SOUTH BAYLO UNIVERSITY

The Effect of Acupuncture Treatment with Five Phase Points Combination for Symptoms of Dyspepsia: A Randomized Controlled Trial

by

Gaseon Baik

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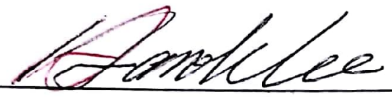
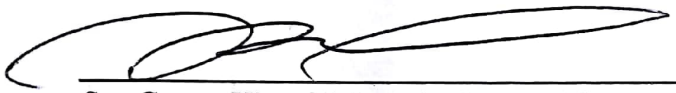
DISSERTATION OF GASEON BAIK

APPROVED BY RESEARCH COMMITTEE

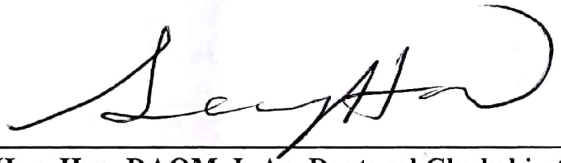
Shan Qin Cui, OMD, L.Ac, Professor



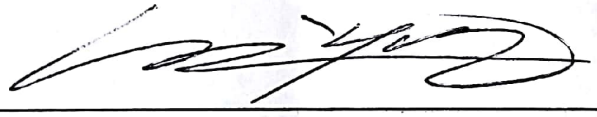
Hanok Lee, DAOM, L.Ac, Clinic Supervisor, Professor



Soo Gyung Kim, OMD, L.Ac, Doctoral Program Student Advisor



Seong Hwa Hue, DAOM, L.Ac, Doctoral Clerkship Coordinator



Joseph H. Suh, Ph.D, OMD, L.Ac, Doctoral Research Coordinator, Professor

South Baylo University

Los Angeles, California

December 06, 2018

The Effect of Acupuncture Treatment with Five Phase Points Combination for Symptoms of Dyspepsia: A Randomized Controlled Trial

Gaseon Baik

South Baylo University at Los Angeles, 2018

Research advisor: Suhkyung D. Kim, MD, OMD, L.Ac.

ABSTRACT

Objective: The purpose of this study was to assess the effect of acupuncture treatment with Five Phase points combination for symptoms of dyspepsia based on the Five Phases concepts (Wood, Fire, Earth, Metal and Water) as five properties inherent in all things.

Method: The design of this study was single-blind randomized controlled trial. A total of twelve patients for symptoms of dyspepsia were randomly divided into two groups: experimental (n=6) and control (n=6). Ten acupuncture points in both groups were chosen for Experimental Group: ST45, LI1, ST43, GB41, ST41, SI5, and Four acupuncture points were applied for Control Group: LIV3, LI4, CV12, ST36. Participants in both groups received two sessions of therapy per week for a three-week period. The evaluation was made before and after treatment using the Tenderness Grading Scale (TGS) and Short Form Nepean Dyspepsia Index (SFNDI).

Results: With 12 participants of chronic dyspepsia symptoms, the analysis of Tenderness Grading Scale was that the cumulative effect mean score on Tender between the control group and the experimental group were 1.00 ± 0.00 and 2.80 ± 0.41(p=0.002), equivalent to statistically significant improvement of 36.10% ± 6.80 and 100.0 ± 0.00% (p=0.002) at the end of treatment respectively. The experimental group had a greater treatment effect

and rate. From the analysis of Short Form Nepean Dyspepsia Index, the experimental group had a greater treatment effect and rate. However, Interference with daily activities (IDA), Eating/Drinking (ED) and Knowledge/Control (KC) did not show them to be statistically significant.

Keywords Symptoms of dyspepsia, Five Phase points combination, five properties, Tenderness Grading Scale (TGS), Short Form Nepean Dyspepsia Index (SFNDI).

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I. INTRODUCTION

Functional dyspepsia (FD) is defined as the presence of persistent symptoms referable to the upper gastrointestinal (GI) tract, in the absence of a structural organic pathology that would explain these symptoms. Functional dyspepsia (FD) is a worldwide common disorder, affecting adults in North America, Europe and Asian parts of the Earth[1]. The prevalence has been reported to range from 5.3% to 40%, due to variation from definition criteria and geographical location[1]. However, despite the high prevalence of functional dyspepsia (FD), the etiology and pathophysiology of this disorder remains poorly understood.

Dyspepsia is defined as having one or more symptoms of epigastric pain, burning, postprandial fullness, or early satiation[2]. Bloating and nausea often coexist with dyspepsia but are nonspecific and are thus not included in its definition. Heartburn is also excluded from diagnostic symptom criteria for dyspepsia since it is thought to primarily arise from the esophagus and it is suggestive of gastroesophageal reflux disease (GERD) although it too may occur concurrently[3].

In the *Precious Mirror of Eastern Medicine*[4] (Dongui Bogam), Symptoms of Dyspepsia is defined etiologically as experiencing problems with digestion due to weaknesses of the spleen and stomach, eating too much, eating raw food or cold food, aggregation- accumulation or bound cluster forms, which causes distention in the pit of the stomach, belching, acid regurgitation, a bluish complexion, and emaciation.

In the conventional approaches, empirical approaches are still employed for the treatment of the dyspepsia, and the current pharmacological options are limited and mostly based on individual symptoms [5,6,7,8]. Improvement of patients with the dyspepsia with

current drug therapy is left with many unmet clinical needs, and the adverse effects associated with drugs also present challenges for clinicians and researchers [9,10].

As a nonpharmacological intervention, acupuncture is increasingly used in the treatment of Symptom of Dyspepsia and has been reported to be effective in altering acid secretion, GI motility, and visceral pain in patients with the dyspepsia[11,12,13]. Moreover, as a type of physiotherapy, acupuncture treatment can avert the long-term side effects and resistance of drugs[14]. But no valid evidence has been found for the effectiveness of these interventions based on the Five Phase concepts in the treatment of this condition. In the previous acupuncture research for the dyspepsia, they have done the trials with only empirical acupuncture points without exploring for the rationalities which get valid, applicable and objective effects.

In the acupuncture and eastern medicine, the etiology and pathology of symptom of dyspepsia are regarded as qi stagnation and damp-heat/cold damp stagnation in Stomach and Spleen. In order to release the qi stagnation, the combination of Five Phase points will be applied to the acupuncture treatment of symptom of dyspepsia as follows: ST45(metal element point of ST meridian), LI1(metal representative/Cheonbu point[15] of Fu organ), ST43(wood element point of ST meridian), GB41 (wood representative/Cheonbu point[15] of Fu organ), ST41(fire element point of ST meridian), SI5 (fire representative/Cheonbu point[15] of Fu organ).

With the theory of organ functionalities based on the *Inner Classic* Chapter 9-11[16], twelve organs are regarded as organs that coordinated each function to their own metabolism respectively.

With the Metal property-taking Qi from the air and controlling the part of the liquid metabolism, LI 1 ad ST45 will be applied to resolve the dampness accumulated in the

Stomach for the dyspepsia treatment. With the Fire property-controlling the blood vessels and is responsible for moving the Blood with adjusting the difference between heat and cold, ST41 and SI 5 will be used to release heat/cold stagnation in the Stomach for the treatment. As the Wood property is of spreading and regulation the Qi throughout the body, ST43 and GB41 will be applied to invigorate qi stagnation in the Stomach for symptom of dyspepsia treatment. With those hypotheses, the study aims to determine the effect of acupuncture treatment with Five Phase points combination for symptoms of dyspepsia based on the Five Phases concepts (Wood, Fire, Earth, Metal and Water) as five properties inherent in all things.

However, this study may not be sufficiently assertive against potential mechanical defects and significant heterogeneity. This study may be an empirical trial for further large-scale trial study based on evidence-based medicine, well-designed RCTs on this topic in the future.

II. OBJECTIVES

This clinical research aims to explore the effect of acupuncture treatment with Five Phase points combination for symptoms of dyspepsia patients.

The specific aspects of the topic that I want to find out for the study are as follows:

1. Comparsion analysis of TGS for two groups by acupuncture treatment effectiveness with Five Phase points combination for symptoms of dyspepsia patients based on the Five Phases concepts.

2. Comparison analysis of SFNDI for the Quality of Life of two groups by acupuncture treatment effectiveness with Five Phase points combination for symptoms of dyspepsia patients based on the Five Phases concepts.

3. Validation statistical analysis of the effectiveness in Five Phase points combination for symptoms of dyspepsia patients based on the Five Phases concepts

III. LITERATUE REVIEW

3.1 Overview of Functional Dyspepsia

The disease entity of functional dyspepsia — discomfort or pain in the upper abdomen, often related to food intake, but with no obvious organic cause — was introduced during the Rome consensus process for the classification of functional gastrointestinal disorders, which started in 1988[17]. Before this, patients who presented with symptoms that resembled functional dyspepsia often received a diagnosis of non- ulcer dyspepsia, irritable stomach syndrome, chronic idiopathic dyspepsia or essential dyspepsia. Major efforts were made to distinguish functional dyspepsia from structural gastrointestinal diseases (such as gastric ulcer-induced symptoms, duodenal ulcer- induced symptoms and gastro-esophageal reflux disease) or unexplained nausea and system was published; in 1991, the gastroduodenal criteria separated functional dyspepsia into ulcer-like dyspepsia, dysmotility-like dyspepsia, reflux-like dyspepsia or unspecified functional dyspepsia to account for the fact that although some patients report pain as their predominant symptom, others report postprandial symptoms (for example, fullness, early satiety (the inability to finish normal-sized meals), nausea or bloating), and many patients experience both kinds of symptoms. This distinction was maintained in the subsequent Rome I (1992) and Rome II (1999) classifications. With the Rome III classification (2006), the definition of functional dyspepsia became more-restrictive, and the subtype labels changed to epigastric pain syndrome (EPS) and postprandial distress syndrome (PDS) (Box1). This distinction was preserved in the Rome IV (2016) classification[20] and is responsible for some of the discrepancies in global epidemiology.

Box 1: Rome IV symptom criteria for functional dyspepsia and its subtypes[18]

- Symptoms of functional dyspepsia include bothersome postprandial fullness, bothersome early satiety, bothersome epigastric pain and bothersome epigastric burning. Functional dyspepsia is diagnosed if a patient reports having ≥1 of these symptoms for the past 3 months with onset at least 6 months before diagnosis, there is no evidence of structural disease that can account for the symptoms and the patient can be classified as having postprandial distress syndrome (PDS), epigastric pain syndrome (EPS) or both.
- PDS is diagnosed if a patient with symptoms compatible with functional dyspepsia complains of bothersome postprandial fullness and/or bothersome early satiety that are severe enough to interfere with daily activities or to prevent finishing a meal for at least 3 days per week. Other digestive symptoms can coexist with PDS.
- EPS is diagnosed if a patient with symptoms compatible with functional dyspepsia reports bothersome epigastric pain and/or bothersome epigastric burning that are severe enough to interfere with daily activities and occur at least once per week. Other digestive symptoms can coexist with EPS.

Functional dyspepsia comprises three subtypes with presumed different pathophysiology and etiology: postprandial distress syndrome (PDS), epigastric pain syndrome (EPS) and a subtype with overlapping PDS and EPS features[19,20]. Functional dyspepsia symptoms can be caused by disturbed gastric motility (for example, inadequate fundic accommodation or delayed gastric emptying), gastric sensation (for example, sensations associated with hypersensitivity to gas and bloating) or gastric and duodenal

inflammation[17]. A genetic predisposition is probable but less evident than in other functional gastrointestinal disorders, such as irritable bowel syndrome (IBS)[17]. Psychiatric comorbidity, psychopathological state and trait characteristics could also play a part, although they are not specific to functional dyspepsia and are less pronounced than in IBS. Possible differential diagnoses include *Helicobacter pylori* infection and peptic ulceration[17]. Pharmacological therapy is mostly based on the subtype of functional dyspepsia, such as prokinetic and fundus-relaxing drugs for PDS and acid-suppressive drugs for EPS, whereas centrally active neuromodulators and herbal drugs play a minor part[17]. Psychotherapy is effective only in a small subset of patients, whereas quality of life can be severely affected in nearly all patients[17].

3.2 Mechanisms / Pathophysiology in Conventional Medicine

Functional dyspepsia is considered a multifactorial disorder in which different pathophysiological mechanisms play a part[21,22], and each one could contribute to all subtypes. Traditionally, functional dyspepsia, in particular PDS, has been associated with disturbances in gastric motor function[23,24]. However, a study showed that gastric physiological disturbances did not correlate with symptoms, and delayed gastric emptying presented to a similar extent in PDS, EPS and overlapping groups[25].

H. pylori-related dyspepsia is considered a separate entity. However, other prior gastrointestinal infections have been described as triggers of functional dyspepsia, by impairing gastric accommodation (a vagal mediated reflex that occurs postprandially and results in a reduction of smooth muscle tone; the stomach relaxes and provides a reservoir for the meal), via immune mechanisms[26,27,28].

Communication between the central nervous system and the enteric nervous system has been recognized for over a century, but the fact that brain–gut communications are bi-directional has only been appreciated more recently[29,30]. Innervation of the gastrointestinal tract regulates secretions, sphincter control, motility, blood flow and enteroendocrine function, and the enteric nervous system also communicates with the intestinal barrier via neuroendocrine and mucosal immune cells[26,31]. The following sections get these different putative pathophysiological mechanisms in more detail.

Gastroduodenal motility

Altered motility and pathological responses to mechanical and chemical stimuli are common sensorimotor disorders of the gastroduodenum in patients with functional dyspepsia[32]. There are distinct motility patterns during interdigestive and digestive states. During interdigestive periods, when the gut is empty, cyclic, recurring migrating motor complexes (MMC) move over the gastrointestinal tract fulfilling 'housekeeper' functions.

Gastroduodenal sensitivity

Gastroduodenal sensitivity to both mechanical and chemical stimuli is altered in functional dyspepsia. Patients with functional dyspepsia show visceral hypersensitivity after distension of the gastric fundus in the fasted state and after meal ingestion[29,33].

Gastroduodenal inflammation

Mechanical and chemical hypersensitivity could result from local immune activation. Most studies have demonstrated an impairment of epithelial barrier function in the duodenum in both patients and biopsy samples. Investigation during endoscopy revealed increased mucosal permeability in EPS, PDS and functional dyspepsia with concomitant IBS[34].

3.3 Diagnosis, screening and prevention in Conventional Medicine

3.3.1 Diagnostic criteria

As defined by Rome IV, functional dyspepsia is a medical condition that has substantial effects on the well-being of those affected[35]. Three main diagnostic categories are defined based on the predominant symptoms: PDS, characterized by meal-induced dyspeptic symptoms (such as postprandial fullness and early satiety, 69% of patients with functional dyspepsia), EPS (7%), in which epigastric pain or epigastric burning that do not exclusively occur after a meal are the main symptoms, and overlapping PDS and EPS (25%), characterized by meal-induced dyspeptic symptoms combined with epigastric pain or burning[36].

3.3.2 Clinical features and physical examination

The diagnosis of functional dyspepsia is based on clinical symptom definitions, recently reformulated and refined in the Rome IV criteria[32]. Patient history and clinical examination should search for alarm symptoms. In particular, patients with functional dyspepsia, especially more-severe cases referred to tertiary centres, could present with substantial weight loss. A large study in Belgium indicated that 16% of 636 patients with functional dyspepsia reported weight loss of >10 kg (Ref. [37]). Thus, when collecting the patient's medical history, clinicians should pay particular attention to this sign. Apart from epigastric discomfort upon palpation of the abdomen, physical examination does not generally reveal valuable diagnostic information in patients with functional dyspepsia.

