EFFICACY OF THE HOMOEOPATHIC COMPLEX REMEDY,

Constipation 6c®

ON THE SYMPTOMS OF FUNCTIONAL CHRONIC CONSTIPATION IN FEMALES

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DECLARATION

I declare that this dissertation is my own, unaided work. It is being submitted for the Degree of Master of Technology at the University of Johannesburg. It has not been submitted before for any degree or examination in any other University.

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Ms Asmita Ramguthy

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ABSTRACT

Estimates extrapolated from the UK, USA and Canada, suggest a prevalence of chronic constipation in South Africa of approximately 700-720,000 in a population of 44 million (Cure Research, 2007). According to Rivkin and Chagan (2006) these US statistics do not accurately represent the true incidence of the problem which is predominantly self managed. The yearly US sale of over the counter laxatives exceeds $600 million (2006).

Allopathic treatments only temporarily alleviate constipation, and overuse of laxatives results in many side-effects. The objective of this study was to determine the efficacy of *Constipation 6c*®, in the treatment of symptoms of functional chronic constipation, in females using the modified Rome II criteria for chronic constipation.

This double blinded study was conducted using matched pairs. Thirty female participants between the ages of 18-35 were recruited using advertisements placed at the Health Training Centre on the UJ Doornfontien campus and Weleda Pharmacy (Fourways). The study was conducted over six weeks, during which time the participants attended weekly consultations. At the first consultation participants signed an information and consent form (Appendix B). For the first week no medication was administrated, however participants were asked to complete a daily recording sheet rating their symptoms (Appendix D) based on the modified Rome II criteria for chronic functional constipation. At the second visit participants were match-paired according to age, severity of symptoms and duration of symptoms (Appendix K). Participants were randomly assigned to either the experimental or the placebo group by an independent administrator. During the follow up consultations participants received the complex homoeopathic remedy, *Constipation 6c*® or placebo, and were instructed to take five pillules three times a day, and to record changes in symptoms on the daily recording sheet (Appendix D). At each follow up visit, the researcher collected the daily recording sheets, completed a focused physical examination and documented any changes in symptoms.

All data was collected from the researcher's weekly consultation notes (Appendix E) and participant's daily recording sheets (Appendix D). The data was analysed using non-parametric tests (Hardy, 2008). Wilcoxon's test was conducted to explore differences over time within each group. Mann-Whitney's test was used to determine the comparability between the experimental and placebo groups. Both groups showed clinically improvement during the course of the trail period. However, the statistical findings demonstrated that this improvement was not statistically significant either over time or between groups.

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INTRODUCTION

1.1 Problem Statement

Approximately 4.5 million Americans suffer from chronic constipation. According to Rivkin and Chagan (2006) these US statistics do not accurately represent the true incidence of the problem which is predominantly self managed. The yearly US sale of over the counter laxatives exceeds $600 million. Estimates extrapolated from the UK, USA and Canada, suggest a prevalence of chronic constipation in South Africa of approximately 700-720,000 in a population of 44 million (Cure Research, 2007).

Allopathic treatments only temporarily alleviate constipation, and overuse of laxatives results in side-effects including long term dependency, abdominal discomfort (bloating), headaches, haemorrhoids, anal bleeding and chronic diarrhoea (Baker and Sandle, 1996).

It was considered possible that Pegasus *Constipation 6c*®, might provide an alternate form of treatment for those who cannot take conventional treatments due to side effects or contra-indications. This homoeopathic remedy is used as an over the counter treatment but no previous research had been conducted on its' efficacy.

1.2 Aim

The aim of this study was to determine the efficacy of the homoeopathic complex remedy *Constipation 6c*®, in the treatment of symptoms of functional chronic constipation in females using the modified Rome II criteria for chronic constipation. Symptoms were evaluated using the daily recording sheet.

1.3 Hypothesis

It was hypothesized that Pegasus *Constipation 6c*® would be more effective than placebo in reducing the symptoms of functional chronic constipation in females, thereby offering a complementary treatment to conventional methods in the treatment of functional chronic constipation.

1.4 Assumptions

1.4.1. Assumption one

It was assumed that the patients would take their medication in the manner, dose and frequency prescribed.

1.4.2. Assumption two

It was assumed that the patients filled out their daily recording sheets accurately and truthfully prior to and until the end of the study.

1.4.3. Assumption three

It was assumed that the patients would refrain from using any medication, as far as possible, that they usually took, for the duration of the study.

1.4.4. Assumption four

It was assumed that the patients would follow their normal lifestyle or dietary habits for the duration of the study.

1.4.5. Assumption five

It was assumed that the medication was prepared in accordance with the established homoeopathic pharmacopoeiae.

CHAPTER TWO

LITERATURE REVIEW

Up to 4.5 million Americans suffer from chronic constipation. The yearly US sale of over the counter laxatives exceeds $600 million. The prevalence of constipation in the United States has been estimated at between 2% and 28%, with more women affected more than men (16% vs. 12%) (Rivkin and Chagan, 2006). Estimates extrapolated from the UK, USA and Canada, suggest a prevalence in South Africa of approximately 700-720,000 in a population of 44 million (Cure Research, 2007). According to Rivkin and Chagan (2006) these US statistics do not accurately represent the true incidence of the problem which is commonly self managed. Allopathic treatments only temporarily alleviate constipation, and over use of laxatives results in side effects including long term dependency, abdominal discomfort (bloating), headaches, haemorrhoids, anal bleeding and chronic diarrhoea (Baker and Sandle, 1996). A treatment without dependency or side-effects would be very useful. The homoeopathic complex, *Constipation 6c®,* is an over the counter (OTC) homoeopathic complex preparation that is sold to treat functional constipation but no previous research has been conducted to confirm its efficacy.

2.1 Constipation

The normal range of human bowel movements is between three times per day and once every three days (Butcher, 2003). However, regularity of bowel movement alone is not enough to claim that a person is not constipated (Jensen, 1999). Individuals may describe constipation as any of four aspects of dysfunctional defecation: infrequency, dyschezia, excessive stool hardness (Schiller, 1996) or a sensation of incomplete evacuation (Butcher, 2003). The extent to which these symptoms co-exist in an individual patient is variable (Schiller, 1996).

The body requires energy which it obtains from the breakdown of foods ingested by the individual. This breakdown of foods which releases energy, results in waste products which need to be eliminated. Food has become more processed and devitalized. Modern foods are often very high in fat. These foods are more difficult to digest and an excessive intake may result in sluggish bowel movements which may lead to constipation.

Acute constipation suggests an organic cause, whereas chronic constipation may be organic or functional (Bharucha, 2007).

When the colon becomes impacted or loaded, it makes a perfect environment for pathogenic bacteria to multiply. Toxins from these bacteria may be absorbed resulting in poisoning the whole body (Gupta, 2005). Intestinal toxaemia is caused by an insufficient diet, an unhealthy lifestyle and not responding to the call for evacuation of the contents of the colon. This results in numerous illnesses ranging from headaches, back pains, sinus problems, bladder infection and kidney disorders to irritability and depression (Jensen, 1999).

2.1.1 Chronic Constipation

Chronic constipation can be caused by a single factor or by multiple factors, including systemic or neurological disorders, metabolic disorders, colonic tumour, idiopathic or functional causes; or it may be caused by medications such as narcotics, iron supplements and antidepressants (Friedel, 2008; Bharucha, 2007).

2.1.1.1 Types of Functional Chronic Constipation

Functional chronic constipation can be classified into three major categories: normal transit constipation, slow transit constipation and functional defecatory disorders (Lembo and Camilleri, 2003). In a study by Lembo and Camilleri (2003), the majority of patients presented with normal transit constipation (59%); a quarter of patients (25%) experienced

defecatory disorders; a smaller number experienced slow transit constipation (13%); and least common was a combination of defecatory and slow transit disorders (3%) .

Normal Transit Constipation

According to Rivkin and Chagan (2006), normal transit constipation is the most common type of constipation. Stool transit time through the colon and the number of bowel movements is normal but the patient may feel that it is not normal. In a study examining the reliability of reported stool frequency in the diagnosis of idiopathic constipation (Ashraf *et al*, 1996), it was concluded that normal transit constipation was primarily based on the patients' perception that they were constipated. This type of constipation usually responds well to increased dietary fibre, especially soluble fibre (Ashraf *et al*, 1996).

Slow Transit Constipation

Slow transit constipation is characterised by slower than normal propulsion of colonic contents from the proximal to the distal colon and rectum (Rivkin and Chagan, 2006). Patients suffering from slow transit constipation may present with the following symptoms: infrequent urge to defecate, bloating and abdominal pain or discomfort (Rao, 2003). Slow transit constipation may be caused by incorrect eating habits such as high animal protein intake and inadequate fluid intake or by psychological symptoms (e.g. obsessive-compulsiveness, depression and/or anxiety) (Rivkin and Chagan, 2006). Slow transit constipation can vary in severity and response to treatment. Patients with more severe slow transit constipation, usually young women, may exhibit a poor response to dietary fibre and/or laxatives (Lembo and Camilleri, 2003). Preston and Lennard-Jones (1986), did a study on severe chronic constipation of young women. In this study, it was concluded that slow transit constipation occurs most commonly in young women. To date no studies have been able to explain why young women are more predisposed to slow transit constipation than men.

Some histopathological abnormalities associated with slow transit constipation are alterations in the number of Myenteric plexus neurons expressing the excitatory neurotransmitters substance P; abnormalities in the inhibitory transmitters, vasoactive intestinal peptide and nitric oxide production; as well as a reduction in the number of interstitial cells of Cajal, which regulate gastrointestinal mobility (Lembo and Camilleri, 2003).

Functional Defecatory Disorders

Functional defecatory disorders are characterized by pelvic floor dysfunction or anal sphincter dysfunction (Lembo and Camilleri, 2003), colonic transit time is abnormal or slightly slow and patients are unable to adequately evacuate the stool from the rectum (Rivkin and Chagan, 2006). Defecatory disorders can be divided into muscular hypertonicity (failure to relax or incomplete relaxation) or hypotonicity. In addition, patients who experience painful defecation due to haemorrhoids or anal fissures, will avoid defecating which may lead to acquired defecatory disorder (Rivkin and Chagan, 2006).

Many lifestyle factors such as: incorrect diet, smoking, insufficient intake of water, lack of response to the urge to pass stool, lack of exercise and chronic or excessive stress contribute to chronic constipation (du Preez, 2006).

The Rome II definition of chronic, functional constipation uses the following criteria to make a diagnosis:

- Straining in > 25% of defecations
- Sensation of incomplete evacuation in > 25% of defecations
- Lumpy or hard stools in > 25% of defecations
- Sensation of ano-rectal obstruction/blockage in > 25% of defecations

- Manual manoeuvres to facilitate > 25% of defecations, (e.g. digital evacuation, support of pelvic floor), and/or
- Fewer than three defecations/week

(Rivkin and Chagan, 2006)

Two or more symptoms must be present for at least twelve weeks, within a twelve month period (Rivkin and Chagan, 2006).

