile laboratories. All participants received treatment for four weeks (28 days).

The treatment group received 25 ml of the complex preparation and the placebo group received 25 ml of the unmedicated complex. Each patient received detail instruction on storage of the remedy i.e.; to keep the medication in a cool, dry place, away from sunlight exposure, cellular phones and computers.

Patients were instructed to take ten drops of the complex, under the tongue three times daily.

They were instructed to take the complex at least thirty minutes away from food and drink. They were asked to refrain from using camphorated creams and ointments and to avoid the intake of peppermint. The patients were also asked to abstain from any other dyspepsia treatment for the duration of the study.

All patients were asked not to make any dietary changes, especially with regards to aggravating foods for the duration of the trial.

An assumption of the study was that patients took the medicines as prescribed; every effort was made to provide clear instructions regarding the frequency and amount of complex to be taken. The researcher emphasized the importance of adhering to these instructions.

3.8 Measurement tools

Quantitative measurement was conducted by means of a Patient Perception Questionnaire (Appendix G) adapted from Hall, 1998. This questionnaire was filled out by the patient at each of the three consultations.

Scores were assigned in the following manner. Patients rated each symptom as either:

0 -Mild

1 -Moderate

2 -Severe

3 –Unbearable

3.9 Consultation Procedures

Once patients were assessed, by the researcher, to confirm suitability for participation in the study (refer to 3.3.1 and 3.3.2), the first consultation was arranged.

At the first consultation, each patient was asked to read the Information Sheet for the Participant (Appendix B) and to sign the Informed Consent Form (Appendix D) along with the Patient Details Sheet (Appendix F).

The researcher conducted a complete medical and homoeopathic case history (Appendix J) as well a complete general physical examination (Bates, 2006) on each patient at both the initial and follow up consultations.

The researcher then assisted the patient with the completion of the Patient Perception Questionnaire (Appendix G). This was done to establish a baseline of the patients' symptoms.

The completed documentation and final prescription were checked and signed by the clinician on duty at The Homoeopathic Day Clinic. Thereafter, the clinic

technician dispensed the medication in accordance with the Randomisation sheet (Appendix I).

Each patient received a full explanation on how to take, handle and store the medication. The medication was taken for two weeks at which time the second consultation (follow up 1) was scheduled.

At the first follow up, the patient's case history and physical examination were reviewed. The Patient Perception Questionnaire was again filled out and the prescription repeated.

The second follow up; two weeks thereafter involved a further assessment of the patient's case history and general physical examination. The third questionnaire was filled in and the patient received no further medication.

3.10 Data Analysis

3.10.1 Statistical Methods

Patients were assessed using a Patient Perception Questionnaire (Appendix G) adapted from the Short –Form McGill Pain Questionnaire (Hall, 1998). The patients were graded according to the severity of their symptoms. The answers to each question were assigned numerical values according to whether the patient graded it as: mild-0; moderate-1; severe-2 or none-3. The questionnaires were completed at all three consultations, the first one used as the base-line measurement. All numerical values were entered on a spreadsheet.

3.10.2 Statistical Analysis

Statistical evaluation of the data was conducted by using SPSS ® Version 12.1 Software Suite. This statistical software program was manufactured by SPSS ® Inc, 444n Michigan Avenue, Chicago, Illinois, USA. Various descriptive and inferential statistical techniques were used. The descriptive procedures used were various tables and graphs and a few summary statistics including but not limited to means, proportions and percentages. Inferential statistics included various hypothesis–testing techniques. Due to the size of the samples, namely 15 in each group, non-parametric statistical tests were used. Type 1 error was set at 5% for all tests or mentioned differently, a = 0.05. If the p value was reported as less than 0.05, a significant result was to be declared and the null hypothesis was to be rejected.

3.10.2.1 Procedure 1 – Friedman's Test

The intra-group analysis was done using the Friedman's ANOVA method, i.e. the questionnaire scores between consultation one (base-line), consultation two and consultation three, were compared. This was done for both the treatment and placebo groups. Each question of the questionnaire was analyzed separately as well as a total score for the entire questionnaire.

(i) Hypothesis Testing

The null hypothesis H_0 states that there is no significant difference between the visits being compared at the a = 0.05 level of significance. The alternate

hypothesis H_1, states that at least two of the visits will differ significantly at the same level of significance.

(ii) Decision Rule

At the a = 0.05 level of significance, the null hypothesis is rejected if p < a, where p is the observed significance level. Otherwise, the null hypothesis is accepted at the same level of significance.

3.10.2.2 Procedure 2 – The Wilcoxon's Signed Rank Test

The Wilcoxon's Signed rank Test was done to determine between which two visits the difference lies. This was only done for the questions for which a significant difference (improvement) between visits was found, i.e. Friedman's test showed a significant difference.

(i) Hypothesis Testing

The null hypothesis H_0 states that there is no significant difference between the two visits being compared at the $\alpha = 0.05$ level of significance. The alternative hypothesis H_1, states that there is a significant difference between the two visits being compared.

(ii) Decision Rule

At the a = 0.05 level of significance, the null hypothesis is rejected if P $\leq$ a/2, where p is the observed significance level. Otherwise, the null hypothesis is accepted at the same level of significance**.**

3.10.2.3 Procedure 3 – Kruskal Wallis Test

The inter–group analysis was done using the Kruskal Wallis non- parametric Analysis of Variance (ANOVA) method. Group one and group two were compared to each other with regard to the scores given to the questions at each consultation.

(i) Hypothesis Testing

The null hypothesis H_0 states that there is no significant difference between the two visits being compared at the a = 0.05 level of significance. The alternative hypothesis H_1, states that at least two of the groups will differ slightly at the same level of significance.

(ii) Decision Rule

At the a = 0.05 level of significance, the null hypothesis is rejected if P $\leq$ a, where p is the observed significance level. Otherwise, the null hypothesis is accepted at the same level of significance.

3.10.2.4 Procedure 4 – Comparison using Bar Charts

Analytical findings were summarized in a visual format by means of bar charts to compare the Treatment and Placebo group with respect to scores given to each question. Means were used to construct the bar charts.

CHAPTER 4

RESULTS

4.1 Introduction

Following the methodology described in Chapter 3, the study produced raw data in the form of completed Patient Perception Questionnaires.

Patients were assessed using a Patient Perception Questionnaire (Appendix G) adapted from the Short –Form McGill Pain Questionnaire (Hall. 1998). This served to grade patients according to the severity of their symptoms.

Questionnaires were completed at all three consultations, with the first being used as the base-line measurement. The numerical values were entered on a spreadsheet which was used both for exploratory data analysis and exported to SPSS ® for the statistical test procedures.

The specific objectives of the analysis were as follows:

- To describe the frequencies of responses to each of the questions in the Patient Perception Questionnaire.
- To compare the frequencies of responses to each of the questions in each of the interviews to determine if there were any significant effects of the treatment process.
- To compare the frequencies of responses to each of the questions between the placebo and treatment groups to determine if there were any significant changes.
- To describe the above results graphically using bar graphs and error plots.

The analysis of the data was done using SPSS® for Windows™ and Excel® XP™.

4.2 Overview of Results Chapter

4.2.1 Descriptive data

Frequency tables and pie graphs were calculated for each of the questions in the Patient Perception Questionnaire. For ease of comparison these are grouped in sections by question with each of the consultations representing one table/graph. These sections are numbered according to the breakdown in Table 4.A.

Table 4.A Table Showing Numbering for Frequency Comparisons

Question Number	Issue Explored in Questionnaire	Consultation Number	Section Heading
A	**How severe would you rate your dyspepsia?**	**1, 2 and 3**	**4.4.1.1**
B	**How often do you experience dyspepsia?**	**1, 2 and 3**	**4.4.1.2**
C	**How long does an attack of dyspepsia last?**	**1, 2 and 3**	**4.4.1.3**
D	**To what extent do you experience dyspepsia after a meal?**	**1, 2 and 3**	**4.4.1.4**
E	**Do you often experience waterbrash (regurgitation of**	**1, 2 and 3**	**4.4.1.5**

	stomach contents/saliva into the mouth)?		
F	**How often does your dyspepsia interfere with your sleep?**	**1, 2 and 3**	**4.4.1.6**
G	**Do you experience chest pain with an attack of dyspepsia?**	**1, 2 and 3**	**4.4.1.7**
H	**Does the pain spread to your abdomen?**	**1, 2 and 3**	**4.4.1.8**
I	**Do you experience nausea or vomiting with an attack of dyspepsia?**	**1, 2 and 3**	**4.4.1.9**
J	**Do you experience feelings of bloatedness and distention in your abdomen?**	**1, 2 and 3**	**4.4.1.10**
K	**Do you experience burping or belching with an attack of dyspepsia?**	**1, 2 and 3**	**4.4.1.11**
L	**What is your attitude towards your condition?**	**1, 2 and 3**	**4.4.1.12**
M	**Rate the level of dyspepsia stress you have to cope with**	**1, 2 and 3**	**4.4.1.13**

	at present?		
N	**How does your dyspepsia interfere with your daily work?**	**1, 2 and 3**	**4.4.1.14**
O	**How does your condition interfere with your family life?**	**1, 2 and 3**	**4.4.1.15**
P	**How does your dyspepsia interfere with your social life?**	**1, 2 and 3**	**4.4.1.16**
Q	**From the onset of treatment have you experienced any changes in your dyspepsia?**	**1, 2 and 3**	**4.4.1.17**
R	**Was it necessary to use any other medication for the dyspepsia?**	**1, 2 and 3**	**4.4.1.18**
S	**Have your energy levels changed since taking the medication?**	**1, 2 and 3**	**4.4.1.19**

4.3 Friedmans Test Analysis

In this analysis Friedmans test is used to determine whether the perceived changes and improvements in the responses were statistically significant.

4.3.1 Friedmans Analysis - Whole Group

Friedmans test was performed using the trial group as a whole. This may not serve to support the treatment protocol as described in Chapter three, however it is indicative of the extent to which the trial was clinically significant in itself.

4.3.2 Friedmans Analysis - Placebo Group

Friedmans test was performed using the placebo group. This assessed the statistical significance of the perceived improvements in the placebo group.

4.3.3 Friedmans Analysis- Treatment Group

Friedmans test was performed using the treatment group. This assessed the statistical significance of the perceived improvements in the treatment group.

4.4 Wilcoxon Signed Rank Test

Wilcoxon's Signed Rank Test was performed in order to assess the statistical significance of the changes from one consultation to the next**.**

4.4.1 Wilcoxon Signed Rank Test Analysis - Whole Group

Wilcoxon Signed Rank Test was performed using the trial group as a whole. This may not serve to support the treatment protocol as described in Chapter three, however it is indicative of the extent to which the trial was clinically significant in itself.

4.4.2 Wilcoxon Signed Rank Test Analysis - Placebo Group

Wilcoxon Signed Rank Test was performed using the placebo group. This assesses the statistical significance of the perceived improvements in the placebo group.

4.4.3 Wilcoxon Signed Rank Test Analysis - Treatment Group

Wilcoxon Signed Rank Test was performed using the treatment group. This assesses the statistical significance of the perceived improvements in the treatment group.

4.5 Kruskal-Wallis Test

The Kruskal Wallis test was performed to assess the statistical significance (if any) of the treatment group responses as compared to the placebo group.

4.5.1 Kruskal-Wallis Test Baseline Consultation: Placebo vs Treatment

The Kruskal-Wallis Test was applied to the results from the baseline consultation. Significant p values were noted.

4.5.2 Kruskal-Wallis Test First Follow Up: Placebo vs Treatment

The Kruskal-Wallis Test was applied to the results from the first follow up consultation. Significant p values were noted.

4.5.3 Kruskal-Wallis Test Second Follow Up: Placebo vs Treatment

The Kruskal-Wallis Test was applied to the results from the second follow up consultation. Significant p values were noted.

4.6 Graphical Comparison of Treatment vs Placebo Groups

The placebo and treatment groups were compared graphically for each of the questions at the levels of the baseline, first and second follow up consultation.

4.7 Abbreviations

Respondent = individual satisfying inclusion criteria who completed the questionnaire

H_0 = null hypothesis

H_1 = alternative hypothesis

S.D. = Standard deviation

z= Standardised z value for statistical measurements

p= two tailed probability of equaling or exceeding z/2

N.S. = No statistically significant difference

S = Statistically significant difference

A 5% level of significance was assumed: If $p < 0.05$ then a significant difference was concluded. If $p > 0.05$ then no significant difference was concluded.

4.8 Criteria Governing the Admissibility of the Data

Only data obtained from the Patient Perception Questionnaires which were completed during this trial were used for statistical analysis. The questionnaires were completed by all participants, at all three consultations. This was done in the presence of the researcher.

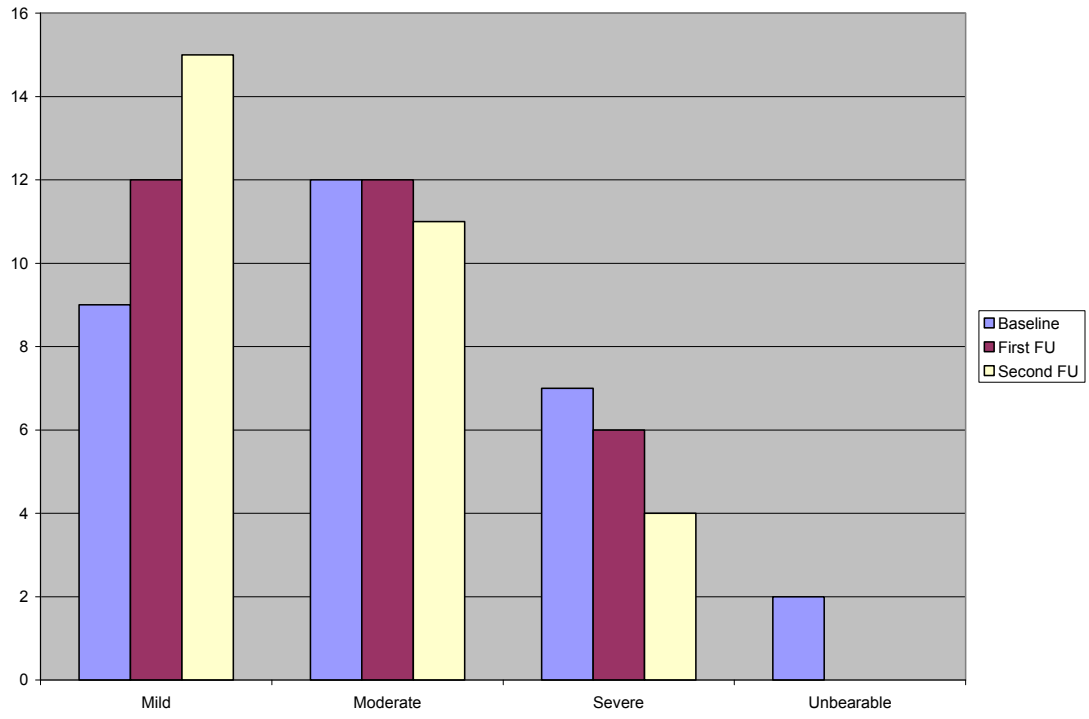
4.9 Descriptive statistics

4.9.1 Frequency Distributions of Responses

The frequency distributions of responses to the Patient Perception questionnaire items were analysed. This was done for each individual item in the questionnaire and the results compared across the three consultations.

4.9.1.1 Question A: How severe would you rate your dyspepsia?

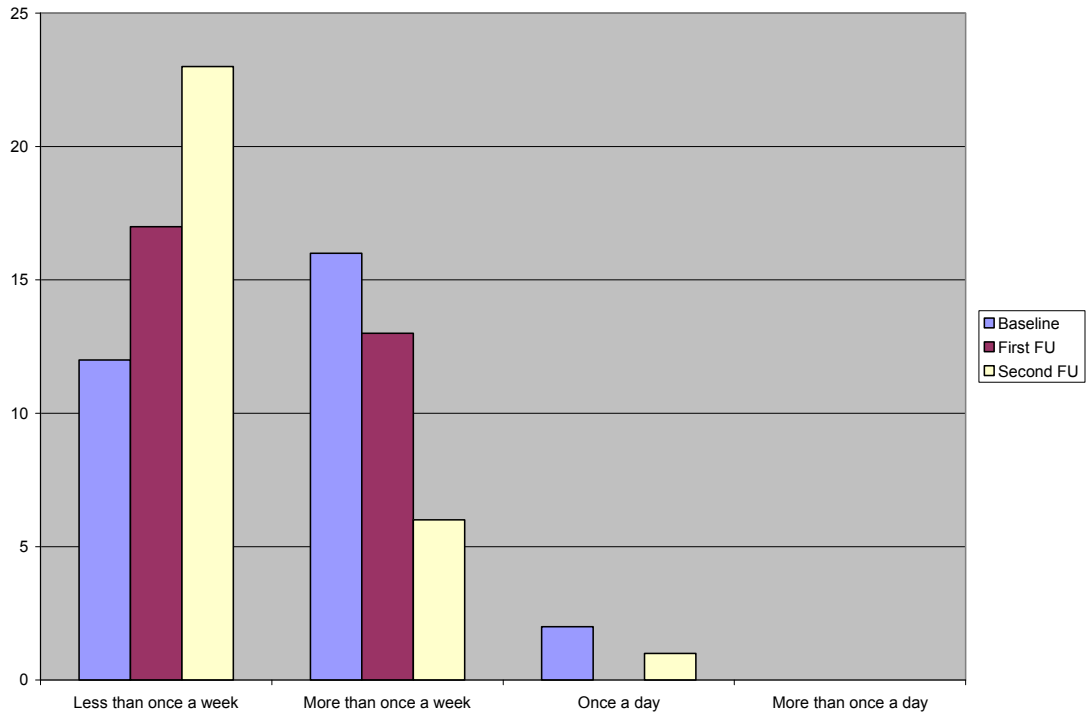
Figure 4.1 Graph showing the frequency distribution of the responses to Question A



The increasing number of 'Mild' responses from the initial to the first and second follow-ups is a reflection of the perceived reduction in severity over the course of the trial. This is paralleled by the decreasing numbers of 'Severe' responses.

4.9.1.2 Question B: How often do you experience dyspepsia?

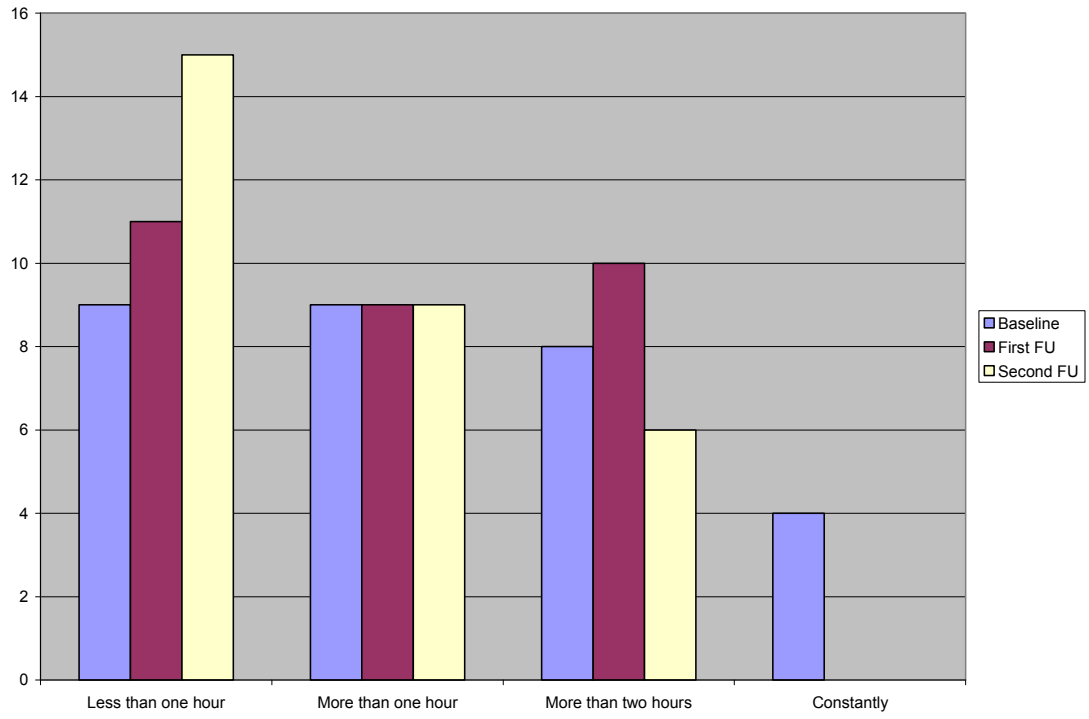
Figure 4.2 Graph showing the frequency distribution of the responses to Question B



The above graph demonstrates the reduction in frequency of attacks over the course of the trial. The number of respondents reporting less than once a week increased while the number of respondents reporting more frequent occurrence, diminished.