Palpation of an abdominal mass obviously prompts further diagnostic work-up. However, symptom definitions remain mostly vague and cannot reliably distinguish between organic and functional dyspepsia[38]. Thus, in clinical practice, physicians should

consider upper endoscopy to rule out organic causes of dyspepsia, especially in case of risk factors or alarm symptoms. The diagnostic value of ultrasonography imaging is less clear, unless the patient has features suggesting biliary pathology. As upper endoscopy is negative in >70% of patients presenting with dyspepsia (whether organic or functional), it is important to complement endoscopy with cross-sectional imaging (such as ultrasonography), particularly in patients with weight loss, to look for carcinoma, cholelithiasis (gallstones) or chronic pancreatitis[17].

Repetitive belching. Epigastric fullness is often misinterpreted by patients as excessive gas in the stomach. In an attempt to release this gas, these patients involuntarily swallow air, which accumulates in the hypopharynx or the stomach and is finally released by belching with a sense of relief [39], thereby reinforcing the patients' conviction.

Abdominal bloating. An experimental gas challenge test (high-rate exogenous gas infusion directly into the jejunum) has shown that patients with functional dyspepsia who complain of bloating have impaired handling of intestinal gas, that is, gas retention, abdominal symptoms or both[40]. However, studies using abdominal CT and MRI scanning in clinical conditions could not correlate abdominal symptoms with excessive intestinal gas in these patients, as in the majority of the patients the volume and distribution of intestinal gas were within the normal ranges[41,42]. Hence, the perception of abdominal bloating could be related to a poor tolerance of normal gut content.

Abdominal distension. A large proportion of patients with functional dyspepsia report visible abdominal distension after meals and attribute the distension to gas production in response to some offending foods[43]. Visible distension is frequently associated with a bloating sensation, but the reverse is not the rule. Patients who complain of postprandial distension indeed develop an increment in girth during the distension

episodes compared with basal conditions, but the volume of gastrointestinal gas is within the normal range[37].

3.3.3 Laboratory tests

If an organic disease, which should be suspected particularly in the presence of alarm symptoms has been excluded (via upper endoscopy), additional testing in functional dyspepsia has limited added diagnostic value[17].

3.4 Reviewing of Symptoms of Dyspepsia in Acupuncture and Eastern Medicine

3.4.1 Etiology and Pathology Mechanism

Traditional medicine regards this condition as a disorder of the Spleen and Stomach. It may arise from a variety of sources. The body may be affected by the Excesses of Heat and Dampness common to summer and fall, or Wind and Cold common to spring and winter.[44]

Irregular eating habits may lead to stagnation and obstruction in the Middle Burner (Stomach and Spleen).[44] If Deficient Spleen Yang produces Cold, the Qi in the Middle may become Deficient, which will disturb the digestive and transportive functions of the Stomach and Spleen.[44] If the body fluids become exhausted after prolonged diarrhea or vomiting, Heat may prevail, causing confusion of the Spirit and Wind in the Liver. If the Yin(fluids) is sufficiently injured, it could affect the Yang such that it too is weakened and unable to secure the fluids in the body.[44] Thus, body fluids become even more depleted and the condition deteriorates as both Yin and Yang become extremely Deficient.

In the *Divine Pivot*, it is said, "Failure to control emotions leads to damage of the five viscera, and damage of the five viscera causes deficiency. When wind and rain penetrate the body when it is deficient, disease forms in the upper body. And when the disease permanently adheres to the meridian vessel, it develops into accumulation. When the disease adheres to the yang brightness meridian, it stays in the umbilical area. Overeating causes this to expand, and fasting causes it to shrink. (Dongui Bogam)

If the disease adheres to the abdominal wall, its symptoms are similar to those of accumulation in the yang brightness meridian, but overeating causes pain and fasting alleviates the pain.

When the disease adheres to the membrane source of the stomach and intestines, the pain extends to the abdominal wall and overeating brings comfort and fasting causes pain.

In the *Inner Classic*, Overeating damages the stomach and intestines. Symptoms of a damaged stomach are as follow: loss of appetite, chest fullness and pain, nausea and vomiting, hiccups, belching, acid regurgitation, yellowish facial complexion, emaciation of body, drowsiness and a tendency to lie down, and frequent diarrhea.

3.4.2 Symptoms

Symptoms of a damaged stomach are as follow: loss of appetite, chest fullness and pain, nausea and vomiting, hiccups, belching, acid regurgitation, yellowish facial complexion, emaciation of body, drowsiness and a tendency to lie down, and frequent diarrhea. (Li Dong-yuan's - *Treatise on the Spleen and Stomach*)

In the *Precious Mirror of Eastern Medicine* (Dongui Bogam), it starts from the gastric cavity to the heart. There is also ribcage pain and obstruction of the diaphragm with

an obstructing sensation in the throat and not being able to swallow food. There are ten symptoms as following; (1) Food Accumulation occurs as the stuffiness and oppression in the chest due to accumulation from indigestion, (2) Alcohol Accumulation occurs as a dark and yellowish complexion and fullness in the abdomen and sometimes vomits phlegm or water due to the accumulation of alcohol damage (Tai Ping Hui Min He Ji Ju Fang), (3) Masses Due to Overeating Barley Noodles occurs due to eating too much flour, (4) Dyspepsia Due to Meat is regarded as accumulation occurs due to having too much meat (The Introduction of Medicine- Yixue Rumen), (5) Accumulation of Fish and Crabs occurs due to eating too much fish and crabs, (6) Accumulation of Fruits and Vegetables occurs due to eating too many vegetables and fruits, (7) Accumulation of Tea occurs When one likes tea so much that accumulation or aggregation occurs or when one eats dry tea leaves. (Compendium of Medicine - Yixue Gangmu), (8) Accumulation of Water occurs due to too much drinking and there is borborigmus and painful strain in the chest and sides, (9) Accumulation of Extravascular Blood is made from static blood, or there is static blood in the chest, and (10) Abdomen from falling or being beaten, one has yellowish complexion and black feces and accumulation of Worms occurs when food accumulation develops into worms.

3.4.3 Acupuncture and Eastern Medicine Treatment for Symptoms of Dyspepsia

Treatment is directed toward strengthening the transportive functions of the Stomach and Spleen.[45] The treatment modalities in Acupuncture and Eastern Medicine are Needling, Moxibustion, Ear acupuncture, Cutaneous acupuncture, Hand acupuncture and Herbal prescriptions.

Treatments for stomach illness are as follows. Control food intake and temperature, clear the mind, stop thinking and wait quietly. Then genuine qi will recover to the normal condition. (Li Dong-yuan's - *Treatise on the Spleen and Stomach*)

In the *Precious Mirror of Eastern Medicine* (Dongui Bogam), When the stomach is excessive, use Calm Stomach Powder (Ping Wei San) and when the stomach is deficient, use Extraordinary Result Powder (Yi Gong San) or Tonify the Center to Augment the qi Decoction (Bu Zhong Yi Qi Tang).

The most frequently used acupuncture points were ST36 (15 trials), PC6 (eight trials), CV12 (eight trials), ST25 (six trials), and LR3 (six trials).[47] In Chines Acupuncture and Moxibustion 3rd ed. 2010 (CAM), ST36(Zu San Li) is located in 3 cun below ST35(Dubi), one finger-breadth (middle finger) from the anterior border of the tibia. ST36 indicates indigestion, gastric pain, vomiting, hiccup, abdominal distention, borborygmus, diarrhea, dysentery, constipation, mastitis, enteritis, aching of the knee joint and leg, beriberi, edema, cough, asthma, emaciation duet to general deficiency, apoplexy, hemiplegia, dizziness, insomnia and mania. The functions are to benefit stomach and spleen, and to harmonize intestines and disperse stagnation, and to tonify qi and blood, and to dispel pathogens and prevents disease, and course wind and transform dampness.

PC6's location is on 2 cun above the transverse crease of the wrist, between the tendons of m. palmaris longus and m. flexor carpi radialis. PC6 indicates cardiac pain, palpitation, stuffy chest, pain in the hypochondriac region, stomachache, nausea, vomiting, hiccup, mental disorders, epilepsy, insomnia, febrile diseases, irritability, malaria, contracture and pain of the elbow and arm. Its functions are to calm the Heart and Spirit, and to relax chest and regulate the qi, and to suppress rebellious qi and stop vomiting, and to suppress pain.

CV12 is located on the anterior midline, 4 cun above the umbilicus. CV12 indicates stomachache, abdominal distention, borborygmus, nausea, vomiting, acid regurgitation, diarrhea, dysentery, jaundice, indigestion and insomnia. The functions are to harmonize Stomach and to fortify Spleen and transform dampness.

ST25 is located on 2 cun lateral to the center of the umbilicus. The functions are to regulate and promote function of intestines, and to relieve food stagnation and pain worse, and to support the earth and transform damp, and to clear stomach or LI heat or damp heat.

LIV3 is located on the dorsum of the food, in the depression distal to the junction of the first and second metatarsal bones. LIV3 indicates headache, dizziness and vertigo, insomnia, congestion, swelling and pain of the eye, depression, infantile convulsion, deviation of the mouth, pain in the hypochondriac region, uterine bleeding, hernia, enuresis, retention of urine, epilepsy, pain in the anterior aspect of the medial malleolus. The functions are to spread liver qi, and to discharge damp heat in lower burner, and to nourish liver blood and yin and to sedate liver yang and extinguish wind.

IV. MATERIALS AND METHODS

4.1. Materials

4.1.1. The needles

Sterile, disposable, 0.20 × 30mm (diameter × length) stainless steel needles (Dong Bang Acupuncture, South Korea) were used once. Needles were generally inserted to a depth of 5–20 mm depending on the acupuncture point without any manual stimulation.

4.2. Methods

4.2.1. Recruitment

Following the approval of the study from South Baylo University IRB (Institutional Review Boards) for the Research Proposal and Informed Consent From, 12 patients with chronic pain in dyspepsia in accordance to TGS were recruited by volunteering from GB Eastern Medical Clinic regardless of age, occupation and gender, and were asked to sign and agree on the Informed Consent Form prior to the beginning of the experiment.

Table 1. Summary of cases in control and experimental groups

Characteristics	Control group	Experimental group
Number of cases	6	6
Gender	Female	Female

4.2.2. Inclusion criteria

All participants were no history of significant medical or psychiatric disorders and provided written informed consent. Patients have had continuous dyspepsia for at least 3 weeks and to rate the intensity of their pain as ≥2 on a 0–4 TGS.

4.2.3. Exclusion criteria

Exclusion criteria were (1) previous acupuncture treatment over two weeks of wash-out period for any condition, (2) previous serious stomach disorders such as tumors, surgery, structure distortion or spinal stenosis, (3) administration of sedative or analgesic drugs within 24 h before the treatment or the use of any additional pain treatments during the entire study period, including histories of taking opioid analgesics or narcotics, (4) conditions that made treatment difficult such as paralysis or seizure disorders, (5) conditions that might confound treatment effects or the interpretation of results, including severe epigastric pain, GI tract inflammation and (6) contraindications for acupuncture or MRI, including clotting and bleeding disorders, or severe psychiatric conditions and claustrophobia.

4.2.4. Withdrawal criteria

Participants were allowed to leave the study unconditionally without reason and instructed to withdraw if they met any of the exclusion criteria at any point during the study.

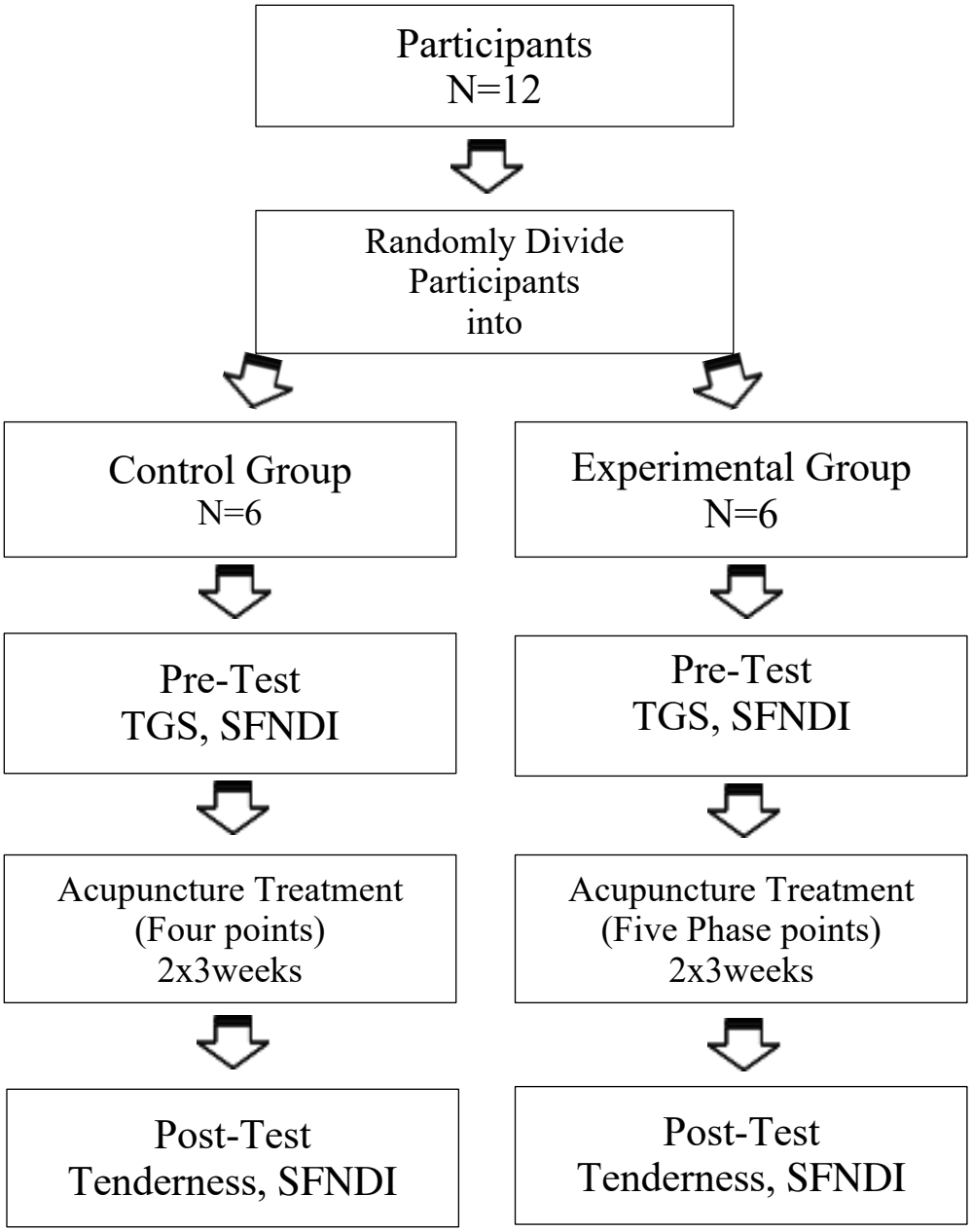

Figure 1. Schematic Diagram Research Design

4.2.5. Study design

This study used a Five phase combination acupuncture prescription that is able to be considered to be effective in Symptoms of Dyspepsia. Ten acupuncture points in the related meridian were chosen for Experimental Group: ST45, LI1, ST43, GB41, ST41, SI5. Four acupuncture points were applied for Control Group: LIV3, LI4, CV12, ST36.