2.2 Pathophysiology

Approximately 1000ml of ileal effluent enters the colon daily. Ninety percent of waste and salt is absorbed by the mucosa as the fluid traverses the colon over a twenty-four hour period (Schiller, 1996). These functions are regulated by neurotransmitters, intrinsic colon reflexes and many learned reflex mechanisms which govern stool transport and evacuation (Lamparelli and Kumar, 2002).

Flow through the colon tends to be sluggish compared with the flow through the small intestine. Colonic motility is responsible for mixing luminal contents to promote absorption of water (Schiller, 1996). Movements of the right colon contribute primarily to the mixing of luminal contents and tend to be slow and non-propulsive. Material stays in the right colon up to eight hours before moving distally. Contents then move from the proximal to the distal segments of the colon by means of propulsive contractions.

Movements of the left colon are more phasic and are involved in the propulsion of luminal contents distally. Episodic mass movements rapidly propel the stool to the rectosigmoid area. The luminal contents remain in the descending colon for a relatively short time but tend to be retained in the sigmoid colon (Schiller, 1996).

The right side of the colon is innervated by the vagus nerve. The vagus nerve receives neurons from the myentric and submucosal plexi. The myenteric plexus controls smooth muscle function of the colon. The submucosal plexus regulates absorption from the

colon. The rest of the colon and rectum is innervated by the sacral nerve root (S2-S4) (Schiller, 1996).

Sympathetic nerves follow the arterial supply to the colon and provide basal tone as well as both general excitation to the sphincter–related muscles and relaxation to the non-sphincter related smooth muscles (Rao, 2003).

Any external stimuli that interrupts the function of these nerves can result in constipation. Examples of stimuli may include drugs, infection (such as Chaga's disease) or trauma. Inherited diseases such as Hirschprung's disease may also affect the functioning of these nerves, resulting in constipation (Lamparelli and Kumar, 2002).

2.3. Defecation

Defecation is a reflex action brought about by the stimulation of the receptors in the rectal mucosa (Dash, 2003).

Contractions in the sigmoid colon increase after meals and propel the stool into the rectum. Rectal distension results in relaxation of the internal anal sphincter via intramural descending neurons. This relaxation allows the stool to come into contact with the sensitive lining of the upper anal canal. The combined sensations of rectal distension and contact are perceived as the need to defecate. Rectal distension also leads to contraction of the puborectalis muscle which prevents immediate defecation and allows time for the rectum to relax, reducing intra-rectal pressure.

There are two defecation reflexes which trigger defecation. These are the intrinsic reflex and the parasympathetic reflexes. The intrinsic reflex is stimulated when faeces enter the rectum.

Afferent nerve signals are transmitted through the myenteric nerve plexus to the descending colon, sigmoid colon and rectum, stimulating peristaltic waves which propel

faeces towards the anus. Defecation occurs when both internal and external sphincter relax at the same time. The intrinsic reflex is a weak reflex that needs to be supported by the parasympathetic defecation reflex.

The parasympathetic defecation reflex involves the sacral segments of the spinal cord. Signals that begin in the rectum (when it begins to distend) are transmitted to the spinal cord. Pelvic nerves then transmit the signal from the spinal cord to the descending colon, sigmoid colon, rectum and anus. Other parasympathetic nerve fibres greatly intensify the peristaltic waves, as well as relax the internal anal sphincter.

As mentioned above, defecation will only occur when both external and internal anal sphincters relax together. The external anal sphincter is under conscious control and will normally relax only when it is socially acceptable for the person to pass stool (Guyton and Hall, 1996).

When a person is ready to defecate, he/she sits or squats, moving the anal sphincter anteriorly, thus causing straightening of the recto-anal angle. Tonic contraction of the external anal sphincter and puborectalis muscle is inhibited and a Valsalva manoeuvre is performed, increasing intra-abdominal pressure and pushing the stool into the anal canal. This is followed by contraction of the rectum and inhibition of tonic contraction of the internal anal sphincter and propulsion of stool through the anus. The puborectalis and internal and external sphincter muscles then resume their normal resting tone (Schiller, 1996).

2.4 Causes of Constipation

Constipation may be the result of a medical condition or a side effect of medication or due to lifestyle choices or age-related where declining muscle tonicity may play a role. However, the commonest cause of constipation is a poor diet and lack of exercise.

2.4.1 Diet

A low-fibre, high fat diet, which lacks sufficient water intake is a major cause of constipation.

Processed foods which are high in fat and sugar, slow the movement of food through the intestines, allowing more time for absorption of water, resulting in dry hard stools.

Alcohol and caffeine have a diuretic effect on the kidneys. The body compensates for this loss by increasing the absorption of water from the colon resulting in hard stools. Similarly dehydration (through poor water intake) exacerbates constipation. Adequate hydration is essential in preventing constipation.

Fibre is a cellulose-like component with a tough exterior which is difficult to digest. It therefore adds bulk to waste products which stimulates peristaltic movements of the colon.

Fibre may be soluble or insoluble. Soluble fibre (e.g. in oats or peeled apples) turns into gel when mixed with fluid (therefore it is softens the stool). Insoluble fibre (e.g. wheat bran in bread) is not able to dissolve in water passes through the body largely unchanged but bulking up the stool and facilitate easier passage. Course insoluble fibre such as unground wheat, unground seeds or nuts, unpeeled fruit or pips may on the other hand aggravate constipation by irritating the colon and causing contraction of the colon, thereby slowing down the passing of fecal matter (Buys, 2007).

Too much insoluble fibre may cause constipation (Friedal, 2008). Small quantities of insoluble fibre should be introduced into the diet, and not all at once.

Therefore a well balanced diet, high in soluble fibre or finely ground insoluble fibre, low in sugar, with plenty of water intake may prevent constipation.

2.4.2 Lack of Exercise

Poor physical activity results in poor tone of the smooth muscle and weakened intestinal activity leading to slow movement of waste products through the colon. Similarly, prolonged bed rest and immobility contribute to constipation (von Schoor, 2009).

2.4.3 Ignoring the Urge to Defecate

In healthy adults bowel movements are under voluntary control (William et al, 2009). Colonic activity is greatest soon after waking and soon after meals (von Schoor, 2009). Withholding or delaying the release of stool is sometimes done due to hurry or, to avoid using public toilets or when travelling when a toilet may not be readily available or, due to unacceptable social surroundings. Repeatedly resisting the urge to defecate can lead to insensitivity of the intestines (Friedal, 2008). This can lead to a disappearance of urges and result in constipation (William *et al*, 2009).

2.4.4 Motility disorders

Restricted ability or an actual inability of intestinal muscles to contract and cause waste to move through the intestines may cause constipation.

2.4.5 Haemorrhoids/Anal Fissures

Inflammation and tears around the anus, anal fissure and haemorrhoids can cause bleeding, itching and/or pain. Patients may withhold stool due to these painful conditions. Patients may ultimately purposely ignore the urge to defecate to avoid pain. Alternatively, constipation can cause straining which may lead to haemorrhoids and anal fissures.

2.4.6 Excessive use of Laxatives

Laxatives are the commonest treatment for constipation, but frequent use may result in constipation (Friedal, 2008). The repetitive use of laxatives reduces the colon's natural ability to contract, leading to failure of the intestines to work properly (Friedal, 2008).

2.4.7. Drugs that cause Constipation

Drugs have specific mechanisms of action which frequently cause constipation (Lamparelli and Kumar, 2002). Common offending medications include:

- Narcotic pain medication such as codeine (for example Tylenol®) with Codeine (acetaminophen and codeine phosphate) , oxycodone (for example, Percocet), and hydromorphone (Dilaudid)
- Antidepressants such as amitriptiline (Elavil) and imipramine (Tofranil)
- Anticonvulsants such as phenytoin (Dilantin) and carbamazepine (Tegretol)
- Iron supplements
- Calcium channel blocking drugs such as diltiazem (Cardizem) and nifedipine (Procardia)
- Aluminium-containing antacids such as Amphojel and Basaljel (William *et al*, 2009).

2.5 Conventional Treatment of Constipation: Laxatives

More than 120 laxative products are available without prescription for the treatment of constipation (Falk, 1992). This leads to their over-use or abuse which can cause the person using laxatives to develop a physical dependency to the laxative in order for them to maintain normal bowel functions (Baer and Williams, 1996). Laxatives may be classified according to their source, degree of action and mechanism of action (Dale *et al.*, 1995).

2.5.1 Bulking agents

Bulk forming laxatives resemble natural dietary fibre. They may contain both natural and semi-synthetic polysaccharides and cellulose (Mckenry and Salerno, 1998). Psyllium, an example of a bulk forming laxative, increases stool bulk by drawing water into its fibre. Bulking agents require adequate concomitant fluid intake (Keshav, 2004). They are hydrophilic, absorbing water from the intestinal lumen to increase stool mass and soften stool consistency (van Scheer, 2008).

2.5.2 Hyperosmolar agents

These agents draw water into the intestinal lumen by osmotic activity (Keshav, 2004). Lactulose (a synthetic sugar) is an indigestible carbohydrate that is metabolized by bacteria in the colon into hydrogen and organic acids. These organic acids osmotically raise the faecal fluid volume leading to larger and softer stool (von Schoor, 2009). Lactulose draws water into the intestinal lumen and may cause dehydration and electrolyte abnormalities in some people (Keshav, 2004).

2.5.3 Saline laxatives

Saline laxatives such as magnesium salts contain poorly absorbable magnesium citrate, magnesium sulphate and magnesium phosphate ions that cause intraluminal water accumulation (Mark et al., 1999).

2.5.4 Lubricant laxatives

Lubricant laxatives such as mineral oil are products that are retained in the stool. The oiliness eases the passage of stool, especially in the presence of haemorrhoids and anal fissures (Keshav, 2004). Lubricant laxatives may impair the absorption of fat soluble vitamins which can ultimately lead to vitamin deficiencies (Baer and Williams, 1996).

2.5.5 Emollient laxatives

Emollient laxatives are widely known as stool softeners, an example being docusate sodium. They work by promoting fluid accumulation in the bowel. This allows water to penetrate the faeces (Baer and Williams, 1996). Emollient laxatives inhibit the absorption of fat soluble vitamins and can cause anal seepage as well as increase the toxicity of drugs which are taken at the same time as laxatives (Balch and Balch, 2000).

2.5.6 Stimulant laxatives

Stimulant laxatives such as bisacodyl, act by stimulating motor activity of the colon or by modulating gut fluid and electrolyte transport (Achkar *et al.*, 1992). Prolonged use can lead to renal, cardiac and respiratory dysfunction as well as deterioration in the functioning of the intestines which may ultimately result in an atonic colon (Reynard and Smith, 1995).