4.9.1.3 Question C: How long does an attack of dyspepsia last?

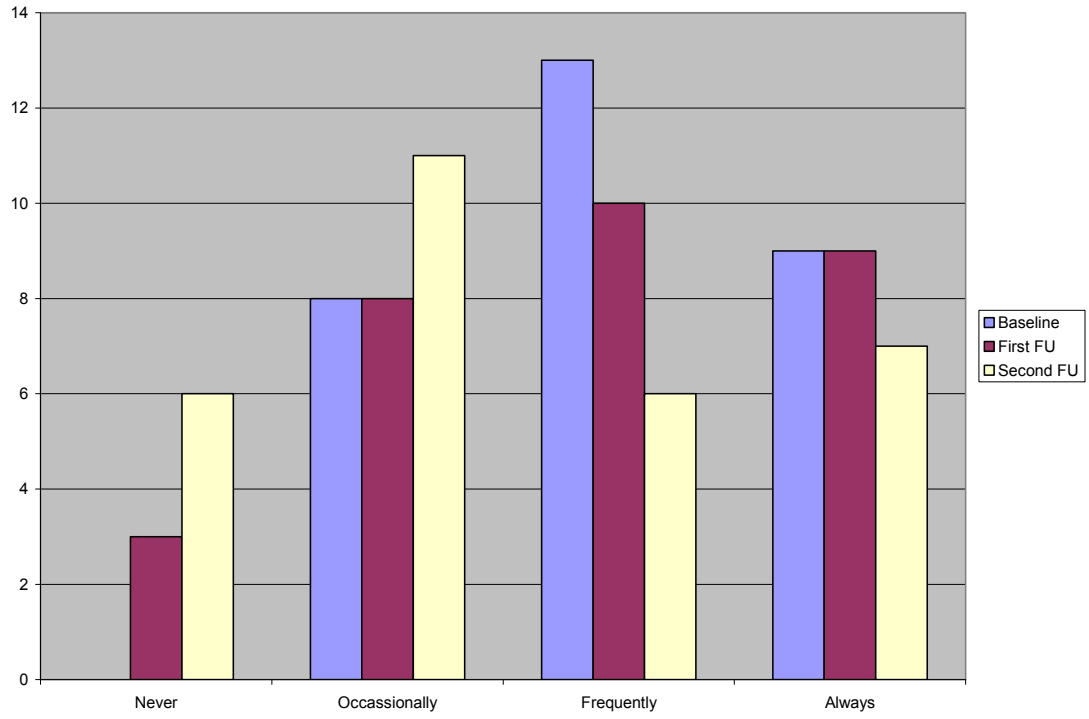
Figure 4.3 Graph showing the frequency distribution of the responses to Question C



The figure above again demonstrates a reported reduction in the duration of attacks experienced by respondents. Noteworthy is the slight increase in the number of respondents who reported duration of more than two hours between the initial consultation and the first follow up. This can be understood by noting the reduction in the number of respondents who reported constant dyspepsia.

4.9.1.4 Question D: To what extent do you experience dyspepsia after a meal?

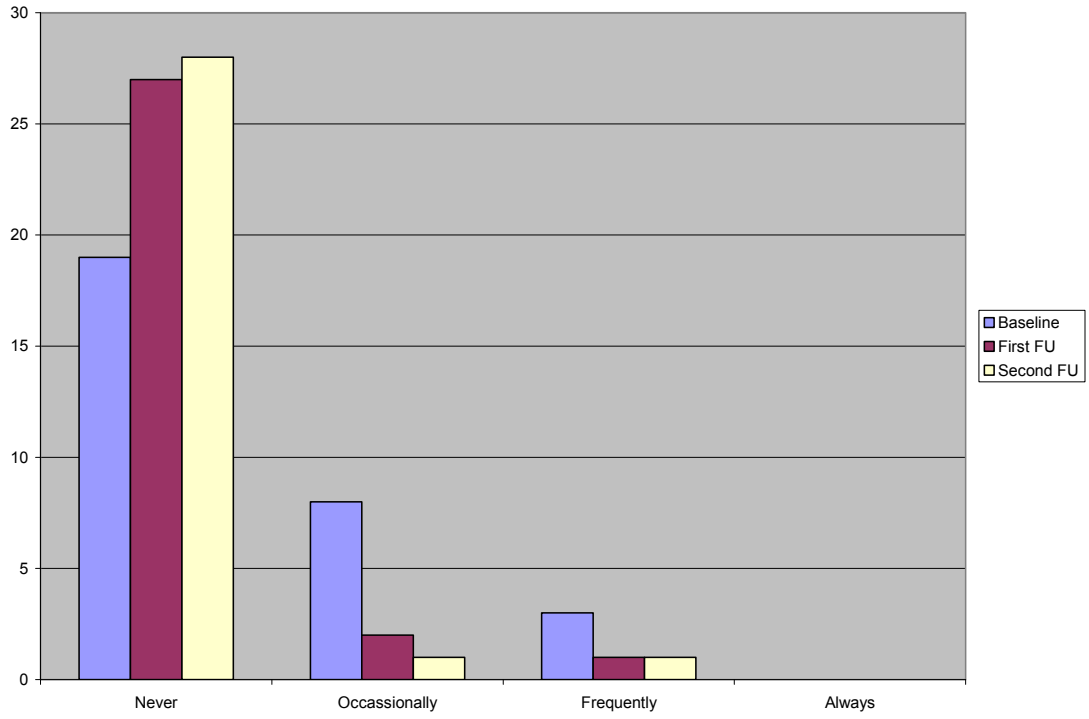
Figure 4.4 Graph showing the frequency distribution of the responses to Question D



The above graph demonstrates the overall decrease in the extent to which respondents suffered symptoms after a meal. The number who always or frequently suffered decreased over the course of the trial while the number who never or occasionally suffered increased.

4.9.1.5 Question E: Do you often experience waterbrash (regurgitation of stomach contents/saliva into the mouth)?

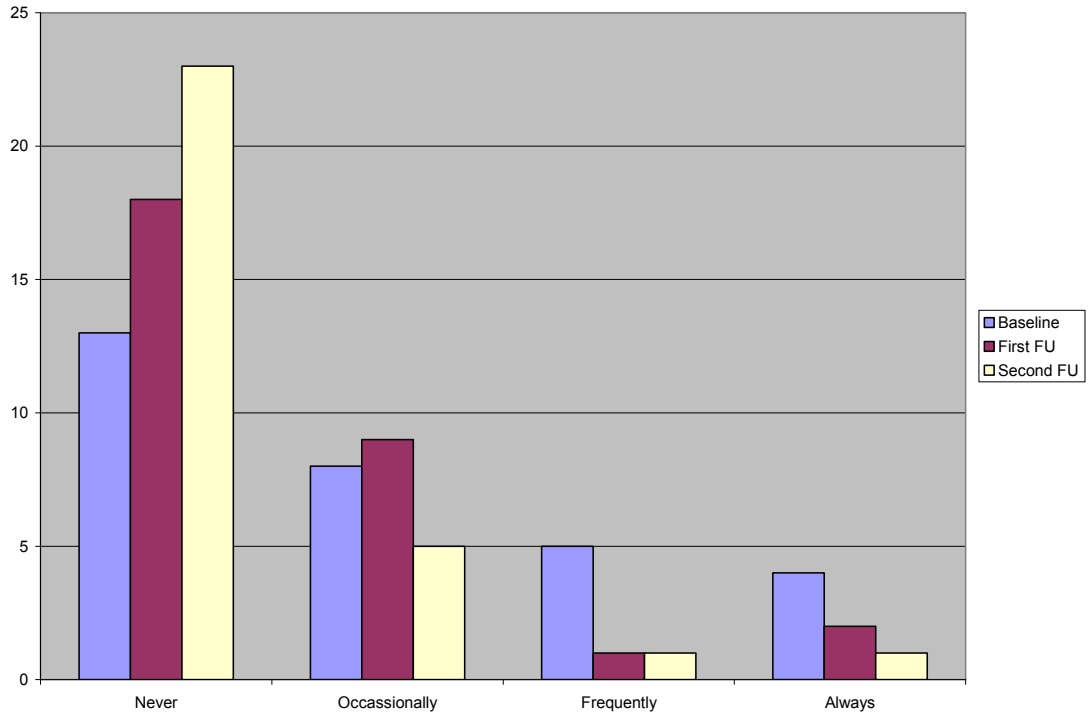
Figure 4.5 Graph showing the frequency distribution of the responses to Question E



The graph again demonstrates a slight improvement over the course of the trial.

4.9.1.6 Question F: How often does your dyspepsia interfere with your sleep?

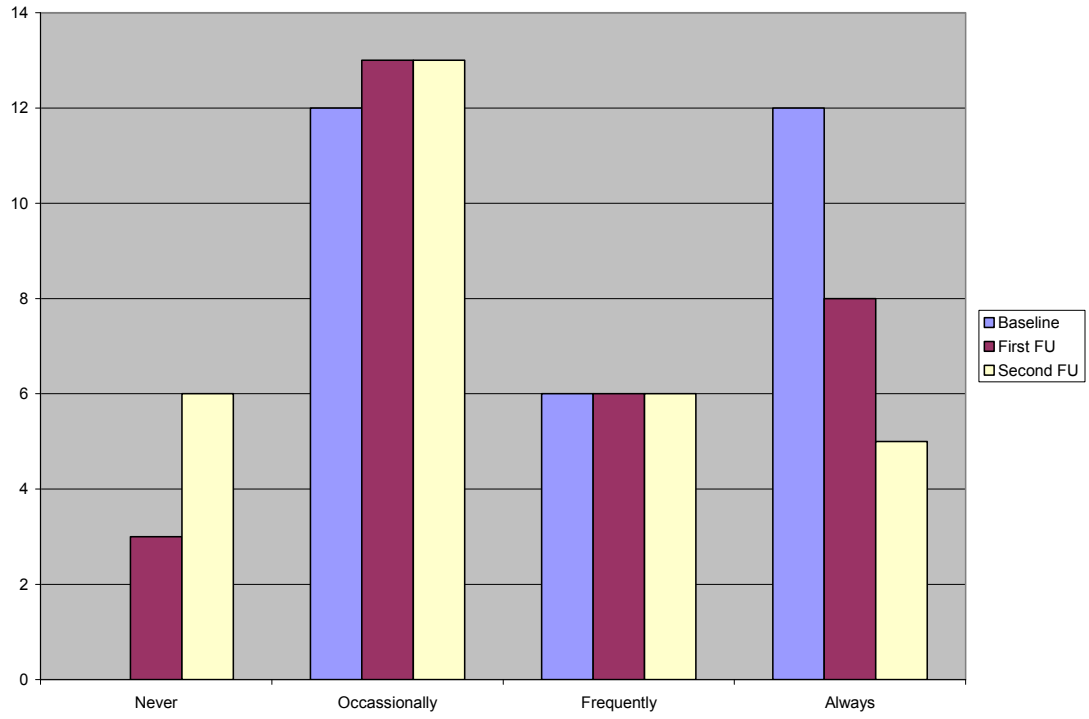
Figure 4.6 Graph showing the frequency distribution of the responses to Question F



The perceived trend in the data was continued in the above graph i.e. a left shift in the frequency distribution. This left shift indicates the decreasing frequency with which the dyspepsia interferes with sleep in the respondents perceptions.

4.9.1.7 Question G: Do you experience chest pain with an attack of dyspepsia?

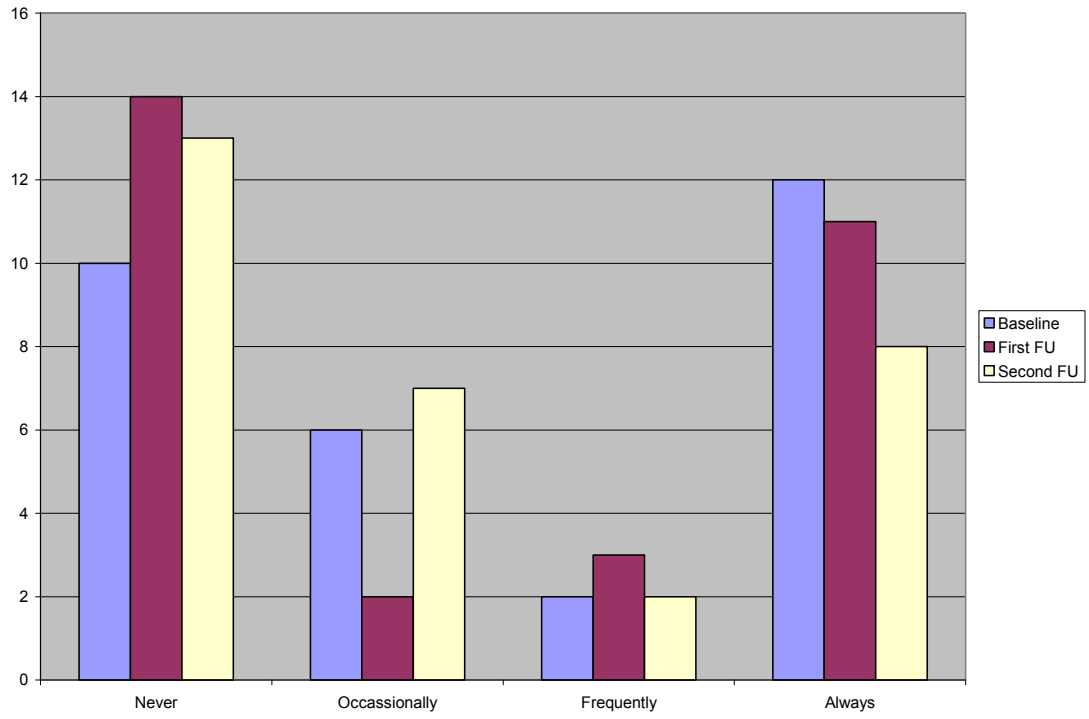
Figure 4.7 Graph showing the frequency distribution of the responses to Question G



Note the decrease in the number of respondents responding ‘Always’. This is paralleled by an increase in the number of respondents responding ‘Never’ and ‘’Occasionally’.

4.9.1.8 Question H: Does the pain spread to your abdomen?

Figure 4.8 Graph showing the frequency distribution of the responses to Question H



Again the trend is towards an overall decrease in frequency as evidenced by the increasing weighting to the left of the graph for later consultations.

4.9.1.9 Question I: Do you experience nausea or vomiting with an attack of dyspepsia?

Figure 4.9 Graph showing the frequency distribution of the responses to Question I

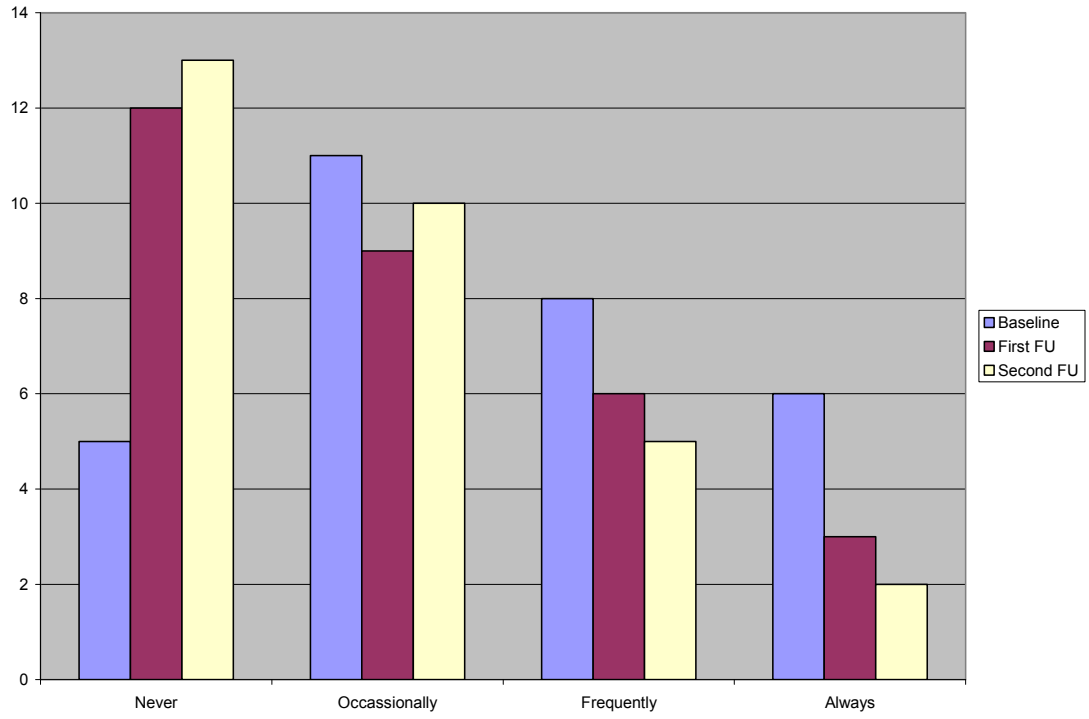
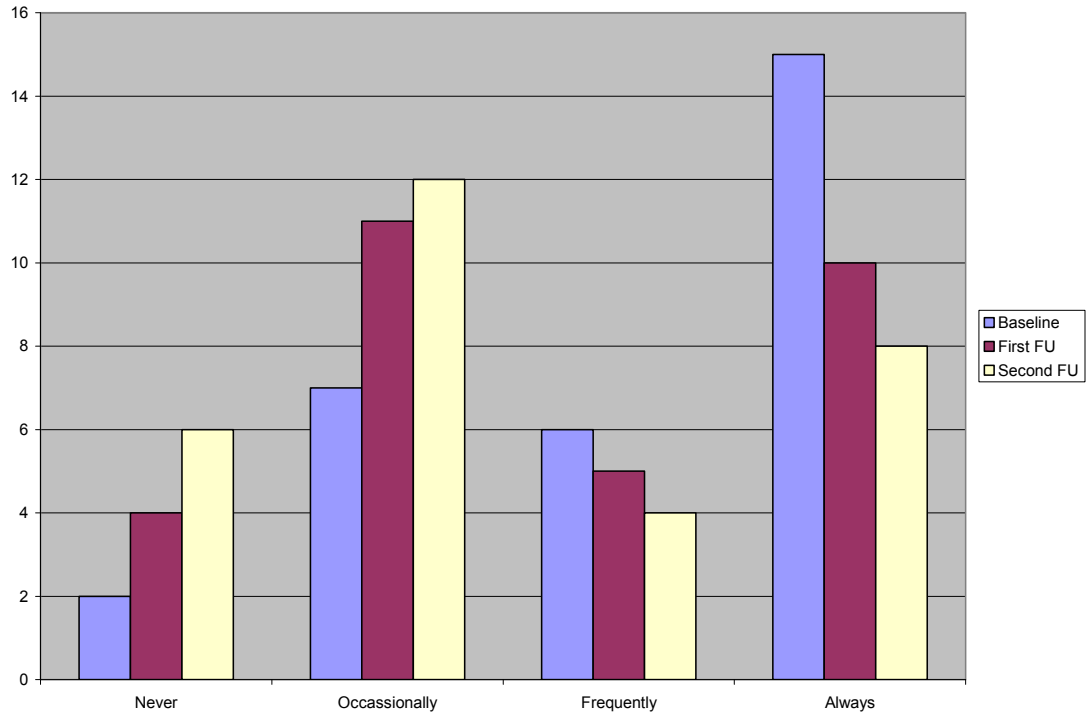


Figure 4.9 above again very clearly demonstrates the marked decrease in the number of respondents claiming to frequently or always experience nausea or vomiting.