Patients were received 25 min acupuncture treatments two times a week for 3 weeks (6 treatments in total).

4.3. Acupuncture Protocol

4.3.1. Point Location

The selected acupuncture points are located according to the proportional *cun* measurement system.

Table 2. The acupuncture points used in study alongside their anatomical position, attributes and functions.

Acupuncture points	Anatomy position	Attributes	Functions
ST45	On the lateral side of the 2nd toe, 0.1 cun posterior to the corner of the nail	Metal Jing-Well Son (Reducing) point	- Frees channel and resuscitates - Courses and discharges pathogenic heat - Harmonize stomach and clears spirit
LI 1	On the radial side of the index finger, about 0.1cun posterior to the corner of the nail	Metal Jing-Well	- Opens portal and revives spirit - Clears exterior Lung heat and benefits throat - Discharges yangming pathogenic heat

			- Brightens the eyes
ST 43	In the depression distal to the junction of the 2nd and 3rd metatarsal bones	Wood Shu-Stream	- Supports spleen qi and transforms damp - Clears stomach heat - Calms the spirit
GB41	Posterior to the 4th metatarsophalangeal joint, in the depression lateral to the tendon of m. extensor digitiminimi of the foot	Wood Shu-Stream Exit point Confluent point of Dai Vessel	- Spreads Liver qi and drains damp heat from wind - Clears and regulates Daimai
ST41	On the dorsum of the foot, at the midpoint of the transverse crease of the ankle joint, in the depression between the tendons of m. extensor digitorum longus and hallucis longus	Fire Jing-River Mother (Reinforcing) point	- Supports spleen qi and transforms damp - Clears stomach heat - Calms the spirit
SI 5	At the ulnar end of the transverse crease on the dorsal aspect of the wrist, in the depression between the styloid process of the ulna and the triquetral bone	Fire Jing-River	- Disperses heat and swelling - Calms the spirit
LIV 3	On the dorsum of the foot, in the depression distal to the junction of the 1st and 2nd metatarsal bones	Earth Tonifying Shu-Stream Yuan-Primary Liver meridian of Foot-Jueyin	- Spreads Liver qi - Discharge damp heat in Lover Burner - Nourishes Liver blood and Yin - Sedates Liver Yang and extinguishes wind
LI 4	On the dorsum of the hand, between the 1st and 2nd metacarpal bones, in the middle of the 2nd metacarpal bone on the radical side	Yuan-Primary Large Intestine meridian of Hand-Yangming Command point for face and mouth Entry point	- Disperses wind, resolves exterior and regulates surface for sweating or stop sweating

			- Free channel and connection vessels - Relieves pain and calms spirit - Clears Lung heat
CV12	On the anterior midline, 4 cun above the umbilicus	Tonifying Front-Mu point Stomach meridian of Foot-Yangming Influential point of Fu organs Intersection Jiao-Hui of CV/ST/SI/SJ	- Harmonizes Stomach - Fortifies Spleen and transforms damp
ST36	3 cun below dubi (ST35), one finger-breadth (middle finger) from the anterior border of the tibia	Earth Tonifying He-Sea point	- Benefits stomach and spleen - Harmonizes intestines and disperses stagnation - Tonifies qi and blood - Dispels pathogens and prevents disease - Courses wind and transforms damp

4.4. Intervention

4.4.1. Practitioner backgrounds

Acupuncture treatment was administered by a licensed acupuncturist who has been in the clinic experience more than two years.

4.4.2. Clinical pain diagnosis method

Diagnosis by palpation includes palpation of the pulse, skin, chest, abdomen and points as traditional eastern medicine theory. Abdominal palpation and palpating points used for this study are parts of diagnosis by palpation.

In general, if the abdomen feels hard, or if it is painful on palpation, this indicates a Full condition; if it feels too soft, or if any ache is relieved by palpation, it indicates Empty pattern.

Abdominal masses that move under the fingers indicate stagnation of Qi. If they do not move and feel very hard, they indicate stasis of Blood.

For palpating points, channel and point diagnosis is based on objective or subjective reactions appearing at certain points. General speaking, any point can be used in diagnosis, following the general principles outlined above for the channels. However, certain points are particularly useful in diagnosis; these are the Back-Transporting points and Front Collecting points.

The *Back Transporting points* are the places where the Qi and Blood of a particular organ 'infuse'. They are directly related to their respective organ and very often manifest certain reactions when the organ is diseased.

As a general principle, any sharp pain (either spontaneous or on pressure) on these points indicates a Full condition of the relevant organ, and a dull soreness (either spontaneous or on pressure) indicates an Empty condition. Each Back Transporting point can reflect the condition of its relevant organ (e.g. BL-21 Weishu for the stomach, BL-23 Daijangshu for the Large Intestine, etc.)

The *Front Collecting points* are particularly reactive to pathological changes of the Internal Organs and are useful for diagnostic purposes. Each Front Collecting point reflects the state of an internal organ. The general principle is that if these points are tender on palpation they usually indicate a Full pattern, whereas if palpation relieved a tenderness it indicates an Empty pattern.

As the diagnosis points for this study, there were used that CV12 Zhongwan for Stomach, ST25 Tianshu for Large Intestine, CV4 Guanyuan for Small Intestine, CV14 Juque for Heart and LIV13 Zhangmen for Spleen as the Front Collecting points.

4.4.3. Clinical pain assessment

This study is designed as Tenderness Grading Scale (TGS) and Short Form Nepean Dyspepsia Index (SFNDI). SFNDI assessment was the first test before the treatment and the second one in a three week, and the results were analyzed and compared whereas TGS assessment was before and after every single treatment to analyze and compare the level of pain for the participants with Symptoms of Dyspepsia.

4.4.4. Tenderness Grading Scale

A Tenderness Grading Scale (TGS) [46] is a measurement instrument that when applying static palpation to joints, muscles, tendons, ligaments, or superficial tissue in general, palpatory pain (i.e. tenderness) can be graded based on the patient's response.

The following is a recommended scale that can be used for initial assessment and as an outcome measure.[47]

Table 3. Tenderness Grading Scale

+1/4 T, or grade 1/4 tenderness	Tenderness with no physical response
+2/4 T, or grade 2/4 tenderness	Tenderness with grimace, wince, and/or flinch
+3/4 T, or grade 3/4 tenderness	Tenderness with withdrawal (positive jump sign)
+4/4 T, or grade 4/4 tenderness	Non-noxious stimuli (e.g., superficial palpation, gentle percussion) results in patient withdrawal or patient refusal to be palpated due to pain

(Modified after Cipriano 2010)

4.4.5. Short Form Nepean Dyspepsia Index

The Short Form Nepean Dyspepsia Index is a reliable and valid measure of quality of life in functional dyspepsia. The SFNDI contains 10 items designed to measure impairment of a subject's ability to engage in relevant aspects of their life because of dyspepsia[48].

4.4.6. Measures of Treatment effectiveness

After TGS assessment, the accumulated treatment effectiveness after every single treatment is based on TGS comparison.

TGS measuring: TGS before Treatment vs. TGS after nth Treatment

nth: is the order of treatment session

SFNDI assessment is based on the comparison of results before the treatment and after the last treatment session for the effectiveness.

SFNDI Scoring: add up the items for each of the five sub-scale scores (range of each sub- scale 2–10).

4.4.7. Statistical analysis

R version 3.5.1 (Feather Spray) was used for statistical computing and graphics.[49] Paired Sample t-test Wilcoxon Signed rank Test, Mann-Whitney U Test and Independent Sample t-test were performed to compare the changes in TGS and SFNDI before and after acupuncture in the patients with Symptoms of Dyspepsia.

V. RESULTS & DISCUSSIONS

The study examined a total of twelve patients for symptoms of chronic dyspepsia were randomly divided into two groups: experimental (n=6) and control (n=6). The experimental group received acupuncture treatment with Five Phase points combination. In comparison, the control group received Traditional four acupuncture points. Participants in both groups received two sessions of therapy per week for a three-week period starting from June 2018 and lasting until August 2018. Statistical data was collected before and after treatment for chronic dyspepsia and measured through the Tenderness Grading Scale (TGS) and Short Form Nepean Dyspepsia Index (SFNDI).

5.1. Homogeneity Test

5.1.1. Homogeneity Test for the General Characteristics of Patients

The gender and age of patients in the control and experimental groups are outlined through a homogeneity test for general characteristics, as shown in Table 4. The p-value for Fisher's Exact Test was greater than 0.05 in both groups, confirming that the experiment was performed under the same conditions for the two variables.

Table 4. General Characteristics of Patients

Variable	Group	EG	CG	p-value*
Gender	Female	6	6	1.000
Age	10's	0	1	0.481
	20's	2	0	
	30's	1	0	
	40's	3	3	
	60's	0	1	
	70's +	0	1	
Race	Asian	6	6	1.000
Duration	Chronic	6	6	1.000

* Fisher's Exact Test

5.1.2. Homogeneity Test for Measurement Variables between CG and EG before treatment

The Tender, Tension, IDA, ED, KC and WS of each measurement variables in the control and experimental groups are outlined through a homogeneity test for measurement variables between CG and EG before treatment, as shown in Table 5. The p-value for Mann-Whitney Test/Independent Sample T-test was greater than 0.05 in both groups, confirming that two groups were tested under the same conditions at the start of the treatment. A bar graph and a box plot for Tender, Tension, IDA, ED, KC, WS values are shown in Figure 2 and 3.

Table 5. Homogeneity Test for Tender, Tension, IDA, ED, KC and WS between CG and EG before treatment

Variables	EG	CG	p-value*
Tender	2.80 ± 0.41	2.80 ± 0.41	1.000
Tension	7.00 ± 1.41	6.50 ± 1.22	0.527**
IDA	4.50 ± 1.76	5.00 ± 1.26	0.585**
ED	6.50 ± 2.07	6.00 ± 1.10	0.613**
KC	4.00 ± 1.10	4.50 ± 1.22	0.476
WS	3.80 ± 0.41	3.30 ± 1.03	0.461

*Mann-Whitney Test / ** Independent Sample T-test

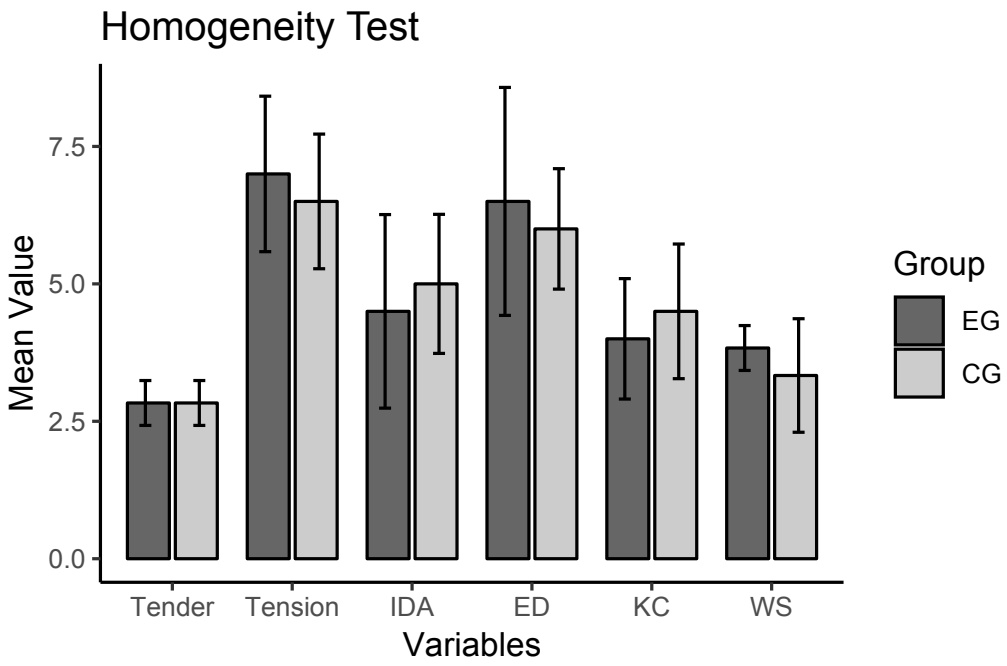

Figure 2. Bar Graph of Tender, Tension, IDA, ED, KC and WS for two groups before treatment.

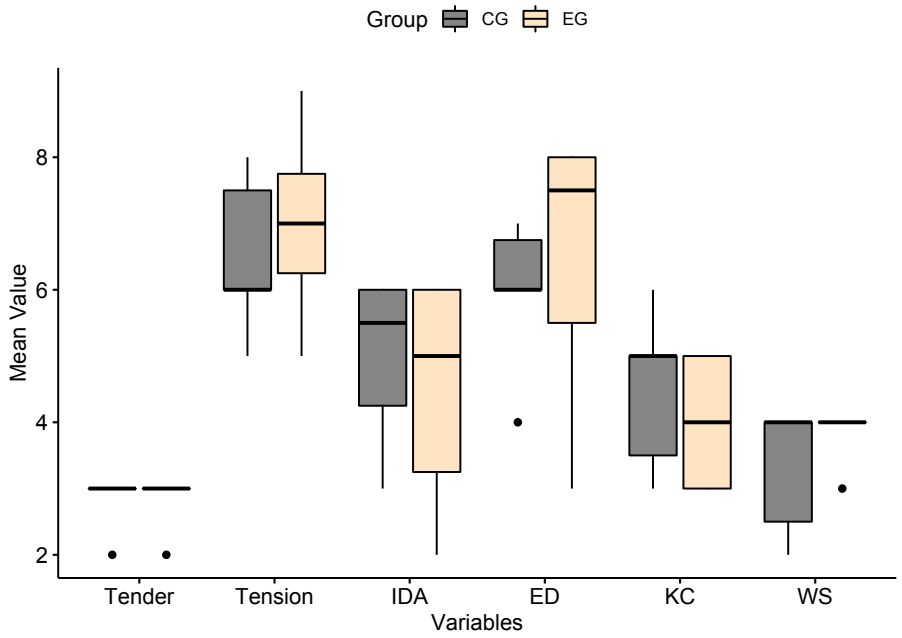

Figure 3. Box plots of Tender, Tension, IDA, ED, KC and WS for two groups before treatment.

5.2. Effect of Tender Between CG and EG

5.2.1. Change of Tender of Before and After Treatment Between CG and EG

Definition of Difference = Tender (Before *n*th Tx) – Tender (After *n*th Tx)

Tender value was measured to assess the symptomatic relief of patients with chronic dyspepsia. Table 6 compares the results of the experimental group with those of the control group measuring the change of Tender difference in every pre-and post-treatment session. Where assumption of normality was met, the Tender value before and after treatment was evaluated using the Paired Sample t-test. When assumption of normality was not met, the Wilcoxon Signed Rank Test was used. As shown in Table 6, the Tender value in the experimental group decreased from 2.80 ± 0.41 to 0.30 ± 0.52 after the first treatment, showing a decrease of 2.5 ± 0.55 (p=0.032). After the second treatment, the scores went down from 2.20 ± 0.41 to 0.20 ± 0.41 after the second treatment, showing a decrease of 2.00 ± 0.00 (p=0.020), After the third treatment, the scores decreased from 0.80 ± 0.75 to 0.00 ± 0.00, showing a decrease of 0.80 ± 0.75 (p=0.042) and the fourth treatment, the scores decreased from 0.30 ± 0.52 to 0.00 ± 0.00, showing a decrease of 0.30 ± 0.52 (p=0.346). The result for the experimental group was statistically highly significant except for the fourth treatment. The result of comparing Tender value of pre-treatment and after the fourth treatment decreased from 2.80 ± 0.41 to 0.30 ± 0.52. The reason why the result of the four treatment did not show them to be statistically significant was because the Tender scores of patients already went down closed to 0.00 before the fourth treatment.