In conclusion, laxatives provide short term relief but over-use may lead to chronic dependence, increased flaccidity of the bowel (Friedel, 2008), and also diarrhoea, abdominal cramping, abdominal bloating, flatulence, dehydration, nausea, vomiting (Lane, 1999) and throat irritation (Baer and Williams, 1996).

2.5.7 Surgery

Patients suffering from severe chronic constipation who are unresponsive to medical treatment may consider surgical treatment (Yalcin *et al,* 2009). The most common surgical procedure is a subtotal colectomy with ileorectal anastomosis (Ringel, 2005). In a recent study of the use of this procedure, over 90% of patients were satisfied with the result of the surgery (Christer *et al,* 2003). Another clinical study done by the Ankara Ataturk Research and Education hospital supported the findings that surgical intervention may be beneficial in patients with chronic constipation that does not respond to medical treatment (Yalcin, 2009).

2.6 Alternative Treatment for Constipation excluding Homoeopathy

2.6.1 Behavioural Biofeedback

Biofeedback is a treatment technique in which people are trained to improve health and well-being, by using signals from their own bodies (Runck, 2009).

Signals which the body transmits in relation to colonic movements are detected using electronic sensors or electrodes (electromyography). These signals are converted to visual or auditory signals which a patient can interpret. Through trial and error the patient can identify stimuli which cause these signals.

The patient then learns to control/prevent these stimuli by relaxing pelvic floor muscles and increasing intra abdominal pressure during these stimuli. Thus constipation is avoided.

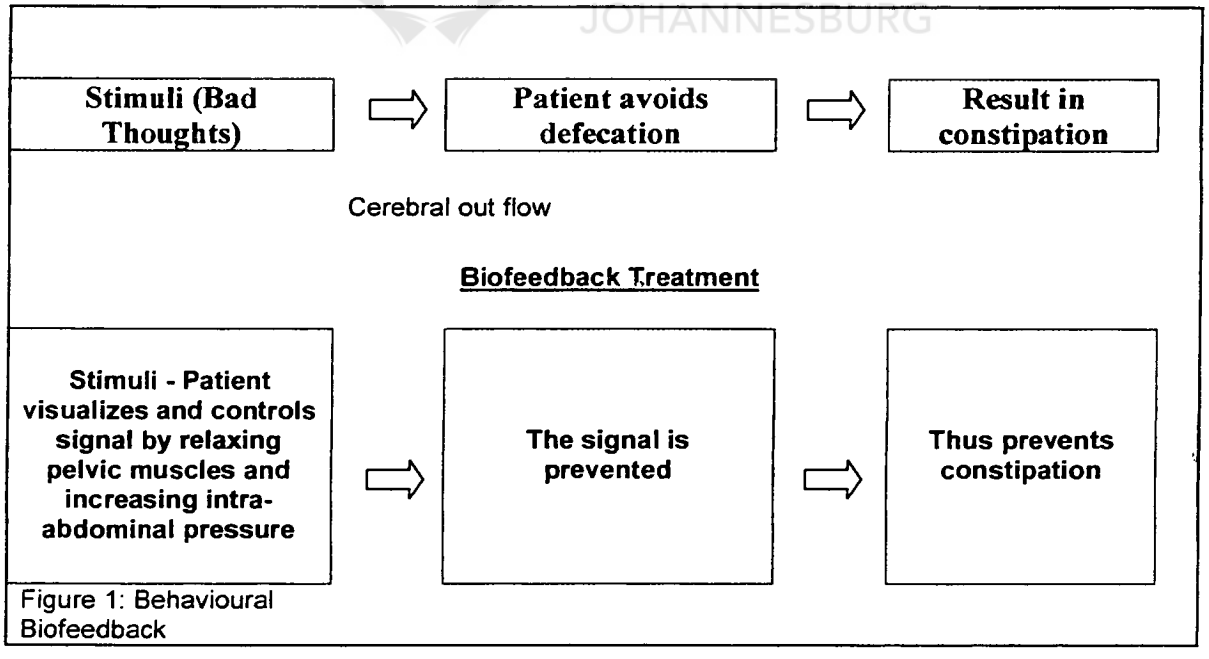


Figure 1: Behavioural Biofeedback

A study done by Emmanuel and Kamm (2001), showed that twenty-nine of forty-nine patients improved symptomatically when biofeedback treatment was used. A subsequent study done in 2003 by the same author, using mucosal laser Doppler flowmetry to measure autonomic activity in the gut. The patient was then taught to retrain nerves and muscle in evacuation disorders (Kamm, 2003).

2.6.2 Probiotics

The World Health Organization defines probiotics as live micro-organisms that give health benefits when taken by the host (WHO, 2009).

The most common micro-organisms used in probiotics are bacteria Lactobacillus and Bifidobacterium (Wojcik, 2009). The use of probiotics has shown excellent effect on gastrointestinal function, by reducing the growth of pathogenic bacteria, improving mucosal immune response and increasing mucosal function (Epstein, 2009). These responses are well documented in a randomised placebo trail done by Bharucha in 2007.

2.7 Homoeopathy

Homoeopathy is also used to treat constipation. It is considered safe, non-invasive and fast acting and without dependencies or side effects.

The term homoeopathy is derived from 'homeo' and 'pathos', which is Greek for "similar suffering". The method was developed by Dr. Samuel Hahnemann who made this principle the foundation of a new system of medicine (Carlston, 2003). It reflects the key principle behind the homoeopathic method, that a substance can cure the symptoms in an ill person that it is capable of causing in a healthy person (Vithoulkas, 1980). "The hom high and only mission is to restore the sick to health, to cure, as it is termed" (Hahnemann, 2008). The above aphorism states that a homoeopath highest and only calling is to restore the sick to health.

2.7.1 Potentisation of Drugs

The preparation of a homoeopathic remedy refers to the law of potentization. Potentisation is a physical process by which the 'latent curative properties of remedies are brought into activity' (Banerjee, 2004).

Each remedy is prepared by a controlled process of successive dilutions alternating with trituration (grinding) or succussion (shaking) (Lilley, 2000). Dilution is a process of mixing two liquids together (Banerjee, 2005), in order to reduce the toxicity of the original crude substance. Serial dilution means that each dilution is prepared from the dilution that immediately preceded it (Banerjee, 2004). Succussion and trituration are methods by which mechanical energy is delivered to preparations in order to imprint the pharmacological message of the original drug upon the molecules of the diluents (Foubister, 2001). Succussion is rhythmical shaking of the diluted substance, either by using hand or machine. Insoluble substances are prepared through the process of trituration. Trituration is prolonged circular grinding of the insoluble substance with pure lactose in a mortar and pestle. Once trituration has been obtained to the dilution of $1/10^6$, this can be dispensed into an alcohol-water diluent as it is now effectively a soluble substance (Banerjee, 2004).

Dr Hahemann introduced the centestimal scale of potentisation. The centestimal 6c scale of dilution (c) is made by diluting one part of the drug substance with a hundred parts of neutral carrier and repeating this dilution six times (Banerjee, 2004).

2.8 Classical versus Complex Homoeopathy

Classical homoeopathy treats an individual according to his/her physical symptoms, as well as his/her mental and emotional symptoms. This is achieved by a thorough case history through an in-depth interview with the patient. The symptom picture of the patient is closely matched to the drug picture.

In classical homoeopathy one remedy and potency is administrated at a time based on the totality of symptoms of the individual (Carlston, 2003). This method is very strict and is rigidly followed. Dr Hahnemann states in the Organon, Aphorism 2: "the highest ideal of cure is a rapid, gentle and permanent restoration of the health, or removal and annihilation of the disease in its whole extent, in the shortest, most reliable, and most harmless way, on easily comprehensible principles" (Hahnemann, 2003). In summary, classical homoeopathy is the administration of a remedy in its smallest and minimum number of doses that is required to restore the patient to health in the most safe, quickest and non-invasive form of cure (Winston, 2009).

Complex homoeopathy is a combination of several remedies in low potencies, selected mainly on the symptoms of the patient's disease rather than an individualized case history. The action of the different remedies used in combination needs to be synergistic (Morley, 2001). Complex homoeopathy is widely used especially in over the counter pharmacy, due to its easy availability.

2.9 Pegasus Homoeopathics

Pegasus Homoeopathics was founded in 2002 by Salter and Wheeller, both B.Pharm (Rhodes University). The Pegasus range of homoeopathic medicines is licensed with the Medicine Control Council of South Africa, as well as with the Pharmacy Council of South Africa. The Pegasus homoeopathic kit called the "The Blue Box' is sold country wide through pharmacies, health stores and practitioners. ''The Blue Box" consists of twenty three complex remedies for over the counter use, one of which is called *Constipation 6c*® (Salter, 2008). Pegasus *Constipation 6c*® is a homoeopathic complex remedy which is sold for treatment of symptoms of constipation such as: passing of hard stools, infrequent passing of stools, straining and incomplete evacuation.

2.9.1 *Constipation 6c®*

The homoeopathic complex, *Constipation 6c®* consists of the following remedies, all in the 6c potency, each typified by certain characteristic indications for the treatment of constipation:

- *Alumina*: sensation of incomplete evacuation, little desire to pass stool; when bowel movement does occur the stool is hard and dry, anus itches and burns which causes bleeding (Nash, 2003)
- *Chelidonium majus*: constipation presenting with hard, round balls which may be yellow or clay colour (Nash, 2003)
- *Graphites*: straining to pass large stools with mucous. Excessive, offensive flatulence and abdominal bloating (Vermeulen, 2001).
- *Lycopodium clavatum*: inactivity of bowels; stools are hard, small, difficult to pass with sensation of incomplete evacuation and blockage, may result in haemorrhoids (Nash, 2003).
- *Natrum muriaticum*: difficult and painful passing of stool which is dry and crumbling (Nash, 2003).
- *Plumbum metallicum*: straining of stools and spasm of anus, resulting in hard black stool (Vermeulen, 2001).
- *Silica*: sensation of obstruction with no urging; stool seems to recede after nearly extruding; stool retained for fear of pain, painful spasm of sphincter, constipation before and during menses (Vermeulen, 2001).

In addition, the complex includes, *Phenolphthalein*, the homoeopathically potentized preparation of an allopathic drug which exerts a powerful peristaltic action on the bowel, eliciting a strong bowel movement (Salter, 2008).

2.10 Research into Homoeopathic Treatment of Constipation

Sabath *et al.*, (2005) undertook a case study into the efficacy of the homoeopathic similimum in LM potency in the treatment of constipation in adults. Ten participants were treated for eight weeks with the LM potency of an individually chosen remedy. There was definite improvement in the frequency of bowel movements in eight out of ten participants.

The over-the-counter (OTC) homoeopathic complex Pegasus *Constipation 6c*® which is sold to treat functional constipation, has had no research study conducted on its efficacy in the treatment of functional constipation

CHAPTER 3

METHOLOGY

The research methodology was passed by the University of Johannesburg Higher Degree Committee and by the Academic Ethics Committee (25 October 2008, AEC NO: 57/08).