4.9.1.10 Question J: Do you experience feelings of bloatedness and distention in your abdomen?

Figure 4.10 Graph showing the frequency distribution of the responses to Question J

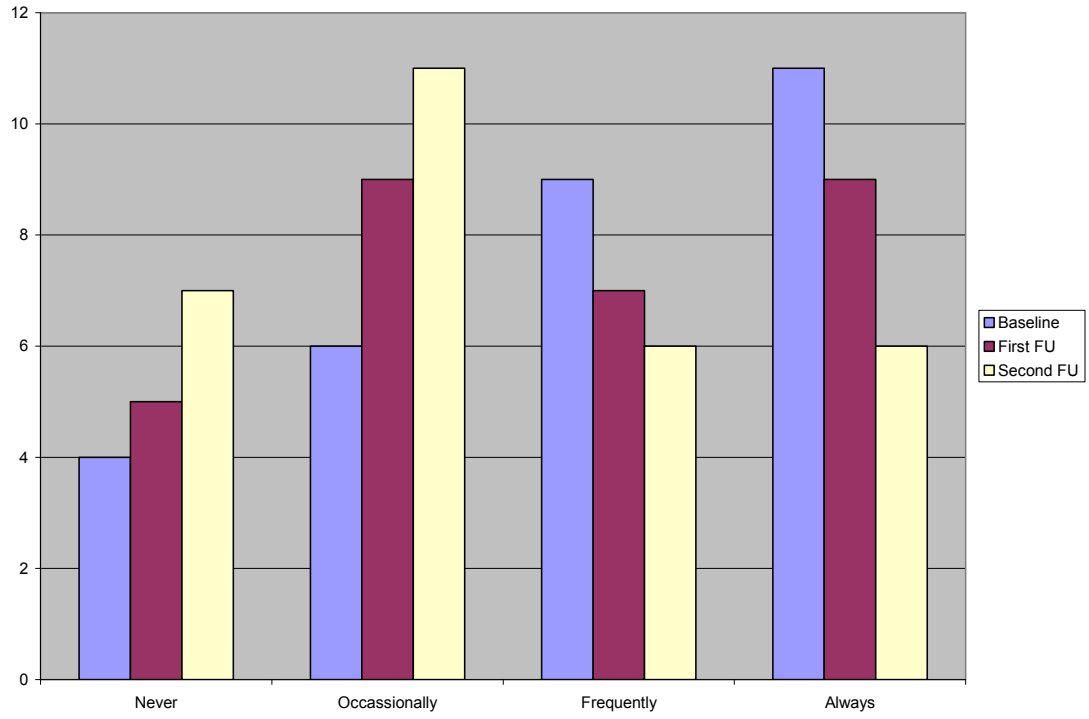


Note the leftshift in the data again. The statistical significance of these observations is assessed in Section 4.2 and 4.3.

The above graph demonstrates the reduction in frequency of attacks over the course of the trial. The number of respondents reporting ‘Never’, increased while the number of respondents reporting more frequent occurrence, diminished.

4.9.1.11 Question K: Do you experience burping or belching with an attack of dyspepsia?

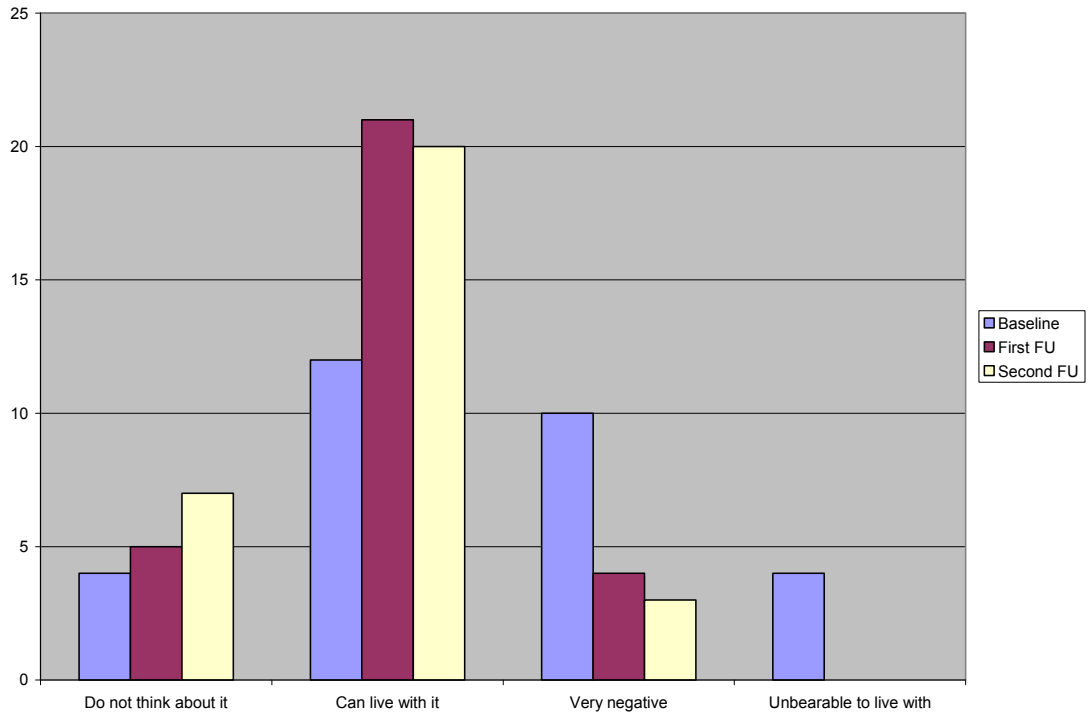
Figure 4.11 Graph showing the frequency distribution of the responses to Question K



The above graph demonstrates the reduction in frequency of attacks characterised by burping or belching over the course of the trial. The number of respondents reporting 'Never', increased while the number of respondents reporting more frequent occurrence, diminished.

4.9.1.12 Question L: What is your attitude towards your condition?

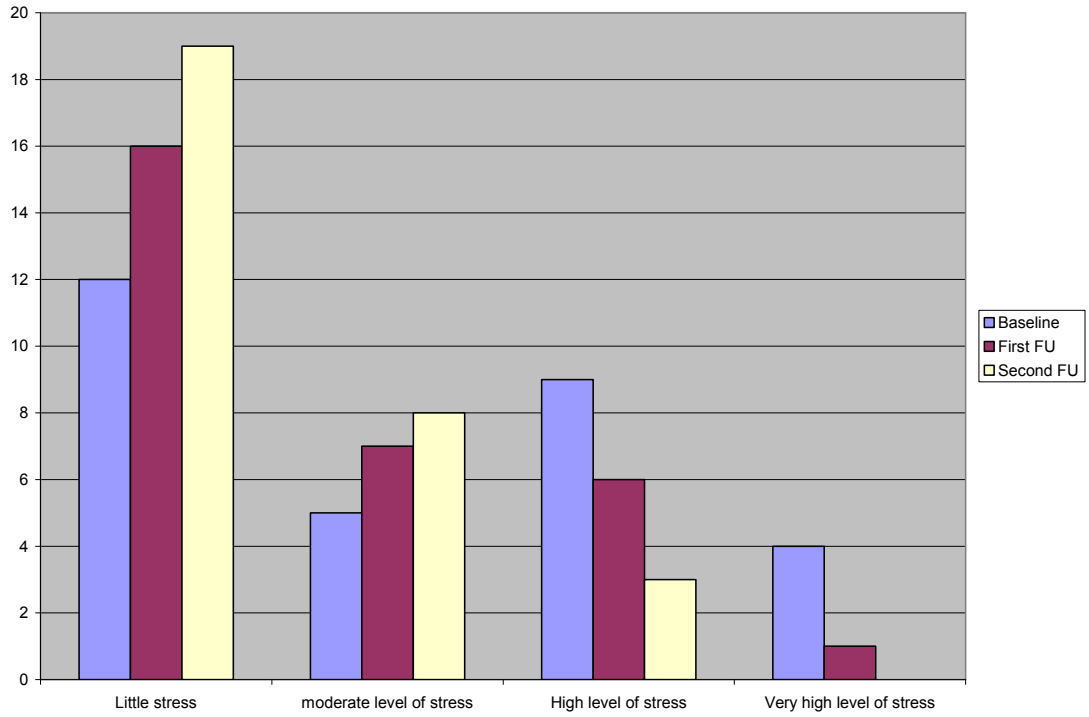
Figure 4.12 Graph showing the frequency distribution of the responses to Question L



The above graph demonstrates the improvement of the attitude of the respondents to their condition over the course of the trial. The number of respondents reporting 'Do not think about it', increased while the number of respondents reporting more intrusive and disruptive attitudes, diminished.

4.9.1.13 Question M: Rate the level of dyspepsia stress you have to cope with at present?

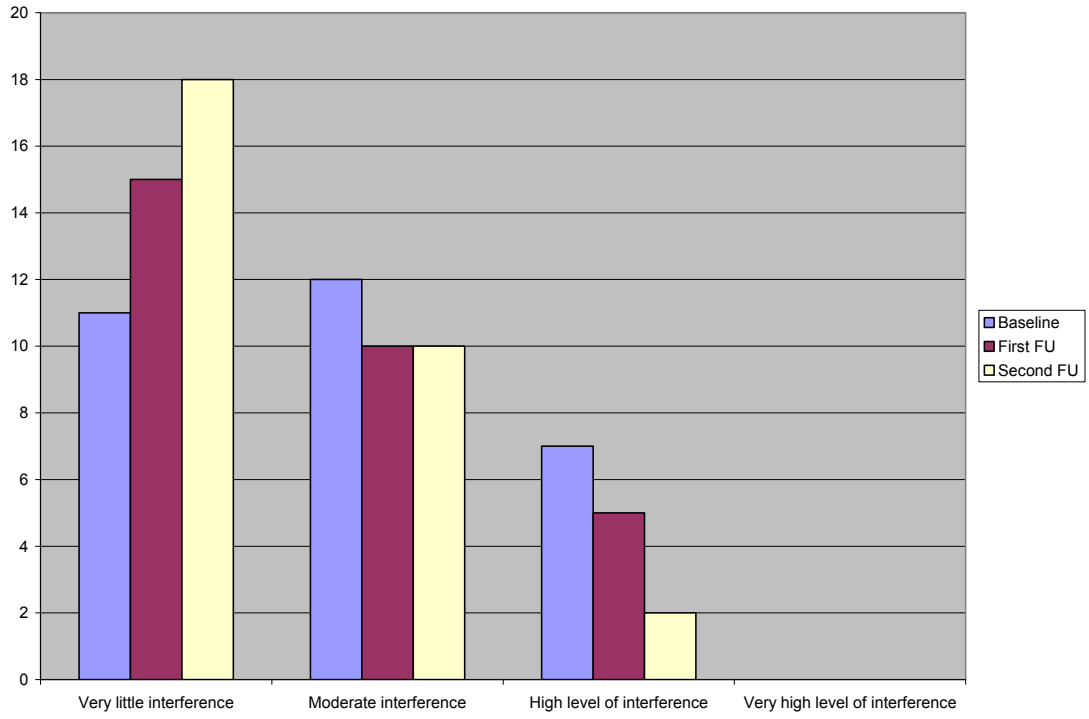
Figure 4.13 Graph showing the frequency distribution of the responses to Question M



The above graph demonstrates the overall reduction in self assessment of stress levels associated with their condition over the course of the trial. The number of respondents reporting ‘Little stress’, increased while the number of respondents reporting higher levels of stress, diminished.

4.9.1.14 Question N: How does your dyspepsia interfere with your daily work?

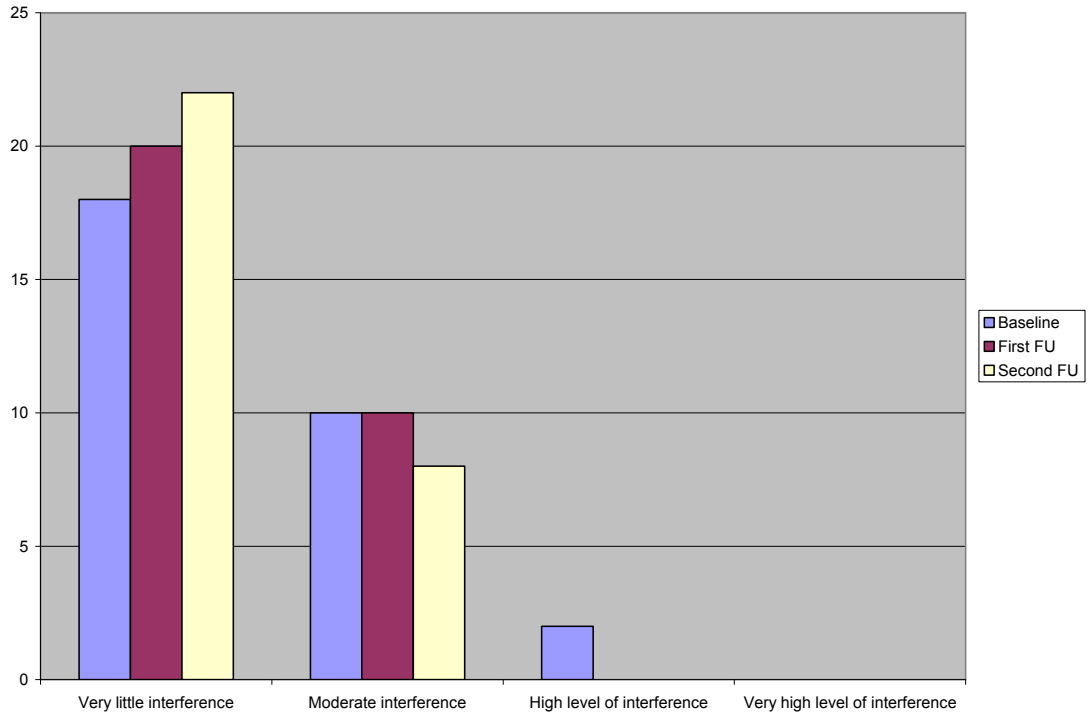
Figure 4.14 Graph showing the frequency distribution of the responses to Question N



The above graph demonstrates the extent to which the respondents rated the effect of their condition on their daily work over the course of the trial. The number of respondents reporting 'Very little interference', increased while the number of respondents reporting more invasive levels of interference, diminished.

4.9.1.15 Question O: How does your condition interfere with your family life?

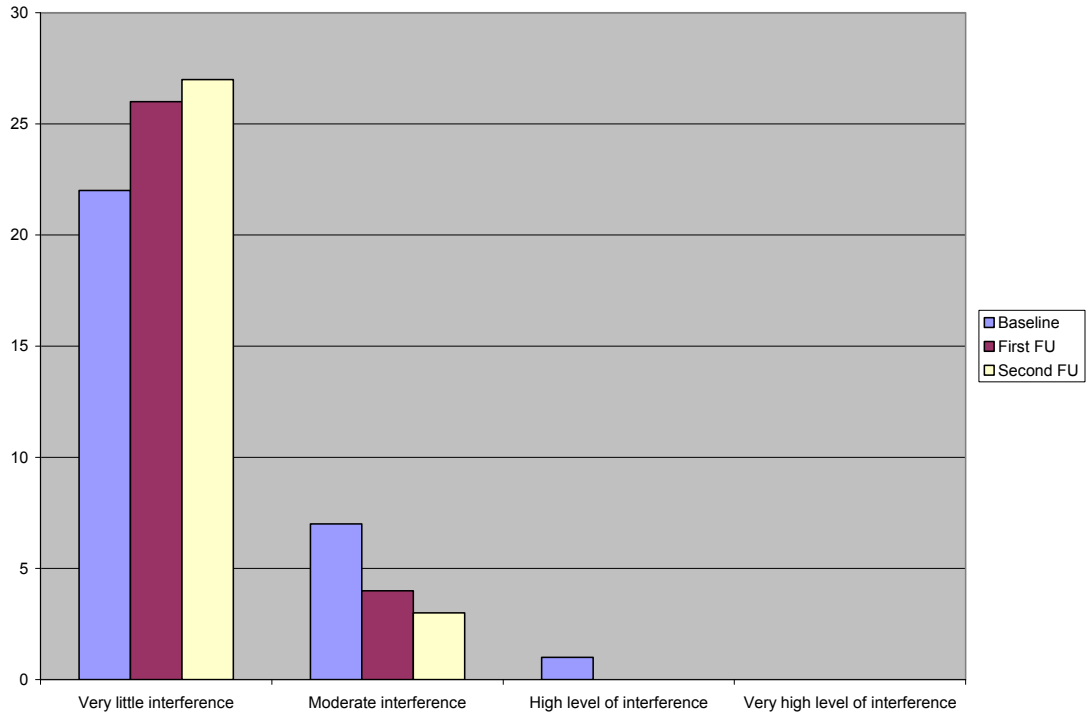
Figure 4.15 Graph showing the frequency distribution of the responses to Question O



The above graph demonstrates the extent to which the respondents rated the effect of their condition on their family life over the course of the trial. The number of respondents reporting 'Very little interference', increased while the number of respondents reporting more invasive levels of interference, diminished.

4.9.1.16: Question P: How does your dyspepsia interfere with your social life?