Four out of six patients in the experimental group were met to treatment goal (TGS < 1) after the third treatment and the rest of them was met to the goal after the fourth and fifth respectively. Therefore, in the case of less than one subject for statistical assessment like in the fifth and sixth treatment, the statistical result was excluded.

Tender value in the control group decreased from 2.80 ± 0.41 to 2.00 ± 0.00 after the first treatment, showing a decrease of 0.80 ± 0.41 (p=0.037). After the second treatment, the scores went down from 2.80 ± 0.41 to 0.20 ± 0.41, showing a decrease of 0.80 ± 0.41 (p=0.037), After the third treatment, the scores decreased from 2.30 ± 0.52 to 1.80 ± 0.41, showing a decrease of 0.50 ± 0.55 (p=0.149), the fourth treatment, the scores decreased from 2.30 ± 0.52 to 2.00 ± 0.00, showing a decrease of 0.30 ± 0.52 (p=0.346), the fifth treatment, the scores decreased from 2.00 ± 0.00 to 1.30 ± 0.52, showing a decrease of 0.70 ± 0.52 (p=0.072), and the sixth treatment, the scores decreased from 2.00 ± 0.00 to 1.30 ± 0.52, showing a decrease of 0.70 ± 0.52 (p=0.072). The results of the first and second treatment are statistically significant according to the Paired Sample t-test/ Wilcoxon Signed Rank Test, but the result after the third, fourth and sixth treatment did not show them to statistically significant. The result of comparing Tender value of pre-treatment and post- treatment in the control group decreased from 2.80 ± 0.41 to 1.30 ± 0.52. Figure 4 and Figure 5 show a bar graph and line graph of Tender before and after each treatment.

Table 6. Change of Tender of Before and After Treatment Between CG and EG

Group	Before	After	Difference	p-value
EG 1st	2.80 ± 0.41	0.30 ± 0.52	2.50 ± 0.55	0.032 **
2nd	2.20 ± 0.41	0.20 ± 0.41	2.00 ± 0.00	0.020 **
3rd	0.80 ± 0.75	0.00 ± 0.00	0.80 ± 0.75	0.042 *
4th	0.30 ± 0.52	0.00 ± 0.00	0.30 ± 0.52	0.346 **
CG 1st	2.80 ± 0.41	2.00 ± 0.00	0.80 ± 0.41	0.037 **
2nd	2.80 ± 0.41	2.00 ± 0.00	0.80 ± 0.41	0.037 **
3rd	2.30 ± 0.52	1.80 ± 0.41	0.50 ± 0.55	0.149 **
4th	2.30 ± 0.52	2.00 ± 0.00	0.30 ± 0.52	0.346 **
5th	2.00 ± 0.00	1.30 ± 0.52	0.70 ± 0.52	0.072 **
6th	2.00 ± 0.00	1.30 ± 0.52	0.70 ± 0.52	0.072 **

* Paired Sample t-test

** Wilcoxon Signed Rank Test

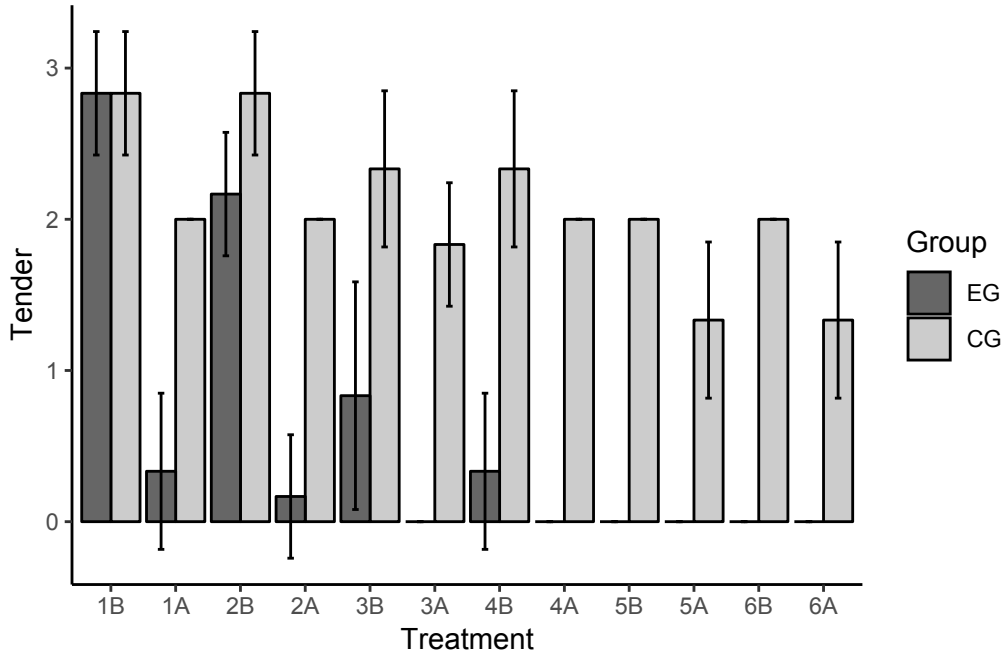

Figure 4. Bar Graph of Tender Before and After each treatment

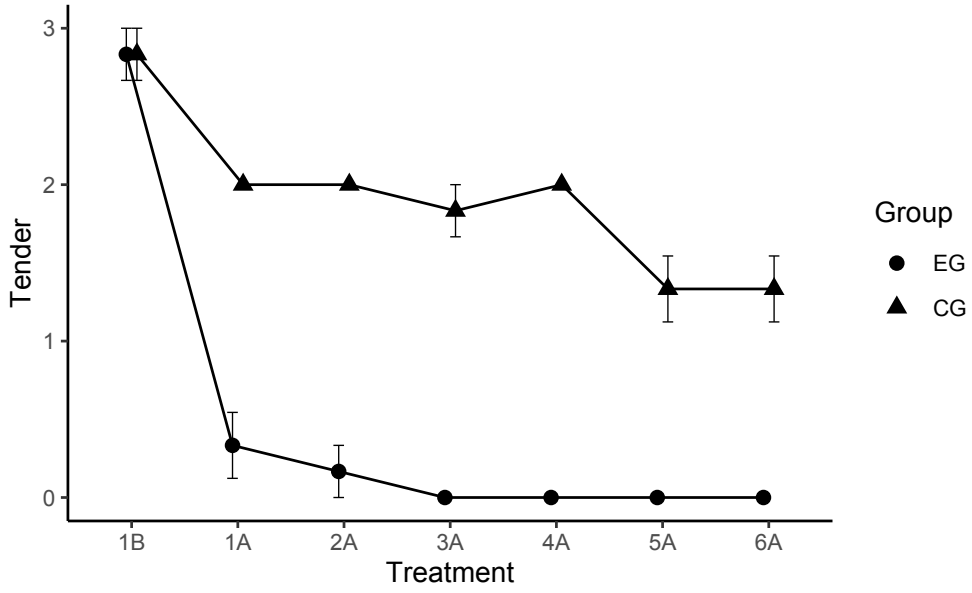

Figure 5. Line graph of Tender Before and After each treatment

5.2.2. Cumulative Effect on Tender between CG and EG

Definition of *n*th Treatment Effect = (Tender Before 1st Treatment - Tender After *n*th Treatment)

As shown on Table 7, In comparing the Tender value of the control and experimental groups, the treatment effect after session was 0.80 ± 0.41 for the control group and 2.50 ± 0.55 for the experimental group (p=0.003). After the second session, the treatment effect was 0.80 ± 0.41 for the control group and 2.70 ± 0.52 for the experimental group (p=0.003). After the third session, the treatment effect was 1.00 ± 0.00 for the control group and 2.80 ± 0.41 for the experimental group (p=0.002). The experimental group showed a higher cumulative treatment effect in all cases and the results showed them to be statistically significant according to the Mann-Whitney U Test (Table 7).

Figure 6 and Figure 7 show a bar graph, a box plot of the cumulative treatment effect after each treatment between CG and EG as determined by Tender Scores respectively.

Table 7. The Comparison of Cumulative Effect on Tender between CG and EG

Treatment	EG	CG	p-value*
1st	2.50 ± 0.55	0.80 ± 0.41	0.003
2nd	2.70 ± 0.52	0.80 ± 0.41	0.003
3rd	2.80 ± 0.41	1.00 ± 0.00	0.002

* Mann-Whitney U Test

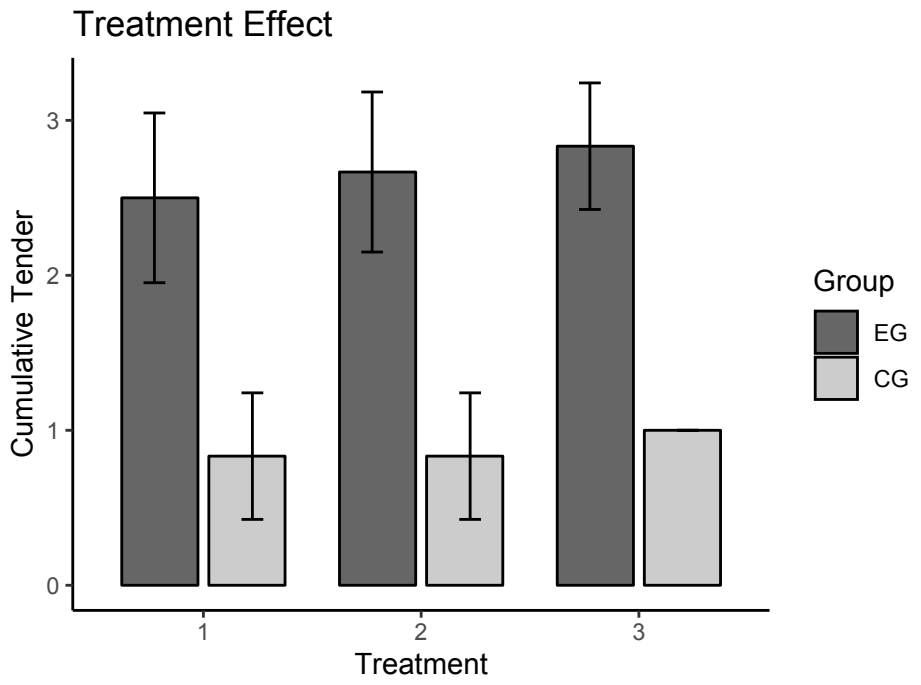

Figure 6. Bar Graph of Cumulative Effect on Tender after each Treatment

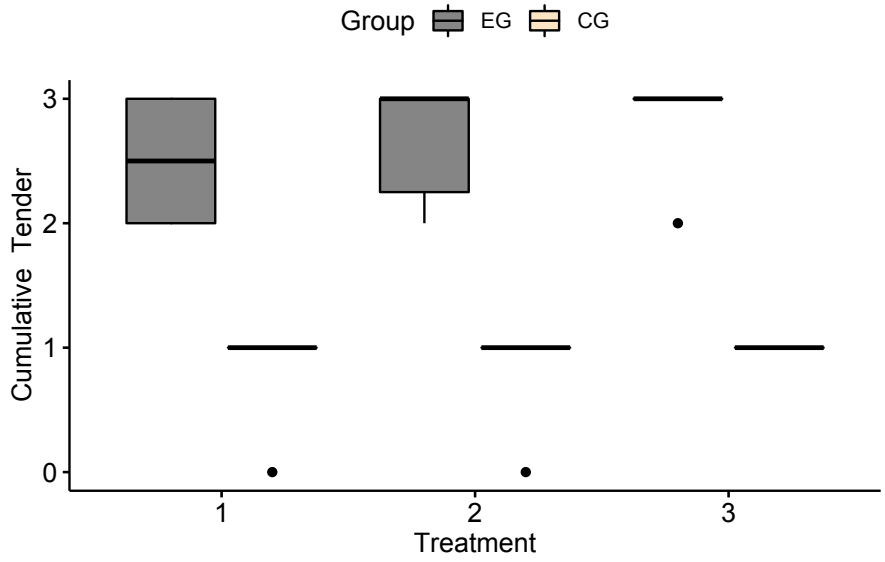

Figure 7. Box plot of Cumulative Effect on Tender after each Treatment

5.2.3. Cumulative Treatment Rate on Tender

*n*th Treatment Rate (%) = 100*(Tender Before 1st Treatment – Tender After *n*th Treatment) / Tender Before 1st Treatment

The results of the comparison between cumulative treatment rate of the control and the experimental groups are shown in Table8. The cumulative treatment rates of the control and experimental groups after the first treatment were 27.80 ± 13.61% and 88.90 ± 17.21% (p=0.003), respectively. After the second treatment, the cumulative treatment rate of the control group was 27.80 ± 13.61% and that of the experimental group was 94.40 ± 13.61% (p=0.003). After the third treatment, the cumulative treatment rate of the control group was 36.10 ± 6.80% and that of the experimental group was 100.0 ± 0.00% (p =0.002).

The cumulative treatment rate increased as the number of treatment sessions increased in both groups. The experimental group showed a cumulative treatment rate that was 64% higher than that of the control group and the results showed them to be statistically significant according to the Mann-Whitney U Test (Table 8). Figure 8 show the bar graph of the two groups' treatment rates.

Table 8. Treatment Rate on Tender between CG and EG

Treatment	EG (%)	CG (%)	p-value*
1st	88.90 ± 17.21	27.80 ± 13.61	0.003
2nd	94.40 ± 13.61	27.80 ± 13.61	0.003
3rd	100.0 ± 0.00	36.10 ± 6.80	0.002

* Mann-Whitney U Test

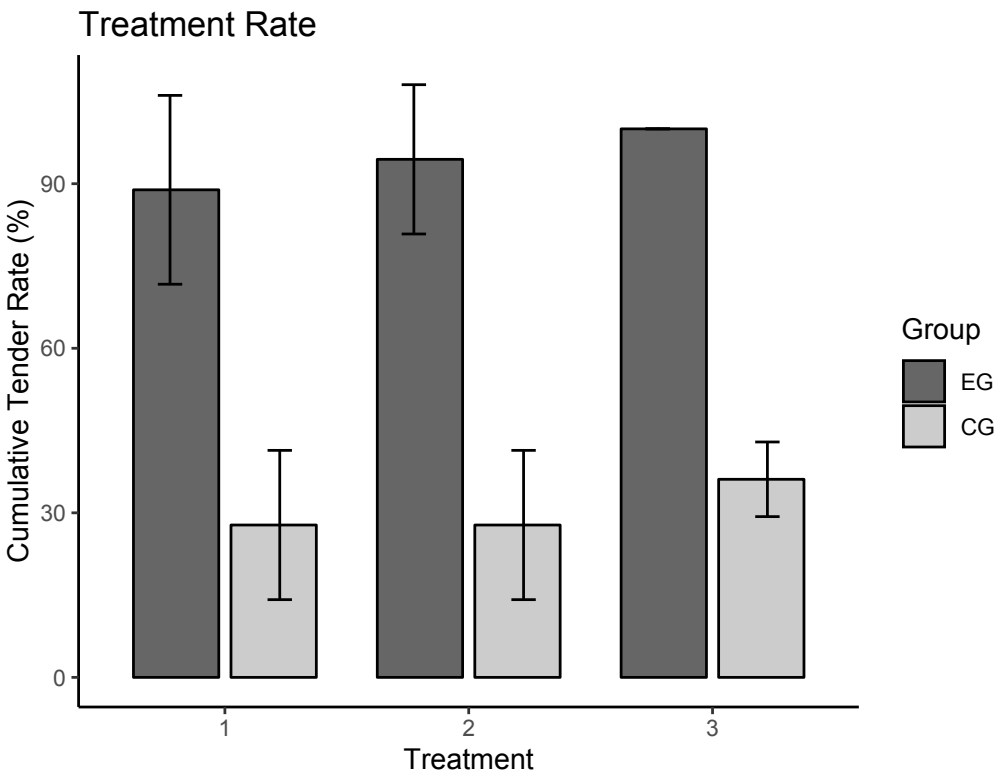

Figure 8. Bar Graph of Treatment Rate on Tender Between Two Groups

5.2.4. Cohen's Distance of Tender

Cohen's distance = (M2-M1) / √ {(SD12 + SD 22) /2}

As shown on Table 8, Cohen's distance was used to compare the effectiveness of the control group treatment to that of the experimental group treatment. Cohen's distance was 0.00 in pre-treatment, 4.56 after the first treatment and 6.35 after the second and third treatments, showing that the treatment given to the latter showed higher effectiveness.