3.1 Research Design

This was a doubled-blinded placebo controlled trial using matched pairs. Participants were matched according to age (18-25 and 25-35), severity of symptoms (mild, fairly severe and very severe) and duration of symptoms ($\leq$3 years and $\geq$3 years).

3.2 Research Sample

Thirty female participants between the ages of eighteen and thirty five were recruited for this study by posters placed in the Health Training Centre at the UJ Doornfontein campus and Weleda Pharmacy (Appendix H).

Inclusion criteria

In order to be included, volunteers were required to have two or more of the following symptoms present for at least twelve consecutive weeks, within the previous twelve month period:

- Passing stools less than three times a week
- Experiencing sensation of incomplete evacuation of stools
- Passing of hard stools
- Straining
- Manual manoeuvres to facilitate defecation
- Females between the ages 18-35

Exclusion criteria

Volunteers were excluded from the study if:

- They were pregnant or lactating,
- They had any rectal haemorrhaging other than haemorrhoids and/or anal fissure (this had to be confirmed under medical supervision)
- They had any previous diagnosis/ symptoms suggestive of Inflammatory Bowel Disease (Appendix L)
- They had any previous diagnosis/ symptoms suggestive of serious colon disease (Appendix L)
- They were using any medication that could cause constipation (Appendix I and A)
- They had sudden recent onset of severe constipation
- They were using stimulant laxatives (Appendix M)

3.3 Research procedure

Potential participants were interviewed by the researcher at the Health Training Centre on the UJ Doornfontein campus or at the Weleda Pharmacy (Fourways). Potential participants were fully informed about the details of the study by the researcher. The initial interview established if the participant met the modified Rome II Criteria for chronic constipation (Appendix A). The research procedure was explained and any questions were addressed. Participants were requested to sign an Information and Consent Form (Appendix B) confirming that they understood the nature of the study.

This was a six week study, during which time the participants were requested to attend weekly consultations. The initial consultation consisted of a brief case history, presenting symptoms, duration of symptoms, focused physical examination to eliminate possible suspicion of other morbidity (Appendix J), as well as vital signs (Appendix C).

No homoeopathic remedies were administered at the first consultation. Participants were asked to complete a daily recording sheet on which they graded their symptoms of constipation using the modified Rome II criteria, recorded doses of laxatives used, and a well-being scale (Appendix D). On completion of week one, a baseline summary of the participant's scale (Appendix K) was handed to the independent administrator. The independent administrator matched-paired participants. Participants were randomly allocated to either the experimental or placebo group by the independent administrator. Participants received either the remedy or placebo. The researcher remained blinded to as to which group each participants had been allocated. The participants completed the daily recording sheet (Appendix D) throughout the trial period, recording all changes in symptoms. Consecutive consultations followed up the initial case history and the researcher repeated the initial focused physical examination, vitals and collected the completed daily recording sheet (Appendix D), and dispensed the allocated medication. The completed daily recording sheet was condensed onto a weekly recording sheet (Appendix E). The researcher enquired about lifestyle changes like smoking, exercise and diet (Appendix F). These were recorded at each consultation.

3.4 Medication administration

After the second consultation, both the experimental and placebo groups were required to take five pillules three times a day. These were dispensed in 25ml, amber glass bottles. The treatment continued at the above mentioned dosage for the full period of the trial. Participants were given an information leaflet on how to take the medication (Appendix G). Participants were required to go about their normal routine and not change any dietary habits during the trial. Participants were advised not to take allopathic, herbal or any other form of drugs or medication during this study. Participants unable to avoid the use of additional non-stimulant were laxatives are requested to document such usage (Appendix D).

3.5 Procedure for double blind study

The placebo, which is an inert substance (lactose), and the remedy looked exactly the same in terms of colour, smell, taste and texture and were packaged, manufactured and grouped by Pegasus, so that the study remained blinded to both the researcher and participants. The researcher provided the independent research administrator with the participant details and a record of the participant's symptoms. The independent administrator matched-paired participants using Appendix K. The independent administrator randomly allocated participants to group A or group B. The researcher remained blinded to which group received the remedy or placebo.

3.6 Reliability and validity measures

Only on completion of the trial, Pegasus revealed the groups on the medication bottles, to reveal which group (A and B) received the remedy or placebo. The modified Rome II criteria are a standard measurement for assessing chronic constipation. Days on which participants used laxatives were excluded from the statistical analysis. Laxative use was monitored with regards to the frequency of use and effect on symptoms.

3.7 Data collection and analysis

Data collected from the participants, using the weekly recording sheet (Appendix E) was analysed by the researcher with the assistance of a statistician. Mann-Whitney U-test, Friedman test, Chi-squared test and Wilcoxon test (Hicks, 2005) are non-parametric tests that were used to compare the outcome of the two study groups. Results are displayed as graphs.

CHAPTER 4

RESULTS

The aim of this research study was to determine the efficacy of *Constipation 6c*®, in the treatment of symptoms of functional chronic constipation in females. The participants were included in the study on the basis that they must have had two or more symptoms of the following symptoms present for at least twelve non-consecutive weeks, within the previous twelve month period:

- Passing stools less than three times a week
- Experiencing sensation of incomplete evacuation of stools
- Passing of hard stools
- Straining
- Manual manoeuvres to facilitate defecation
- Females between the ages 18-35

The research was conducted from January 2009 to November 2009. The study population consisted of females between the ages of eighteen and thirty-five years, from all ethnic groups who were suffering from functional chronic constipation.

This six week trial was a double blind study in which participants were divided into two groups namely the experimental and the control group. In the first week of the trial neither group received medication. The control group received the placebo whilst the experimental group received the remedy from the second to sixth week. All participants recorded severity of symptoms on a daily recording sheet (appendix D). All participants were advised to administer five pillules of the medication supplied, three times a day, from week two to week six.

Each participant attended a weekly consultation. All participants were required to fill in a daily recording sheet during the entire trial. Results from the daily recording sheet were documented on a weekly recording sheet (Appendix E).

Results, which were obtained from the daily recording sheets (Appendix D), were statistically analysed. Comparisons between the experimental and control groups were done to determine if the groups were equivalent at onset. The Mann-Whitney was used to determine the comparability between the control and experimental groups.

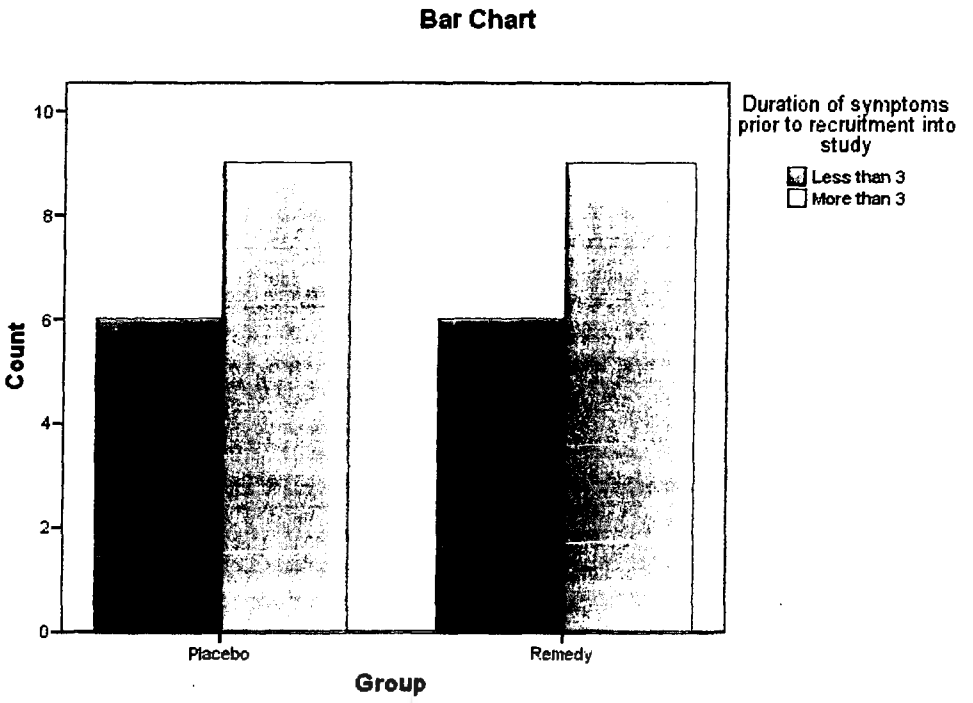
4.1 Matching Criteria

4.1.1 Age

Participants between the ages of eighteen and thirty-five years were recruited. Participants were divided equally into experimental and placebo groups. The mean age of the fifteen participants in the placebo group was 24,73. The mean age of the fifteen participants in experimental group was 24,8.

4.1.2 Duration and Severity of Symptoms

Participants were match paired according to severity of symptoms (mild, fairly severe and very severe) and duration of symptoms ($\leq$3 years and $\geq$3 years) after the first week of trial. Participants were evenly distributed between experimental and placebo groups.



The overall experimental and placebo percentage with participants experiencing symptoms less than three years was 40%. The percentage for participants that experienced symptoms for more than three years in both experimental and placebo groups was 60%.

4.2 Tests for Normality

Normal distribution was obtained during matched pairing. Due to the sample size of thirty participants, non-parametric tests were done.