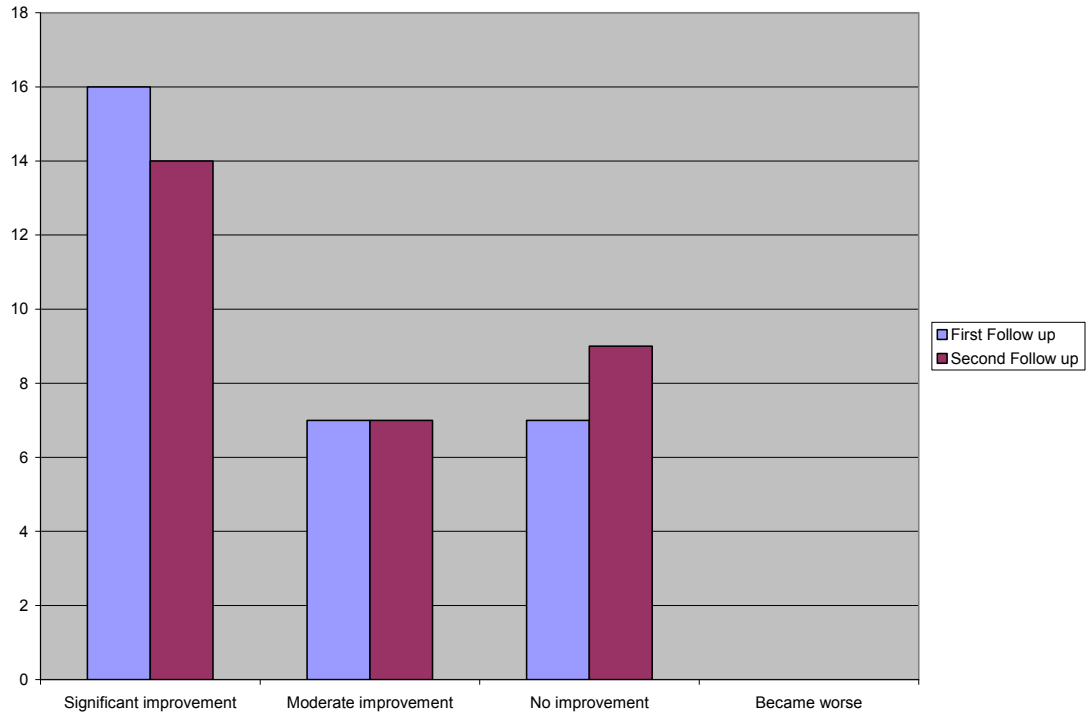
Figure 4.16 Graph showing the frequency distribution of the responses to Question P



The above graph demonstrates the extent to which the respondents rated the effect of their condition on their social life over the course of the trial. The number of respondents reporting ‘Very little interference’, increased while the number of respondents reporting ‘Moderate interference’, diminished.

4.9.1.17 Question Q: From the onset of treatment have you experienced any changes in your dyspepsia?

Figure 4.17 Graph showing the relative frequency distribution for Question Q



The above graph supports the majority of the observations made in the previous questions. The First Follow up series indicates that 23 of the respondents had either significant (16) or moderate (7) improvement between the initial consultation and the first follow up.

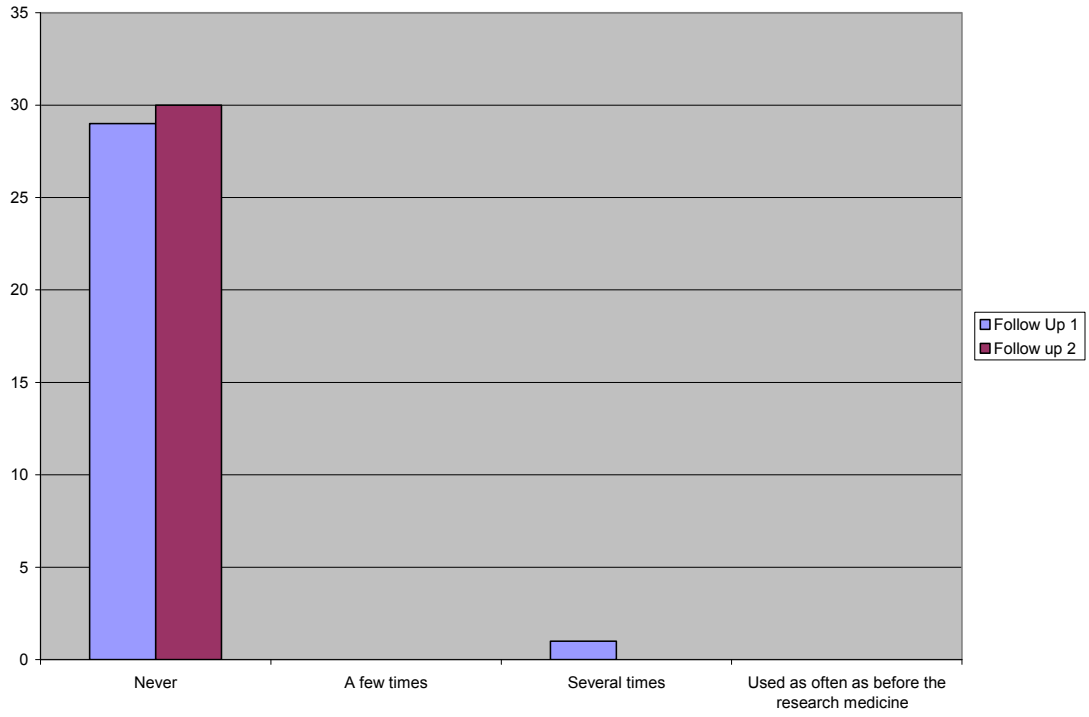
The second follow up series shows that 21 of the respondents had significant (14) or moderate (7) improvement between the first follow up and the second follow up.

It would appear that more improvement occurred between the initial consult and the first follow up than between the first and second follow ups. The difference

however is marginal. The statistical significance of this is assessed in 4.3 and 4.4.

4.9.1.18 Question R: Was it necessary to use any other medication for the dyspepsia?

Figure 4.18 Graph showing the relative frequency distribution for Question R



The above graph again supports the impression of overall improvement.

Between the Initial consultation and the first follow up only 1 respondent found it necessary to use other medication –reporting a frequency of several times.

Between the first and second follow up no respondents found it necessary to use any other medication.

The statistical significance of this observation is assessed in 4.6 and 4.7.

4.10.1. Friedmans Test Analysis

The intra-group analysis was done using the Friedman's test, i.e. the questionnaire scores between consultation one (base-line), consultation two and consultation three, were compared. This was done for the trial group as a whole as well as for the treatment and placebo groups. Each question of the questionnaire was analysed separately as well as a total score for the entire questionnaire.

The Friedman test is the nonparametric equivalent of a one-sample repeated measures design or a two-way analysis of variance. Friedman tests the null hypothesis that k related variables come from the same population. In this case it tests the assumption that the three observed questionnaire responses came from the same population (i.e. no significant difference between responses). The p value returns the chance that the observed results could have been drawn from the same population by chance. A p value less than 0.05 (i.e. 5% level of significance) indicates that the populations are different. This indicates that there was a significant difference between the consultations.

4.10.1.1 Hypothesis Testing

The null hypothesis H_0 states that there is no significant difference between the visits being compared at the a = 0.05 level of significance. The alternate hypothesis H_1, states that at least two of the visits will differ significantly at the same level of significance.

4.10.1.2 Decision Rule

At the a = 0.05 level of significance, the null hypothesis is rejected if $P \leq \alpha$, where p is the observed significance level. Otherwise, the null hypothesis is accepted at the same level of significance.

4.10.2 Group Analysis

Each questionnaire item was compared across the three consultations- taking the trial group as a whole. While not valuable for assessing the efficacy of the treatment protocol against placebo it is useful in that it demonstrates the statistical significance of the observed and reported benefits of the trial. Significant p- values are shown in bold.

Table 4.B Table showing results of Friedman's test with test statistics

Question	Chi Square Value	p Value
How severe would you rate your dyspepsia	17.886	**0.000**
How often do you experience dyspepsia	12.696	**0.002**
How long does an attack of dyspepsia last	11.529	**0.003**
To what extent do you experience dyspepsia after a meal	19.846	**0.000**
Do you often experience waterbrash	18.200	**0.000**
How often does dyspepsia interfere with your sleep	19.163	**0.000**
Do you experience chest pain with an attack of dyspepsia	14.000	**0.001**
Does the pain spread to the your abdomen	6.050	**0.049**
Do you experience nausea or vomiting with an attack of dyspepsia	22.235	**0.000**
Do you experience feelings of bloating and distension in the abdomen	17.915	**0.000**
Do you experience burping or belching with an attack of dyspepsia	14.400	**0.001**
What is your attitude towards your condition	21.385	**0.000**
Rate the level of dyspepsia stress you have to cope with at present	27.444	**0.000**

How does your dyspepsia interfere with your daily work	18.000	**0.000**
How does your dyspepsia interfere with your family life	8.375	**0.015**
How does your dyspepsia interfere with your social life	8.400	**0.015**
Sum of values of all responses	36.136	**0.000**

All the p values for the whole group analysis were significant. This indicates that as a whole the group experienced statistically significant changes (improvement) as measured on the self assessment questionnaires. These changes occurred over the period of the trial.

4.10.3 Placebo Group

Each questionnaire item was compared across the three consultations using the placebo group responses. Significant p- values are shown in bold.

Table 4.C. Table showing results of Friedman's test with test statistics

Question	Chi Square Value	p Value
How severe would you rate your dyspepsia	14.552	**0.001**
How often do you experience dyspepsia	15.935	**0.000**
How long does an attack of dyspepsia last	13.556	**0.001**
To what extent do you experience dyspepsia after a meal	12.000	**0.002**
Do you often experience waterbrash	10.333	**0.006**
How often does dyspepsia interfere with your sleep	16.710	**0.000**
Do you experience chest pain with an attack of dyspepsia	14.000	**0.001**
Does the pain spread to the your abdomen	11.000	**0.004**
Do you experience nausea or vomiting with an attack of dyspepsia	14.114	**0.001**
Do you experience feelings of bloating and distension in the abdomen	13.040	**0.001**
Do you experience burping or belching with an attack of dyspepsia	15.000	**0.001**

What is your attitude towards your condition	12.250	**0.002**
Rate the level of dyspepsia stress you have to cope with at present	15.200	**0.001**
How does your dyspepsia interfere with your daily work	14.000	**0.001**
How does your dyspepsia interfere with your family life	6.615	**0.037**
How does your dyspepsia interfere with your social life	6.500	**0.039**
Sum of values of all responses	27.000	**0.000**

All the p values for the placebo group analysis were significant. This indicates that the placebo group experienced statistically significant changes (improvement) as measured on the self assessment questionnaires. These changes occurred over the period of the trial.

4.10.4 Treatment Group

Each questionnaire item was compared across the three consultations using the placebo group responses. Significant p- values are shown in bold.

Table 4.D Table showing results of Friedman's test with test statistics - Treatment Group

Question	Chi Square Value	p Value
How severe would you rate your dyspepsia	4.000	0.135
How often do you experience dyspepsia	0.400	0.819
How long does an attack of dyspepsia last	0.286	0.867
To what extent do you experience dyspepsia after a meal	8.400	**0.015**
Do you often experience waterbrash	8.000	**0.018**
How often does dyspepsia interfere with your sleep	3.500	0.174
Do you experience chest pain with an attack of dyspepsia	2.000	0.368
Does the pain spread to the your abdomen	0.000	1.000
Do you experience nausea or vomiting with an attack of dyspepsia	8.375	**0.015**
Do you experience feelings of bloating and distension in the abdomen	6.091	**0.048**
Do you experience burping or belching with an	1.200	0.549

attack of dyspepsia		
What is your attitude towards your condition	10.000	**0.007**
Rate the level of dyspepsia stress you have to cope with at present	12.250	**0.002**
How does your dyspepsia interfere with your daily work	6.000	0.050
How does your dyspepsia interfere with your family life	2.000	0.368
How does your dyspepsia interfere with your social life	2.000	0.368
Sum of values of all responses	11.640	0.003

The treatment group did not show the same level of significance across all question items. Statistically significant change was not seen in those items with p values greater than 0.05. At a 5 % level of significance there was not enough evidence to conclude that these items apparent changes were not the result of random variation.

The items that did return significant p values were:

To what extent do you experience dyspepsia after a meal?

Do you often experience waterbrash?

Do you experience nausea or vomiting with an attack of dyspepsia?

Do you experience feelings of bloating and distension in the abdomen?

What is your attitude towards your condition?

Rate the level of dyspepsia stress you have to cope with at present

Sum of values of all responses

The first four items explore the particulars of the patients experiences of dyspepsia (and their relative impact).i.e. extent of suffering after meals, experience of waterbrash, experience of nausea and vomiting or bloating and distension. It may be reasonable to assume that these particulars may be more susceptible to change than general ratings of distress. This may explain why these particulars are statistically significant.

The last two items (bar one) rate abstract and subjective levels of self assessment and as such may be more susceptible to placebo type responses.

The last item illustrates that there was a significant improvement (decrease in total rating value) of the variable derived as the sum of all the questionnaire item values.

Further discussion of these results is found in Chapter 5.

4.11 The Wilcoxon's Signed Rank Test

The Wilcoxon's Signed rank Test was used to determine the statistical significance between the consultations. Again this was performed for the trial group as a whole as well as for the placebo and treatment groups individually.

4.11.1 Hypothesis Testing

The null hypothesis H_0 states that there is no significant difference between the two visits being compared at the a = 0.05 level of significance. The alternative hypothesis H_1, states that there is a significant difference between the two visits being compared.

4.11.2 Decision Rule

At the a = 0.05 level of significance, the null hypothesis is rejected if $p \leq \alpha/2$, where p is the observed significance level. Otherwise, the null hypothesis is accepted at the same level of significance.

The Wilcoxon Signed Rank test compares the distributions of two related samples. By assessing the magnitude as well as the sign of the rank sums, the test returns a test statistic. The p value is the chance that the difference observed between the two populations (from Friedmans analysis) could have been observed by chance in a single population.

4.11.3 Group Analysis

For each questionnaire item where the Friedmans test returned a significant difference across the three consultations, the Wilcoxon signed rank test was applied to determine where the difference could be found i.e. between which two consultations. This was done taking the trial group as a whole. While not valuable for assessing the efficacy of the treatment protocol against placebo it is useful in that it demonstrates the statistical significance of the observed and reported benefits of the trial and may help to elucidate an understanding of protocols in action in a clinical setting. Significant p- values are shown in bold.

Table 4.E Table showing results of Wilcoxon Signed rank test with test statistics

Wilcoxon Rank Test Calculated for:	**Initial – FU 1**		**FU1 – FU 2**	
Baseline – Follow up 1	**Z-value**	**P Value**	**Z-value**	**P Value**
How severe would you rate your dyspepsia	-2.828	0.005	-2.236	0.025
How often do you experience dyspepsia	-2.333	0.020	-1.890	0.059
How long does an attack of dyspepsia last	-2.126	0.033	-2.271	0.023
To what extent do you experience dyspepsia after a meal	-2.121	0.034	-2.636	**0.008**

Do you often experience waterbrash	-2.887	0.004	-1.000	0.317
How often does your dyspepsia interfere with your sleep	-2.812	0.005	-2.333	0.020
Do you experience chest pain with an attack of dyspepsia	-2.326	0.020	-2.496	0.013
Does the pain spread to your abdomen	-1.098	0.272	-1.730	0.084
Do you experience nausea or vomiting with an attack of dyspepsia	-3.419	0.001	-1.633	0.102
Do you experience feelings of bloating and distension in the abdomen	-2.565	0.010	-2.646	**0.008**
Do you experience burping or belching with an attack of dyspepsia	-2.333	0.020	-2.310	0.021
What is your attitude towards your condition	-2.877	0.004	-1.732	0.083
Rate the level of dyspepsia stress you have to cope with at present	-3.357	0.001	-2.828	**0.005**
How does your dyspepsia interfere with your daily work	-2.449	0.014	-2.449	0.014
How does your condition interfere with your family life	-2.000	0.046	-1.414	0.157
How does your dyspepsia interfere with your social life	-1.890	0.059	-1.000	0.317

4.11.4 Placebo Group Analysis

For each questionnaire item where the Friedmans test returned a significant difference across the three consultations, the Wilcoxon signed rank test was applied to determine where the difference could be found i.e. between which two consultations. Significant p- values are shown in bold.

Table 4.F. Table showing results of Wilcoxon Signed rank test with test statistics

Wilcoxon Rank Test Calculated for:	**Initial – FU 1**		**FU1 – FU 2**	
Baseline – Follow up 1	**Z-value**	**P Value**	**Z-value**	**P Value**
How severe would you rate your dyspepsia	-2.449	0.014	-2.236	0.025
How often do you experience dyspepsia	-2.646	0.008	-2.000	0.046
How long does an attack of dyspepsia last	-2.271	0.023	-2.070	0.038
To what extent do you experience dyspepsia after a meal	-1.890	0.059	-1.890	0.059
Do you often experience waterbrash	-2.236	0.025	-1.000	0.317
How often does your dyspepsia interfere with your sleep	-2.887	0.004	-1.890	0.059
Do you experience chest pain with an attack of dyspepsia	-2.264	0.024	-2.449	0.014

Does the pain spread to your abdomen	-1.890	0.059	-1.857	0.063
Do you experience nausea or vomiting with an attack of dyspepsia	-2.887	0.004	-1.000	0.317
Do you experience feelings of bloating and distension in the abdomen	-2.271	0.023	-1.732	0.083
Do you experience burping or belching with an attack of dyspepsia	-2.449	0.014	-2.333	0.020
What is your attitude towards your condition	-2.070	0.038	-1.732	0.083
Rate the level of dyspepsia stress you have to cope with at present	-2.530	0.011	-2.236	0.025
How does your dyspepsia interfere with your daily work	-1.732	0.083	-2.449	0.014
How does your condition interfere with your family life	-1.732	0.083	-1.414	0.157
How does your dyspepsia interfere with your social life	-1.732	0.083	-1.000	0.317

4.11.5 Treatment Group Analysis

For each questionnaire item where the Friedmans test returned a significant difference across the three consultations, the Wilcoxon signed rank test was applied to determine where the difference could be found i.e. between which two consultations. Significant p- values are shown in bold.

Table 4.G. Table showing results of Wilcoxon Signed rank test with test statistics

Wilcoxon Rank Test Calculated for:	**Initial – FU 1**		**FU1 – FU 2**	
Baseline – Follow up 1	**Z-value**	**P Value**	**Z-value**	**P Value**
How severe would you rate your dyspepsia	-1.414	0.157	0.000	1.000
How often do you experience dyspepsia	0.000	1.000	-0.577	0.564
How long does an attack of dyspepsia last	0.000	1.000	-1.000	0.317
To what extent do you experience dyspepsia after a meal	-1.000	0.317	-1.890	0.059
Do you often experience waterbrash	-1.890	0.059	0.000	1.000
How often does your dyspepsia interfere with your sleep	-0.816	0.414	-1.414	0.157
Do you experience chest pain with an attack of dyspepsia	-0.816	0.414	-1.134	0.257

Does the pain spread to your abdomen	-0.378	0.705	0.000	1.000
Do you experience nausea or vomiting with an attack of dyspepsia	-1.890	0.059	-1.414	0.157
Do you experience feelings of bloating and distension in the abdomen	-1.134	0.257	-2.000	0.046
Do you experience burping or belching with an attack of dyspepsia	-0.577	0.564	-0.816	0.414
What is your attitude towards your condition	-2.060	0.039	0.000	1.000
Rate the level of dyspepsia stress you have to cope with at present	-2.236	0.025	-1.732	0.083
How does your dyspepsia interfere with your daily work	-1.732	0.083	0.000	1.000
How does your condition interfere with your family life	-1.000	0.317	0.000	1.000
How does your dyspepsia interfere with your social life	-1.000	0.317	0.000	1.000

The above graph demonstrates that there were very few statistically significant changes in the treatment group from consultation to consultation. Possible reasons for this are discussed in Chapter 5.

4.12 Kruskal Wallis Test

The inter–group analysis was done using the Kruskal Wallis non- parametric Analysis of Variance (ANOVA) method. Group one and group two were compared to each other with regard to the scores given to the questions at each consultation.

4.12.1.1 Hypothesis Testing

The null hypothesis H_0 states that there is no significant difference between the two groups being compared at the a = 0.05 level of significance. The alternative hypothesis H_1, states that at least two of the groups will differ slightly at the same level of significance.