Table 9. Cohen's Distance (Effect Size) between Two Groups of Before and After Treatment

Treatment	Before	1 After	2 After	3 After
Cohen's d	0.00	4.56	6.35	6.35
Meaning	Negligible*	Large**	Large**	Large**

CD < 0.2	Negligible *
CD < 0.5	Small
CD < 0.8	Medium
Otherwise	Large **

5.3. Effect on Tension between CG and EG

5.3.1. Change of Tension of Before and After treatment between CG and EG

Tension value was measured to assess the symptomatic relief of patients with chronic dyspepsia. Table 10 compares the results of the experimental group with those of the control group measuring the change of Tension difference in pre-and post-treatment session. Figure 9 and Figure 10 show a bar graph, a box plot of Tension before and after each treatment between CG and EG.

In comparing the Tension values of pre- and post-treatment between the control and experimental groups as shown on Table 10, the Tension scores of the experimental group decreased from 7.00 ± 1.41 to 2.20 ± 0.41 (p=0.001) and those of the control group decreased from 6.50 ± 1.22 to 4.30 ± 0.52 (p=0.006) after the treatment respectively. The experimental group showed a higher treatment effect in all cases and the results showed them to be statistically significant according to the Paired sample t-Test.

Table 10. Change of Tension of Before and After treatment

Group	Before	After	Difference	p-value *
EG	7.00 ± 1.41	2.20 ± 0.41	4.80 ± 1.60	0.001
CG	6.50 ± 1.22	4.30 ± 0.52	2.20 ± 1.17	0.006

* Paired Sample t-test

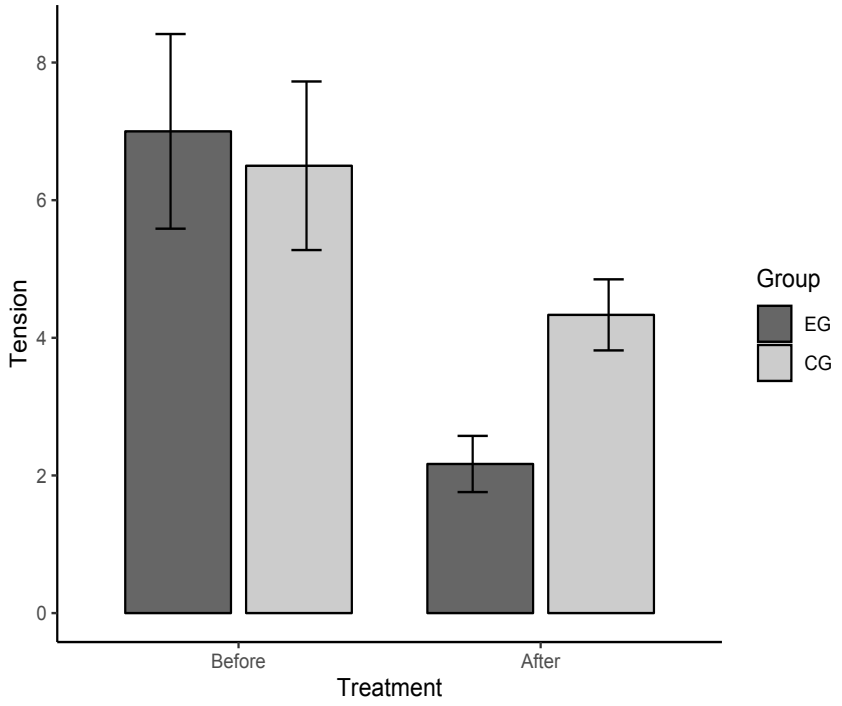

Figure 9. Bar Graph of Tension of Before and After each treatment

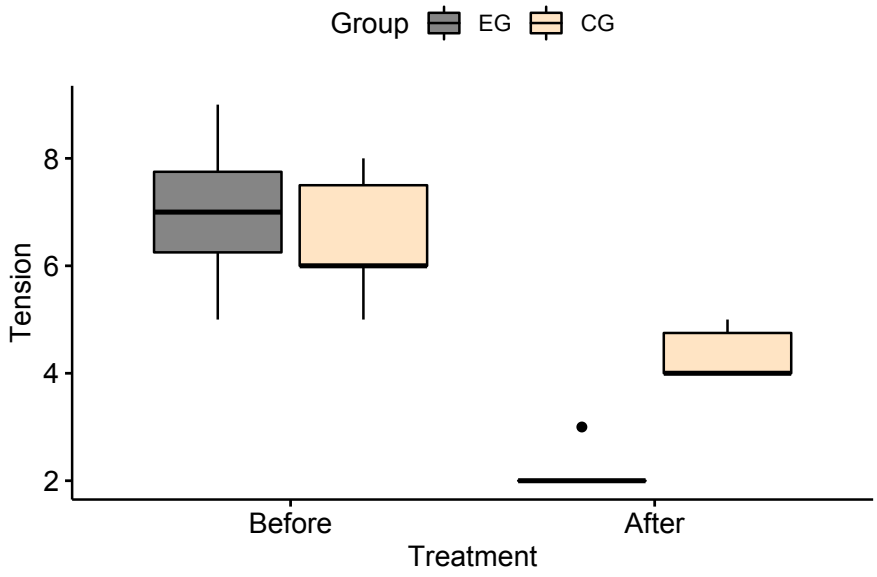

Figure 10. Box plot of Tension of Before and After each treatment

5.3.2. Tension Effect and Rate of Between CG and EG

Definition of Treatment Effect = Tension (Before Tx) – Tension (After Tx)

Tension Treatment Rate (%) = 100*(Tension Before 1st Treatment – Tension After Treatment) / Tension Before 1st Treatment

As shown on Table 11, in comparing the Tender value of the control and experimental groups, the treatment effect after session was 2.20 ± 1.17 for the control group and 4.80 ± 1.60 for the experimental group (p=0.008). The treatment rates of the control and experimental groups after treatment were 31.80 ± 12.14%, and 67.60 ± 10.54% (p=0.000) respectively.

The experimental group had a greater treatment effect and rate and the results showed them to be statistically significant (p<0.05) according to the Independent Sample t- Test (Table 11). Figure 11 show the bar graph of Tension difference and rate of before and after treatment.

Table 11. Tension Difference and Rate of Before and After Treatment

Group	EG	CG	p-value*
Difference	4.80 ± 1.60	2.20 ± 1.17	0.008
Rate (%)	67.60 ± 10.54	31.80 ± 12.14	0.000

* Independent Sample t- test

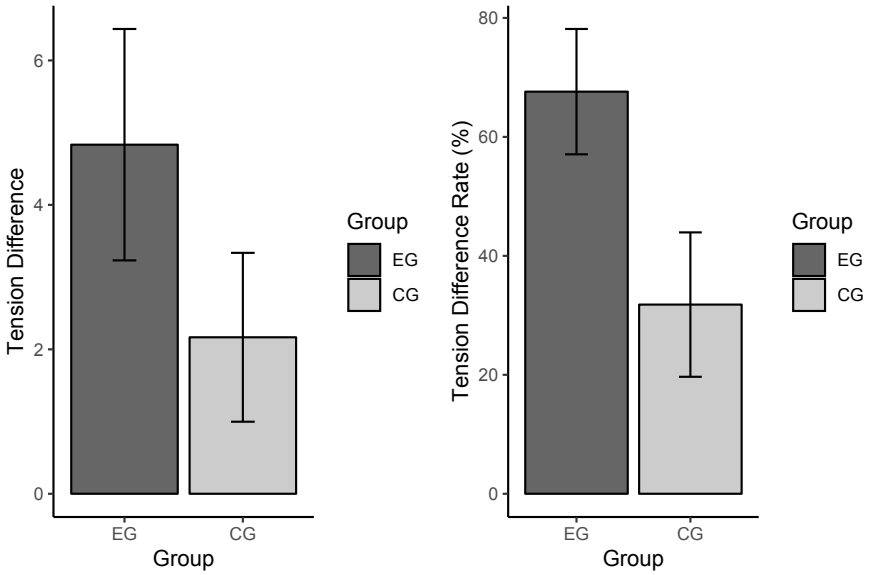

Figure 11. Tension Difference and Rate of Before and After Treatment

5.3.3. Cohen's Distance of Tension

Cohen's distance = (M2-M1) / √ {(SD12 + SD 22) /2}

As shown on Table 12, Cohen's distance was used to compare the effectiveness of the control group treatment to that of the experimental group treatment. Cohen's distance was 0.38 in pre-treatment and 4.65 after post-treatments, showing that the treatment given to the latter showed higher effectiveness.

Table 12. Cohen's Distance (Effect Size) between Two Groups of Before and After Treatment

Treatment	Before	After
Cohen's d	0.38	4.65
Meaning	Small*	Large**

CD < 0.2	Negligible
CD < 0.5	Small*
CD < 0.8	Medium
Otherwise	Large **

5.4. Effect on IDA between CG and EG

5.4.1. Change of IDA of Before and After treatment between CG and EG

IDA value was measured to assess the symptomatic relief of patients with chronic dyspepsia. Table 12 compares the results of the experimental group with those of the control group measuring the change of IDA difference in pre-and post-treatment session. Figure 12 and Figure 13 show a bar graph, a box plot of IDA before and after each treatment between CG and EG.

In comparing the IDA values of pre- and post-treatment between the control and experimental groups as shown on Table 13, the IDA scores of the experimental group decreased from 4.50 ± 1.76 to 2.00 ± 0.00 ($p=0.018$) and those of the control group decreased from 5.00 ± 1.26 to 3.80 ± 0.41 ($p=0.090$) after the treatment respectively. The experimental group showed them to be statistically significant ($p<0.05$) but the result of the control group did not show them to be statistically significant ($p>0.05$).

Table 13. Change of IDA of Before and After treatment

Group	Before	After	Difference	p-value *
EG	4.50 ± 1.76	2.00 ± 0.00	2.50 ± 1.76	0.018
CG	5.00 ± 1.26	3.80 ± 0.41	1.20 ± 1.33	0.090**

* Paired Sample t-test

** Wilcoxon Signed rank Test

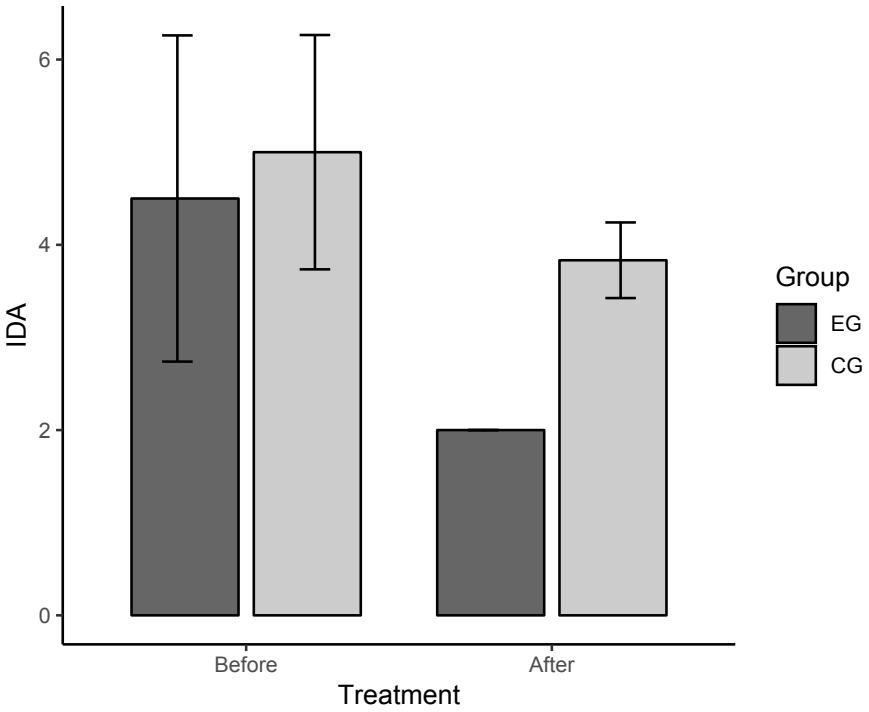

Figure 12. Bar Graph of IDA Before and After each treatment

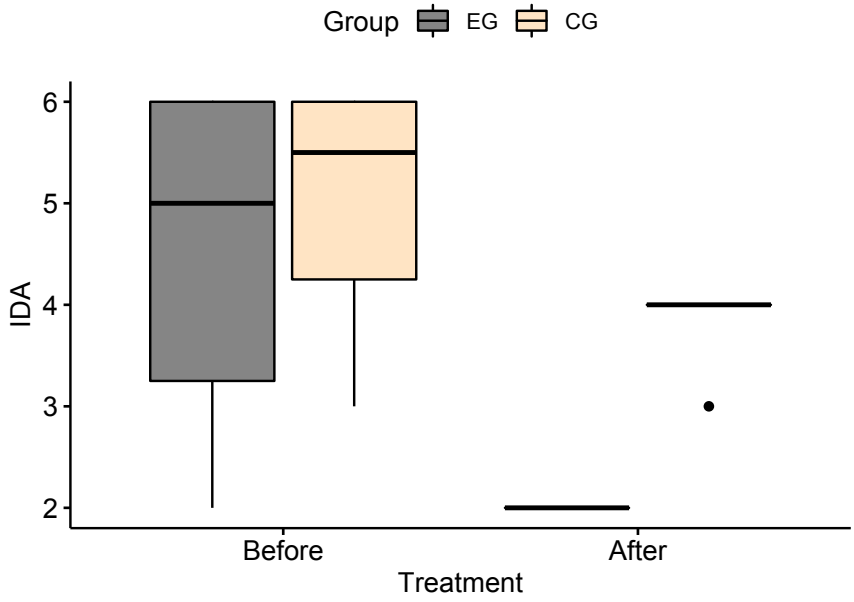

Figure 13. Box plot of IDA Before and After each treatment

5.4.2. **IDA Effect and Rate of Between CG and EG**

Definition of Treatment Effect = IDA (Before Tx) – IDA (After Tx)

IDA Treatment Rate (%) = 100*(IDA Before 1st Treatment – IDA After Treatment) / IDA Before 1st Treatment

As shown on Table 14, in comparing the IDA value of the control and experimental groups, the treatment effect after session was 1.20 ± 1.33 for the control group and 2.50 ± 1.76 for the experimental group (p=0.241). The treatment rates of the control and experimental groups after treatment were 17.28 ± 28.80%, and 47.20 ± 26.70% (p=0.084) respectively.