4.3 Change in Individual Symptoms over the six week period

4.3.1 Results of Passing of Hard Stools

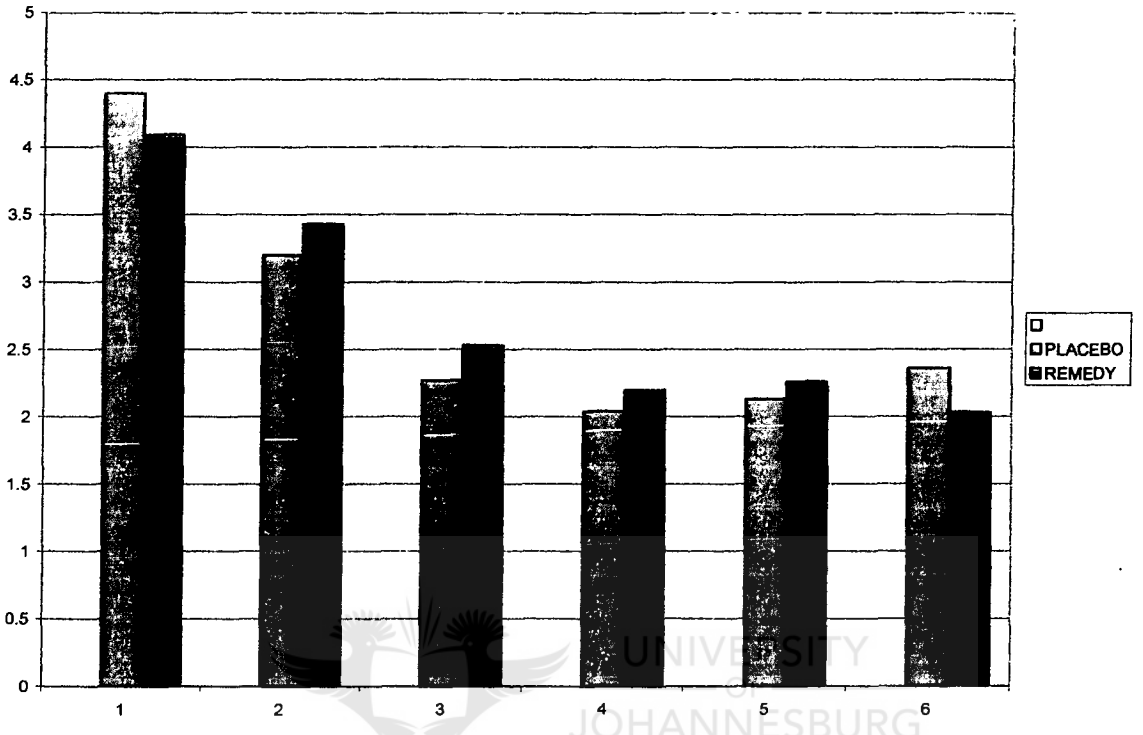


Figure 4.3.1 Passing of Hard Stools

PASSING OF HARD STOOLS						
WEEKS	**1**	**2**	**3**	**4**	**5**	**6**
PLACEBO	4.4	3.2	2.27	2.04	2.13	2.36
REMEDY	4.09	3.43	2.53	2.2	2.26	2.03

Figure 4.3.1 indicates there was no significant improvement in passing of hard stools between the groups and over the period of six weeks. No treatment was given in week one. Participants in the experimental and placebo groups improved gradually from week one even though medication was only given from week two to six. Both groups stabilised at week five. At week six, the experimental group improved slightly more than the placebo group. Results are not significant over time or between groups.

4.3.2 Results for Sensation of Incomplete Stools

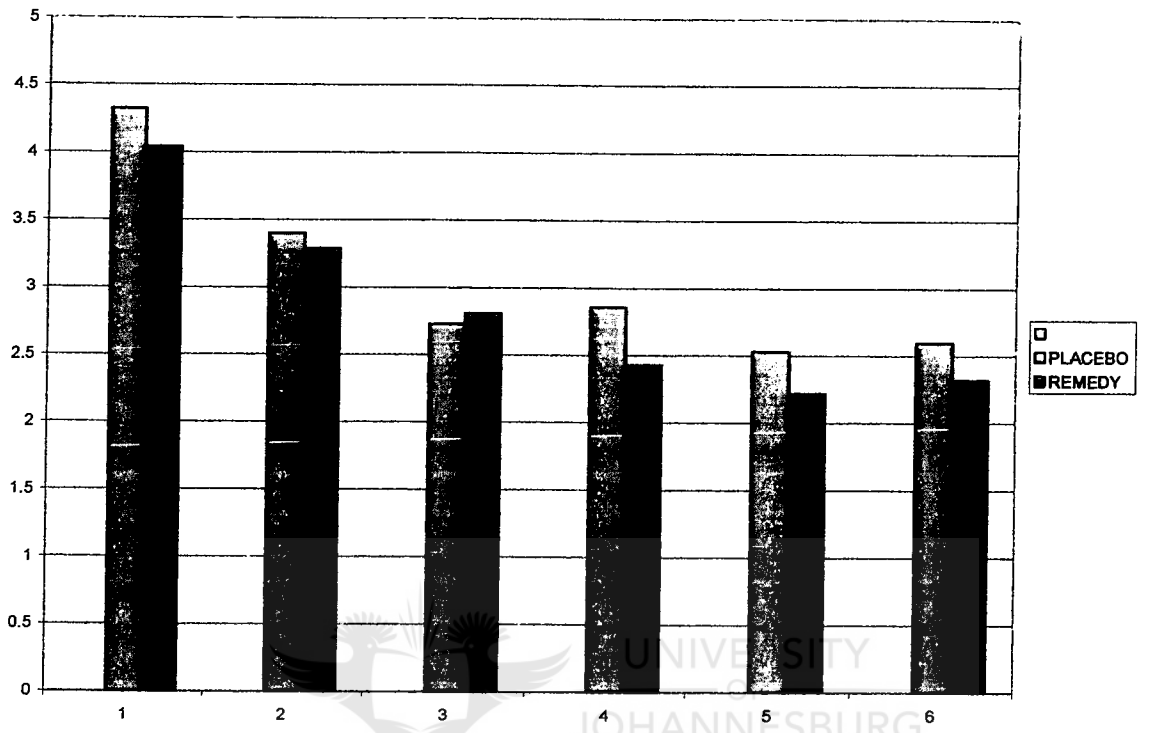


Figure 4.3.2 Sensation of Incomplete Stools

SENSATION OF INCOMPLETE STOOLS						
WEEKS	1	2	3	4	5	6
PLACEBO	4.32	3.4	2.73	2.86	2.53	2.6
REMEDY	4.04	3.29	2.81	2.43	2.22	2.32

Figure 4.3.2 indicates there was no significant improvement in sensation of incomplete stools between the groups and over the period of six weeks. No medication was given in week one. The improvement of symptoms in both the placebo and the experimental groups increased at a gradual pace from week one to week six. Results are not significant over time and between groups.

4.3.3 Results of Difficulty/Straining at Passing Stools

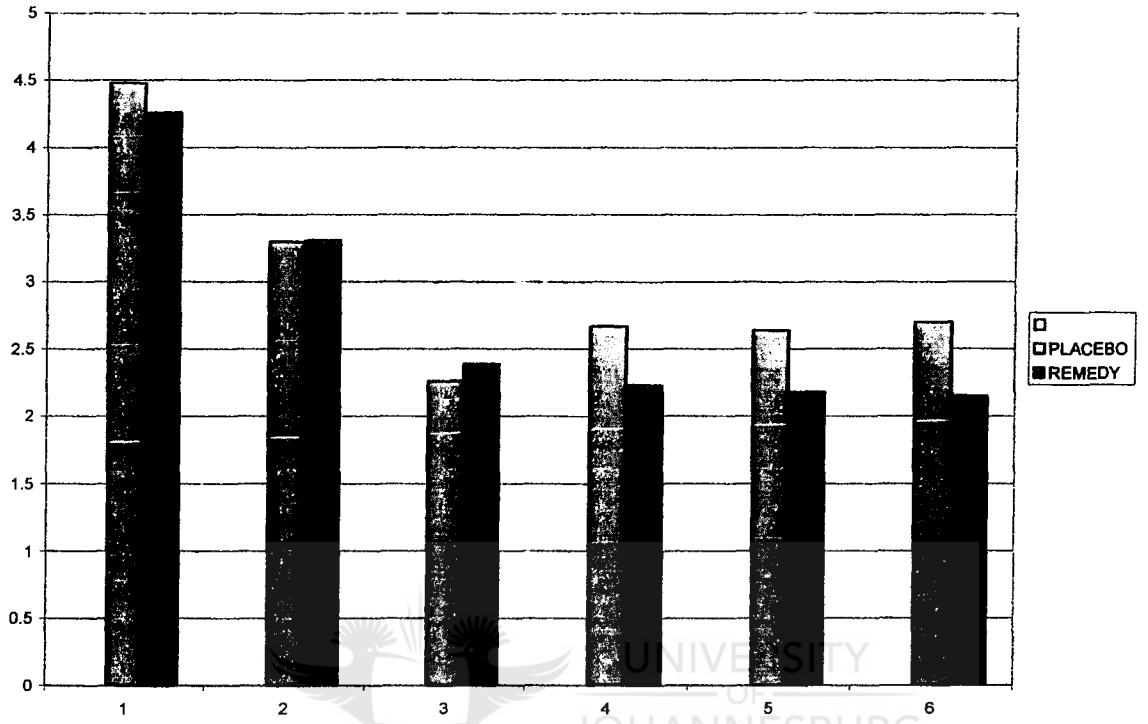


Figure 4.3.3 Difficulty/Straining Passing Stools

DIFFICULTY/STRAINING PASSING STOOLS						
WEEKS	**1**	**2**	**3**	**4**	**5**	**6**
PLACEBO	4.48	3.3	2.26	2.67	2.64	2.7
REMEDY	**4.26**	**3.31**	**2.39**	**2.23**	**2.18**	**2.15**

Figure 4.3.3 indicates there was no significant improvement in the symptom of difficulty/straining while passing stools, between the groups and over the period of six weeks. No medications was given in week one. Both groups improved in symptoms at the same pace from week one to week three. From week three to week six the symptoms in both groups stabilised. The experimental group improved slightly more than the placebo. Results are not significant over time and between groups.

4.3.4 Results of Discomfort Experienced

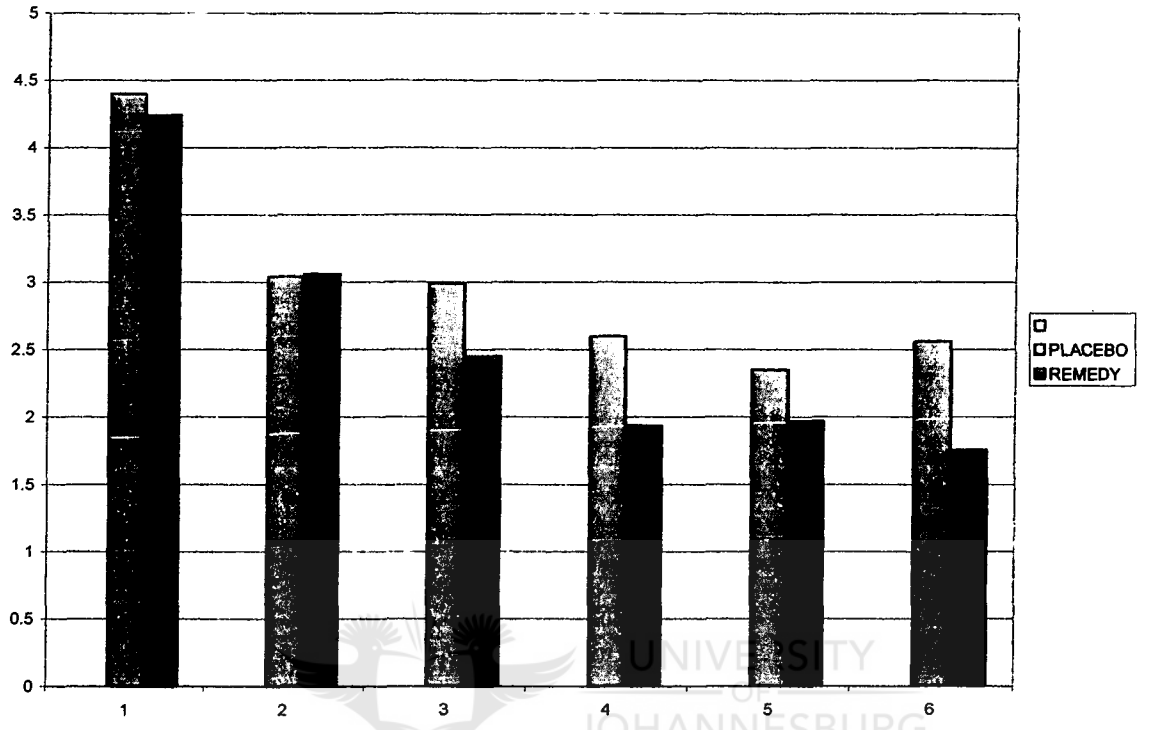


Figure 4.3.4 Discomfort Experienced

DISCORMFORT EXPERIENCED						
WEEKS	1	2	3	4	5	6
PLACEBO	4.4	3.04	2.99	2.6	2.35	2.56
REMEDY	4.24	3.06	2.45	1.94	1.97	1.76

Figure 4.3.4 indicates there was no significant improvement in discomfort experienced between the groups and over the period of six weeks. No medication was given in week one. Participants in the experimental group during week one to week four improved, and by week five the symptom stabilized. At week six they improved slightly. Participants in the placebo group improved over time but at week six the symptoms aggravated a little. Results are not statistically significant over time and between groups.