The Kruskal-Wallis H test is an extension of the Mann Whitney U test. It tests whether sampled populations are equivalent in location. The observations from the groups are combined and ranked, with the average rank assigned in the case of ties. Kruskal-Wallis tests whether several independent samples are from the same population.

For this analysis the responses to each question were compared based on the trial grouping. The differences in responses to the questions between the placebo and the treatment group were assessed for statistical significance. Significant values of p are shown in bold.

Table 4.H Table showing Values of the Kruskal-Wallis H test comparing treatment and placebo group responses

Treatment vs Placebo for Baseline Questionnaire: Initial Consultation	Chi-Square	P Value
How severe would you rate your dyspepsia	3.303	0.069
How often do you experience dyspepsia	3.001	0.083
How long does an attack of dyspepsia last	2.086	0.149
To what extent do you experience dyspepsia after a meal	1.436	0.231
Do you often experience waterbrash	0.005	0.942
How often does your dyspepsia interfere with your sleep	1.675	0.196
Do you experience chest pain with an attack of dyspepsia	0.644	0.422
Does the pain spread to your abdomen	0.625	0.429
Do you experience nausea or vomiting with an attack of dyspepsia	0.292	0.589
Do you experience feelings of bloating and distension in the abdomen	2.326	0.127
Do you experience burping or belching with an attack of dyspepsia	0.953	0.329
What is your attitude towards your condition	0.000	1.000
Rate the level of dyspepsia stress you have to cope with at present	0.210	0.647
How does your dyspepsia interfere with your daily work	0.952	0.329

How does your condition interfere with your family life	2.661	0.103
How does your dyspepsia interfere with your social life	0.453	0.501
Average of all Baseline scores	2.001	0.157

There were no p – values less than 0.05. We therefore need to accept the null hypothesis i.e. the placebo and treatment groups were drawn from the same population. As this represents the initial consultation point, it is in a sense an affirmation of the random nature of the sample and the randomisation procedure. There was no statistically significant difference between the treatment and placebo group for any of the questions at the baseline level.

Table 4.I Table showing Values of the Kruskal-Wallis H test comparing treatment and placebo group responses

Treatment vs Placebo for Follow Up 1	Chi-Square	P Value
How severe would you rate your dyspepsia	1.146	0.284
How often do you experience dyspepsia	0.131	0.717
How long does an attack of dyspepsia last	0.039	0.843
To what extent do you experience dyspepsia after a meal	2.927	0.087
Do you often experience waterbrash	0.406	0.524
How often does your dyspepsia interfere with your sleep	0.036	0.849
Do you experience chest pain with an attack of dyspepsia	0.352	0.553
Does the pain spread to your abdomen	0.025	0.875
Do you experience nausea or vomiting with an attack of dyspepsia	1.895	0.169
Do you experience feelings of bloating and distension in the abdomen	0.017	0.896
Do you experience burping or belching with an attack of dyspepsia	0.000	0.983
What is your attitude towards your condition	0.112	0.738
Rate the level of dyspepsia stress you have to cope with at present	0.005	0.946
How does your dyspepsia interfere with your daily work	1.044	0.307

How does your condition interfere with your family life	2.320	0.128
How does your dyspepsia interfere with your social life	0.000	1.000
From the onset of treatment have you experienced any change in your dyspepsia	3.425	0.064
Was it necessary to use other medication for your dyspepsia	1.000	0.317
Average of the Follow Up 1 scores	0.111	0.740

There were no p values less than 0.05. We therefore need to accept the null hypothesis i.e. there was no difference between treatment and placebo group for any of the questions at the first follow up level.

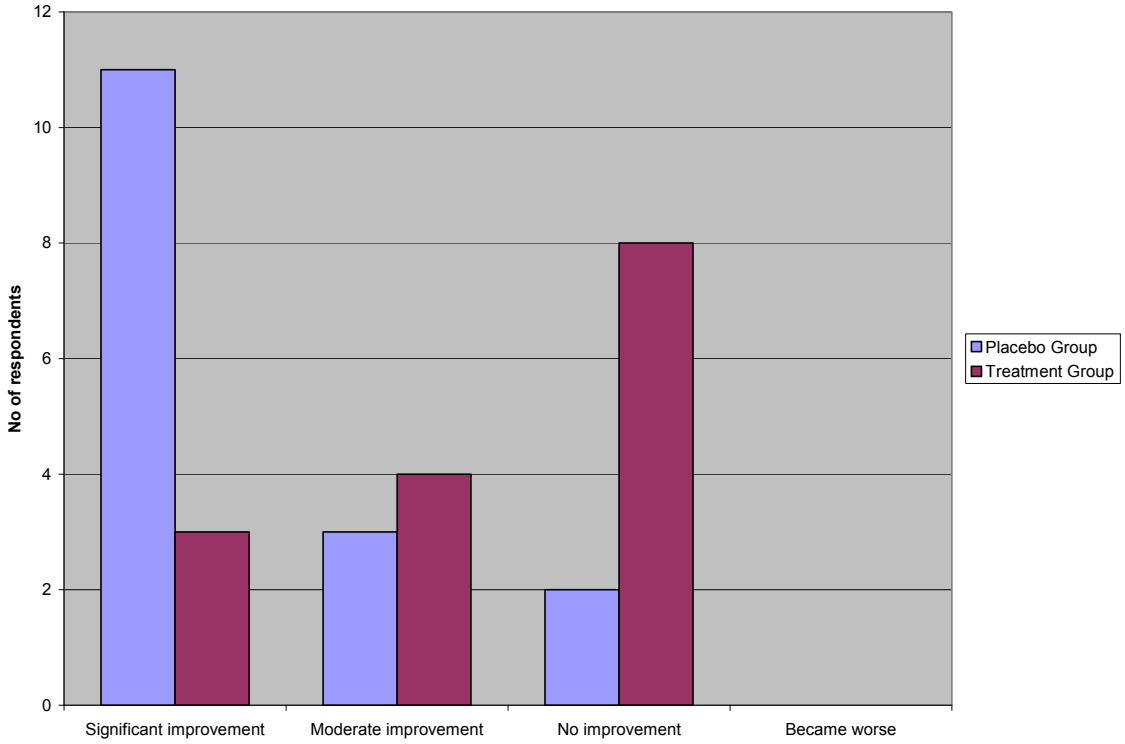
Table 4.J Table showing Values of the Kruskal-Wallis H test comparing treatment and placebo group responses

Treatment vs Placebo for Follow Up 2	Chi-Square	P Value
How severe would you rate your dyspepsia	0.002	0.964
How often do you experience dyspepsia	1.753	0.185
How long does an attack of dyspepsia last	1.330	0.249
To what extent do you experience dyspepsia after a meal	2.908	0.088
Do you often experience waterbrash	2.069	0.150
How often does your dyspepsia interfere with your sleep	1.894	0.169
Do you experience chest pain with an attack of dyspepsia	1.344	0.246
Does the pain spread to your abdomen	0.737	0.391
Do you experience nausea or vomiting with an attack of dyspepsia	2.541	0.111
Do you experience feelings of bloating and distension in the abdomen	0.154	0.695
Do you experience burping or belching with an attack of dyspepsia	0.673	0.412
What is your attitude towards your condition	0.389	0.533
Rate the level of dyspepsia stress you have to cope with at present	0.005	0.942
How does your dyspepsia interfere with your daily work	0.083	0.773

How does your condition interfere with your family life	0.659	0.417
How does your dyspepsia interfere with your social life	0.358	0.550
From the onset of treatment have you experienced any change in your dyspepsia	9.807	**0.002**
Was it necessary to use other medication for your dyspepsia	0.000	1.000
Average of the Follow up 2 scores	2.177	0.140

The only p – value less than 0.05 was for Question Q. There was thus a statistically significant difference between the two groups in there perception of this area. Referring to Figure 4.19 below however, it is clear that the placebo group reported significantly more improvement than the treatment group. Possible reasons for this are discussed in Chapter 5.

Figure 4.19 Graph showing comparison of the responses to Question Q at the Second Follow up



The remainder of the p-values is greater than 0.05 and we therefore accept the null hypothesis: at the second follow up there was no statistically significant difference between the placebo group and the treatment group.

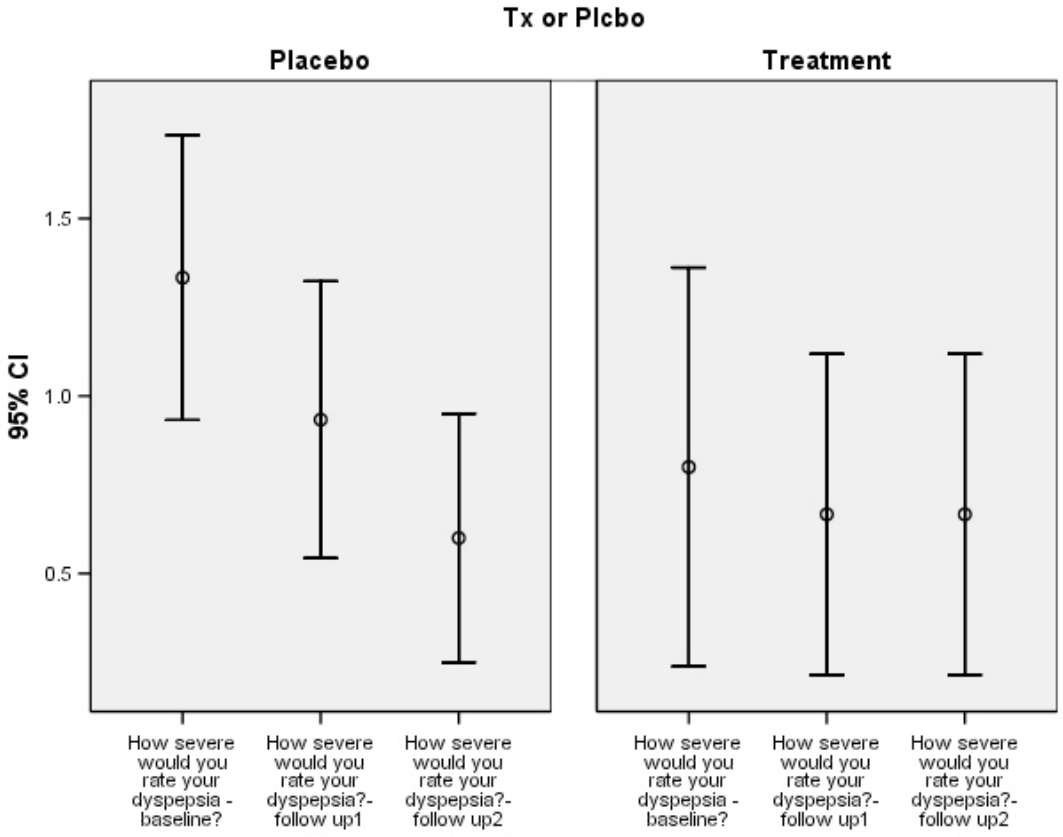
4.12.2 Conclusions based on the Kruskal Wallis H test

It is apparent that there was no statistically significant difference between the treatment and the placebo group. Graphic comparisons of the difference between treatment and placebo group further re-inforce this conclusion.

4.13 Graphical Comparison of the Treatment vs Placebo Distributions

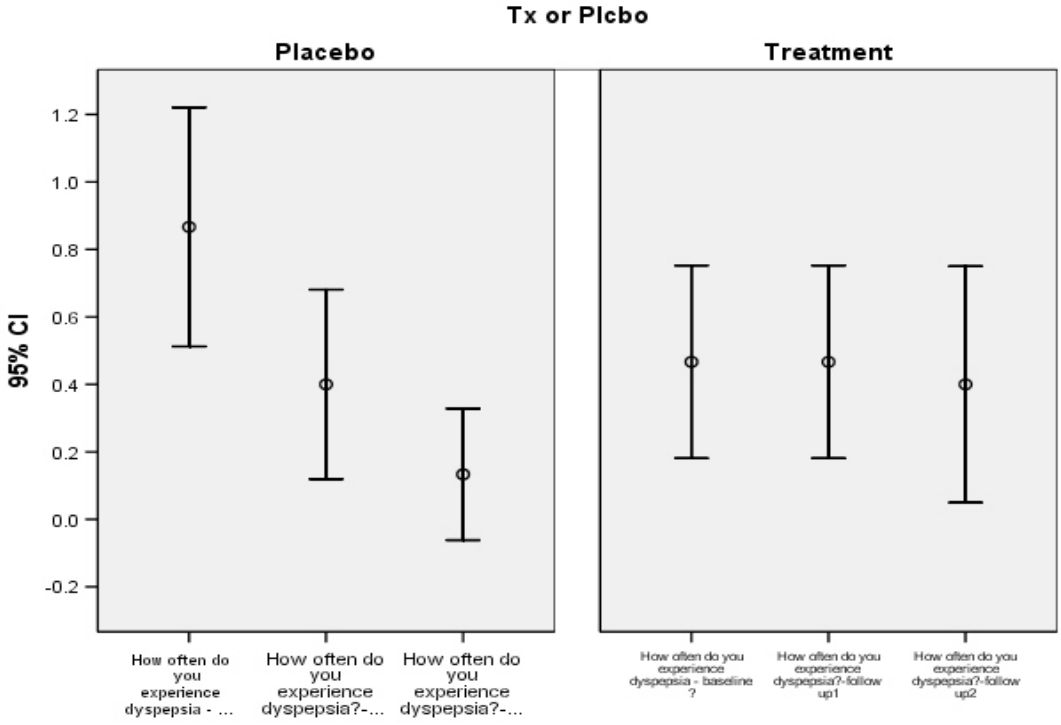
In this analysis the placebo and treatment group were compared by questionnaire item across all three consultations. The graphical analysis serves to illustrate some of the results derived from the Kruskal Wallis tests.

4.13.1 Question A: How severe would you rate your 'dyspepsia'?



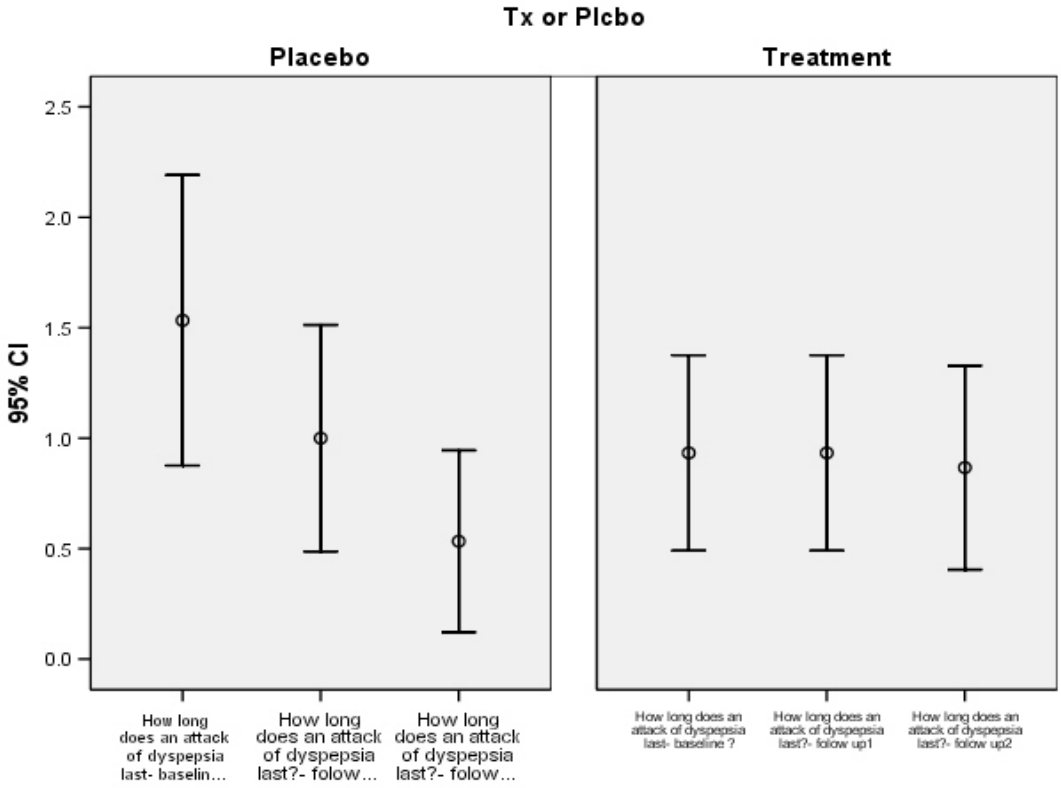
The above graphs show that improvement was noted in both placebo and treatment groups; however the placebo group reported a greater decrease in the severity of symptoms of dyspepsia than the treatment group.

4.13.2 Question B: How often do you experience dyspepsia?



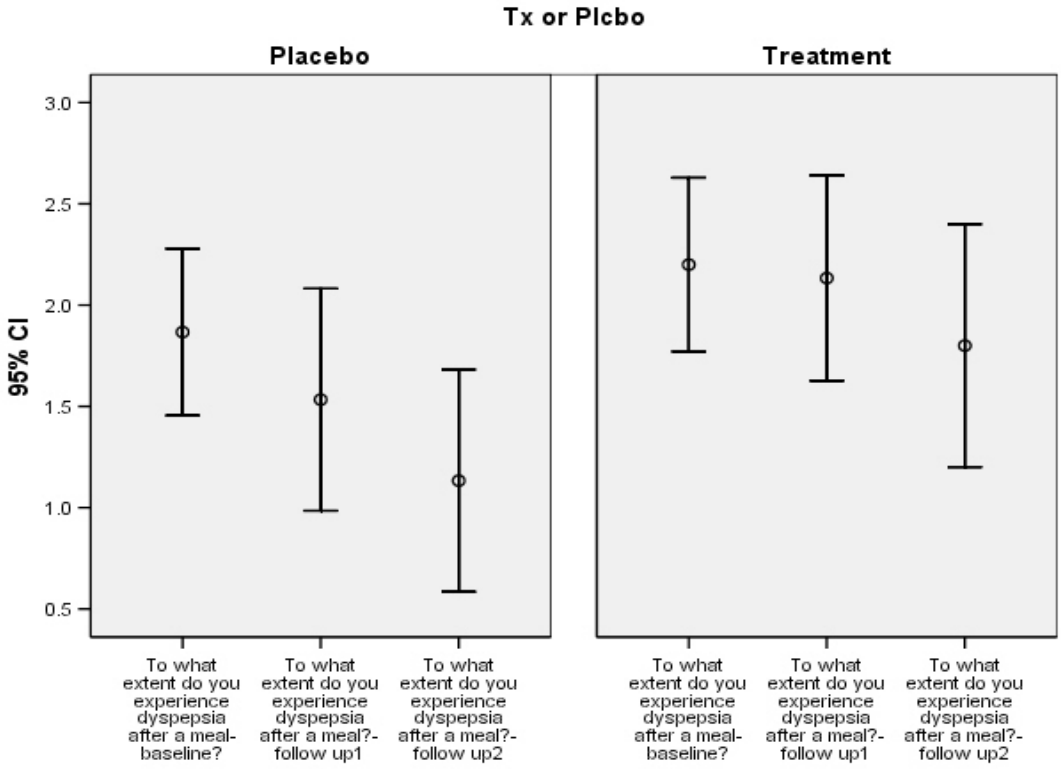
The graphs above illustrate a greater decline in the frequency of dyspepsia in the placebo group when compared to the treatment group.