The experimental group had a greater treatment effect and rate, but the results did not show them to be statistically significant (p>0.05) according to Mann-Whitney U Test (Table 14). Figure 14 show the bar graph of IDA difference and rate of before and after treatment.

Table 14. IDA Difference and Rate of Before and After Treatment

Group	EG	CG	p-value*
Difference	2.50 ± 1.76	1.20 ± 1.33	0.241
Rate (%)	47.20 ± 26.70	17.80 ± 28.80	0.084

* Mann-Whitney U Test

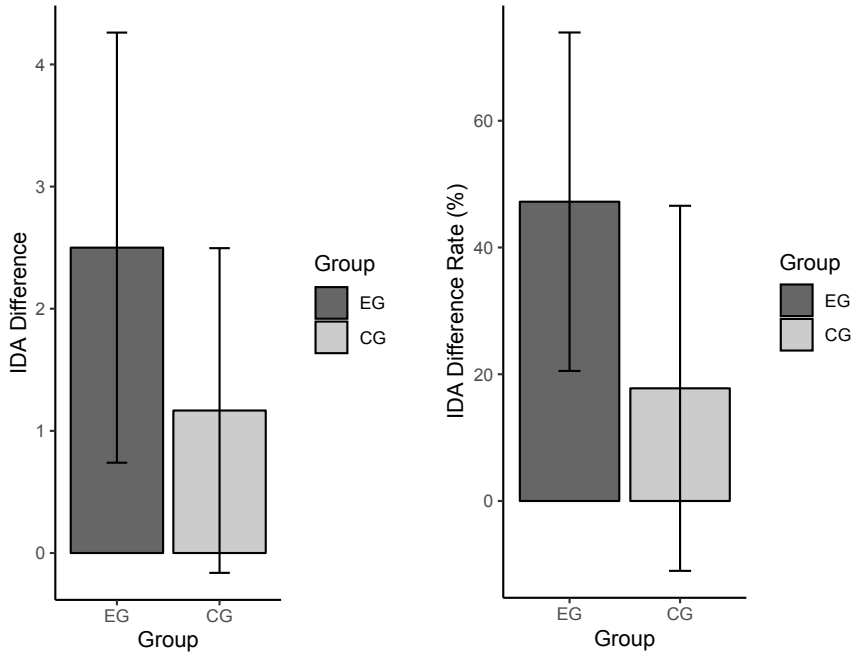

Figure 14. IDA Difference and Rate of Before and After Treatment

5.4.3. Cohen's Distance of IDA

Cohen's distance = (M2-M1) / √ {(SD12 + SD 22) /2}

As shown on Table 15, Cohen's distance was used to compare the effectiveness of the control group treatment to that of the experimental group treatment. Cohen's distance was 0.33 in pre-treatment and 6.35 after post-treatments, showing that the treatment given to the latter showed higher effectiveness.

Table 15. Cohen's Distance (Effect Size) between Two Groups of Before and After Treatment

Treatment	Before	After
Cohen's d	0.33	6.35
Meaning	Small*	Large**

CD < 0.2	Negligible
CD < 0.5	Small*
CD < 0.8	Medium
Otherwise	Large **

5.5. Effect on ED between CG and EG

5.5.1. Change of ED of Before and After treatment between CG and EG

ED value was measured to assess the symptomatic relief of patients with chronic dyspepsia. Table 16 compares the results of the experimental group with those of the control group measuring the change of ED difference in pre-and post-treatment session. Figure 16 and Figure 17 show a bar graph, a box plot of ED before and after each treatment between CG and EG.

In comparing the ED values of pre- and post-treatment between the control and experimental groups as shown on Table 16, the ED scores of the experimental group decreased from 6.50 ± 2.07 to 2.20 ± 0.41 ($p=0.034$) and those of the control group decreased from 6.00 ± 1.10 to 3.80 ± 0.41 ($p=0.001$) after the treatment respectively. Both groups showed them to be statistically significant ($p<0.05$) but the result of the experimental group had a greater treatment effectiveness ($p>0.05$).

Table 16. Change of ED of Before and After treatment

Group	Before	After	Difference	p-value *
EG	6.50 ± 2.07	2.20 ± 0.41	4.30 ± 2.25	0.034
CG	6.00 ± 1.10	3.80 ± 0.41	2.20 ± 0.75	0.001**

* Paired Sample t-test

** Wilcoxon Signed rank Test

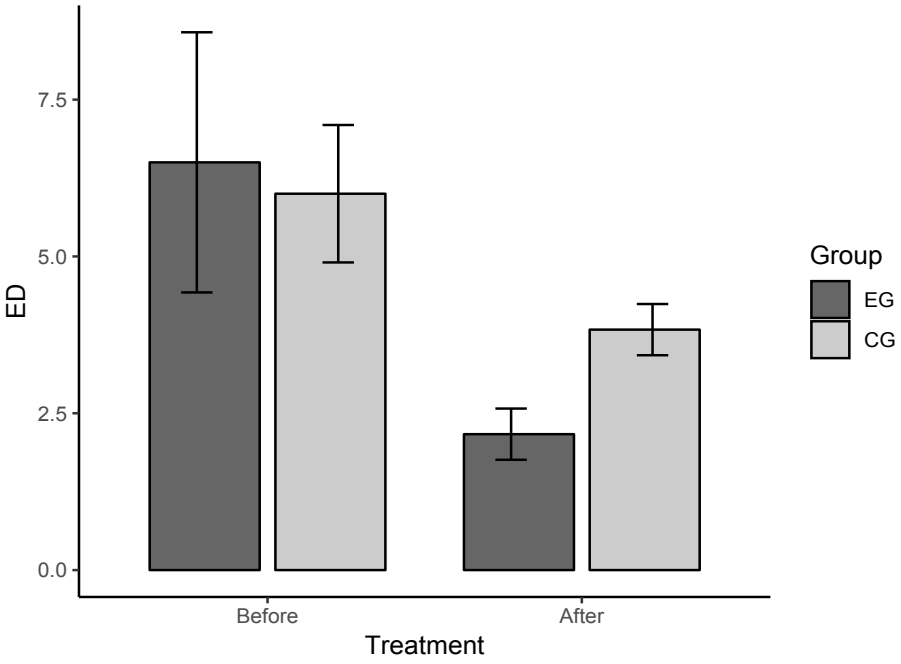

Figure 16. Bar Graph of ED Before and After each treatment

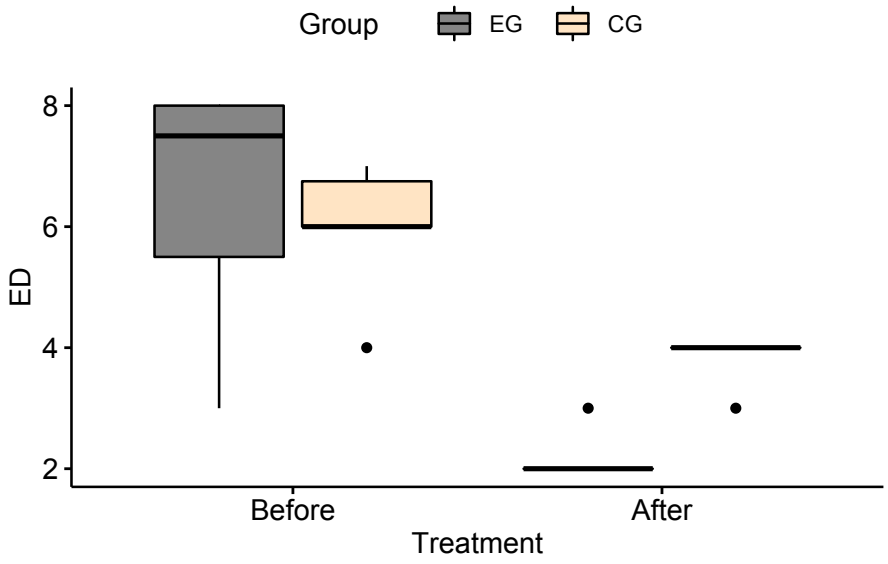

Figure 17. Box plot of ED Before and After each treatment

5.5.2. ED Effect and Rate of Between CG and EG

Definition of Treatment Effect = ED (Before Tx) – ED (After Tx)

ED Treatment Rate (%) = 100*(ED Before 1st Treatment – ED After Treatment) / ED Before 1st Treatment

As shown on Table 17, in comparing the ED value of the control and experimental groups, the treatment effect after session was 2.20 ± 0.75 for the control group and 4.30 ± 2.25 for the experimental group (p=0.066). The treatment rates of the control and experimental groups after treatment were 35.10 ± 6.81%, and 61.60 ± 19.50% (p=0.019) respectively.

The experimental group had a greater treatment effect and rate, but the result of treatment effect did not show them to be statistically significant (p>0.05) while that of treatment rate showed them to be statistically significant (p<0.05) according to Independent Sample t-Test (Table 17). Figure 18 show the bar graph of ED difference and rate of before and after treatment.

Table 17. ED Difference and Rate of Before and After Treatment

Group	EG	CG	p-value*
Difference	4.30 ± 2.25	2.20 ± 0.75	0.066
Rate (%)	61.60 ± 19.50	35.10 ± 6.81	0.019

* Independent Sample t-Test

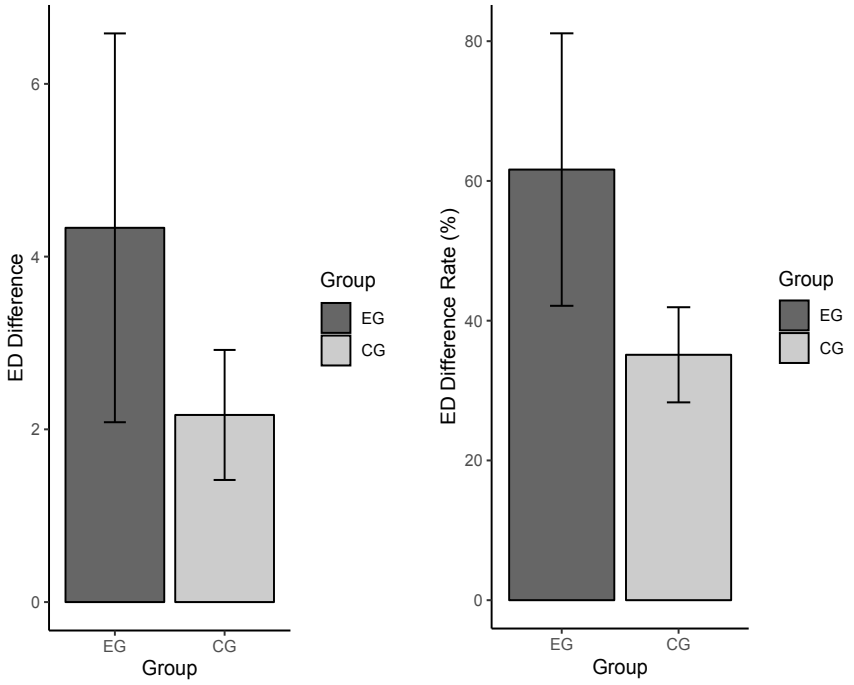

Figure 18. ED Difference and Rate of Before and After Treatment

5.5.3. Cohen's Distance of ED

Cohen's distance = (M2-M1) / √ {(SD12 + SD 22) /2}

As shown on Table 18, Cohen's distance was used to compare the effectiveness of the control group treatment to that of the experimental group treatment. Cohen's distance was 0.30 in pre-treatment and 4.08 after post-treatments, showing that the treatment given to the latter showed higher effectiveness.

Table 18. Cohen's Distance (Effect Size) between Two Groups of Before and After Treatment

Treatment	Before	After
Cohen's d	0.30	4.08
Meaning	Small*	Large**

CD < 0.2	Negligible
CD < 0.5	Small*
CD < 0.8	Medium
Otherwise	Large **

5.6. Effect on KC between CG and EG

5.6.1. Change of KC of Before and After treatment between CG and EG

KC value was measured to assess the symptomatic relief of patients with chronic dyspepsia. Table 19 compares the results of the experimental group with those of the control group measuring the change of KC difference in pre-and post-treatment session. Figure 19 and Figure 20 show a bar graph, a box plot of KC before and after each treatment between CG and EG.

In comparing the KC values of pre- and post-treatment between the control and experimental groups as shown on Table 19, the KC scores of the experimental group decreased from 4.00 ± 1.10 to 2.00 ± 0.00 ($p=0.032$) and those of the control group decreased from 4.50 ± 1.22 to 3.80 ± 0.41 ($p=0.175$) after the treatment respectively. The experimental group showed them to be statistically significant ($p<0.05$) but the control group did not show them to be statistically significant ($p>0.05$).

Table 19. Change of KC of Before and After treatment

Group	Before	After	Difference	p-value *
EG	4.00 ± 1.10	2.00 ± 0.00	2.00 ± 1.10	0.032
CG	4.50 ± 1.22	3.80 ± 0.41	0.70 ± 1.03	0.175**

* Paired Sample t-test

** Wilcoxon Signed rank Test

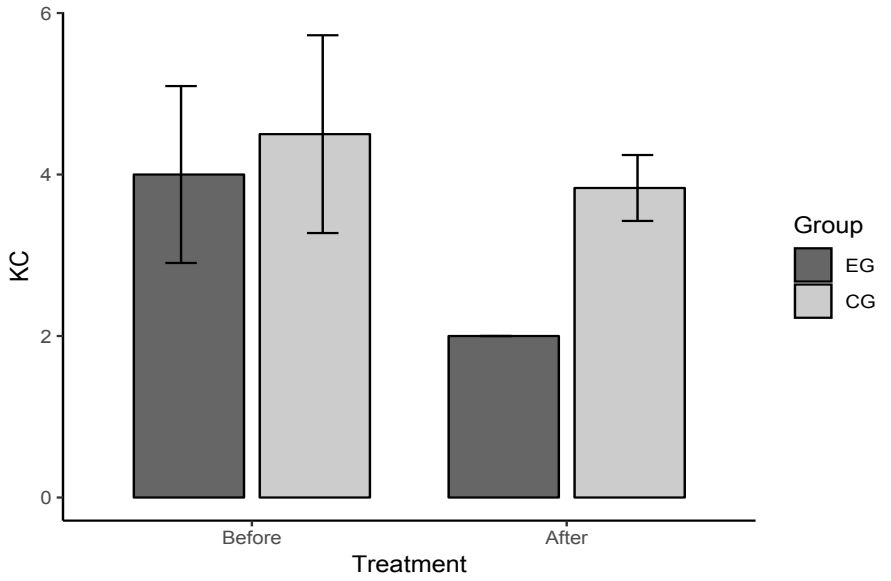

Figure 19. Bar Graph of KC Before and After each treatment

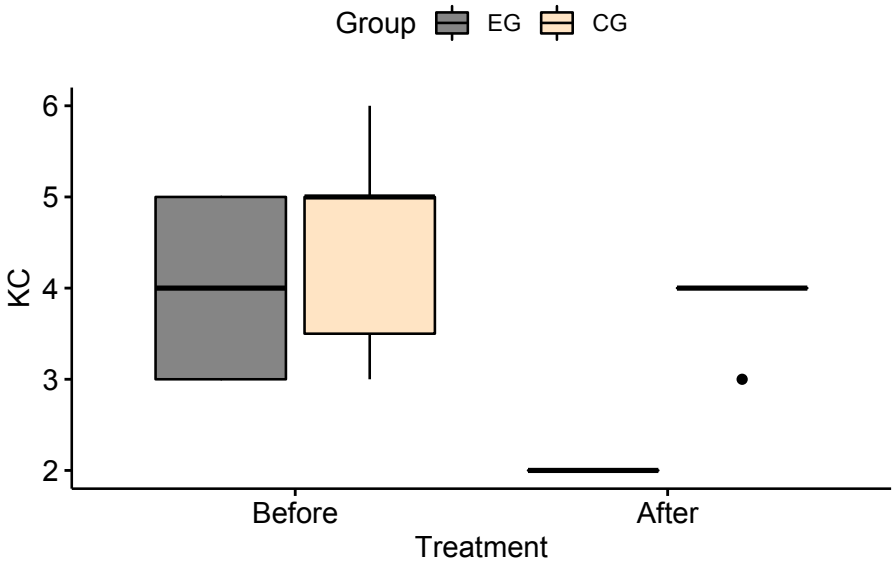

Figure 20. Box plot of KC Before and After each treatment

5.6.2. KC Effect and Rate of Between CG and EG

Definition of Treatment Effect = KC (Before Tx) – KC (After Tx)

KC Treatment Rate (%) = 100*(KC Before 1st Treatment – KC After Treatment) / KC Before 1st Treatment

As shown on Table 20, in comparing the KC value of the control and experimental groups, the treatment effect after session was 0.70 ± 1.03 for the control group and 2.00 ± 1.10 for the experimental group (p=0.055). The treatment rates of the control and experimental groups after treatment were 10.00 ± 23.76%, and 46.70 ± 14.61% (p=0.008) respectively.