4.3.5 Results of Frequency of Stool

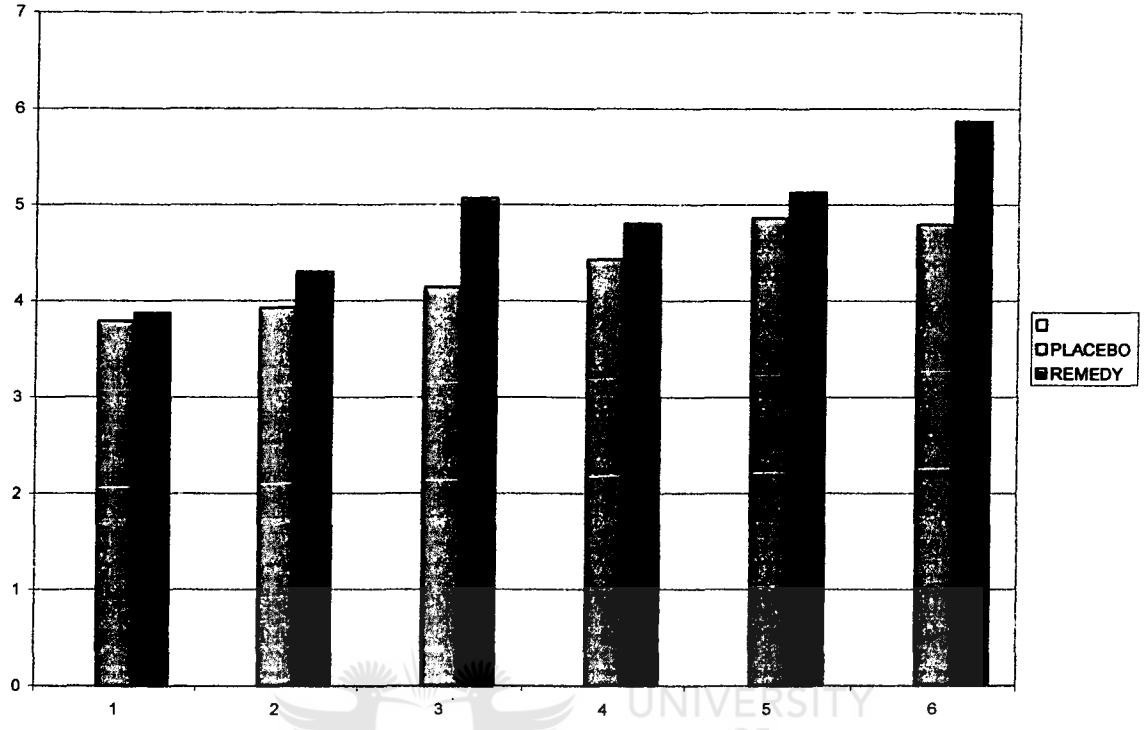


Figure 4.3.5 Have You Passed Stool Today

HAVE YOU PASSED STOOL TODAY						
WEEKS	**1**	**2**	**3**	**4**	**5**	**6**
PLACEBO	3.79	3.93	4.14	4.43	4.86	4.79
REMEDY	3.87	4.3	5.07	4.8	5.13	5.87

Figure 4.3.5 indicates there was clinical improvement in the frequency of stool between the groups and over the period of six weeks. No medication was given in week one. Participants increased stool frequency over the period of week one and week three, in the remedy group. However, by week four, frequency of stool decreased, and then between week five and week six increased in frequency. In the placebo group the frequency of stools passed increased from week one to week five. From week five to week six frequency of stool decreased. Results were not statistically significant over time and between groups.

4.3.6 Results of Frequency of Stool In A Day

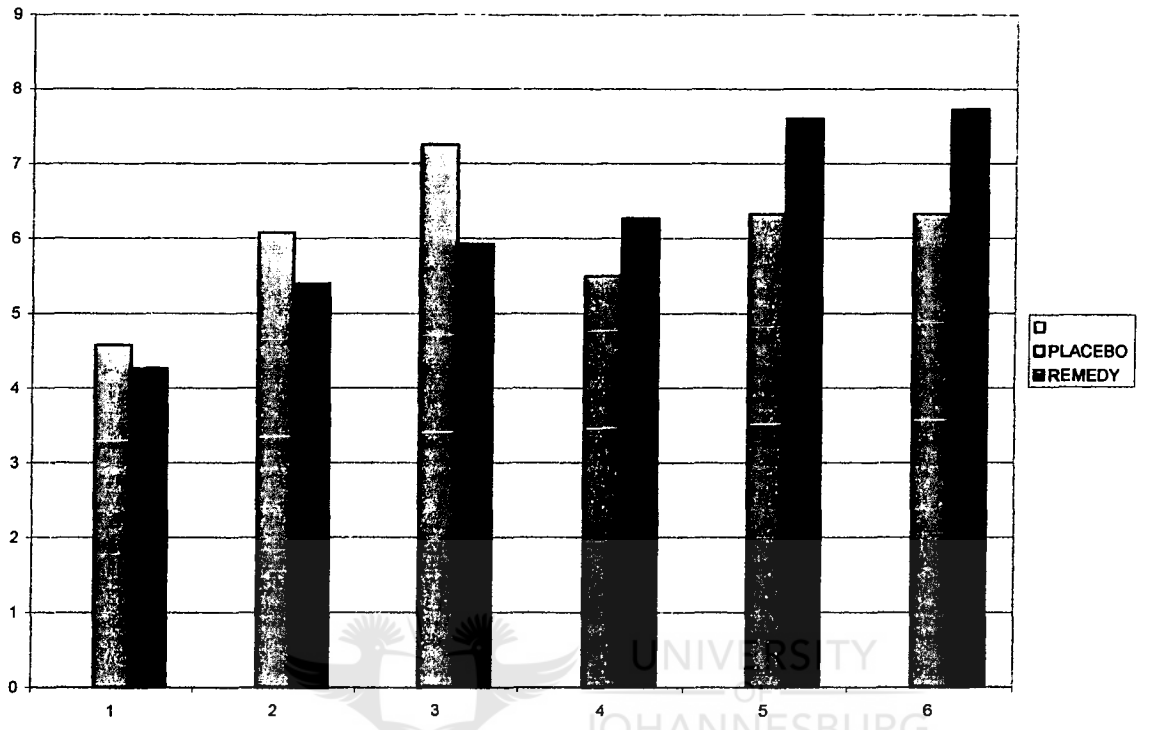


Figure 4.3.6 If Yes How Many Times

IF YES HOW MANY TIMES						
WEEKS	**1**	**2**	**3**	**4**	**5**	**6**
PLACEBO	4.58	6.08	7.25	5.5	6.33	6.33
REMEDY	**4.27**	**5.4**	**5.93**	**6.27**	**7.6**	**7.73**

Figure 4.3.6 indicates the placebo group increased in passing stools over the period from week one to week three. No medication was given in week one. The group deteriorated slightly from week three to week four, and improved slightly from week four to week five. The placebo group stabilised from week five to week six. The experimental group gradually increased from week one to week five. Symptom stabilised from week five to week six. Results are not significant over time and between groups.

4.3.7 Ratio between Frequency and How Many Times of Passing of Stools

Participants were required to indicate if they passed stools for the day and how many times. The ratio was obtained between the two results.

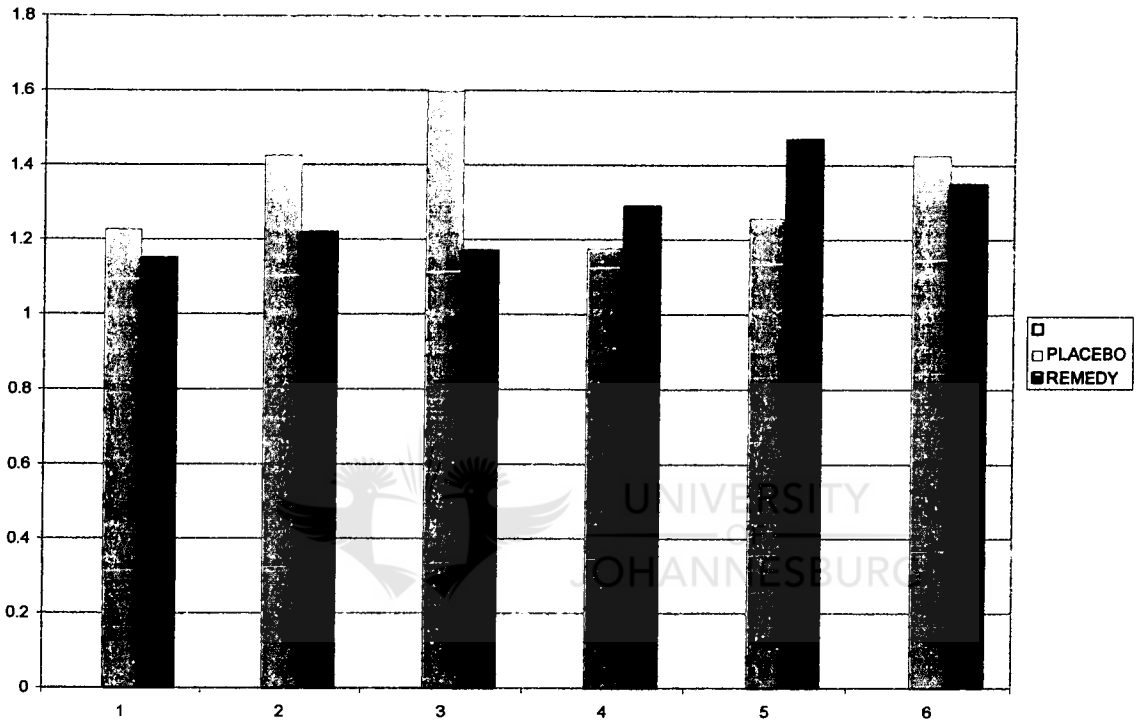


Figure 4.3.7 Ratio If Yes, How Many Times Have You Passed Stool Today

RATIO IF YES,HOW MANY TIMES HAVE YOU PASSED STOOL TODAY						
WEEKS	**1**	**2**	**3**	**4**	**5**	**6**
PLACEBO	1.23	1.43	1.6	1.18	1.26	1.43
REMEDY	1.15	1.22	1.17	1.29	1.47	1.35

Figure 4.3.7 Indicates there was clinical improvement in the ratio of stool between the groups, over the period of the third week (Appendix N). Mann-Whitney U analysis revealed significance between the ratio between FBM2_FBM1 in week three ($z = 2,548$, $p = 0,011$).