4.13.3 Question C: How long does an attack of dyspepsia last?



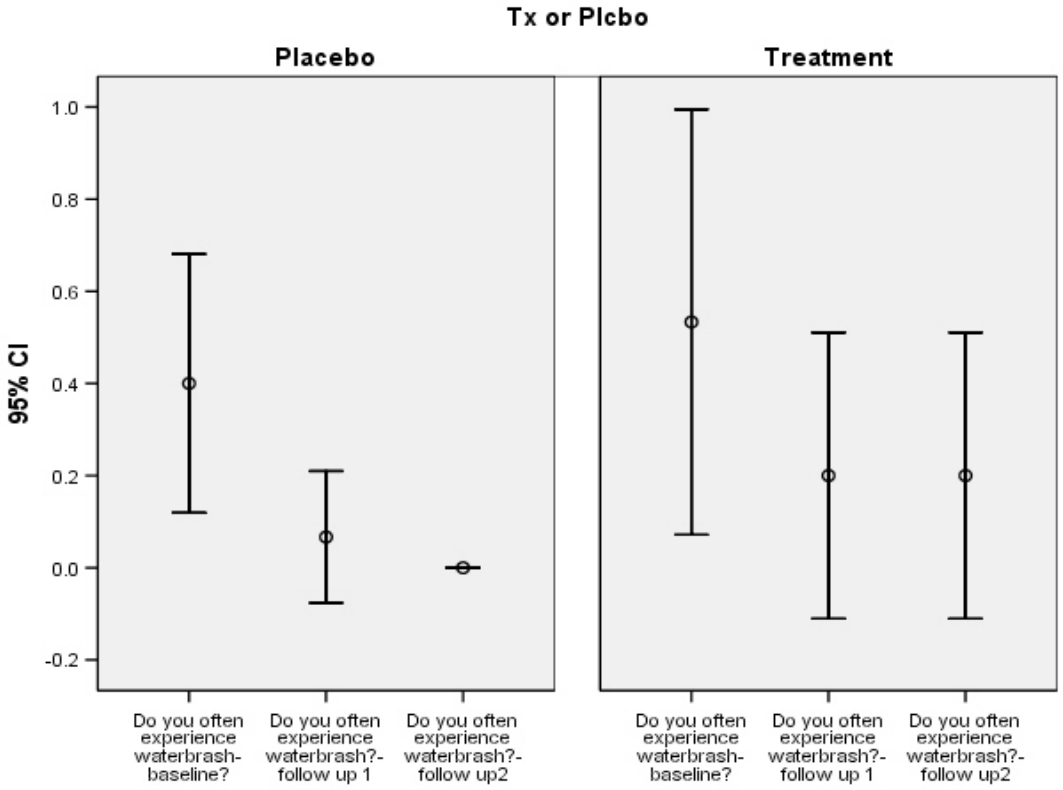
These graphs again show slight improvements noted by the treatment group, whereas the placebo group responded more significantly to this question.

4.13.4 Question D: To what extent do you experience dyspepsia after a meal ?



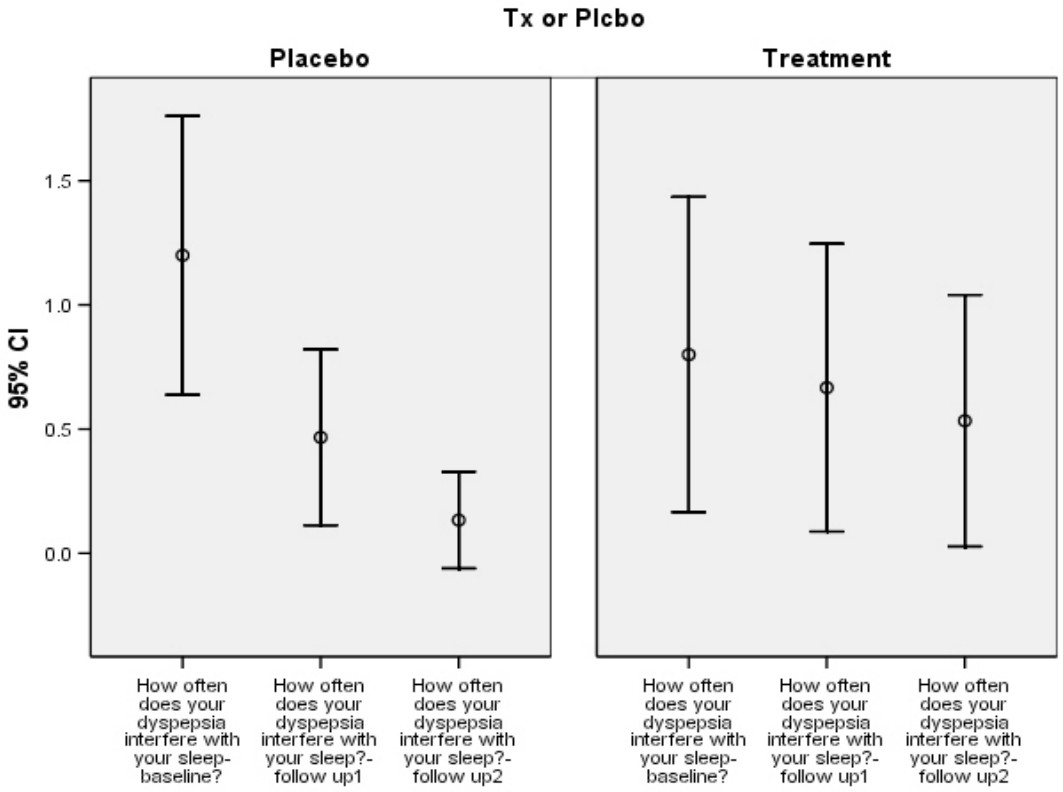
The above graphs demonstrate a more significant response to this question was yielded by the treatment group across all three consultations.

4.13.5 Question E: Do you often experience waterbrash?



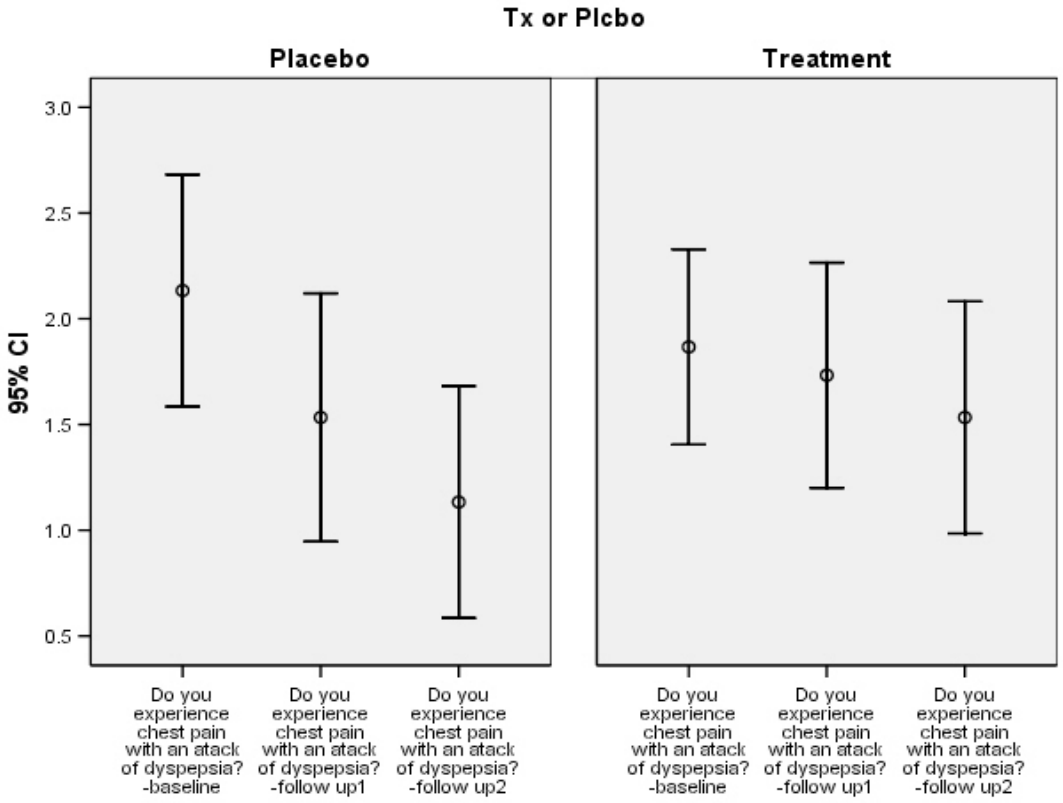
From the above graphs it is obvious that both groups responded significantly to this particular question. It can be deduced that both placebo and treatment groups experienced relief from the symptom of waterbrash for the duration of the trial.

4.13.6 Question F: How often does your dyspepsia interfere with your sleep ?



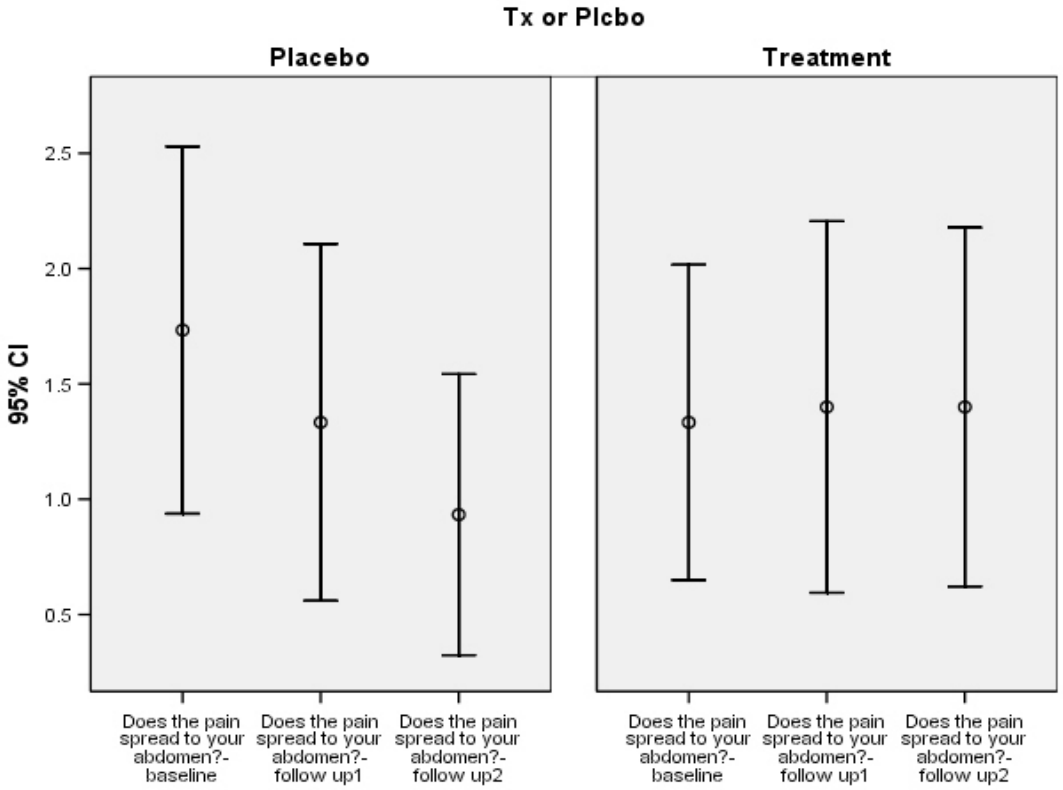
Here again, the placebo group responded more significantly to the question of dyspepsia related sleep interference. This response could be attributed to the placebo phenomenon discussed in Chapter 5.

4.13.7 Question G: Do you experience chest pain with an attack of dyspepsia?



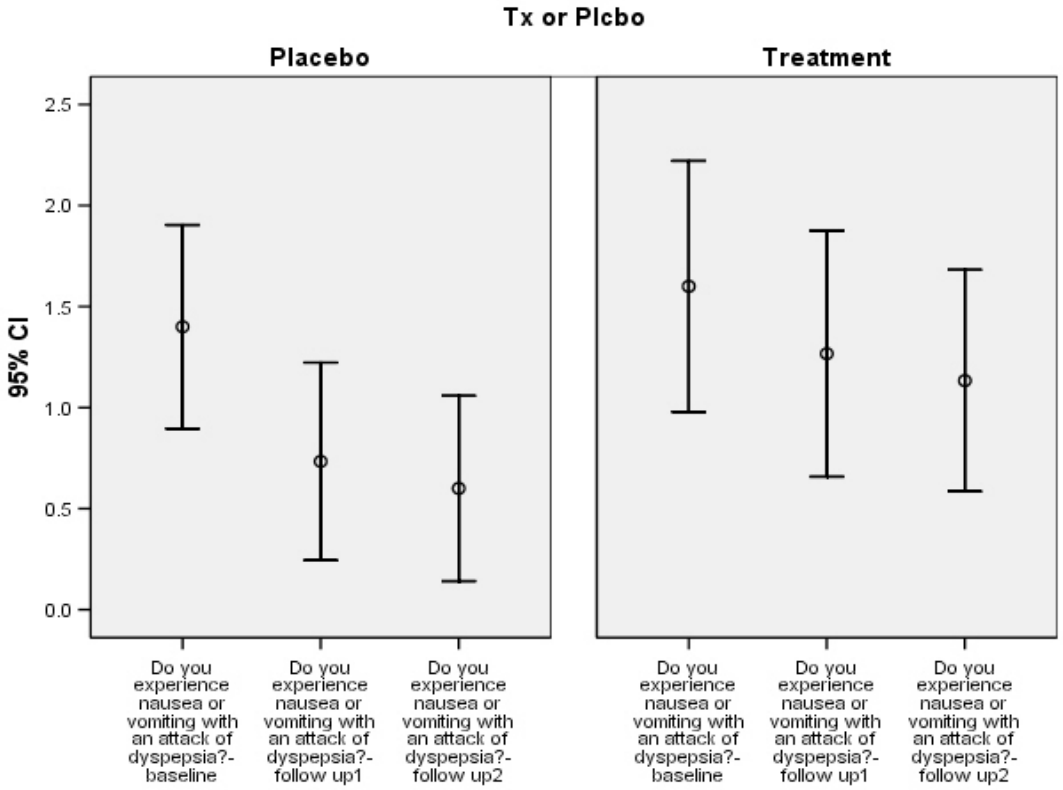
Relief from chest pain was experienced by both groups for the duration of the trial. Here again, although improvement was noted across all three consultations, the results were not statistically significant.

4.13.8 Question H: Does the pain spread to your abdomen?



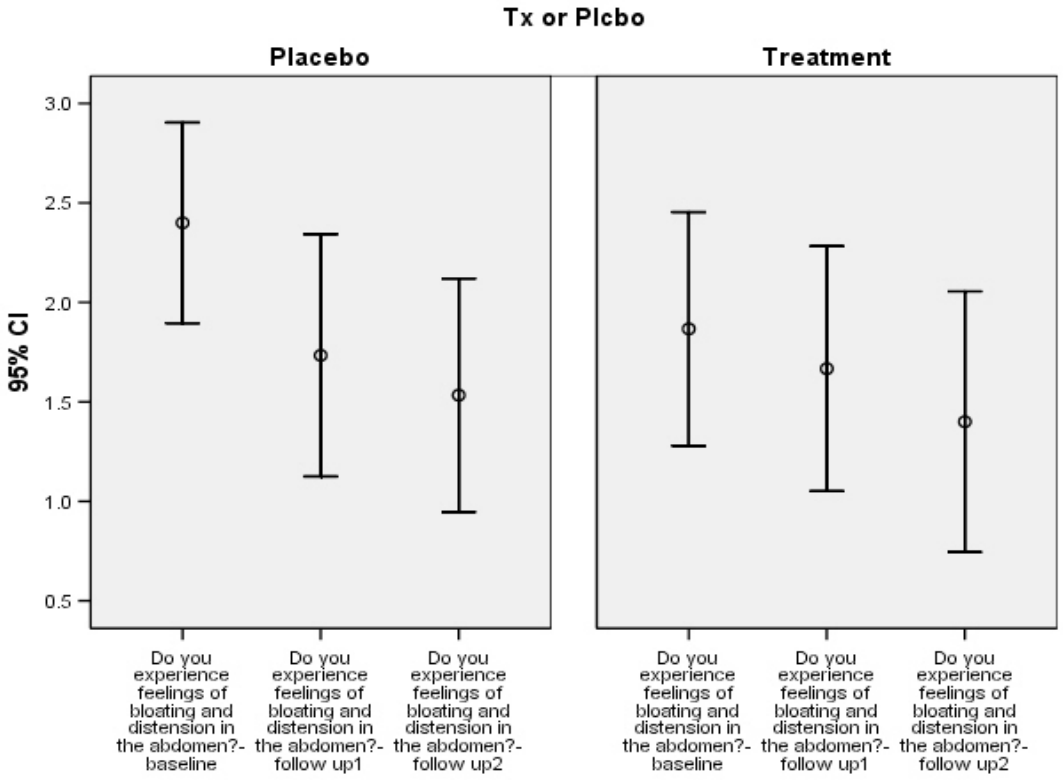
The above graphs indicate no significant responses were yielded from either group with regard to abdominal pain.

4.13.9 Question I: Do you experience nausea or vomiting with an attack of dyspepsia?



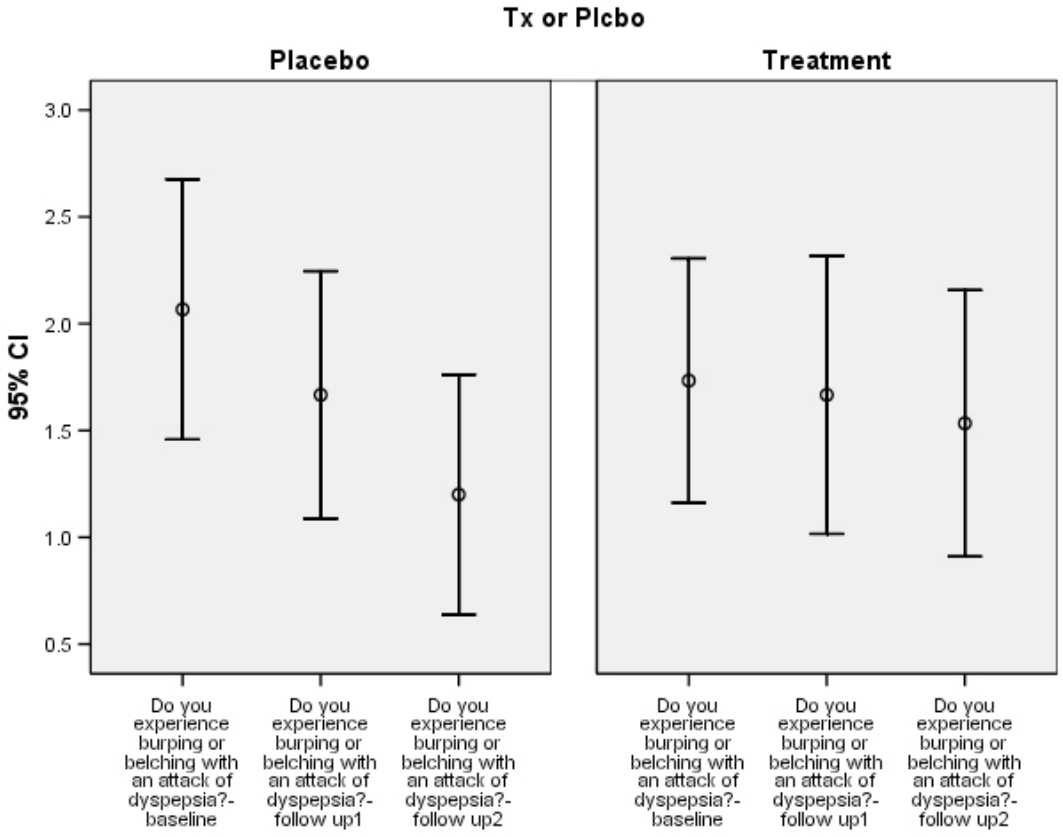
The graphs above demonstrate that more patients in the placebo group noted relief from nausea for the duration of the trial.