The experimental group had a greater treatment effect and rate, but the result of treatment effect did not show them to be statistically significant (p>0.05) while that of treatment rate showed them to be statistically significant (p<0.05) according to Independent Sample t-Test (Table 20). Figure 21 show the bar graph of KC difference and rate of before and after treatment.

Table 20. KC Difference and Rate of Before and After Treatment

Group	EG	CG	p-value*
Difference	2.00 ± 1.10	0.70 ± 1.03	0.055
Rate (%)	46.70 ± 14.61	10.00 ± 23.76	0.008**

* Independent Sample t-test

** Mann-Whitney U Test

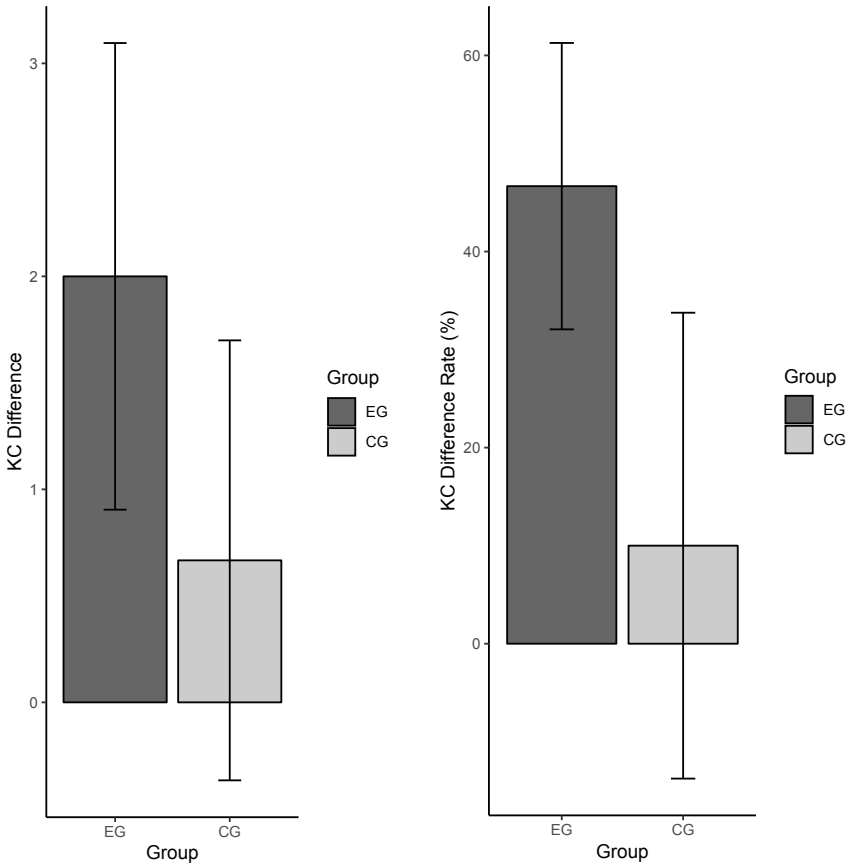

Figure 21. KC Difference and Rate of Before and After Treatment

5.6.3. Cohen's Distance of KC

Cohen's distance = (M2-M1) / √ {(SD12 + SD 22) /2}

As shown on Table 21, Cohen's distance was used to compare the effectiveness of the control group treatment to that of the experimental group treatment. Cohen's distance was 0.43 in pre-treatment and 6.35 after post-treatments, showing that the treatment given to the latter showed higher effectiveness.

Table 21. Cohen's Distance (Effect Size) between Two Groups of Before and After Treatment

Treatment	Before	After
Cohen's d	0.43	6.35
Meaning	Small*	Large**

CD < 0.2	Negligible
CD < 0.5	Small*
CD < 0.8	Medium
Otherwise	Large **

5.7. Effect on WS between CG and EG

5.7.1. Change of WS of Before and After treatment between CG and EG

WS value was measured to assess the symptomatic relief of patients with chronic dyspepsia. Table 22 compares the results of the experimental group with those of the control group measuring the change of WS difference in pre-and post-treatment session. Figure 22 and Figure 23 show a bar graph, a box plot of WS before and after each treatment between CG and EG.

In comparing the WS values of pre- and post-treatment between the control and experimental groups as shown on Table 22, the WS scores of the experimental group decreased from 3.80 ± 0.41 to 2.00 ± 0.00 ($p=0.026$) and those of the control group decreased from 3.30 ± 1.03 to 3.20 ± 0.98 ($p=1.000$) after the treatment respectively. The experimental group showed them to be statistically significant ($p<0.05$) but the control group did not show them to be statistically significant ($p>0.05$).

Table 22. Change of WS of Before and After treatment

Group	Before	After	Difference	p-value *
EG	3.80 ± 0.41	2.00 ± 0.00	1.80 ± 0.41	0.026
CG	3.30 ± 1.03	3.20 ± 0.98	0.20 ± 0.41	1.000

* Wilcoxon Signed rank Test

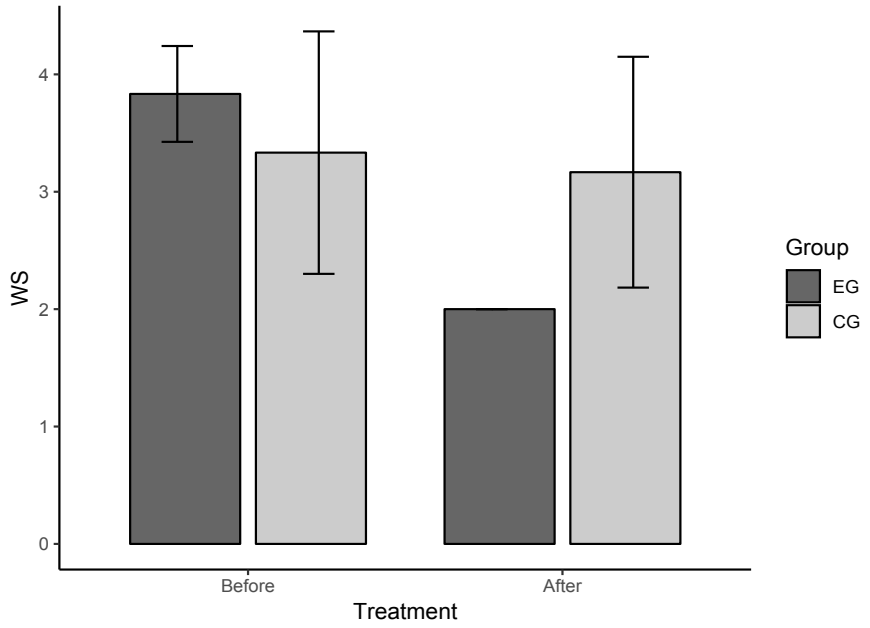

Figure 22. Bar Graph of WS Before and After each treatment

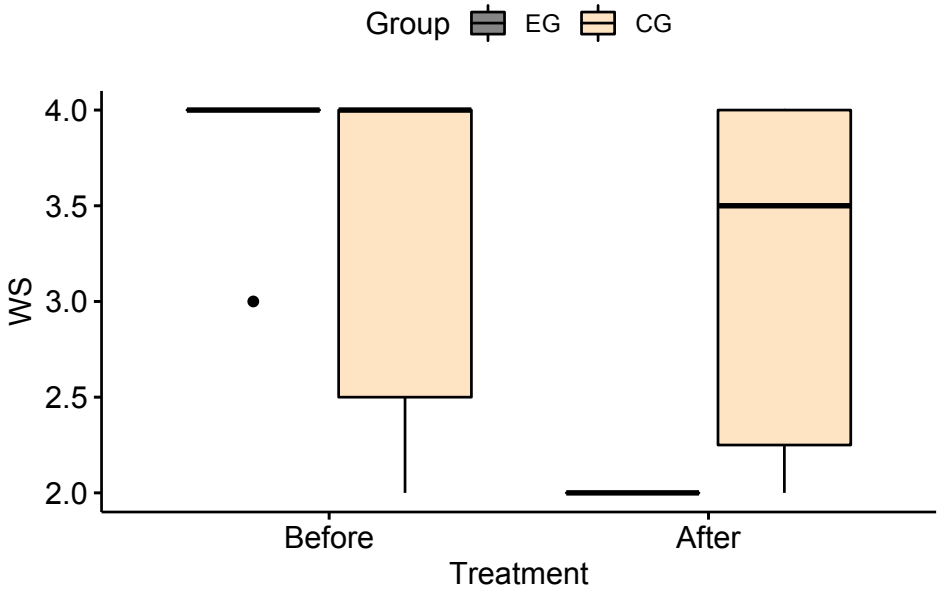

Figure 23. Box plot of WS Before and After each treatment

5.7.2. WS Effect and Rate of Between CG and EG

Definition of Treatment Effect = WS (Before Tx) – WS (After Tx)

WS Treatment Rate (%) = 100*(WS Before 1st Treatment – WS After Treatment) / WS Before 1st Treatment

As shown on Table 23, in comparing the WS value of the control and experimental groups, the treatment effect after session was 0.20 ± 0.41 for the control group and 1.80 ± 0.41 for the experimental group (p=0.003). The treatment rates of the control and experimental groups after treatment were 4.20 ± 10.21%, and 47.20 ± 6.80% (p=0.003) respectively.

The experimental group had a greater treatment effect and rate and the results showed them to be statistically significant (p<0.05) according to Mann-Whitney U Test (Table 23). Figure 24 show the bar graph of WS difference and rate of before and after treatment.

Table 23. WS Difference and Rate of Before and After Treatment

Group	EG	CG	p-value*
Difference	1.80 ± 0.41	0.20 ± 0.41	0.003
Rate (%)	47.20 ± 6.80	4.20 ± 10.21	0.003

* Mann-Whitney U Test

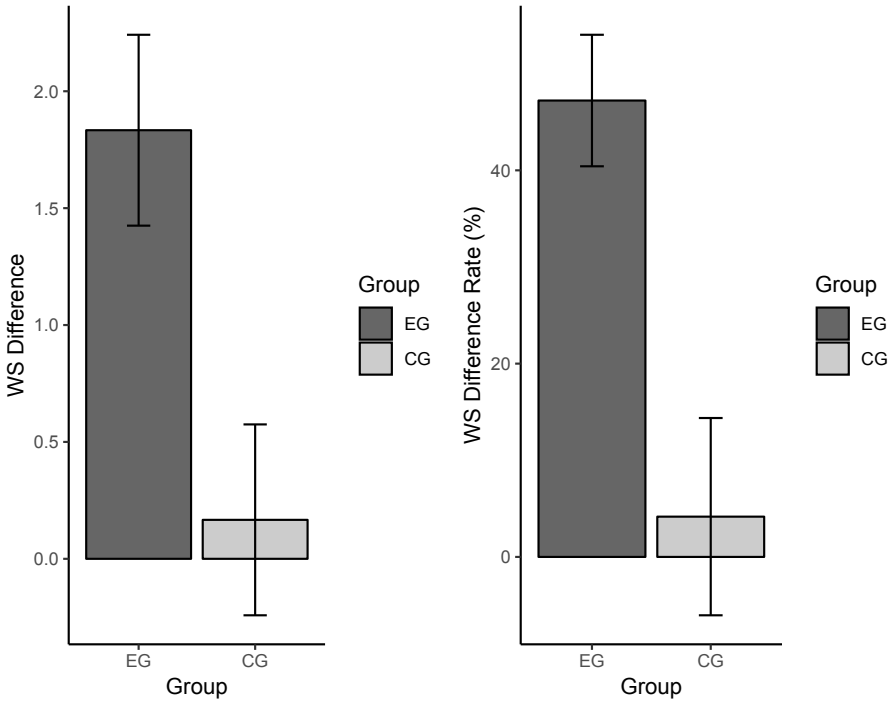

Figure 24. WS Difference and Rate of Before and After Treatment

5.6.3. Cohen's Distance of WS

Cohen's distance = (M2-M1) / √ {(SD12 + SD 22) /2}

As shown on Table 24, Cohen's distance was used to compare the effectiveness of the control group treatment to that of the experimental group treatment. Cohen's distance was 0.64 in pre-treatment and 1.68 after post-treatments, showing that the treatment given to the latter showed higher effectiveness.

Table 24. Cohen's Distance (Effect Size) between Two Groups of Before and After Treatment

Treatment	Before	After
Cohen's d	0.64	1.68
Meaning	Medium*	Large**

CD < 0.2	Negligible
CD < 0.5	Small
CD < 0.8	Medium*
Otherwise	Large **

VI. CONCLUSIONS

The study has the findings that the cumulative effect and rate on Tender between the control group and the experimental group were statistically significant improvement at the end of treatment respectively, and the experimental group had a greater treatment effect and rate. From the analysis of Short Form Nepean Dyspepsia Index, the findings were that both Tension and Work/Study (WS) difference of before and after treatment between the control and experimental group were statistically significant improvement respectively, and the experimental group had a greater treatment effect and rate. But the results of Interference with daily activities (IDA), Eating/Drinking (ED) and Knowledge/Control (KC) difference of before and after treatment between the control and experimental group did not show them to be statistically significant.

This study contributes to preexisting findings about the effectiveness of acupuncture in improving symptoms of dyspepsia. Improvements in patients of both groups after treatment was statistically significant and the experimental group had a greater treatment effectiveness. Although the Five Phase points combination acupuncture to the treatment proved to enhance the effectiveness of the dyspepsia treatment, further study is necessary to determine whether the Five Phase points combination acupuncture to other symptom treatment can be used on its own as an effective treatment for dyspepsia.

REFERENCES

1. Mahadeva, S. & Ford, A. C. Clinical and epidemiological differences in functional dyspepsia between the east and the west. *Neurogastroenterol. Motil.* 28, 167–174 (2016).
2. Tack, J., Talley, N.J., Camilleri, M., Holtmann, G., Hu, P., Malagelada, J.R. et al. (2006) Functional gas-troduodenal disorders. Gastroenterology 130: 1466 1479.
3. Klauser, A.G., Schindlbeck, N.E. and Muller-Lissner, S.A. (1990) Symptoms in gastro-oesophageal reflux disease. Lancet 335: 205 208.
4. 허 준, 이남구. (2011). 동의보감. 법인문화사. pp999-1002, 서울
5. D. A. Drossman, "Rome III: the new criteria," *Chinese Journal of Digestive Diseases*, vol. 7, no. 4, pp. 181–185, 2006.
6. N. J. Talley, V. Stanghellini, R. C. Heading, K. L. Koch, J. R. Malagelada, and G. N. J. Tytgat, "Functional gastroduodenal disorders," *Gut*, vol. 45, supplement 2, pp. II37–II42, 1999.
7. B. E. Lacy, N. J. Talley, G. R. Locke III et al., "Review article: current treatment options and management of functional dyspepsia," *Alimentary Pharmacology and erapeutics*, vol. 36, no. 1, pp. 3–15, 2012.
8. M. Camilleri and V. Stanghellini, "Current management strategies and emerging treatments for functional dyspepsia," *Nature Reviews Gastroenterology and Hepatology*, vol. 10, no. 3, pp. 187– 194, 2013.
9. K. Mo¨nkemu¨ller and P. Malfertheiner, "Drug treatment of functional dyspepsia," *World Journal of Gastroenterology*, vol. 12, no. 17, pp. 2694–2700, 2006.

10. J. H. Yan, M. Yue, Y. Li, and L. Zhu, “Investigation and analysis on adverse drug reaction of functional dyspepsia,” *Modern Digestion & Intervention*, vol. 3, pp. 282–284, 2015 (Chinese).
11. A. Schneider, K. Streitberger, and S. Joos, “Acupuncture treatment in gastrointestinal diseases: a systematic review,” *World Journal of Gastroenterology*, vol. 13, no. 25, pp. 3417–3424, 2007.
12. X. M. Yao, S. K. Yao, R. X. Zhang, and L. L. Chang, “E ect of electroacupuncture stimulation on visceral sensitivity in patients with functional dyspepsia,” *Acupuncture Research*, vol. 4, pp. 228–231, 2006 (Chinese).
13. J. YinandJ.D.Z. Chen, “Gastrointestinal motility disorders and acupuncture,” *Autonomic Neuroscience: Basic and Clinical*, vol. 157, no. 1-2, pp. 31–37, 2010.
14. T. Takahashi, “Acupuncture for functional gastrointestinal dis- orders,” *Journal of Gastroenterology*, vol. 41, no. 5, pp. 408–417, 2006.
15. 정해명 金烏 김홍경의 舍岩鍼法 가설형성배경과 그 運用에 관한 硏究. 大田大學校 한의과대학원 原典學敎室 舍岩鍼法硏究會, World Traditional Medicine Fair & Festival in Sancheong, KOREA 2013
16. O’Connor, J. & Bensky, D. (1981). *Acupuncture A Comprehensive Text*. Seattle: Eastland Press
17. Paul Enck. *Et al*. Functional dyspepsia. *Nature Reviews Disease Primers volume*3, *Article number*: 17081 (2017)
18. Stanghellini, V. *et al*. Gastroduodenal disorders. *Gastroenterology*150, 1380–1392 (2016).

19. Barbara, L. *et al.* Definition and investigation of dyspepsia. Consensus of an international ad hoc working party. *Dig. Dis. Sci.* 34, 1272–1276 (1989).

20. Holtmann, G., Stanghellini, V. & Talley, N. J. Nomenclature of dyspepsia, dyspepsia subgroups and functional dyspepsia: clarifying the concepts. *Baillieres Clin. Gastroenterol.* 12, 417–433 (1998).

21. Tack, J., Bisschops, R. & Sarnelli, G. Pathophysiology and treatment of functional dyspepsia. *Gastroenterology* 127, 1239–1255 (2004).

22. Tack, J. *et al*. Functional gastroduodenal disorders. *Gastroenterology* 130, 1466– 1479 (2006).

23. Tack, J., Piessevaux, H., Coulie, B., Caenepeel, P. & Janssens, J. Role of impaired gastric accommodation to a meal in functional dyspepsia. *Gastroenterology* 115, 1346–1352 (1998).

24. Farre, R. & Tack, J. Food and symptom generation in functional gastrointestinal disorders: physiological aspects. *Am. J. Gastroenterol.* 108, 698–706 (2013).

25. Vanheel, H. *et al*. Pathophysiological abnormalities in functional dyspepsia subgroups according to the Rome III criteria. *Am. J. Gastroenterol.* 112, 132–140 (2017).

26. Kindt, S., Tertychnyy, A., de Hertogh, G., Geboes, K. & Tack, J. Intestinal immune activation in presumed post-infectious functional dyspepsia. *Neurogastroenterol. Motil.* 21, 832–e856 (2009).

27. Futagami, S. *et al*. Migration of eosinophils and CCR2-/CD68-double positive cells into the duodenal mucosa of patients with post infectious functional dyspepsia. *Am. J. Gastroenterol.* 105, 1835–1842 (2010).

28. Mirbagheri, S. S. *et al*. Impact of microscopic duodenitis on symptomatic response to *Helicobacter pylori* eradication in functional dyspepsia. *Dig. Dis. Sci.* 60, 163–167 (2015).

29. Powell, N., Walker, M. M. & Talley, N. J. The mucosal immune system: master regulator of bidirectional gut-brain communications. *Nat. Rev. Gastroenterol. Hepatol.* 14, 143–159 (2017).

30. Furness, J. B. The enteric nervous system and neurogastroenterology. *Nat. Rev. Gastroenterol. Hepatol.* 9, 286–294 (2012).

31. Savidge, T. C. *et al*. Enteric glia regulate intestinal barrier function and inflammation via release of S-nitrosoglutathione. *Gastroenterology* 132, 1344– 1358 (2007).

32. Oustamanolakis, P. ┐Tack, J. Dyspepsia: organic versus functional. *J. Clin. Gastroenterol.* 46, 175-190 (2012).

33. Mertz, H., Fullerton, S., Naliboff, B. & Mayer, E. A. Symptoms and visceral perception in severe functional and organic dyspepsia. *Gut* 42, 814–822 (1998).

34. Ishigami, H. *et al*. Endoscopy-guided evaluation of duodenal mucosal permeability in functional dyspepsia. *Clin. Transl Gastroenterol.* 8, e83 (2017).

35. Stanghellini, V. *et al*. Gastroduodenal disorders. *Gastroenterology*150, 1380–1392 (2016).

36. Carbone, F., Vandenberghe, A., Holvoet, T., Vanuytsel, T. & Tack, J. The impact of Rome IV criteria on functional dyspepsia subgroups in secondary care. *Gastroenterology* 152, S304 (2017).

37. Tack, J., Jones, M. P., Karamanolis, G., Coulie, B. & Dubois, D. Symptom pattern and pathophysiological correlates of weight loss in tertiary-referred functional dyspepsia. *Neurogastroenterol. Motil.* 22, 29–35; e4–e5 (2010).

38. Talley, N. J. & Ford, A. C. Functional dyspepsia. *N. Engl. J. Med.* 373, 1853–

39. Bredenoord, A. J. & Smout, A. J. Physiologic and pathologic belching. *Clin. Gastroenterol. Hepatol.* 5, 772–775 (2007).

40. Lobo, B. *et al*. Effect of selective CCK1 receptor antagonism on accommodation and tolerance of intestinal gas in functional gut disorders. *J. Gastroenterol. Hepatol.* 31, 288–293 (2016).

41. Bendezu, R. A. *et al*. Colonic content in health and its relation to functional gut symptoms. *Neurogastroenterol. Motil.* 28, 849–854 (2016).

42. Bendezu, R. A. *et al*. Intestinal gas content and distribution in health and in patients with functional gut symptoms. *Neurogastroenterol. Motil.* 27, 1249–1257 (2015).

43. Burri, E. *et al*. Mechanisms of postprandial abdominal bloating and distension in functional dyspepsia. *Gut* 63, 395–400 (2014).

44. O'Connor, J. & Bensky, D. (1981). *Acupuncture A Comprehensive Text*. Seattle: Eastland Press

45. Pang, B. *et al*. Acupuncture for Functional Dyspepsia: What Strength Does It Have? A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Hindawi Publishing Corporation Evidence-Based Complementary and Alternative Medicine Volume, Article number: 3862916 (2016)

46. Cipriano JJ. Photographic Manual of Regional Orthopaedic and Neurological Tests (5th edition), Lippincott Williams & Wilkins, Philadelphia, 2010.

47. Magee DJ, Orthopedic Physical Assessment, WB Saunders, Philadelphia, 6th edition, 2014

48. N. J. Talley. *et al*. Quality of life in functional dyspepsia: responsiveness of the Nepean Dyspepsia Index and development of a new 10-item short form. Aliment Pharmacol Ther. 2001 Feb; 15(2): 207–216.

49. R Core Team (2018). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/.

APPENDICES 1

Informed Consent Form

You are invited to participate in a research study about Clinical Studies on The Effect of Acupuncture Treatment with Five Phase Points Combination for Symptom of Dyspepsia. The goal of this research study is to measure he Effect of Acupuncture Treatment with Five Phase Points Combination for Symptom of Dyspepsia. This research will help develop and apply systemic and effective treatment plans in clinic.

This study will be conducted over 3 months from June 2018 to August 2018. The treatment will be done twice a week for three weeks which is a total of six times. This study design is that the patients in experimental group will receive Five Phase Points Combination Points treatment and the patients in control group will receive Four Gates and Ren 12 points Acupuncture treatment on symptom of dyspepsia. Each treatment will only consist of using acupuncture needles and no herbal prescription or treatment methods will be used.

This study is being conducted by Gaseon Baik L.Ac.

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this clinic. You may change your mind later and stop participating even if you agreed earlier.

Participating in this study may not benefit you directly, but it will help to enrich the knowledge on Acupuncture.

If you consent on participating in this study, you will take a Short Form Nepean Dyspepsia Index (SFNDI) to evaluate your daily activity limitations. We will measure the level of

your pain once before and once after treatment. Your level of pain will be marked by using the Tenderness Grading Scale (TGS). For objective results, before the 1st treatment and after the 6th treatment, the patient's improvements will be re-evaluated using the SFNDI.

This treatment can have some unwanted effects. It can cause pain, bleeding, bruise and some temporary swelling around the place where needles are inserted. It is possible that is may also cause some problems that we are not aware of. However, we will follow you closely and keep track of any unwanted effects or any problems. We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may stop the use of one or more drugs. If this is necessary, we will discuss it together with you and you will always be consulted before we move to next stop. By participating in this research, it is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that your condition will not get better and that the new medicine or treatment doesn't work even as well as the old one. If, however, the medicine or treatment is not working, we will give the medication or treatment routinely offered to make you more comfortable. While the possibility of this happening is very low, you should still be aware of the possibility.

The information you will share with us if you participate in this study will be kept completely confidential to the full extent of the law. The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is, and we will lock that information up with a lock and key. It will not be shared with or given to anyone except Gaseon Baik L.Ac.

If you have any question about this study, please contact Gaseon Baik L.Ac., at 949-237-0340 or gbclinic.usa@gmail.com. If you have more questions or concerns regarding your rights as a subject in this study, you may contact Dr. Jaejong Kim, Chair of the South Baylo University Institutional Review Board (IRB) at jaejongkim@sbcglobal.net or 714-533-6077

YOU WILL BE GIVEN A COPY OF THIS FORM WHETHER OR NOT YOU AGREE TO PARTICIPATE.

Certificate of Consent (동의 확인서)

I have read the foregoing information, or it has been read to me. The research study has been explained to me, including risks, possible benefits, and other options for treatment. I have had the opportunity to ask questions about it and any questions that I have been answered to my satisfaction. I understand the information that has been provided and agree that the treatment results will be used for this study.

나는 이 동의서를 읽고 이 연구에서 가질 수 있는 이점과 치료와 측정 방법에 대한 설명을 들었고, 질문할 기회를 가졌으며 주어진 정보를 이해하고 나의 치료 결과에 대한 정보가 연구에 사용되어지는 것에 동의합니다.

_____	_____
Name of Participant (print)	Name of Witness (print)
_____	_____
Signature of Participant	Signature of Witness
_____	_____
Date: Day / Month / Year	Date: Day / Month / Year

Statement by the researcher/person taking consent:

I have accurately explained the information sheet the potential participant. I confirm that the participant was given an opportunity to ask about the study, and all the question asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been giving freely and voluntary.

A copy of this ICF has been provided to the participant.

_____

Print Name of Researcher/person taking the consent

_____

Signature of Researcher/person taking the consent

_____

Date: Day / Month / Year

APPENDICES 2

SHORT FORM NEPEAN DYSPEPSIA INDEX©

Sources: Talley, N. J. *et al*. Development of a new dyspepsia impact scale: the Nepean Dyspepsia Index. *Aliment. Pharmacol. Ther.* **13**, 225–235 (1999).

SHORT FORM NEPEAN DYSPEPSIA INDEX© QUESTIONNAIRE

Tension

1. Has your general emotional well-being been disturbed by your stomach problems in the last 2 weeks?

   1 not at all

   2 a little

   3 moderately

   4 quite a lot

   5 extremely.

2. Have you been irritable, tense or frustrated in the last 2 weeks because of your stomach problems?

   1 not at all

   2 a little

   3 moderately

   4 quite a lot

   5 extremely.

Interference with daily activities

3. Has your ability to engage in things you usually do for fun (recreations, going out, hobbies, sports, etc.) been disturbed by your stomach problems in the last 2 weeks?

1 not at all

2 a little

3 moderately

4 quite a lot

5 extremely.

4. Has your enjoyment of things you usually do for fun (recreations, going out, hobbies, sports, etc.) been disturbed by your stomach problems in the last 2 weeks?

1 not at all

2 a little

3 moderately

4 quite a lot

5 extremely

1 not applicable (I have not been able to do any of these things in the past 2 weeks)

Eating/drinking

5. Has your ability to eat or drink (including when, what, and how much) been disturbed by your stomach problems in the last 2 weeks?

1 not at all

2 a little

3 moderately

4 quite a lot

5 extremely.

6. Has your enjoyment of eating and/or drinking been disturbed by your stomach problems in the last 2 weeks? (Please also include your appetite, and how you feel after food or drink).

1 not at all

2 a little

3 moderately

4 quite a lot

5 extremely

Knowledge/control

7. Have you wondered whether you will always have these stomach problems, in the last 2 weeks?

1 almost never

2 sometimes

3 fairly often

4 very often

5 always

8. Have you thought that your stomach problems might be due to a very serious illness (e.g. cancer or a heart problem), in the last 2 weeks?

1 almost never

2 sometimes

3 fairly often

4 very often

5 always

Work/study

9. Has your ability to work or study been disturbed by your stomach problems in the last 2 weeks?

1 not at all

2 a little

3 moderately

4 quite a lot

5 extremely

1 not applicable (I do not work or study).

10. Has your enjoyment of work or study been disturbed by your stomach problems in the last 2 weeks?

1 not at all

2 a little

3 moderately

4 quite a lot

5 extremely

1 not applicable (I have not worked or studied in the last 2 weeks).

Scoring: Add up the items for each of the five sub-scale scores (range of each sub- scale 2–10)