The median test was performed due to an unusual value only in the third week. The test showed that the difference is not statistically significant ($p = 0,066$).

No medication was given in week one. The placebo group increased the ratio from week one to week three and decreased during week three to week four, and then gradually increased after week four. In the experimental group the ratio improved slightly during week two to week three but during week three and week five it gradually improved. During week five and week six the ratio decreased.

In conclusion, there is a clinical improvement over the period of six weeks in the symptoms of passing of stools as well the frequency of stools passed over a period of six weeks between the experimental group and placebo group (Appendix M). However, the results were not statistically significant.

4.3.8 Results on energy levels for the week

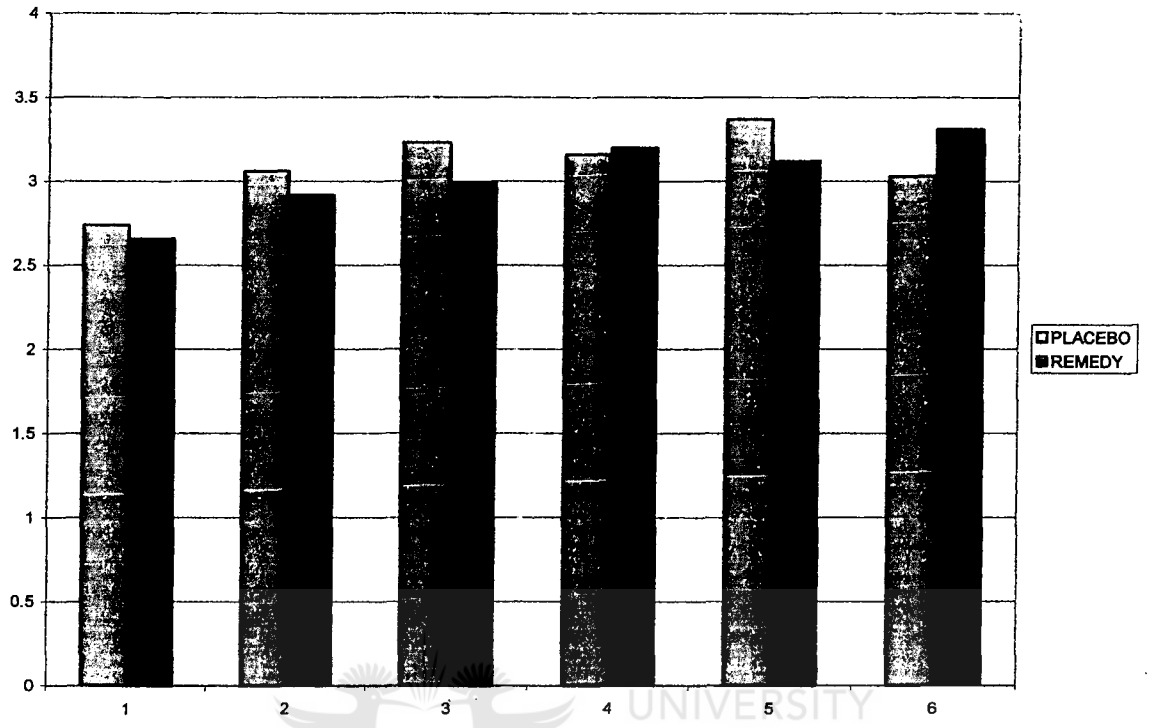


Figure 4.3.8 Rate Your Energy Level For The Week

RATE YOUR ENERGY LEVEL FOR THE WEEK						
WEEKS	**1**	**2**	**3**	**4**	**5**	**6**
PLACEBO	2.74	3.06	3.23	3.16	3.37	3.03
REMEDY	2.66	2.92	2.99	3.2	3.12	3.31

Figure 4.3.8 Indicates there was no significant improvement in the energy levels between the two groups and over the period of six weeks. No medication was given in week one. Energy levels improved slightly in both groups from week two to week three. Both groups stabilised from week three to week four. At week five the experimental group deteriorated slightly and placebo group increased slightly. Between week five and week six the placebo group deteriorated and the experimental group improved. Results are not significant over time or between groups.

4.4 Compliance and Laxative Use

All thirty participants gave full commitment during the trial. No participants recorded using laxatives during the trial. All participants completed the trial.

CHAPTER 5

CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

This study evaluated the efficacy of Constipation 6c® in the treatment of functional chronic constipation in females using the modified Rome II criteria. The results have shown a clinical improvement in symptoms of participants, both in the experimental and the placebo group. Neither the improvement over time, nor the improvement between experimental and placebo treatment was statistically significant.

There was one statistically significant improvement in week 3, between the ratio of bowel movement and frequency of bowel movement (Appendix N). As this was an unexpected result the median test was performed to evaluate its overall significance. The results showed this change not to be statistically significant over all.

The improvement in both groups started from the beginning of the trial, before treatment began and continued at a slow pace with minor variables. It is probable that these changes were due to the effects of being in a trial with possible placebo effects or possible small changes in participants' lifestyles.

5.2 Recommendations

Further research in this field could benefit from the following recommendations:

- A larger sample group should prove beneficial for statistical purposes.

- A healthy diet and exercise are important variables in relation to chronic constipation. It is suggested that participants could be divided into three groups,

placebo and two experimental groups. One of the experimental groups follows a diet high in fibre while the other does not.

- It would also be interesting to do a larger similimum study in order to obtain indications for a new complex remedy in the treatment of chronic constipation.

- It would be interesting to conduct a study to compare the effects of a complex homoeopathic formula with those of a smilimum treatment of chronic constipation.

- A longer trial period, two to three months, as this would be beneficial to determine how long the complex remedy continues to act before it needs to be repeated.

- Modify the method of recording frequency of bowel movement. For instance, to add in other variables that would impact on the symptoms (example: diet, exercise, etc.).

- A study conducted on chronic constipation which monitors the decrease in the use of laxatives over a period of time and the use of a homoeopathic complex remedy.

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APPENDIX A

Modified Rome II Criteria for Chronic Constipation

Do you suffer from two or more of the following:

- Straining
- Lumpy or hard stools
- Incomplete sensation of evacuations
- Manual manoeuvres to facilitate
- Fewer than three defecations/week

Three months of the past twelve months, I have suffered from the above (YES/NO)_____

Exclusion criteria

- Inflammatory bowel disease
- Colon cancer
- Pregnancy
- Irritable bowel syndrome
- Rectal haemorrhaging
- Sudden, recent onset severe constipation

Study Inclusion Criteria

1. Gender: _____
2. Age (18-35) : _____
3. Are you taking any laxatives? _____
4. How often do you take the laxatives? _____
5. How long have you had the presenting symptoms? _____
6. Do you suffer from any other digestive disturbance? _____
7. How many packs of cigrettes do you smoke a week? _____
8. Are you taking any scheduled medication? If yes, which? _____

NUMBER BOTTLE ALLOCATED TO PATIENT: _____

APPENDIX B: PARTICIPANT INFORMATION AND CONSENT FORM

Research into Chronic Constipation

Dear Volunteer,

My name is Asmita Ramguthy. I am a 5th year homoeopathy student at the University of Johannesburg; I am inviting you to participate in this research study for my M.Tech Homoeopathy qualification. I am undertaking this research study into the homoeopathic treatment of constipation.

Chronic constipation is a symptom from which many women tend to suffer often with no relief. This leads to the chronic use of many over-the-counter medications. Homoeopathy is a non-invasive approach to treating constipation.

The purpose of this study is to determine the efficacy of a homoeopathic complex remedy, *Constipation 6c*® made by Pegasus Homoeopathics. This is an over-the-counter homoeopathic product that is sold to treat constipation but there has been no research conducted of its efficacy. The study will last six weeks.

In order to qualify to participate in the research, you must have at least two of the following symptoms: hard stool, incomplete sensation of evacuation, abdominal discomfort or passing stool less than three times a week. The study is not suitable for participants who have inflammatory bowel disease, irritable bowel syndrome, or any anal bleeding, or if you are pregnant, breastfeeding or have taken any stimulative laxatives prior to the start of the research. Consultations will be held at the University of Johannesburg's Homoeopathy Health Training Centre, in Doornfontein, or at Weleda Pharmacy (Fourways). Your treatment will be provided free of charge.

If you have agreed to participate in the study, a case history case will be taken and a physical examination will be done. You will be randomly allocated to one of two groups either: the experimental or the placebo group. The experimental group will get the homoeopathic remedy and placebo group will get unmedicated pillules. Both groups will

be required to record symptoms on a daily recording sheet. No treatment will be given for the first week in order to establish a base line. At your second visit you will then be given a bottle that is labelled A or B. Pegasus Homeopathics marks the bottles, so that neither you nor I will know who receives the treatment and who receives the placebo.

From the beginning of the second week, you will take five pillules three times a day for a period of five weeks. Every week you will be requested to come in to check on your progress. At each follow up visit a focused physical examination will be done and your completed daily recording sheet will be collected. Please do not make use of any allopathic, herbal or any other form of medication during this study. However, if the use of other medication apart from that prescribed to you during the study is unavoidable, you are requested to document this on your daily recording sheet and inform the researcher. There are no anticipated risks of side effects in this study. If you have any concerns, please contact the researcher on the contact numbers below. Participation in this study is voluntary and you are free to withdraw from the study and decline treatment at any time.

A signed copy of this form will be given to you. Information received will be kept confidential at all times. Measures ensuring this include keeping your file in a secure cabinet and replacing your name with a case number. Again, if there are any questions or problems relating to the study, please contact either the researcher or the supervisor (please note the contact numbers below).

Your participation in this study will be much appreciated and will contribute to improving the homoeopathic treatment of chronic constipation. The results of this study will be available to you on request.

Thank you.