4.13.10 Question J: Do you experience feelings of bloatedness and distention in your abdomen?



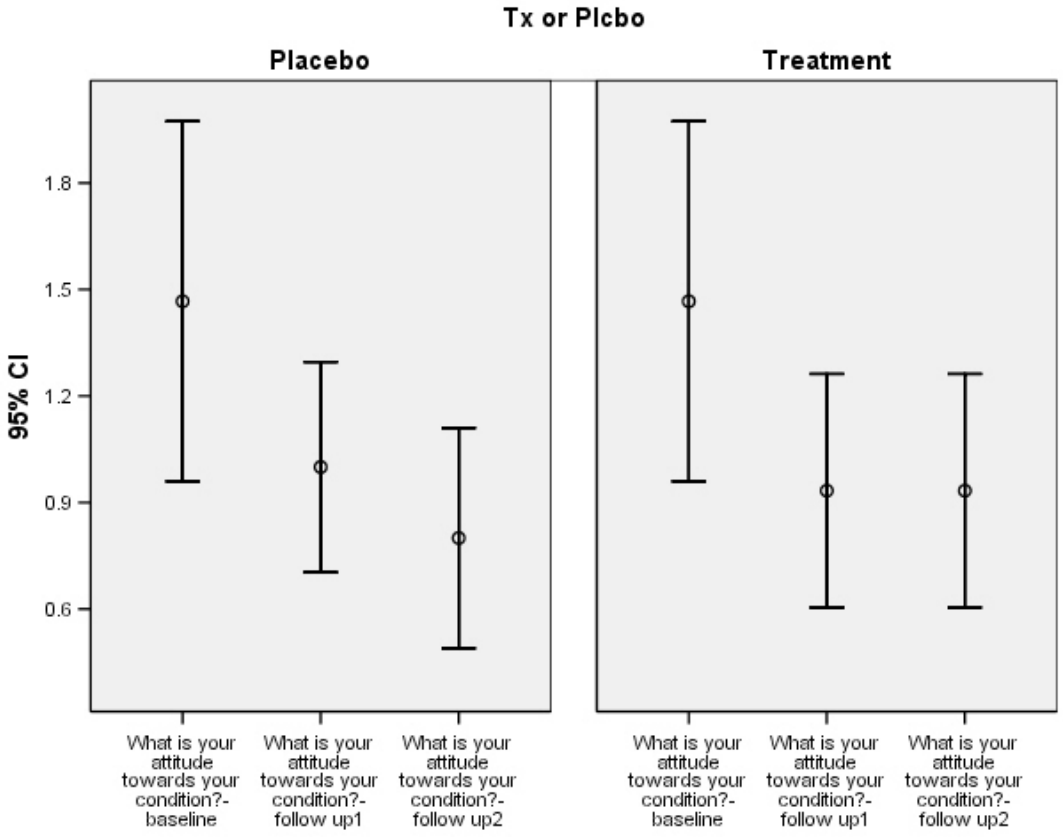
Again, neither group reported significant improvement for the symptoms of bloating and distention.

4.13.11 Question K: Do you experience burping or belching with an attack of dyspepsia?



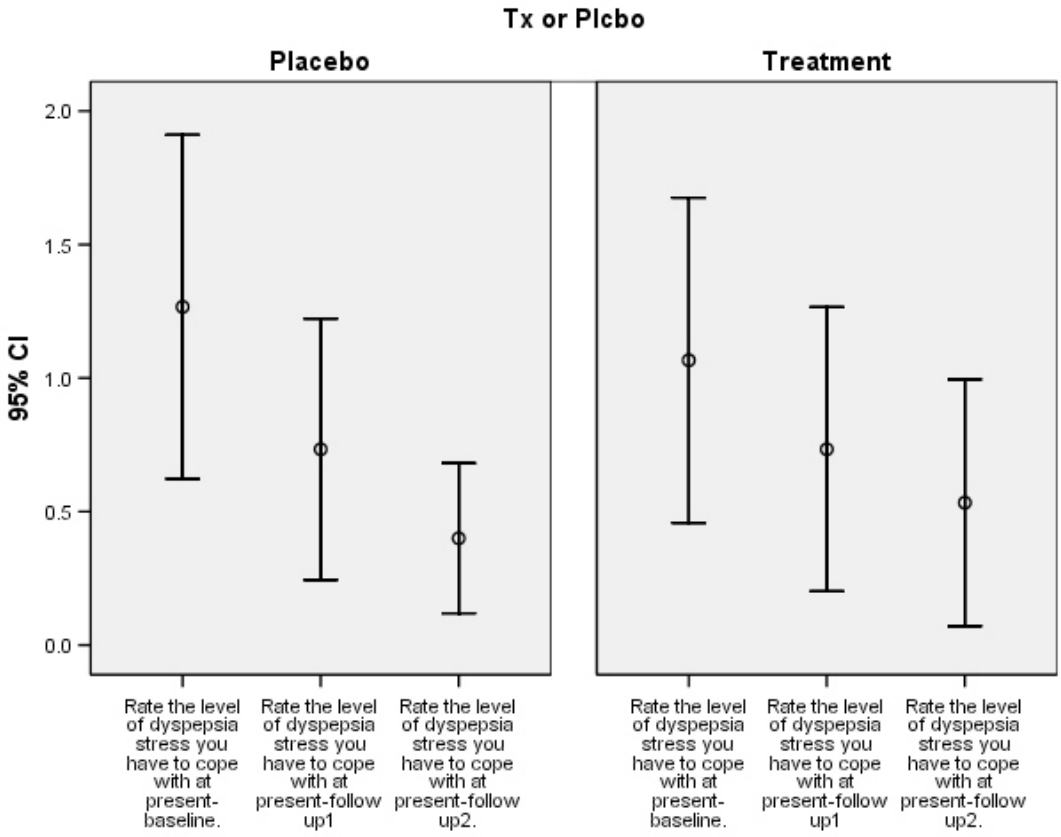
The placebo group once more, reported greater relief from the symptoms of burping and belching than the treatment group across all three consultations.

4.13.12 Question L: What is your attitude towards your condition ?



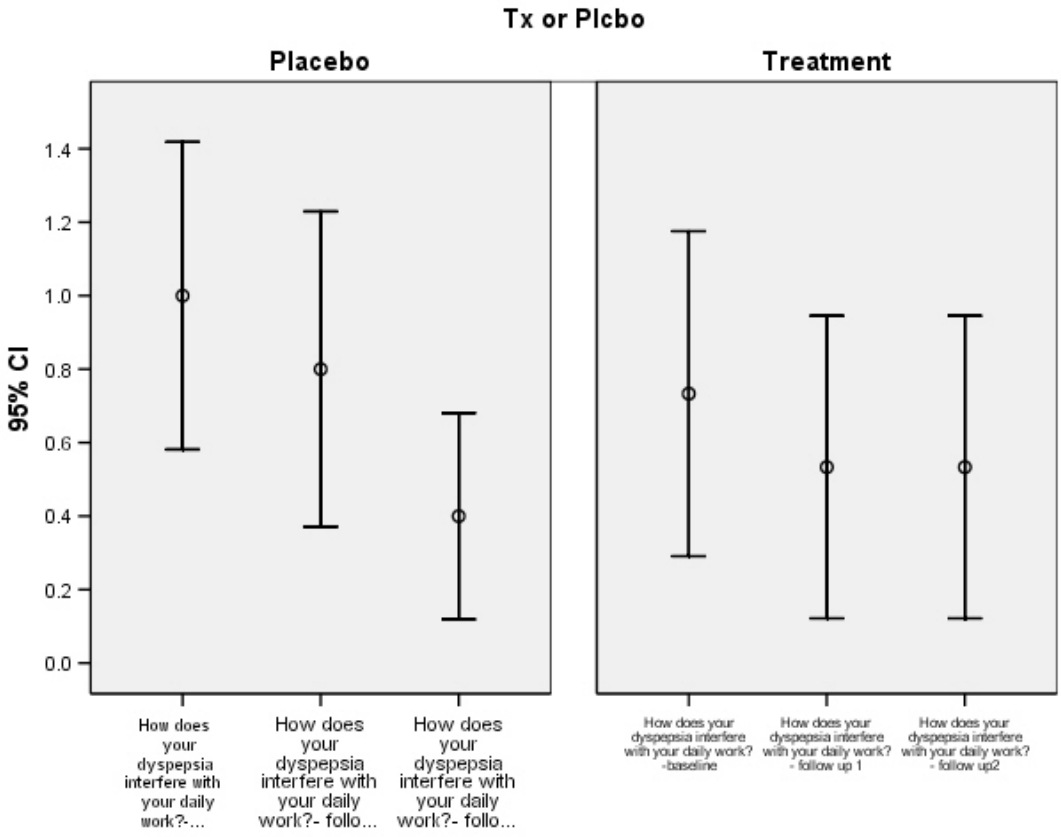
From the above graphs, it can be observed that both groups reported significant changes in attitude toward the condition for the duration of the trial.

4.13.13 Question M: Rate the level of dyspepsia stress you have to cope with at present



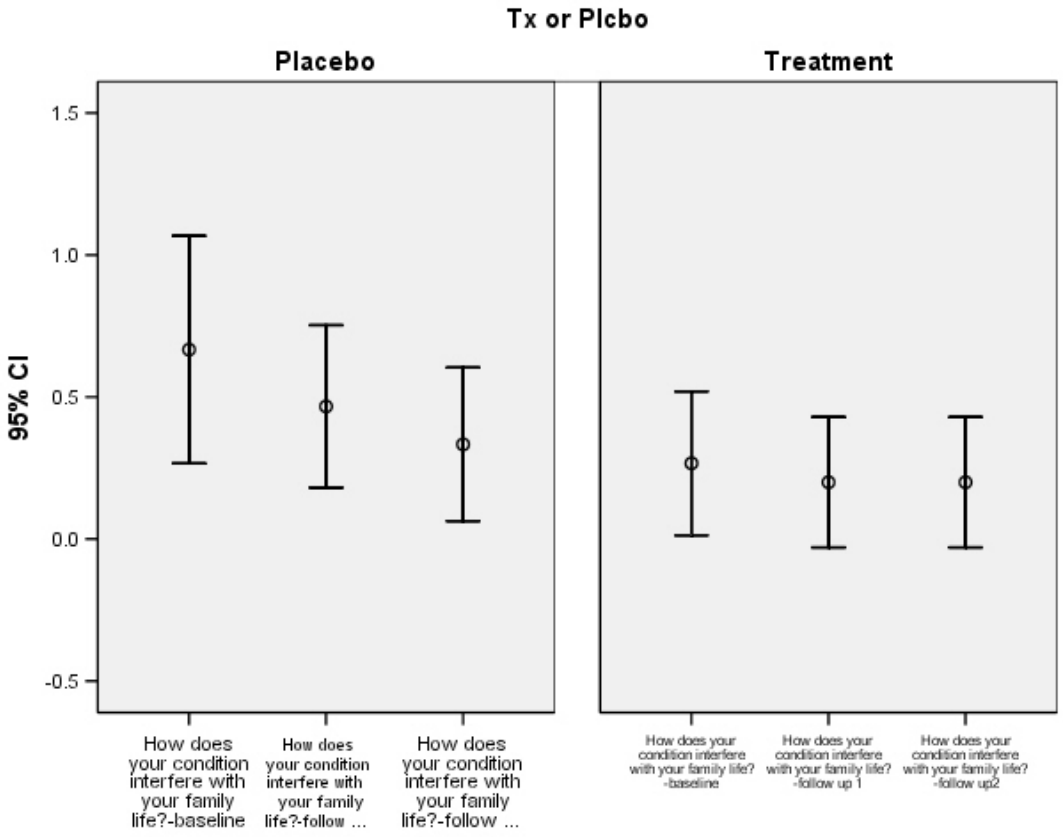
Again, it seems that both groups experienced a reduction in stress levels for the duration of the trial. This could be attributed to a positive mental and emotional response, to merely receiving treatment for a chronic condition (Thompson, 2005).

4.13.14 Question N: How does your dyspepsia interfere with your daily work?



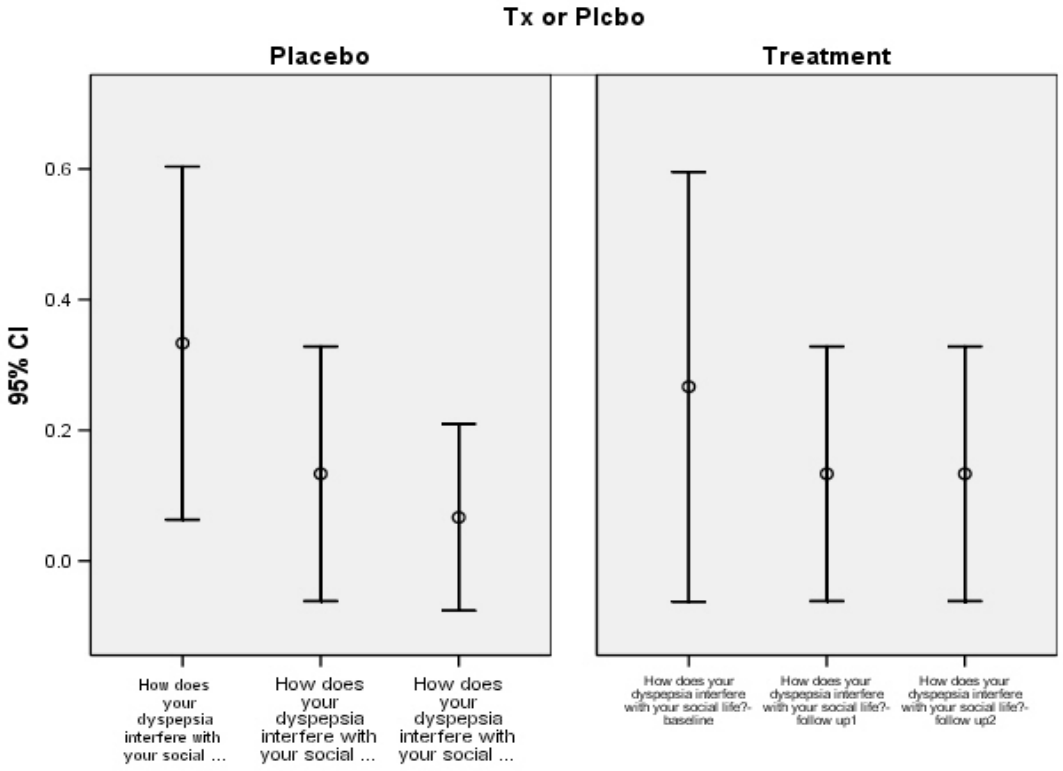
The above graphs demonstrate a slightly greater difference was reported by those in the placebo group for the duration of the trial.

4.13.15 Question O: How does your condition interfere with your family life?



From the above graphs it would seem that a fairly uniform response was yielded by both placebo and treatment groups.

4.13.16 Question P: How does your dyspepsia interfere with your social life?



The graphs above, illustrate that the treatment group yielded a more significant response to this particular question.

CHAPTER 5

5.1 DISCUSSION

A significant improvement was demonstrated within both the placebo and the complex groups. However, the comparisons between the groups yielded no significant difference; therefore the complex (*Carbo Vegetabilis* D9, *Lycopodium Clavatum* D9, *Nux Vomica* D9 and *Robinia Pseudoacacia* D9) did not prove to be effective in the treatment of functional dyspepsia when compared to placebo.

The results of the Patient Perception Questionnaire indicate significant changes for both the treatment group (Group 1) and the placebo group (Group 2). In the treatment group the patient's perceived significant improvements in five out of the twenty four aspects on which they were graded.

These results included the particulars of the patients experiences of dyspepsia (and their relative impact) i.e. extent of suffering after meals, experience of waterbrash, experience of nausea and vomiting or bloating and distension. It may be reasonable to assume that these particulars may be more susceptible to change than general ratings of distress. This may explain why these particulars are statistically significant.

The last two items also rated abstract and subjective levels of self assessment and as such may be more susceptible to placebo response.

When the bar charts are studied for the placebo group, it is evident that there was a statistically greater improvement when compared to the treatment group by the second follow up.
This was evidenced only by **Question Q (From the onset of treatment have you experienced any change in your dyspepsia?).**

This change can be attributed to the placebo effect. This is when improvement occurs even though the patient is on placebo. The patient develops confidence in the researcher and this optimism and expectation of healing often brings about relief in their symptoms. The patient may also desire to please the researcher and therefore not reflect their symptoms accurately (Maharaj, 2006).

When formulating a homoeopathic complex such as the one employed in this study, the ingredients are selected on the basis that their symptomology has a degree of similarity to that of the disease for which it is indicated i.e. each ingredient of this complex is strongly indicated in the treatment of functional dyspepsia, according to their Materia Medica and the law of similars. The Materia Medica from which the indications of each ingredient are derived, is compiled from homoeopathic drug provings of these substances. These substances are proven individually and never in complex or combination form. Mixtures of remedies should be prepared according to the principles of homoeopathy and the effects of the mixtures tested on healthy individuals (provings) rather than relying on information about the ingredients used separately (De Scheeper, 2001).

No provings have been carried out on this or any other complex, in general and little information exists with regard to the summative effect of mixing ingredients or polypharmacy (Kayne, 2002). Thus one cannot ascertain how the individual remedies interact with each other and thus cannot be certain of the effect a complex of remedies will have. Based on the results of this study, one cannot assume that a complex of remedies will have an effect that equals the sum of its parts, i.e. the complex will act by a combined summative effect.

In Aphorism 274, Hahnemann states “it is still impossible to predict how two or more medicinal substances may hinder or alter each other’s actions upon the human body.” Using mixed remedies can confuse the vital force, neutralise remedial effects, disorder the state of sickness and obscure the disease picture (De Scheeper, 2001).

Thus provings would need to be done on combination remedies such as this dyspepsia complex so that their indication for use can be ascertained or confirmed. It may too have been beneficial to assess the remedies individually instead of in complex form.

Another aspect is the possibility of attributing improvement in both groups to the fact that symptoms could have spontaneously changed due to natural progression of the condition.

Although patients were advised not to make any dietary changes for the duration of the trial, an improvement could also have been due to a change in eating habits, which could have been the causative factor of the dyspepsia in the first instance.

The subjectivity of the questionnaire may also be the reason for the lack of significant improvement between the two groups. The answer to each question on the questionnaire was limited to only four responses. A more objective method may have been a more accurate method to measure improvement, by increasing the number of options for each answer on the questionnaire.

Patients were given the homoeopathic complex for a period of four weeks. Patients may however have benefited from a longer treatment period, which would have allowed time for the placebo effect to “wear off.”

A larger sample size may have yielded more significant results. In this study a sample group of thirty patients was used. Increasing the number of participants in this trial could have had a major impact on the statistical analysis.

It was assumed that all patients were compliant and took the medication as instructed. There is always the possibility that this was not done which could have affected the efficacy of the complex.