I, the voluntary participant, have been completely informed about the procedure of this study. I acknowledge that I may at any time withdraw my participation in this study. I acknowledge that I am free to enquire about the research and ask questions, which will be answered by the researcher and/or supervisor to the best of their ability.

Signature: _____ Date: _____

I, the researcher, have given a full explanation of the intended study procedures and treatment. I will provide the best explanations that I can with regards to questions posed by the participants.

Signature: _____ Date: _____

Contact details:

Researcher: Asmita Ramguthy 083 500 6646

Supervisor: Dr K. S. Peck 082 824 2280

APPENDIX C

Case Taking Form

Presenting symptoms (duration of symptoms)

Physical Examination:

Vital signs:

Blood Pressure: _____ Respiratory Rate: _____ Pulse Rate: _____

Temperature: _____

JACCOLD:

Abdominal Examination:

Observation:

Auscultation:

Percussion:

Palpation:

APPENDIX D

Daily Recording sheet

Week No: _____ *Bottle Number ::*_____

1----------2----------3----------4----------5

Improved **Mild Improvement** **Unchanged** **Fairly Severe** **Very Severe**

	Passing of hard stools	*Sensation of incomplete stools*	*Difficulty/ Straining passing stools*	*Manual manoeuvre*	*Discomfort experienced*
Monday					
Tuesday					
Wednesday					
Thursday					
Friday					
Saturday					
Sunday					

Frequency of Bowel Movements

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Have you passed stool today?							
If YES,how many times?							

Rate Your Energy Levels

1----------2----------3----------4----------5

I feel drained **Very Low Energy** **Energy Levels Varies a bit** **Reasonably Energetic** **Very Energetic**

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Rate your energy levels for the day							

Laxative Use

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Have you taken any laxatives today							
If yes, how many?							

APPENDIX H

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Do you experience the following symptoms?

- **Passing stools less than three times a week**
- **Experiencing sensation of incomplete evacuation of stools**
- **Passing of hard stools**
- **Straining**
- **Manual manoeuvres to facilitate defeacation**
- **Bloating**

If you are a female between the ages of 18 and 35 years and suffer from 2 or more of the symptoms, you may qualify to participate in a Research Study being conducted through the Department of Homoeopathy on

The effects of **Constipation 6c®** on chronic constipation.

Ethical Clearance Number:

57/08

Participation is voluntary and strictly confidential.

Consultations and treatment are

FREE OF CHARGE!

For more information please contact: **Asmita Ramguthy 083 500 6646**

APPENDIX E

Weekly Report:

Date: _____ Bottle number: _____

Symptom	Constant	1st Week with no treatment	2nd Week	3rd Week	4th Week	5th Week	6th Week
Passing of hard stool	2						
Sensation of incomplete stools	2						
Difficult/straining passing of stools	2						
Manual manoeuvres	2						
Severity of discomfort							
Total							

Laxatives Use

	No Treatment	2nd week	3rd week	4th week	5th week	6th week
Total amount of laxatives used						

Well-being

	No Treatment	2nd week	3rd week	4th week	5th week	6th week
Total: Energy levels						

APPENDIX F

Follow up Forms

Presenting Symptoms:

Have your eating habits changed?

How many times per week have you exercised?

How many cigarettes have you smoked a day?

Physical Examination:

Vital signs:

Blood Pressure: _____ Respiratory Rate: _____ Pulse Rate: _____

Temperature: _____

JACCOLD:

Abdominal Examination:

Observation:

Auscultation:

Percussion:

Palpation:

APPENDIX G

Information leaflet: medication administration

Presentation:

25ml amber glass bottle

Texture:

small white round balls (pillules)

Taste:

Sweet

Dosage:

5 pillules three times a day

How to take the medication

- Transfer 5 pillules from the bottle to the lid.
- Place under the tongue and allow to dissolve. Medicine is best absorbed in mouth directly through the mucous membranes, its best not to wash it down with water.
- Do not return the excess in the bottle because you may contaminate the remainder of your medicine.
- Medicine should be taken with clean mouth i.e mouth should be free of food, drink, tobacco, smoke, toothpaste, mouthwash, mints (e.g. peppermint), or any matter except plain water.
- Put nothing in the mouth except water fifteen minutes before or after the dose.

APPENDIX I

Medication treatment that will be excluded during the trial:

- Narcotics used to treat pain
- Antidepressants
- Antihypertensives
- Antidiarrheals
- Antacids contain aluminium and calcium
- Calcium supplements
- Tranquilizers
- Iron supplements
- Antihistamines
- Antispasmodic drugs
- Diuretics (medicine that increases the production of urine)
- Chemotherapy

(Friedel, 2008)

APPENDIX J

Abdominal Examination:

1. **Inspection**
    - Starting from usual standing position at the right side of the bed, inspect the abdomen.
    - Observe peristalsis and the skin (scars, striae, dilated veins, rashes and lesions), the umbilicus, the contour)

2. **Auscultation**
    - It is used to obtain important information about bowel frequency.
    - Place the diaphragm of the stethoscope gently on the abdomen. Listen for bowel sounds and note their frequency and character.
    - Listen over all four quadrants.

3. **Percussion**
    - Percussion helps to assess the amount and distribution of gas in the abdomen and to identify possible masses that are solid or fluid filled.
    - Percuss the abdomen lightly over the four quadrants over the abdomen to the distribution of tympany and dullness.

4. **Palpation**
    - Light Palpation – Keep hand and forearm on a horizontal plane, with fingers together and flat on the abdominal surface, palpate the abdomen with a light, gentle, dipping motion. Moving smoothly, palpating quadrants.

    - Deep Palpation – using the palmer surfaces of your fingers, palpate in all four quadrants. Identify any masses and note their location, size, shape, consistency, tenderness, pulsations and any mobility with respiration or with the examining hand.

APPENDIX K

Baseline Summary for Participants

Participant Name	*Age*	*Severity of symptoms scores as determined by weekly report*	*Duration of symptoms prior to recruitment into study*	*Medication (A or B)*
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.				

APPENDIX L

Symptoms suggestive of Colon Cancer

- Sudden onset of alternation of bowel movements, or sudden severe constipation
- Sense of fullness
- Unexplained weight loss
- Blood in stool
- Fatigue
- Thin stool

(Lane, 1999)

Symptoms suggestive of Irritable Bowel Syndrome (IBS)

Symptoms of IBS:

(IBS is classified as a type of functional constipation)(Bharucha, 2007)

1. Alternating constipation and diarrhoea

2. Abdominal pain or discomfort for at least 3 days per month in the last 3 months that is associated with two of the following:

- the pain or discomfort is improved with defecation,
- the pain or discomfort is associated with an increase or decrease in stool frequency, and/or
- the pain or discomfort is associated with the stools becoming harder or softer in consistency
- no weight loss
- no blood in stool

(Keshav, 2004)

APPENDIX M

Stimulative Laxatives

- Cascara sagrada
- Caster oil – not recommend since it will irritate your colon
- Correctol® – contains Bisacodyl
- Dialose plus® – contains phenolphthalein
- Dulcolax® – contains bisacodyl
- Exlax® – contains bisacodyl and sennosides
- Feenamint ®– contains bisacodyl
- Perdiem® – contains senna
- PeriColace® – contains casanthranol

Any other products containing any of the above ingredients.

(Silva, 2003)

APPENDIX N

Test Statistics

	Mann-Whitney U	Wilcoxon W	Z	Asymp. Sig. (2-tailed)
Age	111.000	231.000	-0.063	0.950
Mean_POHS_w1	74.000	179.000	-0.518	0.604
Mean_POHS_w2	81.500	172.500	-0.462	0.644
Mean_POHS_w3	109.500	229.500	-0.125	0.900
Mean_POHS_w4	100.500	205.500	-0.197	0.844
Mean_POHS_w5	93.500	184.500	-0.186	0.852
Mean_POHS_w6	68.500	159.500	-1.347	0.178
Mean_SOIS_w1	82.000	187.000	-0.749	0.454
Mean_SOIS_w2	90.500	195.500	-0.346	0.729
Mean_SOIS_w3	79.000	184.000	-0.586	0.558
Mean_SOIS_w4	79.000	184.000	-0.877	0.380
Mean_SOIS_w5	90.500	181.500	-0.024	0.981
Mean_SOIS_w6	65.000	170.000	-0.983	0.325
Mean_DSPS_w1	66.500	171.500	-1.205	0.228
Mean_DSPS_w2	85.000	205.000	-0.876	0.381
Mean_DSPS_w3	69.000	160.000	-0.8	0.424
Mean_DSPS_w4	76.500	196.500	-1.251	0.211
Mean_DSPS_w5	76.000	181.000	-1.015	0.310
Mean_DSPS_w6	63.000	168.000	-1.614	0.107
Mean_DE_w1	83.000	203.000	-1.233	0.217
Mean_DE_w2	92.500	197.500	-0.547	0.585
Mean_DE_w3	70.500	175.500	-1.513	0.130
Mean_DE_w4	89.500	209.500	-0.96	0.337
Mean_DE_w5	112.000	232.000	-0.021	0.983
Mean_DE_w6	63.500	168.000	-1.348	0.178
Sum_FBM1_w1	110.000	230.000	-0.105	0.916

Sum_FBM1_w2	108.000	228.000	-0.19	0.850
Sum_FBM1_w3	80.500	200.500	-1.361	0.174
Sum_FBM1_w4	91.000	196.000	-0.644	0.520
Sum_FBM1_w5	107.000	227.000	-0.233	0.816
Sum_FBM1_w6	76.000	196.000	-1.562	0.118
Sum_FBM2_w1	82.000	202.000	-1.014	0.310
Sum_FBM2_w2	82.000	202.000	-0.725	0.469
Sum_FBM2_w3	90.000	210.000	-0.668	0.504
Sum_FBM2_w4	88.000	193.000	-0.766	0.444
Sum_FBM2_w5	103.000	223.000	-0.398	0.690
Sum_FBM2_w6	93.000	213.000	-0.819	0.413
Ratio_FBM1_w1	84.000	204.000	-0.989	0.323
Ratio_FBM1_w2	80.000	200.000	-0.834	0.404
Ratio_FBM1_w3	47.500	167.500	-2.548	0.011
Ratio_FBM1_w4	86.000	191.000	-0.861	0.389
Ratio_FBM1_w5	91.000	211.000	-0.907	0.364
Ratio_FBM1_w6	100.500	220.500	-0.501	0.616
Mean_REL_w1	101.000	221.000	-0.481	0.631
Mean_REL_w2	93.500	198.500	-0.504	0.614
Mean_REL_w3	89.500	209.500	-0.686	0.493
Mean_REL_w4	105.000	225.000	-0.313	0.754
Mean_REL_w5	90.000	210.000	-0.937	0.349
Mean_REL_w6	93.000	213.000	-0.811	0.417

b.Grouping Variable: Group