5.2 The Homoeopathic Complex

In Chapter 2, the concept of complex prescribing in homoeopathy was discussed. This topic is a source of much debate in the homoeopathic community. Kayne (2002), argues that there is certainly a place for complex prescribing in modern homoeopathy, whereas other “classical” homoeopaths, strictly prescribe only single remedies. In this trial the complex employed (*Carbo vegetabilis* D9, *Lycopodium clavatum* D9, *Nux vomica* D9 and *Robinia Pseudoacacia* D9) proved not to be significantly effective in the treatment of functional dyspepsia. This could have been due to a variety of other factors, but this result alone serves to question the real advantages of complex prescribing.

Dr. Hans Heinrich Reckeweg, M.D. of Germany reasoned that "if there were ten remedies that did the same thing, then it would be prudent to add all ten to one formula, and let the patient’s system choose the one that it wanted." (Schmiedal, Klein, 2004).

The greatest advantage of complex prescribing lies in its convenience as it can save much time and effort (Kayne, 2002).

However, the advantages of this method of prescribing seem to have been only limited to the prescriber and not the patient, which was the initial objective of the trial.

The specific complex employed in this trial, when compared to placebo failed to yield positive results according to patient perception. Whether this is reflective of the inefficacy of complexes in general, is a question that can only be answered by further research.

5.3 The Placebo Effect

The placebo effect has always been a greatly controversial issue in medical circles; however its place in patient care is undeniable.

It is a key, perhaps under recognized component of the doctor patient relationship (Thompson, 2005).

The results of the trial revealed that the placebo group, yielded significantly more positive results than the treatment group.

According to Thompson (2005), without medical evidence it is impossible to know whether a treatment is more beneficial, more harmful or no better than placebo, which gives rise to the urgent need for further research.

The power of placebo is not limited to patient treatment, but extends to the doctor-patient relationship as well. The doctor himself acts as a placebo, exerting a beneficial effect through a healing relationship or a harmful nocebo effect through a poor relationship (Thompson, 2005).

A clinical trial was conducted by Linde, (1997) to determine whether the clinical effects of homoeopathic treatment are merely the effects of placebo. The results concluded that the success of homoeopathy could not be attributed to placebo. Therefore, despite the beneficial effects of homoepathic placebo it is by no means the reason homoeopathy has produced such excellent results in patient care (Linde, 1997).

CHAPTER 6

CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

The results of this study lead to the conclusion that the homoeopathic complex (*Carbo Vegetabilis* D9, *Lycopodium Clavatum* D9, *Nux Vomica* D9 and *Robinia Psuedoacacia* D9) was shown to be statistically no more effective than placebo in the treatment of functional dyspepsia.

6.2 RECOMMENDATIONS

The following recommendations are made for further research:

- The study should be conducted over a longer period to adequately assess the action of the medication over such a chronic condition.

- A homogenous sample group should be used to conduct the trial. For instance, participants in the trial should be limited to either male or female, or even restricted to a particular race group. This would serve to limit the variables and hence provide a more conclusive result.

- Dietary habits and lifestyle modifications play a vital role in this condition and should therefore be included in a subsequent study.

- More objective measurement tools should be employed. The questionnaire should include more questions and more options should be included for each answer.

- A pain questionnaire, like the Shotform- Mcgill Pain Questionaire should also be used in conjunction with the Patient Perception Questionnire, to provide more definitive results.

- The study should be repeated using a larger sample group in order to gauge a more accurate result.

- Prior to participation in the study, patients should undergo an endoscopy to confirm a diagnosis of functional dyspepsia by excluding other causes.

- The study should be conducted to determine the efficacy of homoeopathic simillimum in the treatment of functional dyspepsia.

- Other homoeopathic remedies, such as *Pulsatilla Praentis, Nux Moschata* or *Arsenicum Album* should be used in the complex to establish their effect in the treatment of functional dyspepsia.

- The remedies employed in the complex should be of higher potency (30 CH) to determine their effect on the condition.

- The study should be repeated using a complex containing more remedies (five to ten) to further assess the effectiveness of a homoeopathic complex in treating functional dyspepsia.

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APPENDIX A

DO YOU SUFFER FROM DYSPEPSIA (HEARTBURN/ INDIGESTION)?

FREE TREATMENT IS BEING OFFERED AT THE HOMOEOPATHIC DAY CLINIC.

If you are between the ages of 18-55 years and would like to participate, contact the Homoeopathic Day Clinic on the number below to see if you meet the inclusion criteria.

Potential participants may qualify for free treatment.

RESEARCHER:

EROSHA SURJOODEEN

072 216 1449

HOMOEOPATHIC DAY CLINIC

(031) 373 2041

Thank you

Dr A.H.A Ross

HEAD OF DEPARTMENT

APPENDIX B

INFORMATION SHEET FOR THE PARTICIPANT

The efficacy of a homoeopathic complex (Carbo vegetabilis D9, Lycopoduim clavatum D9, Nux vomica D9 and Robinia pseudoacacia D9) in the treatment of functional dyspepsia.

Thank you for volunteering to participate in this study.

Dyspepsia, commonly referred to as heartburn or indigestion is a symptom often experienced by many people and is characterised by pain or discomfort in the upper part of the stomach. It is associated with symptoms of nausea, regurgitation, vomiting, heartburn, prolonged abdominal fullness or bloating after a meal, stomach discomfort or pain, and early fullness.

This study seeks to investigate the effectiveness of a homoeopathic complex in the relief of the above-mentioned symptoms.

There will be two groups of participants in this trial. There is a 50% chance of participants being in a placebo group. Placebo means that the complex will not contain the active ingredients. These participants will be offered free treatment at the end of the study. Participants may benefit from this trial in they may obtain relief from dyspepsia.

The trial will last a period of 28 days, during which you will be required to attend 3 consultations each of 1 hour duration. At these consultations you will be required

to fill in a set of questionnaires regarding your perception of the treatment. The researcher will be available for questions whilst you fill in these questionnaires, so that she can assist you with any questions you may have with regards to this study.

The researcher will give you instructions on how and when to take the remedies given to you. It is important note that homoeopathic medicines must be handled with care. Please ensure that they are not stored in direct sunlight and they are kept away from strong smelling substances such as camphor and perfumes. You are ensured of complete confidentiality at all times and you will be free to withdraw from this trial at any given time without providing reasons for doing so. Once again, thank you for your kind participation in adding to the homoeopathic pool of knowledge.

Erosha Surjoodeen

(Researcher)

Cell: 072 216 1449

Dr. C Hall; B.Sc; MTECH (Hom)

(Supervisor)

Tel : (031) 373 2041

APPENDIX C

INFORMATION SHEET-ZULU

INDIKIMBA YENCWADI YENCAZELO

ULWAZI MAYELANA NOCWANINGO LALOWO OZOZIBANDAKANYA

Umphumeta wamakhambi ayinxubevange e Homoeopathy (i-Carbo vegetabilis D9, I-Lycopodium clavatum D9, i-Nux vomica D9 kanye ne Robinia pseudoacacia D9) ekwelapheni ukuqunjelwa ohuhambisana nesilungulela. Ngiyabonga ngokuzinikela kwakho ukuba uzibandakanye kulolu cwaningo.

ISINGENISO

Ukuqunjelwa okuvamise ukubanezimpawu zesilungulela kuyinto ejwayelekite kakhutu kubantu abaningi, futhi kuye kwenzeke ukuthi lokhu kuqunjelwa nesilungulela kubuye kuhambisane nobuhlungu esiswini noma kwenye ingxenye ethile yesisu nesifuba. lzimpawu okuvamise ukuba zibandakanyeke nesilungulela yilezi ezilandelayo; ukuba nenhliziyo emnyama necefezelayo kubesengathi uzohlanza, ukutshokoza ukudla osukudlile, ukuhlanza, isilungulela, ubumuncu emphinjeni nasesifubeni, ukuzizwela sengathi isisu sigcwele umoya nokuqunjelwa emmveni kokudla, ukuhlaba kwesisu nezinhlungu, nokushesha ukususutha.

Lolucwaningo luzobe luhlola ukusebenza kwenxubevange yamakhambi e Homoeopathy ekwelapheni nasekudambiseni lezizimpawu ezingenhla. Kuzoba namahlelo ezigaba amabili kulolucwaningo kulabo abazozinikela ekuzibandakanyeni kulolucwaningo. Kuzoba namaphesenti angu 50 okuba

ungaba noma kusiphi isigaba. Kungenzeka ukuba ubesesigabeni salabo abazothola ikhambi locwanongo elingenaso isithako eselaphayo okusho I Placebo, lokhu okusho ukuthi uyothola ukwelaphwa mahhala uma ucwaningo seluphelile ukuze nawe uthole ukusizakala njengabanye. Labo abazibandakanyile bayosizakala kulolucwaningo ngoba izimpawu zesilungulela ziyodamba.

Lolucwaningo luyothatha izinsuku ezingu 28, lapho okuyodingeka khona ukuba ubonwe izikhathi ezintathu, ngenye indlela kusho ukuthi ubonwa njalo emva kwamaviki amabili. Kulokhu kubonwa uyocelwa ukuba ugcwalise amaphepha anemibuzo mayelana nekhambi lokwelapha nendlela owelashwa ngayo. Umcwaningi uyokuba khona ngesikhathi ugwalisa lemibuzo yocwaningo ukuze akwazi ukuba akusize lapho udinga khona usizo mayelana nalolucwaningo.

Umcwaningi uyobe esekunika imiyalo yendlela yokuphuzwa kwemithi yakho. Kubalulekile ukuba wazi izindlela zokuphuzwa nokugcinwa kwemithi yakho ye Homoeopathy. Qaphelisisa ukuthi awuyigcini endaweni enokukhanya nokushisa kwelanga, kanye nokuthi uyigcine yaqhelelana nezinto ezinamaphunga amakha okuziqhola kanye nekhemfa.
Konke lokhu kubonwa kwakho kuyothathwa njengemflhlo futhi akunakudalulwa nanoma ingasiphi isikhathi futhi awuphoqiwe ukuba uzibandakanye, uma uzizwela ukuthi ufuna ukuhoxisa awunakunqatshelWa futhi awuyukubuzwa imibuzo ngokuhoxisa kwakho.

Ngiphinde futhi ngibonge ngokuzibandakaflYa kwakho kulolucwaniflgO oluzokwenza ukuba ulwazi lwe Homoeopathy lidlondlobale.

EROSHA SURJOODEEN (Umcwaningi)

Cell: 072 216 1449

APPENDIX D

PATIENT CONSENT FORM

AN INVESTIGATION INTO THE EFFECTIVENESS OF A HOMOEOPATHIC COMPLEX IN THE TREATMENT OF FUNCTIONAL DYSPEPSIA.

PLEASE CIRCLE THE APPROPRIATE ANSWER

1. Have you read the research information sheet?

YES/NO

2. Have you had the opportunity to ask questions regarding this study?

YES/NO

3. Have you received satisfactory answers to your questions?

YES/NO

4. Have you had opportunity to discuss this study with the researcher?

YES/NO

5. Have you received enough information about this study?

YES/NO

6. Do you understand the implications of your involvement in this study?

YES/NO

7. Do you understand that you are free to withdraw from this study?

YES/NO

a. at any time

b. without having to give reason for withdrawing and

c. without affecting your future health care?

8. Do you agree to voluntarily participate in this study?

YES/NO

If you have answered no to any of the above questions, please obtain information before signing.

I,_____hereby give consent for the proposed procedure to be performed on me as part of the above mentioned research project.

_____SIGNATURE _____DATE

APPENDIX E

PATIENT CONSENT FORM-ZULU

NGENCAZELO YEMITHETHO YOKUZIBANDAKANYA

ISIHLOKO SOMKLAMO WOCWANINGO

Uyacelwa ukuba / zongolozele leyo mpendulo oyikhethayo

1. Ingaba uyifundite indinkimba yencwadi yencazelo ?

……YEBO/CHA

2. Ingaba usutholile isikhathi / ithuba lokubuza imibuzo

…….YEBO/CHA

kuleyo imibuzo yakho?

3. Ingaba uthole izimpendulo ezikugculisayo

kuleyo mibuzo yakho? ……YEBO/CHA

4. Ingaba ulitholile yini ithiba lokubonisana

nokuxoxisana ngalolucwaningo? …….YEBO/CHA

5. Ingaba unayo imininingwane eyanele

mayelana nalolucwaningo? ……..YEBO/CHA

6. Ingabe uyayazi yini imigomo yalolucwaningo

ozozibandakanye kulo? ……..YEBO/CHA

7. Ingaba uyakuqonda yini ukuthi wamukelekile ukuba

uzihoxise noma mini kulolucwaningo? . ……YEBO/CHA

(a) noma ingasiphi isikhathi

(b) ngaphandle kokunikeza incazelo futhi nokuthi loku angeke kuphazamise indlela yokulashwa kwakho ngengomuso

8.Ingaba uyavuma ukuzibandakaflya, nokuthatha iqhaza

kulolucwaningo

……..YEBO/CHA

Uma ngabe ukhona umbuzo ophendule ngoCHA kuwo, zama ukuthola

Ulwazi ngaphambi kokuba usayine isivumelwaflo.

Mina…….. ngiyazinikela ukuvuma ukuzibandakaflYa kulolucwaniflgo.

ISAYINI YESIVUMELWANO…… USUKU

ISAYINI YOMCWANINGI …… USUKU

APPENDIX F

PATIENT DETAILS

AN INVESTIGATION INTO THE EFFECTIVENESS OF A HOMOEOPATHIC COMPLEX IN THE TREATMENT OF FUNCTIONAL DYSPEPSIA.

SUPERVISOR: DR. C. HALL; MTECH (Hom)

RESEARCHER: EROSHA SURJOODEEN 5TH YR STUDENT

TO BE COMPLETED BY PARTICIPANT [Please print]

SURNAME: _____

FIRST NAMES: _____

POSTAL ADDRESS: _____

_____

TELEPHONE NO:(H) _____

(W) _____

(C) _____

SIGNATURE: _____

DATE: _____

APPENDIX G

PATIENT'S PERCEPTION QUESTIONNAIRE (adapted from C.M Hall 1998, Heartburn, Appendix I)

VISIT NO: _____

NAME: _____

DATE: _____

INSTRUCTIONS:

1. The answers to this questionnaire are strictly confidential, and used for research purposes only
2. Please answer as objectively as possible.
3. Please ensure you have answered all questions.
4. Please read all questions carefully, and make sure you understand the question. If there are any queries please ask for assistance from the researcher.
5. Please answer the questionnaire honestly! It is designed to assess your opinion of the treatment you are going to receive.

DYSPEPSIA: indigestion or heartburn, characterised by pain or discomfort in upper parts of the stomach. Is often accompanied by symptoms of nausea, regurgitation, vomiting, heartburn, prolonged abdominal fullness or bloating after a meal, stomach discomfort or pain, and early fullness**.**

For each question, mark the number that you think is most applicable to you. If after this you have anything to add, please use the space provided.

A. How severe would you rate your ‘dyspepsia’ ?

0 -Mild

1 -Moderate

2 -Severe

3 -Unbearable

Comment_____

B. How often do you experience dyspepsia ?

0-Less than once a week

1-More than once a week

2-Once a day

3-More than once a day

Comment_____

C. How long does an attack of dyspepsia last ?

0-Less than one hour

1-More than one hour

2-More than two hours

3-Constantly

Comment_____

D. To what extent do you experience dyspepsia after a meal ?

0-Never

1-Occassionally

2-Frequently

3-Always

Comment_____

E. Do you often experience waterbrash (regurgitation of stomach contents/ saliva into the mouth)?

0-Never

1-Occassinally

2-Frequently

3-Always

Comment_____

F. How often does your dyspepsia interfere with your sleep ?

0-Never

1-Occassinally

2-Frequently

3-Always

Comment_____

G. Do you experience chest pain with an attack of dyspepsia?

0-Never

1-Occassinally

2-Frequently

3-Always

Comment_____

H. Does the pain spread to your abdomen ?

0-Never

1-Occassinally

2-Frequently

3-Always

Comment_____

I. Do you experience nausea or vomiting with an attack of dyspepsia ?

0-Never

1-Occassinally

2-Frequently

3-Always

Comment_____

J. Do you experience feelings of bloatedness and distention in your abdomen?

0-Never

1-Occassinally

2-Frequently

3-Always

Comment_____

K. Do you experience burping or belching with an attack of dyspepsia ?

0-Never

1-Occassinally

2-Frequently

3-Always

Comment_____

L. What is your attitude towards your condition ?

0-Do not think about it

1-Can live with it

2-Very negative

3-Unbearable to live with

Comment_____

M. Rate the level of dyspepsia stress you have to cope with at present

0-Little stress

1-moderate level of stress

2-High level of stress

3-Very high level of stress

Comment_____

N. How does your dyspepsia interfere with your daily work ?

0-Very little interference

1-Moderate interference

2-High level of interference

3-Very high level of interference

Comment_____

O. How does your condition interfere with your family life ?

0-Very little interference

1-Moderate interference

2-High level of interference

3-Very high level of interference

Comment_____

P. How does your dyspepsia interfere with your social life ?

0-Very little interference

1-Moderate interference

2-High level of interference

3-Very high level of interference

Comment_____

Answer the following only from second consultation onward:

Q. From the onset of treatment have you experienced any changes in your dyspepsia ?

0-Significant improvement

1-Moderate improvement

2-No improvement

3-Became worse

Comment_____

R. Was it necessary to use any other medication for the dyspepsia?

0-Never

1-A few times

2-Several times

3-Used as often as before the research medicine

Comment_____

S. Have your energy levels changed since taking the medication ?

0-Not at all

1-Slight improvement

2-Moderate improvement

3-Great improvement

4-Got worse

Comment____

APPENDIX H

EXAMPLE OF A RANDOMISATION SHEET

(COMPILED BY DR CORNE HALL- 07/02/05)

PATIENT NUMBER	TREATMENT	PLACEBO
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		
16.		
17.		
18.		
19.		

20.		
21.		
22.		
23.		
24.		
25.		
26.		
27.		
28.		
29.		
30.		
31.		
32.		

APPENDIX I

CASE HISTORY

(Bates 2006; 5-70)

IDENTIFYING DATA

Name: _____

Age: _____

Sex: _____

Race: _____

Place of birth: _____

Marital status: _____

Occupation: _____

Source of referral: _____

Source of History: _____

Past surgical History: _____

PAST MEDICAL HISTORY

1. Have you ever had any serious medical problems?

   (TB, Cancer, Peptic ulcer disease)

2. Childhood illnesses

   (Mumps, measles, chicken pox, German measles, tuberculosis)

3. Have you ever been in hospital for anything?

4. Do you have allergies?

5. What vaccinations/ immunizations have you had recently?

6. Are you taking any medication?

(NSAIDS, pills, vitamins, minerals, herbs, homoeopathy)

(Know: onset, duration and dosage)

7. Do you smoke?

(onset, amount/day, type)

FAMILY HISTORY

Possible family history problems: Diabetes, Heart disease, High blood pressure
Stroke, Cancer, Kidney problems, Anemia,
Epilepsy,etc

MAIN COMPLAINT

History of main complaint

Onset

Location

Duration

Aetiology

Character

Modalities

Concomitant

Radiation

Patient's response to symptoms and incapacity

APPENDIX J

PHYSICAL EXAMINATION

VITAL SIGNS;

Temperature:

Pulse rate;

Respiratory rate:

Blood Pressure;

Height;

Weight:

GENERAL EXAMINATION:

(jaundice, anemia, cyanosis, clubbing, dehydration, oedema, lymphadenopathy)

E.N.T:

CHEST EXAMINATION:

ABDOMINAL EXAMINATION: