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**EVALUATING THE ROLE OF KINESIOLOGY, AS AN
ADJUNCT THERAPY, IN THE MANAGEMENT OF
PATIENTS WITH CROHN'S DISEASE.**

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Submitted for the degree of
Master of Arts (Research Psychology),
In the department of Psychology,
Faculty of Humanities
University of Cape Town

2002

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ACKNOWLEDGMENTS

This thesis has been completed under the supervision and direction of:

Professor Sally Swartz, Director of the Child Guidance Clinic, University of Cape Town. Frank Bokhorst, Lecturer, Psychology Department, University of Cape Town and Professor Trevor Winter, Gastrointestinal Unit, Groote Schuur Hospital. I wish to thank them for their enthusiasm and support.

I also wish to thank the following individuals:

Dr Gerard Van Hoorn for his assistance and encouragement throughout the course of this project.

Sister Heather Paterson for taking blood samples and for her concern and support. As well as Sister Gloria Africa for assisting with blood samples.

Mrs. Karin Fenton for her endless support and assistance.

Sister Urda Kotze for her concern and assistance with data planning.

Mrs Marie Callanan and Mrs Tessa Marks for their concern and support.

The patients of the GIT Unit at Groote Schuur Hospital for participating in the study. As well as the staff members for their assistance.

The UCT Council B Scholarship and University Scholarship Committee for their financial support, without which this project could not have been completed.

And finally my two sons, Reza and Riaz, for their love, support, understanding and encouragement.

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ABSTRACT

This randomized controlled experimental study was designed to determine whether Kinesiology, as an adjunct to medical therapy, would improve the management of patients with Crohn's disease. One hundred and fifty consecutive Crohn's disease patients, attending the Gastrointestinal Clinic at Groote Schuur Hospital, were randomly assigned to a Kinesiology (n=50) and a Control Group (n=50). In order to assess the effect of physical contact, a third group who received Massage (n=50), was also included. All participants attended their monthly hospital visits and continued taking their prescribed medication. In addition, the Kinesiology Group received a 60-minute Kinesiology session and the Massage Group a 60-minute massage session on a monthly basis for four months.

Disease activity was assessed by means of the Crohn's Disease Activity Index (CDAI), quality of life by the Short Inflammatory Bowel Disease Questionnaire (SIBDQ) and psychological state by the Profile Of Mood States (POMS). Assessments were performed at entry into the study, following four months of therapy and again at three-month follow-up. At entry into the study, patients were assessed in accordance with their disease activity (Active-CDAI>200, Quiescent-CDAI<150, Indeterminate-CDAI 150-200). At entry into the study, the three groups were equivalent in terms of demographics, haematology, biochemistry, disease activity, quality of life, and psychological mood states.

Following a four-month intervention period for the patients with active disease: the Kinesiology Group demonstrated a significant reduction in CDAI ($p<0.001$). This significant reduction was maintained at follow-up ($p<0.001$) whereas the Massage and Control Groups did not show any significant results. The Kinesiology Group also demonstrated a significant improvement in quality of life (SIBDQ) at follow-up ($p<0.05$) but not the Massage and Control Groups. Although the POMS did not present significant results, the pattern of

improvement in the Kinesiology Group remained consistent throughout, compared to the Massage and Control Groups who deteriorated. For the patients with quiescent disease: Kinesiology was associated with maintenance of remission whereas the Control and the Massage Groups demonstrated deterioration at follow-up. This study demonstrates that Kinesiology has a beneficial adjunctive role in the management of patients with Crohn's disease, particularly improvement in quality of life and maintenance of remission.

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CHAPTER 1

INTRODUCTION

Crohn's disease is a chronic gastrointestinal disorder of unknown etiology (Casellas et al., 2000). Individuals with the disease may experience recurrent episodes of abdominal pain, diarrhea, fever, vomiting associated with weight loss, chronic gastrointestinal bleeding, anemia, and systemic manifestations (Garret, Brantley, Jones and McKnight, 1991). Crohn's disease can occur in any area of the gastrointestinal tract, from the mouth to the anus (Rosenberg et al., 1994). The clinical course of the disease is commonly marked by periods of remission and exacerbation. Approximately 25-50% relapse annually (Prantera et al., 1996; Riley et al., 1990).

The incidence of Crohn's disease is around 1-6 per 100,000 and could be higher in females, by as much as 30% (Stenson, 1991). The peak age of onset is between the ages of 15 and 25 years. Another smaller peak also seems to occur between the ages of 55 and 65 years (Stenson, 1991).

The prevalence of Crohn's disease has been reported to be around 10-100 per 100,000 in the developed countries (Calkins et al., 1996). Even though this prevalence may seem small, the cost of the disease is high. In a study undertaken in Sweden it was found that in 1994, the total cost of Crohn's disease calculated from hospital admissions, ambulatory care, drugs, sickness leave, and early retirement was US \$43.1 million (Bernstein et al., 2000). Two percent of all patients were responsible for 10% of the total admissions during 1994. This finding was similar to findings in the USA and the UK. Drug therapy was responsible for only 6% of the total cost, whereas morbidity of the patients resulted in 71% of the cost (Hay & Hay, 1992).

A recent study has reported that the average cost of care for Crohn's disease is approximately \$12,500 per patient (Hewitt, 1994). Furthermore, 20% of the cases of Crohn's disease account for 80% of the total cost of the disease, generally due to hospitalization, with an average cost of \$37,000 per hospitalized patient (Feagan et al., 2000). This highlights the need for efficient, cost effective patient care and treatment, in order to keep patients in remission and out of hospital.

Medical interventions in the management of Crohn's disease include corticosteroids and immunosuppressives. Corticosteroids, in oral, intravenous or topical form, have been the mainstay in the treatment of acute Crohn's disease for induction of remission. The main problems with its use are related to its significant side effects such as moon face, hirsutism, acne, metabolic bone disease, osteoporosis, growth retardation etc (Thomsen et al., 1998). Side effects occur regardless of the route of administration, and even though the newer preparation such as budesonide are safer, side effects remain a problem. A significant number of patients have steroid resistant disease, or become steroid dependent (Brzezinski, 2000).

Most patients with Crohn's disease will require one or more surgical procedures during their lifetime (Yazdanpanah et al., 1997). In recent years the surgical approach has changed from extensive intestinal resections for cure to limited surgery on diseased intestine for improved function (Ralandelli, 1994). Surgery is, unfortunately, often associated with recurrence of disease, and is therefore not curative. Surgical procedures is generally reserved for the management of complications of Crohn's disease, such as obstruction or fistulae formation (Latimer, 1978).

Patients suffering from a chronic illness such as Crohn's disease, often have worries and concerns pertaining to their condition. For example, the fear of having surgical procedures and eventually requiring an ileostomy (Casellas,

2000). Having an ileostomy may lead to long periods of disability with disruption of family, school and business responsibilities, long and frequent hospitalizations, malabsorption and malnutrition (Latimer, 1978). Patients requiring ileostomy are also exposed to inconvenience related to emptying these bags. There is the risk of embarrassment should the bag break or appliance fail (Murray, 1984). The psychological disturbance related to having an ileostomy could therefore have an adverse effect on the patient's general well-being.

At present, no specific cure exists for Crohn's disease. Despite reasonably effective medical management, relapses and the development of complications remain unpredictable, and side effects to treatment common. This uncertainty of disease compromises quality of life.

There is increasing clinical and research evidence that stressful life events, traumas, and major losses may have a profound and detrimental impact on physical and mental health status (Thompson et al., 1992; Adler et al., 1994; Creed, 1985; Lowman et al., 1987). Stress is defined as a psychological response composed of negative cognitive and emotional states, elicited when demands imposed by events exceed the individual's ability to cope (Cohen and Herbert, 1996). However, there is enormous inter-individual variability in the response to stress (Sklar, 1979). This variability may be due to differences in subconscious or conscious processing of stressful stimuli. Thus an emotional traumatic childhood may enhance the subconscious emotional response to stressful stimuli, resulting in enhanced physiological responses to stress, increased productions of immunosuppressive neuropeptides and hormones. There is some evidence that psychosocial disruption in utero, postnatally and during childhood can have long-term consequences on the immune system (Coe et al., 1987; Ackerman et al., 1988).

Psychological disturbances may mediate the development or exacerbation of Crohn's disease symptoms (Drossman, 1995). Psychological distress generally

lowers symptom threshold, thereby increasing the number and severity of reported symptoms for many medical conditions (Drossman, 1994). These factors are frequently not appreciated by the attending physician.

Similarly, Crohn's disease symptoms combined with existing psychosocial difficulties, amplify the symptom experience and lead to health-care seeking, refractoriness, and ultimately, referral (Creed, 1985; Berkman, 1985; Lazarus et al., 1984). Continued referral is reinforced because the health care system provides only incomplete relief of somatic symptoms, and possible reinforcement of pain and suffering through submission to unneeded diagnostic and therapeutic procedures (Whitehead et al., 1982). A "vicious cycle" of psychological difficulties, increased symptom severity caused by refractory symptoms, and health-care seeking is therefore perpetuated. Refractory symptoms amplify psychological disturbances, which in turn worsens symptoms and illness behaviour. The cycle continues when the physician does not consider the psychosocial determinants of these disorders and responds to the patient's distress by administering unneeded testing or treatments (Drossman, 1995).

It is evident that Crohn's disease is a very complex illness and therefore requires a multidimensional approach in its management. Complementary medicine could be a useful adjunct to conventional medicine in dealing with a disease of this chronic nature. Complementary or mind-body medicine is defined as practices that are not in conformity with the standards of the medical community and that are not taught as part of the undergraduate curriculum of orthodox medicine (Eisenberg et al., 1993).

The early custodians of health in most cultures treated both the mind, with trances and rituals, and the physical symptoms of the body, with herbs and natural remedies. Gradually, treatments for the mind and spirit became separated from treatments for the body. This separation gave birth to two schools of thought, namely the mechanists and the vitalists. Mechanists

spawned the subsequent development of reductionism and the biomedical approach to ill health, with its emphasis on physical disease, while vitalism was more aligned to the principles of Complementary Medical Practice (Watkins, 1995). However, it has been recognized for some time that mechanistic and materialistic ideas are insufficient to explain the human condition and the genesis of disease. There have been various attempts to reconcile vitalistic and mechanistic approaches to health. The concept of “wellness” evolved out of the idea that a healthy mind produced a healthy body and reduced the risk of disease. This concept was embraced by some arms of the medical community under the guise of holistic or mind-body medicine (Watkins, 1995).

From the perspective of holistic medicine, mind and body were seen as part of the same whole, connected and related in function. Mind-body medicine is therefore, seen as a metaphor for an approach to health that focuses not just on the physical body and the conscious mind, but also incorporates unconscious emotional life, and an individual’s spiritual dimension. These forms of intervention cover a wide variety of therapeutic practices, from counseling and cognitive-behavioural therapy to various complementary medical practices such as acupuncture, kinesiology, and massaging which focus on “restoring the energy” or electromagnetic flow in the body in an attempt to restore homeostasis to a body which has been “unbalanced” through physical or psychological trauma (Gallo,2000).

Although physicians commonly measure the electro-magnetic emissions from the body in the form of the electrocardiogram (ECG), electromyogram (EMG), electroencephalogram (EEG), it has been difficult to correlate these with the “energy field” utilized by practitioners of Complementary Medicine, and research in this area has largely been neglected.

Recently, there has been much interest in the possibility that psychological interventions could be used, even as an adjunct to conventional medical

treatments, for the alleviation of chronic pain related to Crohn's disease (Maunder & Esplen, 1999; Jantchek et al., 1998; Schwarz & Blanchard, 1991; Shaw & Ehrlich, 1987). Similarly, attempts have been made to determine if relaxation therapies such as meditation, hypnosis, and autogenic training can alter the human response to disease (Astin, 1997; Hershfield et al., 1993; Baum, 1981).

Unfortunately, most of the available studies, utilizing relaxation therapies, suffer from design flaws: lack of control groups, lack of follow-up data, biasing in the selection of participants, treatment confounds, and inadequate statistical analysis (Wiklund, 1995; Irvine, 1995). What is needed at present are: (1) adjunct therapies which take into account the physical, psychological, and biochemical aspects of the patient; (2) well-controlled studies, with objective measurement before and after treatment, and appropriate statistical analysis of the data; (3) follow-up data after the treatment has ended; (4) the use of disease-specific health-related quality of life indices to determine the effect of therapy on patient's quality of life, and (5) the use of individuals as participants who are drawn from the Crohn's disease population, for experimental and control groups - a healthy group, or participants from any other disease population, would not be suitable as controls due to the chronicity of Crohn's disease.

The present study was designed to take account of these needs. The modality, Kinesiology, which was selected as an adjunct to medical therapy has not yet been scientifically researched. However, many claims have been made to its efficacy. Therefore, the present study was designed to critically evaluate the benefits of this complementary therapy.

The aim of this study was to determine the role of Kinesiology as adjunctive treatment in the management of patients with Crohn's disease.

The objectives of this study included the possibility that patients receiving Kinesiology in comparison to a group receiving massaging, and a non-treatment control group would:

- (1) Reduce the activity of their disease (measured by lower scores on the Crohn's Disease Activity Index).
- (2) Increase their quality of life (measured by higher scores on the Short Inflammatory Bowel Disease Questionnaire).
- (3) Beneficially affect certain psychological characteristics associated with Crohn's disease patients (measured by lower scores on the Profile Of Mood States).
- (4) Maintain remission of the disease.

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CHAPTER 2

LITERATURE REVIEW

2.1.1 Crohn's Disease

Crohn's disease is a chronic and highly unpredictable nonspecific inflammatory disease that affects the gastrointestinal tract. The etiology, diagnosis, treatment, and even the definition have challenged physicians since Crohn first described it in 1932 (Jewell, Chapman & Mortensen, 1992). The affected areas are characterized by a chronic inflammatory reaction, which may be granulomatous, necrotizing, ulcerating, and scarring in nature, and which may extend through the entire intestinal wall (Baum, 1981). The inflammatory response in the bowel wall may lead to ulceration of the mucosa, narrowing of the lumen. These conditions may be characterized by intermittent uncomplicated attacks, but often results in complications such as obstruction, abscess formation and fistulisation (Schachter & Kirsner, 1980). Crohn's disease is one of two inflammatory bowel diseases, the other being ulcerative colitis. Ulcerative colitis is confined to the large bowel, whereas Crohn's disease can occur in any area of the gastrointestinal tract, from the mouth to the anus (Rosenberg et al., 1994; Stenson et al., 1991).

The ileum is the part of the bowel most often affected (see Figure 1). Both the ileum and the colon could be inflamed simultaneously (ileocolitis) or only the colon could be diseased (Crohn's colitis). It is not uncommon to have a normal area of the bowel between two areas of inflammation. This is termed "skip lesions" (Sages, 1995).

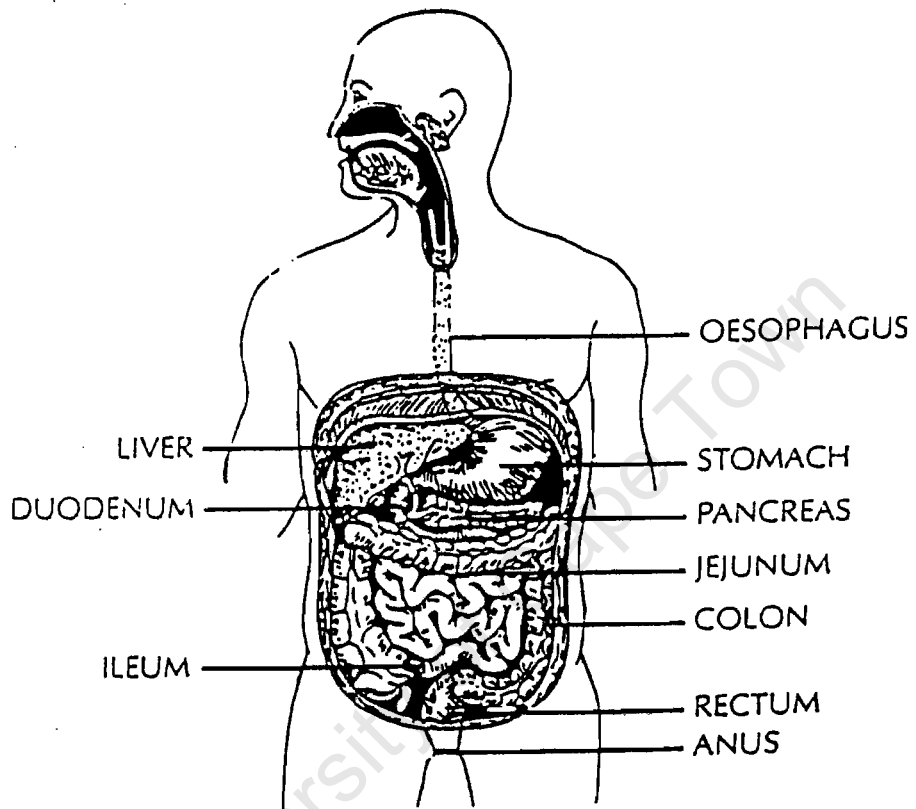


Figure 1: The Gastrointestinal tract (Sages, 1995).

2.1.2 Clinical Features

The disease presents itself with diverse clinical manifestations depending on the location, extent, and acuteness of the inflammatory lesion, and its relationship to contiguous structures. The majority of patients, 45%, will have ileocaecal disease, but 30% will have only ileal disease and in 25% the disease is confined to the colon (Kirsner & Shorter, 1988). The major systemic manifestations include weight loss, fever, nausea and vomiting, anorexia and weakness. Weight loss is generally attributed to the patient's anorexia and decreased food intake, as well as the catabolic state induced by the active inflammatory process, and may be exacerbated in the malnourished patient who is on corticosteroid therapy. Fever reflects the underlying inflammatory process, which sometimes indicates the presence of an inflammatory mass with localized perforation and multiple abscess formation. Nausea and vomiting are common – often as an indication of a mechanical intestinal problem such as narrowing of the bowel lumen or as a consequence of active intestinal inflammation and swelling (Schachter & Kirsner, 1980).

The most common clinical symptoms of Crohn's disease include diarrhea and episodes of crampy abdominal pain. The most common clinical signs include fever, perianal disease, internal or external fistula formation, and an abdominal mass (Kyle, 1972). While some patients experience little or no change in bowel habits, most of them have diarrhea of varying severity. This diarrhea is related to an alteration in motility in the diffusely inflamed small and/or large intestine (Schachter & Kirsner, 1980). Abdominal pain in Crohn's disease is caused by transmural inflammation of the bowel including the adjacent mesentery. Spasm of the diseased bowel segments and distension of the narrowed inflamed intestine may contribute to the discomfort. The often palpable abdominal mass is composed of inflamed, thickened intestinal loops, and adherent inflamed mesentery, frequently with associated intra-mesenteric abscesses and/or internal fistulas (Weterman, 1976; Kyle, 1972).

2.1.3 Epidemiology

The incidence and prevalence of Crohn's disease varies in different geographic regions. The highest rates are reported in the Scandinavian countries and Scotland, followed by England and North America (Kildebo et al., 1990). In the Western world the most rapid increase in the frequency of Crohn's disease occurred during the period 1965 – 1980 and, after a slower increase, reached a plateau in most centers and subsequently decreased in some (Sandler, 1994). The incidence of Crohn's disease may be higher in women by as much as 30%. The peak age of onset is between the ages of 15 and 25 years. Another smaller peak is reported to occur between the ages of 55 and 65 years (Russel et al., 1996).

Tentative epidemiological findings indicate that the disease occurs among all races, with a higher incidence among Jews. There is a relatively smaller incidence among Blacks (Latimer, 1978). A familial tendency gives patients one chance in five of having other cases of inflammatory bowel disease among their blood relatives (Mendeloff, 1974).

Because the disease is chronic, and permits long survival with extensive disability, the financial drain on patients and their families can be devastating. According to the Report to the Congress of the National Commission on Digestive Diseases in 1979, the annual cost of Crohn's Disease and Ulcerative colitis was estimated at \$645 million, a sum exceeded only by costs for lymphatic cancer, cirrhosis of the liver, and gall bladder disease (Baum, 1981). Beyond the economic costs resulting from expenditures for medical treatment, social welfare, and health insurance, there are psychological costs from long periods of disability, disruption of family life, education, and business responsibilities. The recurrent threat of hospitalization and surgery poses a further problem. This highlights the need for efficient, cost effective patient care and treatment in order to keep patients in remission and out of hospital.

2.1.4 Etiology

While the etiology of Crohn's disease remains unknown, a variety of pathophysiological mechanisms and etiological areas have been explored. These include bacterial and viral organisms, disorders of the mesenteric arteries, genetic or familial predisposition, immunological deficits, and psychogenesis (Glickman & Isselbacher, 1977; Mendeloff, 1974; Baum, 1981). Familial predisposition is seen as a possible factor in the etiology of Crohn's disease, and therefore, genetic traits could play a role in the pathogenesis of the disease. Family and twin studies have shown that between 10 – 20% of patients have another first-degree member of the family affected, and 41% of identical twins are affected (Gitnick, 1996).

There is no evidence that Crohn's disease is contagious. However, some cases appear to commence after episodes of gastroenteritis (Smith, 1993). Some researchers (Wakefield et al., 1994) suspect an unusual immunological response to an organism which is usually relatively harmless, for example the measles virus or mycobacteria (a micro-organism resembling the bacillus causing tuberculosis). It is also reported by the same authors that the body's own defense mechanism, the immune system, which provides protection against infection, is activated in Crohn's disease and may be involved in causing damage to the mucosa (the inner lining of the bowel wall). Most drugs used to control Crohn's disease do so by suppressing functions in the immune system (Gitnick, 1996). Although not a proven cause, periods of emotional stress have been linked with flare-ups of the disease (Garret et al., 1990).

Despite such clinical and pathological investigations, the cause of Crohn's disease remains an enigma. Some investigators (Latimer, 1978; Wybrow & Ferrel, 1973) have noted that the disease does not have the characteristics of a single cause either intrinsic or extrinsic, but is likely to stem from multiple interrelated etiologic possibilities. Winter (2002) has likened the disease to a

seed and soil analogy, where the disease is only experienced when an ecological factor (the seed) comes in contact with a predisposed individual (the soil). Nevertheless, in order to understand how the disease is perceived from a medical perspective, it seems appropriate to view the various models used for this purpose.

2.1.5 The Biomedical Model

The biomedical model (Figure 2), which is traditional and dominant within Western medical education and research, proposes that a biological predisposition leads, in a linear fashion, to the development of a medical disease. This disease may also be modified by environmental exposure. Furthermore, the disease fully explains the illness. Finally, the disease and illness determine the clinical outcome, which may also be modified by a psychological overlay, acting as a secondary influencing factor (Drossman, 1998). It has been noted by Engel (1977) that illness without disease does not fit this model. From a biomedical perspective, this illegitimate condition does not exist, and may be labeled as "psychosomatic", often this term is used to question the credibility of the symptoms, even though they are very real to the patient.

The term "psychosomatic" refers to the mind-body concept. "Psycho" conveys the study of the mind, while "soma" refers to the physical body (Pert, 1997). Physicians who adhere to the biomedical model, would have the tendency to separate mind and body; to view psychological and social aspects of health and illness as unrelated to biological aspects of the disease (Zuckerman, 1989). Separation of the psychological from the somatic also permits physicians to ignore psychosocial data and interventions and concentrate more on easily defined data obtained from laboratory and physical examinations (McKegney, 1975). Data obtained by these methods are frequently inadequate for a

satisfactory understanding of the patient's problems and their subjective experience of the disease (Zuckerman, 1989).

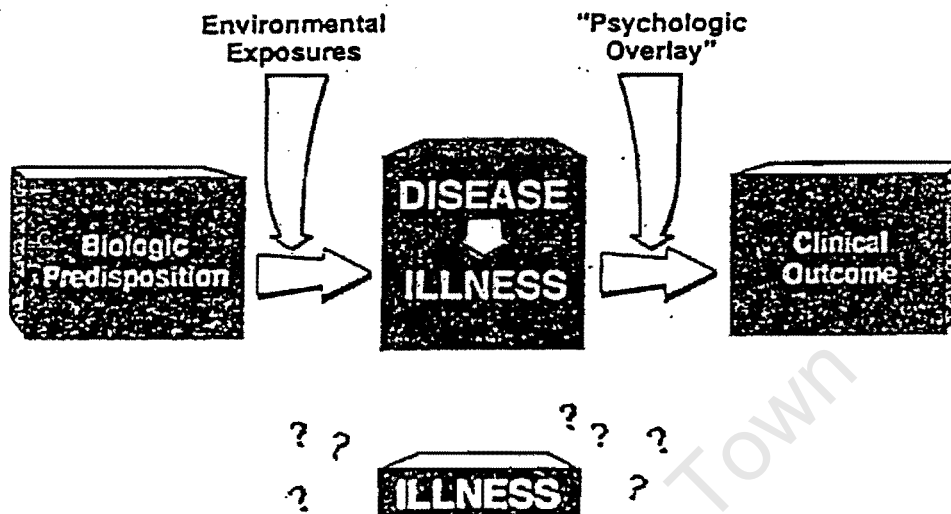


Figure 2: Schematic representation of the Biomedical Model (Drossman, 1998).

2.1.6 The Biopsychosocial Model

The biopsychosocial model (Figure 3) was proposed by Engel (1977) as an alternative understanding of illness and disease. This model proposes that illness and disease result from simultaneous interacting systems at the cellular, tissue, organismal, interpersonal and environmental levels. It integrates biological science with the unique features of the individual, and determines the degree to which biological and psychosocial factors interact to explain the disease, illness and outcome (Engel, 1977). The biopsychosocial understanding

of Crohn's disease therefore, proposes that early life factors (eg. genetic predisposition and environmental exposures) influence later psychosocial and physiological functioning, the clinical features of the condition, and, ultimately the outcome such as taking medications, physician visits, daily functional status, and quality of life.

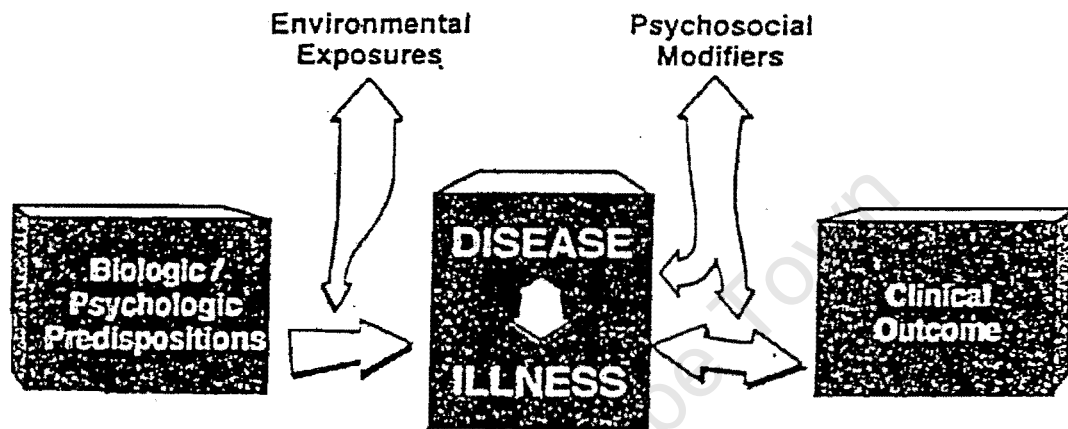


Figure 3: Schematic representation of the Biopsychosocial Model (Drossman, 1998).

2.1.7 Patient's Disease-related Worries and Concerns

Complaint-related cognitions and the patient's attribution style are believed to influence the course of functional abdominal complaints (Dulmen et al., 1995). Illness-related fears and beliefs about disease, somatic attributions concerning gastrointestinal tract and catastrophic cognitions are thought to play an important part in the genesis of a physical illness and lead to differences in the way symptoms are perceived and acted upon. Illness attitudes will also exert an

influence on how severe a symptom is judged to be, which in turn, might prompt the individual to focus anxiously on physical sensations, which may actually serve to amplify these initial sensations (Barsky, 1992; Salkovskis, 1989).

It is reported that patients suffering and simultaneously trying to cope with a chronic illness such as Crohn's disease, have many worries and concerns related to their condition. As a result, these worries may have a negative impact on health related quality of life (Drossman et al., 1989). Since these patients often suffer from specific and socially difficult problems (Moody et al., 1992), their level of psychosocial functioning is also greatly compromised. The highest levels of concern relate to: a) the uncertainty of having Crohn's disease, b) the effect of treatments such as medication, surgery and eventually having an ileostomy, c) developing cancer, d) concerns of a personal or interpersonal nature – low energy level, being a burden to others, the ability to achieve one's potential, disturbance of sexual life, and e) issues related to body-image – diarrhoea, fear of faecal incontinence, and flatulence (de Rooy et al., 2001). Patients with a colostomy have an added concern of having an odour or that the bag may rupture or leak. This may lead to restrictions in social and professional life (Moser et al., 1995). Mayberry and associates (1992) reported that up to 30% of patients with Crohn's disease actively conceal their illness from employers.

Clinical signs and patient symptoms do not embody the illness experience and physicians often underestimate or fail to recognize the functional disabilities reported by patients (Calkins et al., 1991). Therefore, in Crohn's disease as well as other chronic ailments, clinical evaluation must also include the patients physical, psychological, and social functioning level.

2.1.8 Medical Treatment and Management of Crohn's Disease

Despite continuous research (Thomsen, et al., 2002), no specific cure exists for Crohn's disease. The broad assortment of approaches which are attempted attests to the shortcomings of conventional medical care in treating this chronic disorder. Medical therapy has at one time or another included any number of the following combinations of medication: 5-aminosalicylate, corticosteroids, immunosuppressive drugs, antibiotics and metronidazole. Corticosteroids are effective in reducing inflammation during episodes of acute flare-ups (Slonim et al., 2000). Specific immunological therapies such as the use of anti-TNF antibiotics have been shown to be effective in the management of Crohn's disease. Similarly, drugs including immunosuppressives (azathioprine 6MP) and 5-aminosalicylate (for colonic disease) have been shown to be useful in reducing subsequent relapses (Hueschkel et al., 2002). Unfortunately, these very same medications may also be associated with side effects such as osteoporosis, cataracts, glaucoma with possible damage to the optic nerves, bone marrow depression and psychic derangements (Sages, 1995).

Other accepted medical interventions have included surgical procedures, involving resectioning the diseased portion of the bowel, or a bypass which excludes the involved area. Even though 70-90% of Crohn's patients eventually undergo surgical procedures it is generally avoided and usually reserved for the management of complications of Crohn's disease, such as obstruction, abscesses, and fistulisation. The reason for such caution is that a greater than 50% recurrence rate exists five years postoperatively (Casellas et al., 2000). Surgical measures are therefore not viewed as curative but seen as a means of eliminating complications of the disease.

2.1.9 The Stress-response and Crohn's Disease

It is generally accepted that stress can produce or aggravate physical symptoms although there is no consensus about its role. Human and animal studies have shown effects on vascularity, secretion and motility of the gastrointestinal tract (Beaumont, 1949). The same author observed changes in gastric activity and mucosal appearance in response to psychological and physical stimuli in a patient with a traumatic fistula. Others have shown distinct changes in gastric function as a response to different emotional states (Almy et al., 1947). For example, fear or depression are associated with mucosal pallor and diminished activity and secretion in the stomach, whereas the opposite is found in such emotional states as intense pleasure or anger (Whorwell et al., 1992).

Physiological abnormalities have also been shown to occur in other areas of the gastrointestinal tract. Jacobson and colleagues (1927) reported that strong emotions induced esophageal spasms, and in a more recent study by Young et al. (1987) it was shown that when patients with esophageal spasms were exposed to complex psychometric tests, high amplitude, high velocity esophageal contractions occurred as a response to these stimuli.

The role of acute chronic life stress has also been studied extensively in inflammatory bowel disease. Garret et al. (1991) examined the effect of minor daily stressors on the primary indices of Crohn's disease and found a relationship between daily stress and self-rated disease severity even after controlling for the effects of major life events. Piper and Tennant (1993) reported broadly similar results in their patients with chronic peptic ulcer disease.

According to Thomas Leaman (1992), emotional stress can affect the autonomic nervous system of the gut resulting in disruption of the normal peristaltic activity. This in turn, can result in a variety of symptoms including altered bowel habits

(discontinuous and/or constipation), flatulence and bloating as typified by the irritable bowel syndrome.

The above evidence suggests that psychopathology is intrinsic to inflammatory bowel disease. How far psychological processes can be implicated in the etiology and maintenance of the disease is much less clear. One can only assume that psyche and soma are intimately involved and it is important that disease of this nature should be approached holistically.

2.1.10 The Complex Links between Stress and Disease from a Psychoneuroimmunological perspective

The word Psychoneuroimmunology (PNI) indicates that the mind (psychology) is connected through the brain and nervous system (neurology) to the immune system (immunology), thus influencing the body's natural defenses (Hassed, 1998). PNI therefore, studies the link between stress, psychology, and disease. Pavlov in his Nobel Prize talk, first acknowledged the collaboration between neural (nervism) and endocrine systems (Winter, 2001).

There is substantial evidence suggesting that the autonomic, endocrine, and immune systems are not autonomous, and that the mind and body communicate with each other in a bi-directional flow of neuropeptides, hormones, and cytokines (Watkins, 1997; Rossi, 1993). The function of this interactive dialogue between autonomic, endocrine, and immune systems, the higher perceptual centers and limbic emotional centers is to sustain life and combat disease (Watkins, 1997).

Disease related to stress has been described as "information overload", in which the body-mind network is so overloaded with suppressed trauma or unresolved emotions that it becomes strained, and the normal flow of chemical messengers

for largely autonomic processes such as breathing and blood flow is compromised (Pert, 1997; Pert et al., 1985). Rossi (1993) indicates that it is the body's inability to turn off body-mind signals which leads to a chronic excess of these arousal messages within the body and consequently an eventual compromise, of the body-mind that we call "stress", the "psychosomatic response".

Since it is assumed that Crohn's disease could be a psychosomatic illness (Sheffield & Carney, 1976), it could be valuable to look at psychological theories of Crohn's disease in order to determine whether there are any reasons for suppressed emotions in this population, which could eventually lead to somatization of a chronic illness such as Crohn's disease.

2.1.11 Psychological Theories of Crohn's Disease

Literature reviews based on the relationship between psychological variables and physical symptoms of Crohn's disease (Binder et al., 1977; Cohen, 1979) focus on constellations of personality characteristics associated with the disease; family systems and traumatic childhood experiences; and life events involving loss and separation. These studies conclude that the most reported personality characteristics are dependence, repressed rage, suppression of feelings, obsessive-compulsiveness, and anxiety (Miller, 1976; Gerbert, 1980; Cohen, 1979). Others (McKegney et al., 1970) theorize that patients with Crohn's disease have a constant desire "to be rid of" events in their lives. This characteristic can be acted out through the physical symptoms of vomiting and diarrhea.

Clinical and empirical studies, based on family systems and traumatic childhood experiences, report that the causal dynamic was the symbiotic tie between mother and child. Disruption of this bond leads to rage and grief that is imploded

inward, affecting the digestive system (Paull & Hislop, 1974; Levitan, 1977; Engel, 1980; Gerson et al., 1998). Another study (Jackson & Yalom, 1966) reported in thirty out of thirty three patients with Crohn's disease who described their childhood as traumatic, one or both of the parents were described as exhibiting one of the following patterns of behaviour during much of the patients childhood – offering the patient little affection or closeness, being overly domineering or controlling, being physically or verbally abusive, conveying to the child a feeling of rejection or being unwanted, or abandoning the patient outright. These findings were supported by other researchers (Sojit, 1969; Schwartz & Schwartz, 1982).

The theory of loss and separation was developed within the psychoanalytic approach (Von Wietersheim et al., 1992). Authors, Fitzpatrick et al. (1992), point out that not only the actual event but also fears of loss and separation can lead to the onset of illness. Crohn's disease patients were also described as presenting with a rather bleak and negative future perspective which should be interpreted in the context of their dependence on others, not only parents but also partners (Küchenhoff, 1933; Gitnick, 1996; Jantchek et al., 1998). Two important points should be noted in assessing these data: (1) since most of the studies reviewed were retrospective in nature, one cannot conclude whether or not the psychiatric morbidity preceded, antedated, or evolved during the course of illness; and (2) such psychological variables are frequently found in patients suffering from a variety of chronic physical disorders.

Recent research has been based on the growing evidence that a history of sexual and physical abuse is associated with gastrointestinal illnesses such as Crohn's disease (Drossman, 1994; Felitti, 1991; springs, 1992; Fry, 1993). Psychologists and psychiatrists now recognize several psychiatric syndromes (for example, somatization disorder, severe depression, post-traumatic stress disorder, anxiety and personality disorder) as consequences of abuse (Stein, 1988; Bagley, 1985). However, only in the last few years has attention turned to

the physical concomitants of sexual and physical abuse, that is, their association with certain medical disorders and their effect on health care (Felitti, 1991; Briere, 1992; Springs et al., 1993; Laws, 1993).

It was found that patients with functional Crohn's disease who are seen in medical centers have a high frequency of psychiatric comorbid conditions (Walker et al., 1992; Lydiard et al., 1993) and are likely to communicate psychological distress through physical symptoms. Furthermore, they may not acknowledge a relation between psychological difficulties and their symptoms (Drossman et al., 1988; Toner et al., 1992), which reinforce their belief that they have a serious medical disorder.

2.1.12 Abdominal Symptoms and the Mind

Gut reactions have been reported to be spontaneous feelings not filtered by a sophisticated cerebral cortex (Watkins, 1997). Most people are quite accustomed to the sensation of "butterflies" or urgency and bowel frequency when faced with a stressful event. These and other abdominal symptoms, particularly those due to changes in intestinal motility, are thought to be mediated by the autonomic nervous system, indicating a clear connection between brain and the gut (Creed, 1992).

History indicates that beliefs about changes in mood were also focused on the abdomen. Melancholia, that is "black bile", believed to be the predecessor of depression, was thought to emanate from an abnormality of alimentary functions (Thompson, 1993). Many early remedies for mood disorder is reported to have focused on the alimentary tract which seemed to be an approachable target for the herbal remedies of early medicine (Creed, 1992). The importance of abdominal symptoms that are not related to any defined organic disease is no longer contested. Functional abdominal symptoms as they are known, are

extremely common. They have even affected and sometimes dominated the lives of many highly successful individuals. Charles Darwin was racked with abdominal pain which, in later life, restricted his movements away from home, as did the abdominal symptoms of Thomas Carlisle. Sigmund Freud clearly recognized the importance of the gastrointestinal tract as a mirror of the mind and our emotions, and based some aspects of his analytical theories of personality development on the beginning and end of the gastrointestinal tract, namely the mouth and the anus (Watkins, 1997). Since it appears that there is some link between mind and gut, it seems appropriate that treatment in the maintenance of gastrointestinal disorders should involve psychological intervention with a focus on teaching patients more effective coping mechanisms.

2.1.13 Psychological Intervention with Gastrointestinal Disorders

A number of uncontrolled and semi-controlled studies using psychological treatment approaches have been carried out with gastrointestinal disease patients (Svedlund et al., 1983; Blanchard et al., 1988; Latimer, 1978). Much of the earlier work was based on patients who were seen after several previous medical referrals, ineffective attempts at treatment, and a variety of potentially conflicting explanations of the problem. There is now a greater emphasis on liaison work, with those involved in psychological treatment working in primary and secondary medical settings. The four main types of psychological treatments that have been used include psychotherapy, hypnotherapy, behaviour therapy and cognitive-behavioural therapy.

2.1.13.1 Psychotherapy

It is interesting that even though a relationship between psychological variables and the disease was recognized by Crohn himself (Crohn, 1949), few investigators have examined this relationship, and still fewer have attempted to influence these factors through experimentation. Paulley's work (1971) is one of the rare reported studies acknowledging the above association, and one which attempts to influence it through psychotherapeutic intervention. Paulley utilized long-term psychotherapy together with conventional medical care (Corticosteroids and antibiotics) in the treatment of 40 Crohn's patients. From the patient's responses (39) to questionnaires, he determined that psychotherapy was a decisive influence in the recovery of 30 respondents. Unfortunately, Paulley's methodology is vulnerable to criticism since he does not provide an adequate control condition, nor does he elaborate on how or who determined that psychotherapy was a decisive factor in recovery.

Another example of using psychotherapeutic intervention with Crohn's disease is offered by Sperling (1960). In her single case study, the technique of psychoanalysis was employed to successfully treat a 44-year old male with a greater than 20 year history of illness.

The conclusions of both Paulley's and Sperling's studies can be faulted on a variety of methodological issues. At the same time, they have also neglected practical problems of costs and feasibility in their choice of intervention strategies. Specifically, individual psychotherapy and psychoanalysis are but a further burden for the Crohn's patient since these treatments are costly in both time and money. Paulley was seeing some patients for up to 18 years, and Sperling's work lasted 3 years (Baum, 1981). Furthermore, Paulley's approach and Sperling's psychoanalytic method quite realistically might have precipitated and/or magnified existing attitudes of dependency, thereby contributing to the patient's problems and prolonging treatment.

2.1.13.2 Hypnotherapy

This technique deals directly with the problem at hand, and involves what is termed gut-centered hypnosis, which enables the patient to exert some control over the activity of their gastrointestinal tract. In a study by Whorwell et al. (1984), the therapeutic effects of hypnotherapy were assessed and compared with the use of supportive psychotherapy in 30 patients with refractory Irritable Bowel Syndrome (IBS). In the group receiving hypnotherapy, seven 30-minute sessions of gut-centered hypnosis were administered to each patient. In addition the patients were given an auto-hypnosis tape to be used at home on a daily basis.

At the end of the three-month study period, the hypnotherapy group reported a significant reduction in their IBS symptoms. In addition, an overall improvement in their general well-being was also reported. These findings differed significantly from both the psychotherapy and control group. There were however, small but significant improvements reported by the psychotherapy group and these were confined to abdominal pain, abdominal distension, and general well-being. At follow-up, the hypnotherapy group reported no incidences of relapses or no other new symptoms (Whorwell et al., 1984). Whorwell's group has extended its work on the use of hypnosis in gastrointestinal disorders and found that these patients also responded favourably to gut-centered hypnosis (Whorwell, 1991).

2.1.13.3 Behavioural Therapies

The application of behavioural therapy involves teaching the patients various exercises and strategies to aid symptom control. Progressive muscle relaxation therapy and thermal biofeedback have been used to treat patients with inflammatory bowel disease. The results of these studies showed that in both

this patient group a clinically significant reduction in their gastrointestinal symptoms was achieved (Milne et al., 1986; Corney et al., 1991).

2.1.13.4 Cognitive-behavioural Strategies

One of the most effective psychological treatments now being offered to patients is a combination of relaxation techniques and cognitive-behavioural strategies (Skinner et al., 1990). This multidimensional approach is aimed at changing the way in which patients evaluate the meaning of their abdominal symptoms. It is also aimed at changing maladaptive behaviours that the patient has developed as a response to coping with their illness. For example, changes in toilet use, avoidance behaviour and excessive use of medication to help control bowel functioning (Watkins, 1997)

From the above evidence supporting the effectiveness of psychological intervention in the management of gastrointestinal disease, it is reasonable to explore further the beneficial effects of other forms of psychotherapeutic intervention, which may prove more practical and efficient in the treatment of Crohn's disease. With these considerations in mind, the psychotherapeutic procedures of Kinesiology and Massaging was proposed as the treatment of choice for this study.

2.2 KINESIOLOGY

Kinesiology, while practiced by a large number of therapists over the last 30 years, has to date accumulated mostly anecdotal clinical data and has not been subjected to critical clinical investigation in the experimental setting. Except for a few Kinesiology text books and workshop manuals, no research articles on Kinesiology were available. Therefore, other fields of literature, dealing with stress release therapies (e.g. meditation, psychotherapy, and autogenic training) in the treatment of Crohn's disease, were also reviewed.

Kinesiology is a psychophysiological form of psychotherapy designed to self-generate a state of psychological and physical relaxation, thereby, restoring the body's homeostasis – a state completely opposite to that elicited by stress. Through the generation of this balanced state, it is believed that the recuperative and self-healing processes of the body are facilitated, “the emphasis is not on trying to control the natural system, but rather on helping natural systems use their inherent potential of self-regulatory adjustment more fully” (Luthe, 1979, p. 167).

The concept of “self-healing” was well appreciated by the ancient Greeks. Hippocrates observed in his treatise *Of the Epidemics*, that, in most diseases, there was a natural tendency to cure (Margotta, 1996).

2.2.1 Psychological Science and Kinesiology

With regard to psychological functioning and dysfunction, there are a variety of theoretical models or frameworks that attempt to explain and make predictions, with psychotherapies and other kinds of interventions resting upon them. For instance, we can think of psychological disturbance as a manifestation of unconscious dynamics, cognitive schemas, schedules of reinforcement and

conditioning, systemic interaction, maladies of brain structures and neurochemistry, heredity, and so on. We assume that all of these facets and conceptualizations are relevant and valid to a greater or lesser extent, depending on the condition under consideration. Therefore, if we were to consider depression as if it were solely a chemical imbalance, without attending to the psychological and physical aspects of the condition, we would be limited in our ability to assist the patient in achieving ongoing relief. Many reductionistic models reach their limits of applicability quickly (Gallo, 2000). It is therefore necessary to search for a broad field theory of mind that will allow one to determine precisely which aspects of functioning are most relevant.

The technique of Kinesiology is based on the “Triangle of Health” principle (Figure 4). This paradigm presents humans as existing in physical, psychological, and biochemical dimensions (Thie, 1996). Therefore, from a Kinesiologic perspective, it is believed that any stressful event would negatively influence biochemistry. This in turn may cause further imbalance in the psychological state, which could then impact negatively on the physical structure creating signs and symptoms of disease (Deal, 1998).

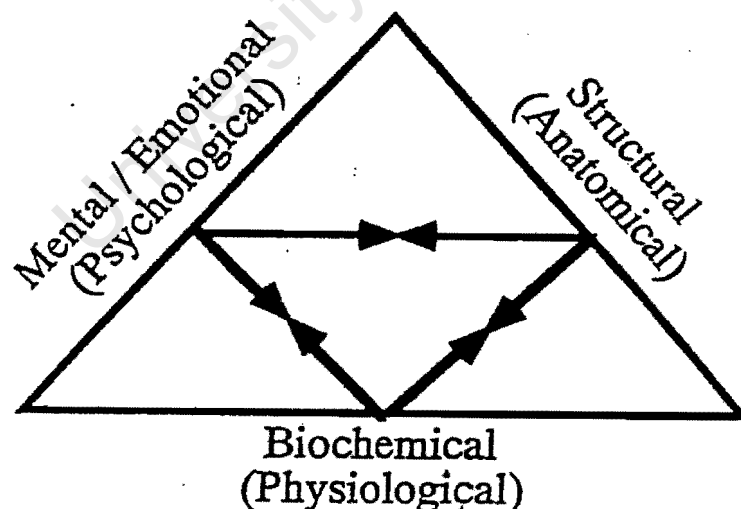


Figure 4: An equilateral representation of the “Triangle of Health” (Thie, 1998).

2.2.2 The Origin of Kinesiology

The word “Kinesiology” is derived from the Greek and generally translates as “study of motion”. In this case it refers to the study of the mechanics of bodily motion, especially muscle movements and their relationship to the rest of the complex body system. The science of manual muscle testing was first developed in the early 20th century by a Boston orthopaedic surgeon, R.W. Lovett. He applied muscle testing to trace spinal nerve damage because it was found that muscles testing “weak” often had a common spinal nerve (Krebs, 1998).

Dr George Goodheart, a Detroit based Chiropractor, began to implement the use of muscle monitoring in his practice. He found some patients had specific muscles that would test weak when they had certain types of diseases. For instance, he noted the pectoralis major clavicular muscle (PMC) would generally test weak in patients who complained of stomach ulcers. He would apply a certain chiropractic manipulation, called origin and insertion (stimulating the muscle joint and bone that serves as a lever for muscle contraction), for the treatment of ulcers and reassess the strength of the PMC muscles. After these treatments the muscles showed strength indicating that the ulcers have improved. This finding seemed to provide evidence of a relationship between ulcers and the muscle response, and the efficacy of the chiropractic treatment (Goodheart, 1986).

In his quest for answers, Goodheart showed interest in the work of an early American osteopath, Frank Chapman, who had observed that many types of pathologies, or the symptoms of diseases, had their origin in sluggish lymph flow. which means that over time, tissues become more toxic and less functional (Guyton, 1991). Chapman theorized that there were many points on the bodies of individuals indicating various symptoms of disease, which, when palpated or massaged, would be tender. With continuous massage, they were found to

become less tender and this was associated with improvement in the disease condition. He called these Chapman Reflex Points (Walther, 1981). Goodheart suggested that many of the disease conditions described by Chapman as being associated with a specific Chapman Reflex Point could also be associated with a specific muscle weakness. He then found that rubbing the reflex point which Chapman had assigned to a disease would often strengthen the muscle associated with the same pathology (Krebs, 1998).

In the 1930's another American Chiropractor, Terence Bennett, presented his model of restoring health based on proper blood flow. Like the lymph system, when blood flow becomes congested, tissues do not get the right amount of oxygen and nutrition. He reasoned that this set up the prime condition for diseases to manifest. Like Chapman, Bennett had worked out his own set of reflex points. Most were on the head and upper body with a few below the waist and on the legs. Bennett theorized that the application of light pressure to these points would stimulate increased blood flow to the associated tissues and organs. As with Chapman's work, it was shown that stimulation of these Bennett Reflex Points would often result in major improvement in the condition being treated (Bennett, 1977).

By synthesizing these theories, Goodheart pioneered a system that combined work done by his predecessors: Chapman's Points (for lymphatic function), Bennett's Points (for vascular function), the origin/insertion technique (for muscle problems), and muscle testing/monitoring for feedback in both diagnosis and therapeutic efficacy (Gallo & Vincenzi, 2000).

Dr Goodheart, who had made the seminal breakthrough that remains the core of Kinesiology therapy, made a further contribution. He believed that when muscles did not respond either to origin/insertion stimulation, Chapman's or Bennett's Reflex Points, that running his hand just above a specific meridian (energy) pathway in the direction of flow that the Chinese had outlined, the weakened

muscles would strengthen. Again it was assumed that a relationship between a specific muscle response and a specific meridian existed (Goodheart, 1966). The Chinese system had provided a layout of thousands of years of observations about the energetic system and the principles by which it works. To this body of knowledge, Goodheart added the muscle response correlation, which meant the energy balance of these meridians and associated organs could be readily and consistently ascertained by direct muscle feedback (Krebs, 1998).

2.3 KINESIOLOGY CONCEPTS AND ASSUMPTIONS

2.3.1 The Body's Bio-energy System

The philosophical basis of Kinesiology is that health is wholeness and balance of subtle bio-energy and that ill health relates to an imbalance of this energy (Seaward, 1994).

Subtle energies have been long recognised within Eastern traditions and are known by different names, for example, Ch'i or Prana. Ch'i is based on the Eastern philosophy that there is an energy that flows within us in a harmonious, balanced way, an active balance that is known as health. It is believed that when this energy is not flowing as it should, there is disharmony and imbalance, which is known as illness (Dawson, 1999). Teeguarden (1987) defines Ch'i or Prana as a life force of subtle bio-energy which influences balance both in the body and in the psyche and can regulate physical and psychological functioning.

With these cautions in mind, it has been proposed by Gallo (2000) that psychological functioning in general and psychological disturbances in particular can be effectively viewed, to a significant degree, in terms of subtle bio-energy information or configurations. Healthy psychological functioning, as well as

health in general, is assumed to be consistent with a balance or unobstructed current of bio-energy, while psychological disturbances are consistent with imbalance or encumbered "flow".

The use of energy to heal human illness has been known throughout history (Gerber, 1988). Chinese acupuncture heals, based on restoring the flow of Ch'i. Healing in the deepest sense is difficult to perceive. Modern medicine is not certain what it is that enables healing to occur. Five thousand years of Chinese health care and philosophy, 3,000 years of Indian Ayurvedic and the more recent Western Homeopathic philosophy all reason that there is an innate intelligence in the body which is always moving toward dynamic balance and therefore wellness (Chopra, 1989; Passwater, 1994; Capra, 1982).

2.3.2 Meridians

The meridian system (energy pathways) is believed to communicate energetic information throughout the human body (Gallo & Vincenzi, 2000). The theory of the human energy system eventually led to the development of acupuncture. This is a procedure by which the body's energy is assumed to be altered by stimulating, with needles, specific points (acupressure points) along twelve major energy pathways that are known as meridians (Gerber, 1996).

According to Chinese medicine, there are 14 major meridians in the body. Two of these meridians, the Governing and Central meridians, is believed to flow up from the region of the crotch. The Central meridian runs up the midline in front of the body to a point just below the bottom lip. The Governing meridian runs from the coccyx, up the spine, over the top of the skull to a point just below the nose on the upper lip. The other 12 meridians are bilateral (Xinnong, 1987). Each of the meridians is believed to flow through a specific organ in the body for which they are named: lung, heart, spleen, stomach, kidney, gallbladder, liver, small

intestine, large intestine or bladder (Figure 5). The entire system is assumed to be interconnected so that the life energy travels from one meridian to the next, circulating throughout the body (Gerber, 1996).

It is believed that each one of these meridians consists of acupressure points. In acupuncture treatments, these points are used. It has been assumed that acupressure points perform various functions. Therefore, during acupuncture therapy, needles are inserted into the body at selected tonification or stimulation points (to increase the flow of energy), or at selected sedation points (to decrease the flow of energy). Through trial and error, acupuncture has been developed and used by Chinese physicians to eliminate pain and to treat a wide variety of illnesses. Several countries now use acupuncture as an alternative anesthesia during surgery (Gallo & Vincenzi, 2000).

Although acupuncture has been developed and used by Chinese physicians, increasingly, people are accepting acupuncture as a viable alternative health care treatment (Gallo & Vincenzi, 2000). The World Health Organisation cited 104 conditions that can be treated by acupuncture, including gastrointestinal disorders (Burton Goldberg Group, 1993).

From a scientific viewpoint, trying to prove that there is an energy system with acupressure points is very difficult. There have been several attempts to document the existence of this energy system. Langman (1972) examined the relationship between energy and disease. He found that in a sample of 123 women with malignant cervical conditions, 5 had a positive energy charge in the cervix and 118 had a negative energy charge. The numbers were reversed in the control sample that had no cancerous conditions. This study does not prove that negative polarity causes cancer, because it is possible that cancer itself leads to the negative charge. However, this research does suggest that a specific energy difference exists between those who are healthy and those with disease (Langman, 1972).

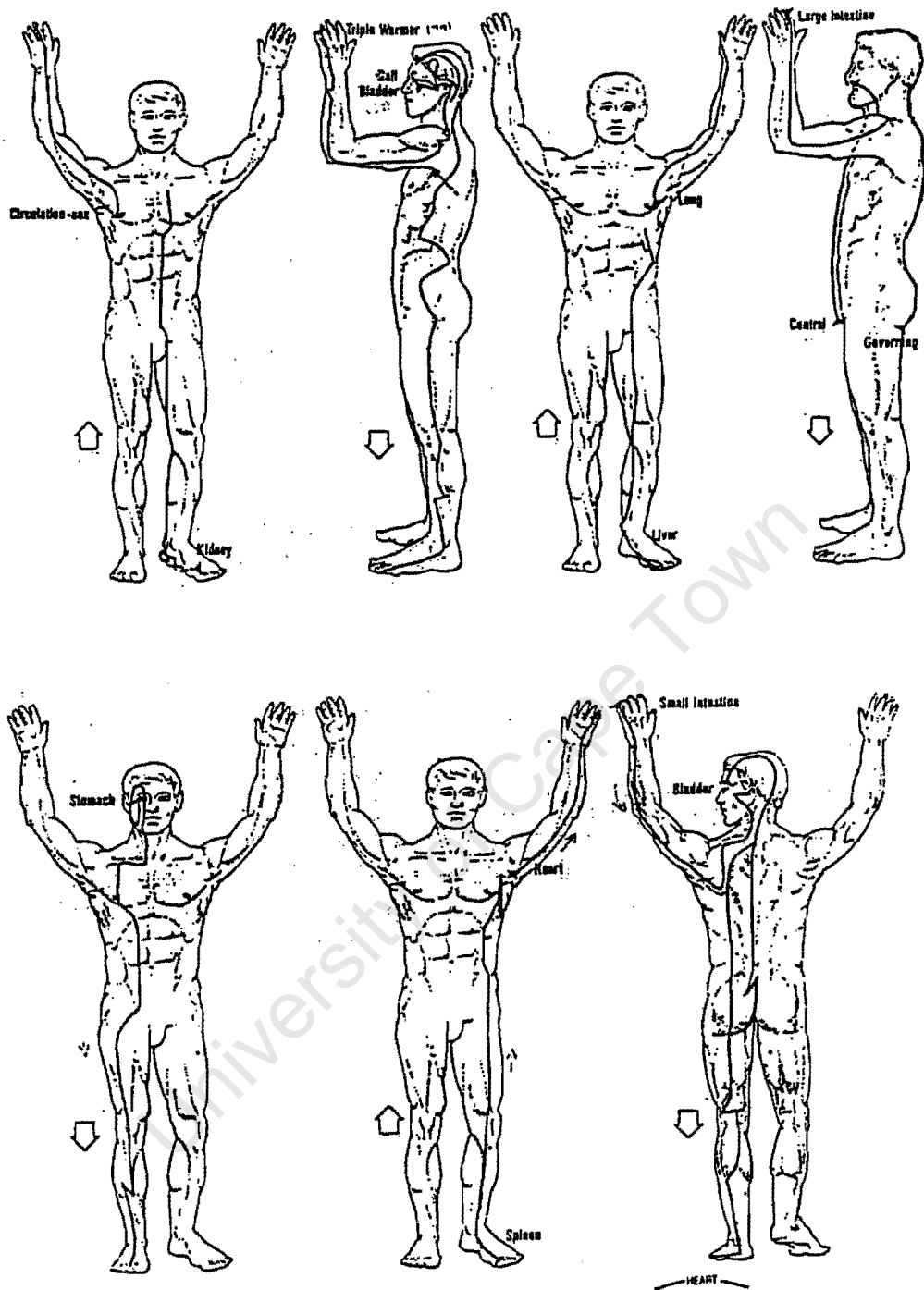


Figure 5: The 14 major meridians providing the flow of energy throughout the body (Thie, 1998).

2.3.3 Acupressure Points

There have been several attempts to document the existence of acupressure points. Robert Becker (1990), an orthopedic surgeon, examined the theory that meridian acupressure points are electrical conductors and that meridians are used to send messages back and forth from the brain and the injury site – to promote healing and create the conscious perception of pain. He developed an interesting and pertinent research approach. He proposed that the meridians were the electrical conductors that relay information from the site of an injury to the central nervous system. He thought that perhaps acupuncture needles served to block the pain message from getting to the brain by short-circuiting the electromagnetic current in the meridian (Becker & Seldon, 1985).

Another researcher, Maria Reichmanis (1976), a biophysicist, and her associates developed a device that could be rolled along the assumed meridians to detect differences in electrical skin resistance. They theorized that if an electrical charge truly existed at the location of the acupressure point, there would be a difference in skin resistance at that point as compared to the surrounding skin. Their findings were consistent enough across subjects to strongly suggest that meridians and acupressure or acupoints exist (Reichmanis, Andrew & Becker, 1976).

It is further suggested that many of these acupressure points, depending upon their location on the meridians, have distinct functions, accounting for unique vibrations or energy frequencies as well as neurologic specificity (Gallo, 2000). It is believed that at some locations there is a very subtle difference (Yang, 1989). This is consistent with the literature on acupuncture, which describes a rich variety of individual points. For example, “alarm points”, which are employed in a number of systems, are utilized for diagnosis and treatment. “Sedation points”, are believed to balance overactive meridians, while “tonification points” are assumed to balance under-active meridians (Walther, 1988). According to the

model presented above, it is believed that meridians are not only associated with specific organs and muscles (Goodheart, 1987; Thie, 1973), but also with specific emotions (Diamond, 1985).

2.3.4 Meridians and Emotions

It is believed that there is an interface between meridians and emotions, such that various positive emotions are evident when the meridians are balanced (i.e. love, joy, cheerful, forgiveness, tranquility) and various negative emotions predominate when the meridians are disrupted (i.e. hate, sadness, unhappiness, anger, disgust). It has been reported by some authors (Becker & Selden, 1985) that an association between specific meridians and certain emotions exist. Although there is one continuous, interconnected bio-energy system, the system is nonetheless divided into segments or meridians, and within each of the meridians are acupuncture points (Becker & Selden, 1985). Diamond (1997) asserts that he arrived at his designations by way of manual muscle monitoring.

2.3.5 The Concept of Muscle Monitoring

The term "indicator muscle" was introduced to describe a muscle which showed a transient loss of isometric muscle strength in relation to a stimulus (Walther, 1988). Research to test the validity of this new evaluation tool was initially conducted by chiropractors in clinical practice (Walther, 1988; Goodheart, 1985), however, these findings were never published.

Rolfes (1996) evaluated the nature and phenomenon of muscle monitoring which she termed "indicator muscle change" (IMC). Firstly, she evaluated the

relationship between individual muscles and spleen meridian. In a double-blind study, she tested the hypothesis that indicator muscle response would be changed when the magnetic energy in the spleen meridian was altered. Two examiners tested three groups of healthy participants. The first group consisted of 29 students and Examiner A performed 290 tests. The second group consisted of 30 different students and Examiner A performed 300 tests. The third group consisted of 24 students and a different examiner, Examiner B who performed 240 tests. Rolfes (1996) found that IMC was a reliable tool to evaluate change of magnetic polarity over specific acupressure points.

In the second part of her study, Rolfes (1996) considered whether stressful stimuli and negative emotional attitudes could elicit IMC. The results of her experiments revealed that IMC or "Kinesiographical muscle testing" monitors a subtle loss in neuromuscular integrity due to stressful stimuli.

The above study investigated whether negative emotional attitudes would give a changed indicator muscle response, hence the term – indicator muscle change. It is thus clear that muscle monitoring is simply that, monitoring a change, which obviously entails issues of reliability and validity. The test is employed as an indicator. In this regard, if a muscle test were to indicate that treating a specific meridian was needed to alleviate a disturbance in the energy system of the body, the test would not be accepted as the final authority. The outcome would be noted. If the outcome was positive, one would be inclined to conclude that the test was accurate, that it correlated well with treatment needs. If, on the other hand, the problem is not alleviated, one could question the validity of the test in that particular context. While some other factor might be involved, one would nonetheless scrutinize the test results (Gallo, 2000)

2.3.6 The Muscle - Emotion Interface

It was theorized that the subconscious area of the brain, that controls or elicits our emotions, is located in the limbic brain (Noback, 1991). There are direct neurological connections between the limbic brain and the pathways that control the muscle tone and tension (Strominger & Demarst, 1991). Tightness in the neck when we are anxious and worried; churning stomach when we are nervous, are examples of mental events that have a telling physical effect on our bodies. This is thought to occur because the part of the brain that controls our emotional and physical survival programs also subconsciously sets the tone of our muscular system (Gallo, 1998). Therefore, it is assumed that our emotional states are very graphically portrayed in our physical postures – a depressed or unhappy person would present with a posture of slumped shoulders, dropped head, drooping mouth or downcast eyes.

Since Kinesiology monitors muscle tone, it is linked to the emotions that are setting that tone. When monitoring a muscle, it is assumed possible to get in touch with the interface between the neurological physical body, and the emotions and thoughts that affect that body (Krebs, 1988). Emotions and thoughts may affect muscle function through two pathways (Figure 6). One is through the Limbic brain and its effects on muscle tone. The other is via the energy systems and their effects on the physiology of muscle response (Krebs, 1988).

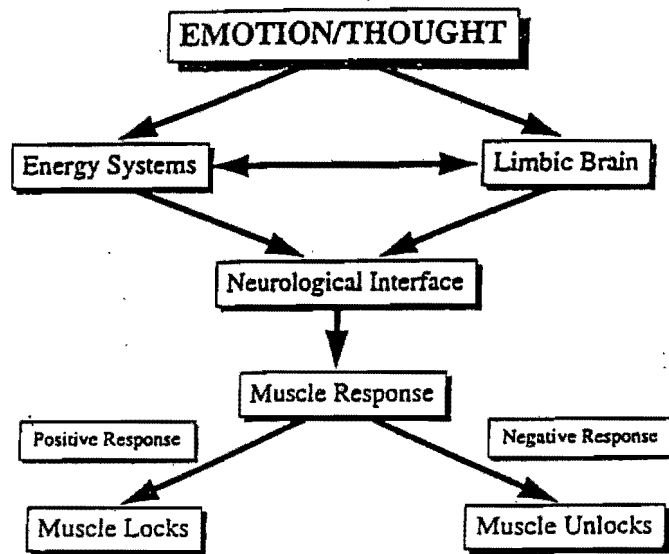


Figure 6: The Emotional – Muscle Interface (Krebs, 1998).

2.3.7 Emotional Stress Defusion (ESD)

Stokes and Whiteside (1985), while working with severely depressed patients, discovered that unresolved emotional stress was the basis of most blockages in the bodily system which hampered personal, emotional and spiritual growth, as well as the body's own self-healing mechanism. They developed an emotional defusion technique which was not just the release of emotions, but it served to diffuse and then reintegrate into the system what had otherwise been unresolved emotional experiences (Krebs, 1998).

ESD is a technique that is believed to alter the blood flow patterns in the brain – under stress the brain redirects blood flow, which contains vital oxygen and glucose, to those areas of the brain that are most important for survival. When the individual is confronted with a threatening experience the limbic

centers become extremely active and access the cortical areas at the back of the brain where past memories have been stored. These areas therefore, demand high levels of blood flow. This flow of blood to areas in the frontal brain, that are involved with associational thinking, our conscious thoughts, is temporarily shut down so that our thoughts do not interfere with the ability to react. Threatening circumstances require one to react and not think about action. This immediate action is really a re-action or a re-enactment of a survival program that has been successful in the past. In other words, when the brain becomes aware of threat, within 1/500th of a second the limbic brain reviews all of the experiences you have had that closely resembles the one you are presently undergoing. Without your conscious awareness, the limbic brain chooses the past program that had the highest survival rate in similar situations. This program is then relayed and directs your behaviour, serving as a reference, so you can re-enact the behaviour that enabled you to survive in the past (Krebs, 1998).

Information regarding the origin of the specific emotional issue is obtained by implementing the technique of muscle monitoring.

2.4. KINESIOLOGY THERAPY

Kinesiology therapy is based on six main procedures – (1) Assessing for neurologic disorganization; (2) a 14 muscle assessment utilizing the process of muscle monitoring; (3) a neurolymphatic stimulation (using Chapman's Reflex Points) to stimulate the lymph flow; (4) a spinal reflex stimulation to enhance the flow of cerebrospinal fluid; (5) a neurovascular stimulation (using Bennett's Reflex Points) to increase energy flow from the brain to all parts of the body; and (6) Emotional Stress Defusion (ESD) to desensitize all emotional and psychological blockages (Gralton & Gralton, 1999).

2.4.1 Neurologic Disorganization

The phenomenon of neurologic disorganization, also referred to as polarity switching, is a significant block to energy diagnostic and treatment effectiveness. When using manual muscle testing as an indicator for therapeutic approach, it is assumed necessary that the nervous system be organized to provide correct information, otherwise, the therapy might be directed to the wrong area of the body (Walther, 1988).

The functioning of muscles in healthy neurologically organized people shows consistently predictable characteristics. Most muscles are paired, so that one side tenses or facilitates when the opposite side relaxes or inhibits. This coordinated action of muscles is mediated by the spinal cord and the central nervous system through an intricate interplay of afferent (conduct impulses from the periphery of the body to the brain or spinal cord) and the efferent (conduct impulses from the central nervous system or spinal cord to effectors, either muscles or glands that are capable of responding to the nerve impulse) signals. The various sensory receptors send signals to the central nervous system, which in turn regulates facilitation and inhibition of the respective muscles in a coordinated, organized fashion. When conflicting afferent signals are sent to the central nervous system the person becomes neurologically disorganized (Gallo, 2000).

Disorganized muscle functioning appears to entail disorganization of the cerebral hemispheres, as well as bodily polarity imbalances. For example, disorganization between the hemispheres and the body's bilateral symmetry is consistent with right side/left side polarity imbalance and anterior/posterior (i.e. front/back) and superior/inferior (i.e. top/bottom) directionality (Gallo, 2000).

2.4.2 Fourteen – Muscle Assessment

Muscle monitoring is used as a biofeedback mechanism that allows for the assessment of the body's functioning level, and to assess for compromised areas so that correction procedures may be performed which will allow the body to perform its natural functions of self-healing, regenerating and repairing. Muscle monitoring consists of assessing each one of the 14 muscles (Figure 7) that are related to the 14 major meridians in the body (Table 1). An unlocked muscle response will indicate a restriction in the energy flow of the related meridian which will have to be corrected by means of a Neurolymphatic massage, Spinal reflex stimulation, Neurovascular stimulation or an Emotional Stress Defusion (Gralton & Gralton, 1999).

Table 1: 14 Muscles used for Muscle monitoring and their corresponding meridians.

MUSCLE	CORRESPONDING MERIDIAN
Supraspinatus	Central
Teres Major	Governing
Pectoralis Major Clavicular	Stomach
Latissimus Dorsi	Spleen
Subscapularis	Heart
Quadriceps	Small Intestine
Peroneus	Bladder
Psoas	Kidney
Gluteus Medius	Circulation Sex
Teres Minor	Triple Warmer
Anterior Deltoid	Gall Bladder
Pectoralis Major Sternal	Liver
Anterior Serratus	Lung
Fascia Lata	Large intestine

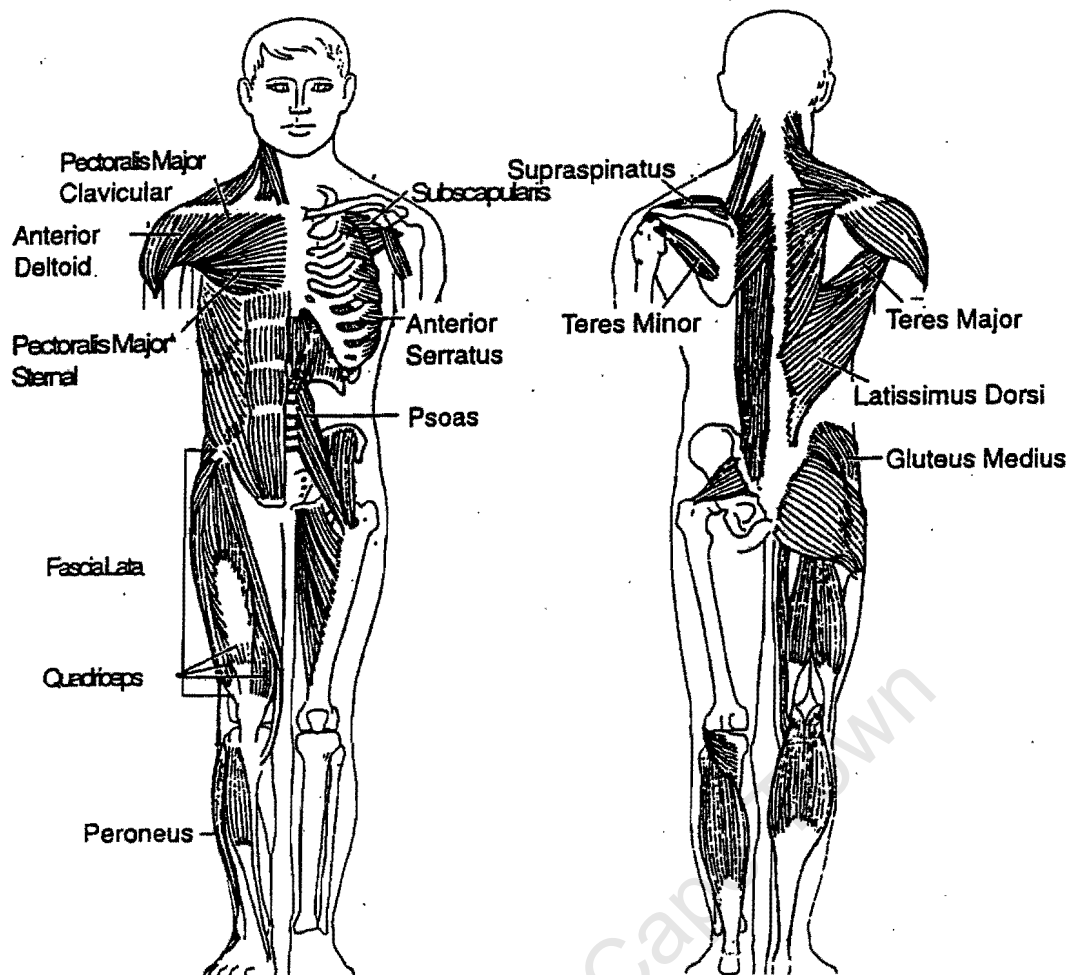


Figure 7: 14 Muscles used for assessment (Thie, 1998).

2.4.3 Neurolymphatic Massage

The lymphatic system is part of the overall circulatory system. The lymph acts as a drainage system. It also produces antibodies, and transports a quarter of the white blood cells which are responsible for fighting infection (Gerber, 1996). Neurolymphatic reflex points are located mainly on the chest and back of the body (Figure 8). Their location does not necessarily correspond to the lymph glands, but are related energetically. Stimulation of the neurolymphatic reflexes is believed to aid in lymph flow. Therefore, when a muscle does not lock, massaging the neurolymphatics for that muscle can unblock the energy flow to

the specific organ and will reinstate the integrity of the muscle. The previously unlocked muscle should now lock when tested (Gralton & Gralton, 1999).

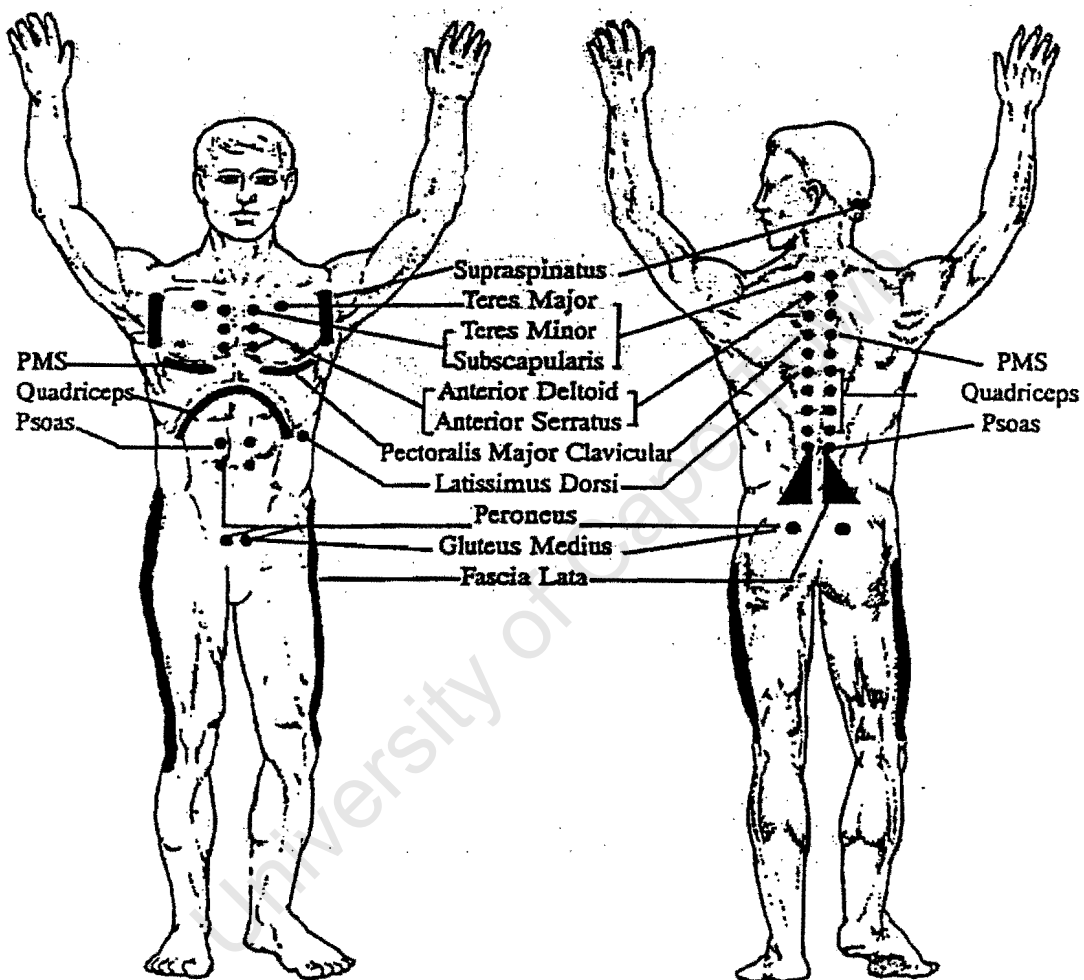
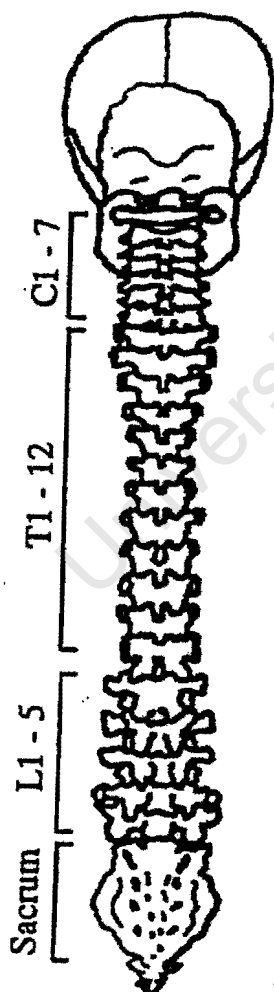


Figure 8: Neurolymphatic or Chapman Reflex points situated on the front and back of the body (Gralton & Gralton, 1999).

2.4.4 Spinal Reflex Stimulation

When the muscle weakness is bilateral (both sides unloading), the spinal reflex points should be stimulated first. Unlike neurolymphatics, these rubbing points are located on the spine itself (Table 2). The spinal reflex point is rubbed up and down the vertebrae, covering one or two levels above and below the involved correction point. If, after having attempted the neurolymphatic massage as well as the spinal reflex stimulation, the muscle still tests weak, the neurovascular holding point will be the next option (Gralton & Gralton, 1999).

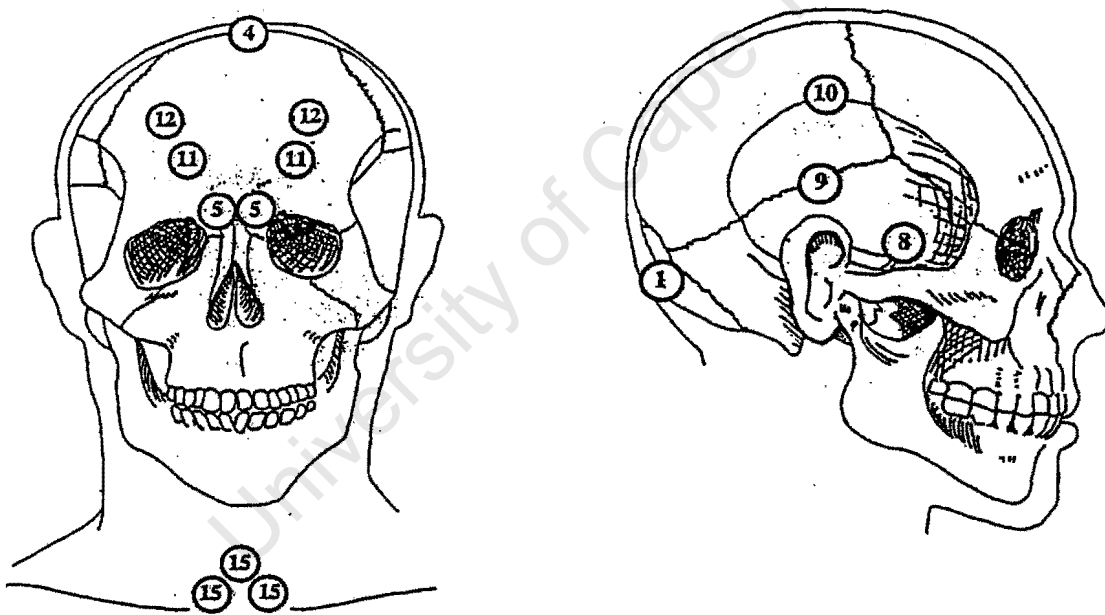
Table 2: Spinal reflex points situated on the spine and the corresponding muscles (Gralton & Gralton, 1999).



MUSCLE	SRP
Supraspinatus	C1-2
Teres Major	T2
Pectoralis Major Clavicular	T5
Latissimus Dorsi	T7
Subscapularis	T2
Quadriceps	T10
Peroneus	T12
Psoas	T11-12
Gluteus Medius	L5
Teres Minor	T2
Anterior Deltoid	T4
Pectoralis Major Sternal	T5
Anterior Serratus	T3-4
Fascia Lata	L2

2.4.5 Neurovascular Holding Points

The neurovascular holding points are located mainly on the head (Figure 9). By holding the appropriate point the neuronal associations and acupuncture meridians are stimulated. This in turn promotes increased blood flow to the muscle and the related organ or gland. The previously unlocked muscle should now lock when tested (Gralton & Gralton, 1999). At the end of this session the body will be assessed for emotional blockages using muscle monitoring to determine the specific years when traumas or emotional disturbances occurred. If, however, there is an indication that emotional or psychological issues are present, the second session will consist of the ESD procedure to desensitize all these issues (Thie, 1998).



4 Supraspinatus	1 Psoas
Subscapularis	8 Teres Major
Anterior Deltoid	Teres Minor
Anterior Serratus	9 Latissimus Dorsi
5 Peroneus	

11 Supraspinatus	10 Quadriceps
Pectoralis Major Clavicular	Gluteus Medius
Peroneus	Fascia Lata
12 Pectoralis Major Sternal	
15 Teres Minor	

Figure 9: Neurovascular holding points or Bennett Reflex points situated on the head and their corresponding muscles (Thie, 1998).

2.4.6 Emotional Stress Defusion

The Emotional Stress Defusion is a very important aspect of Kinesiology therapy. During this session, deep rooted emotional stress, related to past traumas, accidents, emotional overload, pressure from work or relationships etc. are released and desensitized. Patients are taught the necessary skills to deal with future issues in a positive way. Since a number of researchers indicate that Crohn's patients have unresolved issues (Jackson & Yalom, 1966; Sojit, 1969; Schwartz & Schwartz, 1982), the emotional stress therapy would be most appropriate for this population.

2.4.7 Kinesiology Therapy and Crohn's Disease

While there are no published reports of utilizing Kinesiology therapy with Crohn's disease patients, there are numerous experimental findings demonstrating the beneficial effect of relaxation and stress release therapies upon patients with a similar inflammatory bowel disease, Ulcerative colitis (Schwartz & Blanchard, 1991), as well as Crohn's disease (Jantschek et al., 1998; Hershfield et al., 1993;

Baum, 1981). According to these researchers, relaxation therapies (Meditation, Autogenic training, Psychotherapy, Hypnosis etc.) may psychophysiologicaly facilitate normal intestinal functioning by relieving stress and normalizing autonomic regulation – contributory, and possible causative factors in exacerbations of Crohn's disease symptomatology. However, all of these studies used very small samples, and none employed adequate comparative control groups. With this cautionary note, a review of this pertinent literature follows.

The largest sample utilizing a relaxation therapy, Autogenic training, with a nonspecific, ulcerative disease of the colon is Schaeffer's (1966) study. He investigated 32 Ulcerative colitis patients, of which 9 cases were judged clinically mild, 10 were moderate, and 13 were severe. In 23 cases "rest-hypnosis" and Autogenic training was occasionally added to medical care. Medication was used sparsely, and in some cases not at all. Results indicated that only 3 patients showed no improvement, the remainder improved significantly, and 23 went into complete remission (Schaeffer, 1966). These results were drawn after treatment periods ranging from 12 months to 12 years. Schaeffer concluded from his work the following:

Autogenic training (a) stabilizes and normalizes disturbances of relevant autonomic functions better than any other method; (b) reduces progressively the frequency of relapses; (c) shortens and diminishes the degree of severity of relapses; and (d) eliminates the necessity of medication in most cases or reduces required medication in others (in Luthe, 1969, p. 24).

Another study (Shaw, 1987) cites the use of relaxation therapy with 20 inpatients. Each patient received 6 weekly training sessions in the technique of progressive relaxation. Another 20 patients with the same condition constituted the control group. There were no significant differences between experimental and control subjects before treatment but immediately after treatment and also at the 6-week follow up, the experimental and control subjects differed significantly on 6 to 7

measures. The experimental group showed a remarkable improvement. Some examples of the changes reported were: weight gain, improved mood, reduced stress level, less pain, increased appetite and normal stool.

Additional supportive evidence for the use of relaxation and stress release therapies with Crohn's disease is taken from its demonstrated ability to improve psychological symptoms commonly found among these patients – anxiety and depression (Porcelli et al., 1994; Richards et al., 1994; North et al., 1994; Schwartz et al., 1982).

In sum, since Kinesiology therapy is a process of restoring balance to a body that has been debilitated physiologically as well as psychologically, it appears an appropriate choice of treatment for Crohn's disease for the following reasons: (1) there is evidence to suggest that relaxation and stress release therapies are useful in diminishing Crohn's disease symptoms; (2) it would be helpful in treating anxiety, depression, and other emotional conditions; (3) the degree of dependence on the attending physician is minimal since patients learn to do some of the therapeutic work by themselves at home; (4) the combination of correction techniques available allows the therapist to tailor an effective flexible treatment program to the patients and the particular disorder; (6) it has the potential of providing a cost-effective therapeutic procedure; and most importantly (7) these are all effects which could be valuable in adaptation to Crohn's disease and thereby improve the quality of life in this population.

CHAPTER 3

METHODOLOGY

3.1.1 Participants

One hundred and fifty Crohn's disease patients, attending the Inflammatory Bowel Disease (IBD) clinic at Groote Schuur Hospital, were recruited for this study. Following acquisition of informed consent (see Appendix 1), patients were randomized into 3 groups of 50 by means of a number draw. The random selection of the patients was to ensure that each group was similar, and resembled the Crohn's disease population as closely as possible. Thus, the results of this study could be generalized to the population as a whole (Harris, 1996).

Permission to perform this study was obtained from the Research and Ethics committee, University of Cape Town (see Appendix 2). Good clinical practices (GCP) were maintained throughout the study and participants continued with their prescribed medication. Participants were assured of anonymity with regard to documentation of all data. Therefore, each participant was assigned a code number which was used instead of their names.

3.1.2 Study Design

The Kinesiology Group received a 60-minute Kinesiology session on a monthly basis for four months (four sessions). The Massage Group received a 60-minute Massage session on a monthly basis for four months (four sessions). The Control Group continued with their usual clinical management, and medical therapy was continued as usual in all three groups. The three groups were assessed at entry into the study to acquire baseline data, and then at the end of

the four-month intervention period and three-month follow-up to determine the effectiveness of the intervention (see Figure 10 for study design).

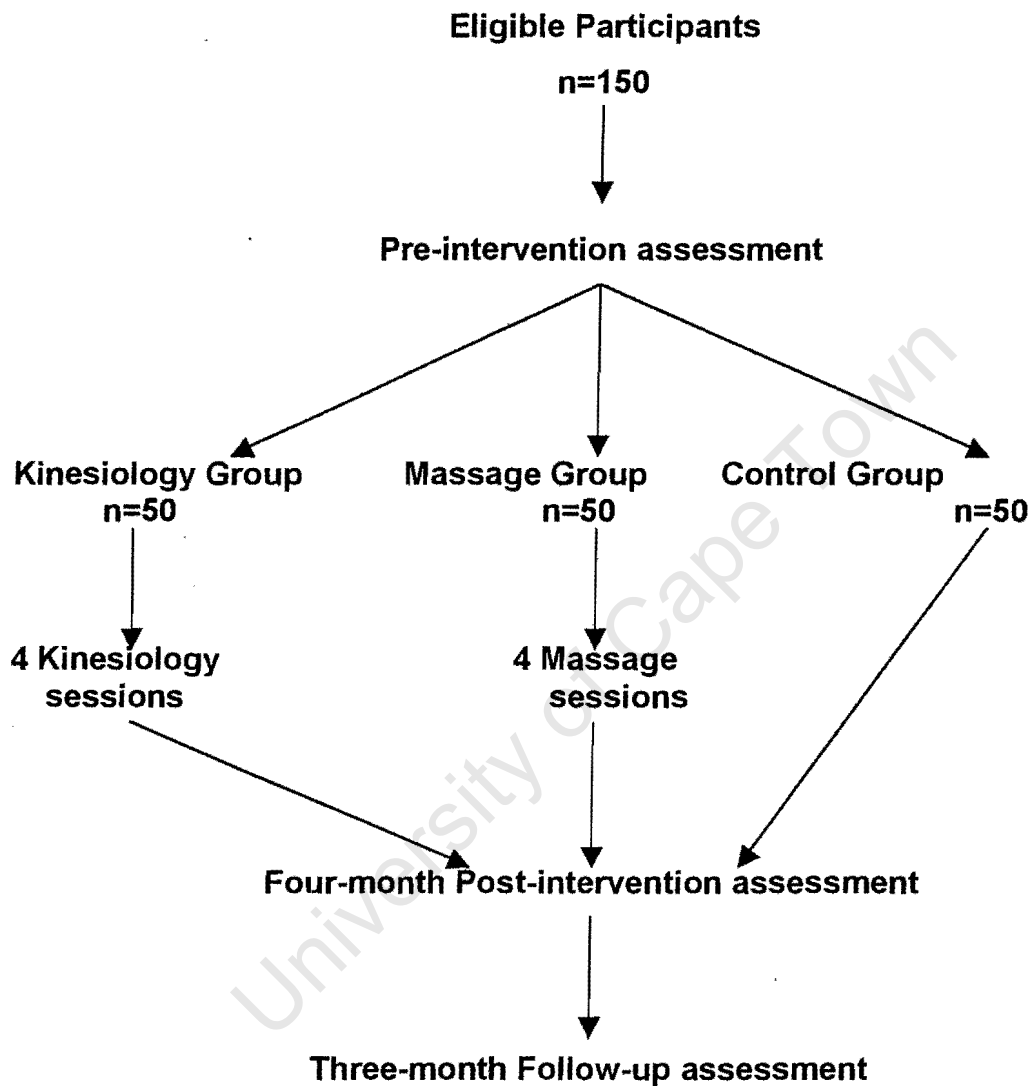


Figure 10: Study Design

3.1.3 Inclusion Criteria

At the time of enrolment participants had to:

1. Have a definite diagnosis of Crohn's disease based on histologic or radiologic findings
2. Be 18 years of age and above
3. Have had the disease for at least 5 years
4. Be English speaking in order to comprehend the instructions on the questionnaires

3.1.4 Review of Case Notes

Each patient's folder was reviewed to obtain the following information:

Demographic Data

1. Name
2. Gender
3. Date of birth (see Appendix 3)

Medical History

1. Date of diagnosis
2. Extent of the disease
3. The number and duration of clinical relapses in the last year
4. The number of Crohn's related surgeries (see Appendix 3).
5. Steroid or immunosuppressive usage

3.2 PARAMETERS USED FOR THIS RESEARCH

Disease activity was assessed by means of the Crohn's Disease Activity Index (CDAI). Quality of life by means of the Short Inflammatory Bowel Disease Questionnaire (SIBDQ), and psychological state by means of the Profile Of Mood States (POMS). A decrease in CDAI indicates an improvement in disease activity and a decrease in POMS an improvement in psychological mood states, whereas an increase in SIBDQ indicates an improvement in quality of life.

3.2.1 Crohn's Disease Activity Index (CDAI)

The CDAI is a numerical index of the patient's degree of illness designed to allow a systematic means of evaluating a patient's medical disease activity (Best, Bechtel, Singleton & Kern, 1976). The CDAI includes eight physiological measures related to Crohn's disease activity which are weighted and totaled to arrive at an activity index score (see Appendix 4 for a copy of the form). Index values of 150 and less are considered to indicate remission, values above 200 and below 450 reflect an active disease process, and values above 450 suggest very severe disease activity (Best et al., 1976). Parenthetically, Best et al. (1976) state that they consider a cut-off value between active and remission to lie in the 100 to 200 range. They chose the midpoint of 150 as a reasonable compromise.

The CDAI consists of 8 items. Information for items 1-3 was provided by the participants through their daily record on Symptom Recording Sheets (i.e. the frequency of loose stools, the extent of abdominal pain, and general well being) which were recorded during the seven days before their hospital visit. Items 4-8 were provided by the attending physician from data gathered during the patient's examinations. It is important to note that activity is not synonymous with the presence of extensive disease. The limitations of the Activity Index are merely

because of various factors which results in the end state of the patient's clinical status in Crohn's disease (Teixeira & Ferguson, 1979, p.72).

3.2.2 Short Inflammatory Bowel Disease Questionnaire (SIBDQ)

Health-related quality of life (HRQOL) is an important determinant of health outcomes in chronic diseases such as inflammatory bowel disease (IBD). Disease-specific questionnaires are the most effective type of HRQOL instruments to define fluctuations in health status or response to treatment (Guyatt et al., 1993). The Inflammatory Bowel Disease Questionnaire (IBDQ) has been valuable for assessing disease outcomes in patients with IBD (Mitchell et al., 1988; Guyatt et al., 1989; Irvine et al., 1994). However, administration, scoring, and interpretation of this questionnaire may be quite cumbersome for clinicians. Therefore, the Short Inflammatory Bowel Disease Questionnaire (SIBDQ), which is a shorter version of the IBDQ was used for this study (see Appendix 5).

The SIBDQ, being a disease-specific, health-related quality of life questionnaire, has been specifically designed for practical use by community physicians to aid with the treatment of Crohn's disease (Irvine et al., 1996). In the clinical setting, the IBDQ takes approximately 20 minutes to complete when interviewer-administered, or 15 min when self-administered. Previous research has shown that results are valid for both self and interviewer administration (Mitchell et al., 1988; Guyatt et al., 1989; Irvine et al., 1994). It was estimated that after one test administration, patients could complete the SIBDQ in approximately 5 minutes. It can thus be noted that this method of assessing health status in Crohn's disease patients has the advantage of being short, easy to administer, and most importantly, easily understood by patients.

The SIBDQ consists of 10 items. Each item is scored on a 7-point graded scale where 1= "All of the time"; 2= "Most of the time"; 3= "A good bit of the time"; 4=

“Some of the time”; 5= “A little of the time”; 6= “Hardly any of the time”; and 7= “None of the time”. Absolute SIBDQ scores thus range from 10 (poor HRQOL) to 70 (optimum HRQOL) with 49-70 considered as normal. These items purport to measure Social, Emotional, Bowel, and Systemic functioning during the last two weeks prior to the patient’s clinical visit.

The SIBDQ was generated from a large study population of 149 patients and was tested in two other populations to avoid bias. Since these scores were found to be valid, reliable, and responsive to important clinical changes (Irvine et al., 1996), it seemed an appropriate choice for this research.

The SIBDQ was tested on one of the trials in which the IBDQ was fully validated (Irvine et al., 1994; Feagan et al., 1994). The SIBDQ explained over 90% of the variance of the IBDQ and correlated very well (r range, -0.3 to -0.7) with disease activity indices in Crohn’s disease. Mean SIBDQ scores differed in patients with active and inactive disease (discriminant validity) and gave comparable results among groups of Crohn’s patients with similar disease severity (convergent validity). Consistent SIBDQ scores were maintained when no important changes in clinical status had occurred – of 141 patients with Crohn’s disease who had not experienced a relapse by the first follow-up visit, the mean SIBDQ scores were not significantly different from baseline, indicating good reliability. Interclass correlation coefficients were comparable for the SIBDQ, IBDQ, and disease activity indices, supporting their limited measurement error and good test-retest reliability (Irvine et al., 1996).

3.2.3 Profile Of Mood States (POMS)

Evaluation of the adverse impact of Crohn’s disease on patient’s quality of life and the psychological distress related to them has been recognized as having great clinical importance. Previous studies (Porcelli et al., 1994; Garrett et al., 1990; Schwartz et al., 1982; Gerbert, 1980; North et al., 1994) have found

distress to be a common psychological characteristic among patients with Crohn's disease. The present study sought to assess participant's distress to determine whether these levels of distress were affected by the treatment.

The understanding of the psychology of emotions requires not only the inclusion of psychological and behavioural data but also subjective data of feeling and mood. To meet this need the POMS has been developed to measure six identifiable mood or affective states: Tension-Anxiety; Depression-Dejection; Anger-Hostility; Vigor-Activity; Fatigue-Inertia; and Confusion-Bewilderment. The POMS consists of a list of 65 adjectives. Respondents indicate the degree to which each adjective describe themselves during the last week using a 5-point Likert-Scale format. Standard scoring of the POMS provides a global distress score referred to as Total Mood Disturbance (TMD) as well as scores for the six subscales. Completion of the POMS takes approximately 3 to 7 minutes in healthy populations. Physically ill or otherwise compromised individuals may require up to 20 minutes to complete the POMS (Schacham, 1983). This could place an undue burden on an individual, particularly when the POMS is embedded in an assessment protocol consisting of multiple measures.

For the purpose of this research the POMS-Short Form (POMS-SF: Shacham, 1983) was used (see Appendix 6). The POMS-SF consists of 30 adjectives which an average individual can easily understand. Completion of this scale takes approximately 3-5 minutes. As with the original POMS respondents indicate the degree to which each adjective describes themselves during the last week using a 5-point Likert-Scale format. Where 0= "Not at all", 1= "A little"; 2= "Moderately"; 3= "Quite a bit"; and 4= "Extremely". Each mood factor consists of 5 adjectives. All items defined in each factor are keyed by adding one, except for the adjective "Efficient" in the confusion scale. This item receives a negative weight in calculating the factor scores. The Total Mood Disturbance score is obtained by adding the five scale scores of Anxiety, Confusion, Depression, Fatigue, Tension, and Vigor. The score for Vigor is then subtracted from these

scores (McNair et al., 1992). The Total Mood Disturbance score gives a range from 30 (no distress) to 124 (severely distressed).

The POMS-SF provides both an overall TMD score as well as scores from each of the six subscales contained in the original POMS. In the development of the POMS-SF, several items from each POMS subscale were eliminated on the basis of their impact on subscale internal consistency and face validity (Curran, Andrykowski & Studts, 1995). In a study using data collected from 83 cancer patients, TMD and subscale scores from the POMS-SF were highly correlated with TMD and subscale scores from the POMS (all r 's $>.95$). Internal consistency estimates of the POMS-SF scales using coefficient alpha ranged from .80 to .91, and internal consistency estimates using the original POMS scales ranged from .74 to .91 (Curran et al., 1995). These results suggest that the POMS-SF is an excellent alternative to the more time-consuming POMS - it preserves subscale information available in the original POMS without any significant decrease in internal consistency.

This scale has since been used to measure psychological distress in a variety of medical populations, including bone marrow transplant survivors (Baker, Curbow & Wingard, 1991), seriously ill patients and their families (Oye, Laudefeld & Jayes, 1990), and homosexual men with AIDS or AIDS-related complex (Mouton, Sweet, Temoshok & Mandel, 1987).

3.2.4 Use of Tests

The Crohn's Disease Activity Index is a published test and can be used freely for assessing Crohn's disease patients in a medical setting. The Short Inflammatory Bowel Disease Questionnaire and the Profile Of Mood States assessment test was purchased directly from the authors by the researcher. The researcher was therefore, fully licensed to use these tests.

3.3 PROCEDURE

3.3.1 Diary Card

During the recruitment period, individuals meeting the inclusion criteria were given a diary card (see Appendix 7) which they had to complete daily during the 7 days prior to their hospital visit. Instructions were given on how to complete the form. This data included:

1. Number of liquid or very soft stools
2. Abdominal pain (defined as none, mild, moderate, severe)
3. General well-being (defined as generally well, slightly under par, poor, very poor or terrible)
4. Use of diphenoxylate, loperamide or other opiates for diarrhea.

3.3.2 Clinical Crohn's Disease Assessment

The following information was provided by the attending physician after completion of the patient's routine examination

1. The presence of abdominal mass (defined as none, questionable or definite) for the CDAI calculation
2. The presence or absence of known complications such as:
 - a) Arthritis, arthralgia
 - b) Eye problems: iritis, uveitis
 - c) Skin conditions: erythema nodosum, pyoderma gangrenosum, aphthous stomatitis
 - d) Anal fissure, fistula, or abscess
 - e) Other fistulae
 - f) Fever over 37.8°C (100°F) during the past week prior to the clinical visit.

3.4 PRE-TREATMENT DATA

1. A nursing sister, who was blind to the group designation, took blood samples from each patient who was on the trial. The blood was sent to the lab to be analyzed for the following results:
 - a) Haematology: full blood count, ESR
 - b) Biochemistry: Iron, Magnesium, Calcium, Liver profile (see Appendix 8)
2. Each patient was weighed in light street clothing by the same nursing sister
3. Height was measured in stocking feet and the Body Mass Index (BMI=weight/height²) was then calculated from this data
 - a) BMI of less than or equal to 16kg/m² was considered severely malnourished
 - b) BMI of between 16 and 19kg/m² was considered to be moderately malnourished
 - c) BMI of between 19 and 25kg/m² was in the normal range
 - d) BMI between 25 and 30kg/m² was considered overweight
 - e) BMI of greater than 30kg/m² was termed obese
4. A Clinical Disease Activity Index (CDAI) was completed by using the data from the patient's diary card together with data from the clinical Crohn's disease assessment
5. The Short Inflammatory Bowel Disease Questionnaire was completed
6. A Profile Of Mood States (POMS-SF) was also completed by each patient
7. Another diary card was given to each patient to take home to be filled out every day for a week prior to the following visit to ensure accuracy of the data.

Questionnaires were issued to the patients by the same nursing sister who took their blood samples. Patients then completed these questionnaires while waiting on the physician for their routine examination. The information recorded in their folders by the physician, was require to complete the CDAI. The completed questionnaires were returned to the nursing sister.

At time of entry into the study, patients were assessed as either Active (CDAI >200), Quiescent (CDAI<150) or Indeterminate (CDAI 150-200). In this way it could be determined whether therapy had an effect on improving disease activity (in the Active Group) or in maintaining remission (in the Quiescent Group). Patients in the Kinesiology Group received their Kinesiology sessions on alternate days to the Massage. By scheduling Kinesiology and Massage Sessions on different days, it was hoped that patients in the Massage Group, while waiting for their therapy session, would not discuss their therapy with a patient receiving Kinesiology or vice versa.

3.5 THERAPY

The Kinesiology and the Massage therapy were conducted in a room adjacent to the consulting room of the attending physician at Groote Schuur Hospital. The Kinesiology and the massage therapy were implemented by the researcher who is a registered Kinesiologist as well as a registered Massage therapist. These therapy sessions were conducted on the same day when patients attended the GIT clinic for their monthly check-ups to alleviate unnecessary disruption to their routine.

Patients in the Kinesiology and the Massage Group were told that they would be receiving a 60 minute massage session on a monthly basis for four months (4 sessions in total) to release the stress from their bodies. None of these patients were aware of the difference in therapies. The Control Group was managed in accordance with the usual clinical routine.

3.5.1 Kinesiology Group (First Session 60 Minutes)

Step 1: Correction of Neurological Disorganization

Before commencing with the actual therapy, it is believed, from a Kinesiological perspective, as essential to rectify the body's electrical charge in order to ensure accurate muscle monitoring. To correct side-to-side electromagnetic switching problems the left hand is placed on the navel. This is believed to bring attention to the gravitational center of the body and is also believed to stimulate the core muscles, situated in this area, which are important contributors to body balance. The right hand gently rubs the indentations between the first and second ribs, directly under the clavicle, to the right and left of the sternum using the thumb and middle finger. It is believed that this procedure enhances blood flow to the brain. Since the right hemisphere of the brain controls the left side of the body and vice versa, right side/left side polarity imbalance is assumed to be rectified. The process is repeated by changing over of hands (Hannaford, 1995).

To correct top and bottom electromagnetic switching problems, the left hand is placed over the navel while the right hand rubs acupressure points above the top and below the bottom lip. The Central meridian, which is believed to provide energy to the front of the body, is assumed to flow from the pubic bone upwards ending underneath the bottom lip. The Governing meridian, which is believed to provide energy to the back of the body, is assumed to flow from the coccyx up the spine, over the head ending above the top lip. Rubbing these two acupressure points is believed to rectify top and bottom polarity imbalance. The procedure is repeated by changing over of hands (Gralton & Gralton, 1998).

Front and back electromagnetic switching problems are rectified by placing the left hand on the navel while the right hand rubs the acupressure point which is situated in the area of the coccyx. The process is repeated by changing over of

hands so that the right hand is placed on the navel while the left hand rubs the acupressure point on the coccyx (Gralton & Gralton, 1998).

Step 2: Assessing for an accurate indicator muscle

Checking for an accurate indicator muscle, usually the anterior deltoid, is very important for correct assessment of restricted or blocked energies in the body. The testee is asked to raise both arms straight to about 30° in front of the body. The tester now pushes on both arms, above the wrists, to move them back to the sides of the body, using less than 1 kilogram of pressure, for about 2 seconds to see if the muscle produces a locked response. The arms will either stay firm and “lock” or feel weak and “unlock”. If the muscle unlocks, the fingers of the one hand is placed on top of the head while using the other hand to rub the third, fourth, and fifth rib spaces beside the breastbone on the front of the chest (these are the acupressure points related to this muscle). The muscle should now lock, and is suitable to be used as an accurate indicator muscle for assessing compromised areas (restricted flow of energy) in the body (Diamond, 1985).

Step 3: Assessing the body’s energy level

It is believed, when energy to the brain is compromised, poor concentration, confusion and vagueness result. The Central meridian energy flow must therefore be checked. The tester flushes the meridian by brushing the hand up and down several times, ending with two or three traces from the crotch to the bottom lip. The muscle of the forearm is assessed for a “locked” response. If the muscle “unlocks” the Central meridian requires more stimulation (Gralton & Gralton, 1999).

Step 4: Fourteen Muscle Assessment

The 14 muscles, which are related to the 14 major meridians in the body, are assessed. An unlocked muscle response will indicate a restriction in the energy flow of the related meridian which will have to be corrected by means of a Neurolymphatic massage, Spinal reflex stimulation, Neurovascular stimulation or and Emotional Stress Defusion.

Step 5: Neurolymphatic Stimulation

The Neurolymphatic or Chapman Reflex Points, located on the front of the body, are stimulated when required, to increase and enhance the flow of energy.

Step 6: Spinal Reflex Stimulation

If the muscle weakness is bilateral, the Spinal Reflex Points should be stimulated first. These points are located on the spine itself. The involved spinal reflex point is rubbed up and down the vertebrae, covering one or two levels above and below the actual point. If the muscle test still indicates an unlocked response, the Neurovascular Holding Points would be the next option.

Step 7: Neurovascular Holding Points

The Neurovascular Holding Points (Bennett Reflex Points) are located mainly on the head. By holding the appropriate acupressure point, the neuronal associations and acupuncture meridians are stimulated. This in turn, promotes increased blood flow to the muscle and the related organ or gland. The previously unlocked muscle should now lock when tested. This procedure (side-to-side, top-to-bottom, front-to-back switching; muscle monitoring; neurolymphatic massage; spinal reflex stimulation; and neurovascular holding

points) concludes the first therapy session which usually lasts 60 minutes (the third and fourth session will be the same as the first session).

Emotional Stress Defusion (ESD) (Second Session 60 Minutes)

During this session the patient is questioned about the most stressful /emotional issue at this point in his/her life. To evoke the emotional context of that experience, the patient is asked to think about the issue. A muscle is monitored to ascertain if any subconscious stress exists pertaining to this issue. If the muscle unlocks, it would be an indication that there is indeed unresolved subconscious stress, related to the issue, present. While the patient continues to think about the stressful issue, the Kinesiologist holds the ESD points, which are situated on the forehead above each eye brow, and re-monitors the muscle after a while. If the muscle locks, it indicates a change in response. In other words, thinking of the stressful issue created an energy frequency of imbalance. Holding the ESD points on the forehead also activates an energy frequency. If the energy frequency of the stress matches the energy frequency of the ESD points, the muscle will lock. If the muscle does not lock the ESD points should be held longer until the different frequencies vibrate in harmony with each other (Krebs, 1998).

If the issue is of an emotional nature and is causing an imbalance in the patient's bodily function, the Kinesiologist will assess for the origin of a problem by implementing the age recession process. To determine the time and origin of this emotional stress, the Kinesiologist has the patient state "present" and monitors the muscle. No change in the muscle response indicates that there is no energy frequency match. The patient says "future". If there is still no muscle change the patient says "past". A change in the muscle indicates that the origin of this emotional issue is in the patient's past. Starting with the current age and working back towards birth, the patient says each year while the Kinesiologist muscle monitors all the way until there is a muscle change. The unlocking of the

muscle is an indication that the cause of the emotional response, in the current circumstance, originates from something that occurred between birth and the specific age when the muscle unlocked. The patient repeats the year and age. While doing this, it is believed that the limbic brain immediately inspects all experiences at that age for their emotional content. Simultaneously it is also assessing how they relate to the current issue. In the subconscious, what is triggered from memory is "now" and those same neuropathways that were activated during the original event become active once again. The ESD procedure is applied until the energy frequencies, pertaining to this particular emotional issue, is balanced.

Further information regarding the emotional issue is gained via muscle monitoring to determine who was relevant at the time, a male or a female. The specific emotion evoked at the time is also ascertained. To locate the meridian most out of balance, the alarm point for each meridian is assessed. Because the energy flow in each meridian is disturbed or unbalanced by a different type of emotion, the alarm point that unlocks the muscle being monitored when touched, reveals the nature of the emotion associated with the issue (see Appendix A for table of meridian-related emotions). The ESD technique is applied to assist the patient in resolving the causal issue by holding the acupuncture points on the frontal eminences. After a while, the synchronous pulsing in both points on the forehead is believed to indicate that the subconscious and conscious review of the past has defused the stress from the original event. Finally, the muscle is monitored as the patient states the ages from the year when the issue had occurred to the current age. If there is no further muscle response, the issue has been cleared.

The Emotional Stress Defusion experience varies with each individual and with each issue dealt with. Some people recall infinite detail of an experience while others become emotional to the point of tears. The end result is usually appreciated by the patient involved.

3.5.2 Massage Group

Massage was selected as a therapy for the Massage Group. Since massaging also involves physical touch as with Kinesiology, it was thought to be appropriate as a comparison for control purposes in this study. Massage is believed to have direct psychological and physiological benefits. Physically, massage increases metabolism, relaxes and refreshes the muscles, and facilitates the function of the lymphatic system. It also improves circulation of blood, thereby improving the delivery of oxygen and nutrients to the cells as it enhances the removal of metabolic wastes. Massage therapy is believed to be effective in the management of pain (Greene, 1997).

Psychologically, massage relieves fatigue, reduces tension and anxiety, calms the nervous system, and promotes a sense of relaxation, renewed energy, and a feeling of well being (Greene, 1997).

First Session (60 Minutes)

Step 1: The back

The back was massaged by first working broadly over the whole area then concentrating on the smaller portions in turn - shoulder blades and upper back, lower back, and finally the spine itself.

Step 2: Back of legs

The legs were massaged from the bottom up, working each leg separately, and then from the thigh down to the foot.

Step 3: Shoulders, neck and scalp

On the front of the body the shoulders were massaged, working on both front and back simultaneously. Turning the head to one side each shoulder was then done separately ending with a full scalp stimulation.

Step 4: Face

A full facial massage was done starting from the forehead down to the chin working outward from the center to the sides

Step 5: Arms and hands

Each arm was massaged separately. Working up the limb, draining it, then down the limb using a kneading method and ending with the wrist and hand.

Step 6: Front of torso

After focusing on the ribcage and sides of the torso, the abdomen and belly area was massaged very gently using long sweeping strokes. Special care was taken not to cause any discomfort since these were very tender areas in Crohn's disease patients. The aim was to release and not create stress.

Step 7: Front of legs

As for the back of the legs, the front was massaged from the bottom up to drain the leg, circling the kneecap during the process, and down again using a kneading method and ending with the feet.

Step 8: Connecting

Finally, all parts of the body were linked using long “connecting” Strokes.

The second, third, and fourth sessions were the same as the first session.

3.6 POST-TREATMENT DATA

1. A second blood sample was taken from each patient.
2. The blood was sent to the lab to be analyzed for the following results:
 - a. Haematology: full blood count, ESR
 - b. Biochemistry: Iron, Magnesium, Calcium, Liver profile
3. Each patient was weighed in light street clothing by the same nursing sister
4. Height was measured in stocking feet and the BMI was then calculated from this data
5. A Clinical Disease Activity Index (CDAI) was completed by using the data from the patient's diary card together with data from the clinical Crohn's disease assessment
6. The Short Inflammatory Bowel Disease Questionnaire was completed
7. A Profile Of Mood States (POMS-SF) was also completed by each patient
8. Another diary card was given to each patient to be filled out at home on a daily basis for a week prior to the following visit to ensure accuracy of the data.

3.7 THREE-MONTH FOLLOW-UP

1. A third blood sample was taken from each patient.
2. The blood was sent to the lab to be analyzed for the following results:
 - a. Haematology: full blood count, ESR
 - b. Biochemistry: Iron, Magnesium, Calcium, Liver profile
3. Each patient was weighed in light street clothing by the same nursing sister
4. Height was measured in stocking feet and the BMI was then calculated from this data
5. A Clinical Disease Activity Index (CDAI) was completed by using the data from the patient's diary card together with data from the clinical Crohn's disease assessment
6. The Short Inflammatory Bowel Disease Questionnaire was completed
7. A Profile Of Mood States (POMS-SF) was also completed by each patient.

3.8 DATA ANALYSIS

At the end of the final assessment all questionnaires were scored by an independent medical doctor. The data from these questionnaires as well as the blood results were coded and captured into Microsoft Excel 7.0 (see Appendix 9 for lists of data). The disk containing the raw data was handed to a statistician for computation. Data was analyzed using the Statistica for Windows computer package.

A series of t -tests was applied to the data collected at the pre-intervention observation to determine whether the Kinesiology, Massage and Control Groups differed significantly on the demographic and dependent variables under study. The groups were compared on pre-treatment, post-treatment and three-month follow-up differences on each variable using analysis of variance. The mean scores of these calculations were presented in table form and also as box and whisker plots. In addition, the significance of pre-treatment, post-treatment, and three-month follow-up changes within each group was analyzed through analysis of variance. Given the large number of tests, post-hoc comparisons were done using Scheffe's statistical test which is considered conservative (Howell, 1997).

Due to the unpredictable nature of Crohn's disease, patients were at varying levels of disease activity and were therefore stratified into those with an active disease (CDAI>200), quiescent (CDAI<150), and indeterminate disease (CDAI 150-200). Assessments were done separately according to these sub-groupings. The correlations between the ESR, CDAI, SIBDQ, and POMS scores taken at pre-treatment, post-treatment, and follow-up observations were presented in the form of scatterplots.

Results were considered to be significant when the p value was found to be less than 0.05.

CHAPTER 4

RESULTS

4.1 PATIENT CHARACTERISTICS

In the absence of a prior estimate, using an α value of 0.05 to achieve a power of 90%, a sample size of 50 (total $N=150$) was calculated as sufficient to demonstrate a significant difference (Howell, 1997). Therefore, 150 consecutive Crohn's disease patients were studied. These patients were randomly assigned to three groups: Control Group ($N=50$), Massage Group ($N=50$), and Kinesiology Group ($N=50$). All participants remained on the program for the entire duration of the research.

4.1.1 Age

The mean age of the Control Group was 41.50 ± 13.49 , in comparison to the Massage Group with a mean age of 43.32 ± 12.40 , and the Kinesiology Group with a mean age of 44.04 ± 11.96 . The mean age of the group was 42.95 ± 12.59 years (Table 3).

Table 3: Age

Group	N	Mean	Std. Dev.
Control	50	41.50	13.49
Massage	50	43.32	12.40
Kinesiology	50	44.04	11.96
All Groups	150	42.95	12.59

There was no significant difference between the groups ($F=0.53$; $p=0.58$).

4.1.2 Sex Distribution Between Groups

The Control Group consisted of 14 (28%) males and 36 (72%) females in comparison to a Massage Group with 13 (26%) males and 37 (74%) females and a Kinesiology-Group with 15 (30%) males and 35 (70%) females (Table 4).

Table 4: Sex Distribution Between Groups

Group	Male	Female
Control (%)	14 (28%)	36 (72%)
Massage (%)	13 (26%)	37 (74%)
Kinesiology (%)	15 (30%)	35 (70%)

There was no significant difference in sex distribution between the groups ($\chi^2(2) = 0.19$; $p=0.90$).

4.1.3 Body Mass Index (BMI)

At entry, 38% of the patients had BMI values greater than 25 kg/m² (Table 5). 21.33% were overweight and 25% were obese. 53% of the patients were of normal weight, 9.39% were under weight with 8.6% being moderately malnourished and 1.33% severely malnourished.

Table 5: Body Mass Index (kg/m²)

	< = 16	16-19	19-25	25-30	>30
Entry	2(1.33%)	13(8.6%)	78(53%)	32(21.33%)	25(16.67)
Post-trmt	1(0.67%)	15(10%)	75(50%)	37(24.67%)	22(14.67%)
Follow-up	2(1.33%)	13(8.67%)	73(48%)	39(26%)	23(15.33%)

BMI of greater than 30 is obese, 25-30 is overweight, 19-24.9 is normal. 16-18.9 is undernourished (moderately malnourished) and BMI below 16 is severe malnutrition (Roche Diagnostics, 2000).

Table 6 illustrates the BMI values between groups across the three treatment levels.

Table 6: Body Mass Index (kg/m²) Between Groups

Group	Entry	Post-treatment	Follow-up
Control	24.60 ± 5.77	24.59 ± 5.67	24.41 ± 5.73
Massage	25.81 ± 6.49	25.95 ± 6.28	25.90 ± 6.13
Kinesiology	24.82 ± 5.48	25.15 ± 5.49	25.49 ± 5.71

Results = mean ± standard deviations (SD).

There were no significant differences in BMI values between groups across the three levels (F=1.27; p=0.28).

4.1.4 Duration of Disease

Duration of the disease in years is illustrated in Table 7. The Control Group had a mean duration of 11.62 ± 5.83 in comparison to a Massage Group with a mean of 12.70 ± 6.52 and Kinesiology Group with a mean of 13.34 ± 5.85 . The mean duration of disease of the whole group was 12.5 ± 6.08 years.

Table 7: Duration of Disease

Group	N	Mean (years)	SD
Control	50	11.62	5.83
Massage	50	12.70	6.52
Kinesiology	50	13.34	5.85
All Groups	150	12.55	6.08

There was no significant difference in duration of the disease between the groups ($F=1.02$; $p=0.36$).

4.1.5 Site of Disease

The disease location was assessed as ileal, colonic, and ileocolonic. Table 8 illustrates the distribution of the disease location between the groups. Of the whole group, twenty two patients had ileitis, twenty seven had colitis, and one hundred and one patients had ileocolitis

Table 8: Site of Disease

Group	ileitis	colitis	ileocolitis
Control (%)	8 (16%)	9 (18%)	33 (66%)
Massage (%)	6 (12%)	10 (20%)	34 (68%)
Kinesiology (%)	8 (16%)	8 (16%)	34 (68%)

There was no significant difference in the disease location between the groups ($\chi^2(4) = 0.60$; $p=0.96$).

4.1.6 Disease Activity

At entry, 48 patients were in remission ($CDAI < 150$), and 87 had evidence of active disease ($CDAI > 200$). Table 9 illustrates the distribution of disease activity between the groups.

Table 9: Disease Activity Between Groups as Measured by the CDAI

Group	CDAI<150	CDAI=150-200	CDAI>200
Control	23 (85.65±42.79)	6 (177.03±13.69)	21 (315.86±92.72)
Massage	16 (103.81±31.20)	6 (179.65±12.96)	28 (307.34±86.32)
Kinesiology	9 (102.76±29.12)	3 (178.57±8.47)	38 (306.38±78.01)

n(mean CDAI ± SD)

Although there were significantly more active patients in the Kinesiology Group ($\chi^2(4)=12.35$; $p=0.01$), mean CDAI scores were similar in the three groups, and the groups were therefore considered probabilistically equivalent for further study.

4.1.7 Disease Relapse Rates

Fifty percent of the sample had experienced one or more active episodes in the year preceding the study (Table 10).

Table 10: Relapse Rates in the Preceding Year

Group	Patients with relapses	% of group
Control	22	44.00%
Massage	24	48.00%
Kinesiology	29	58.00%
All Groups	75	50.00%

There was no significant difference in the number of relapse rates, experienced during the year preceding the study, between the groups ($\chi^2(2) = 2.08$; $p = 0.35$).

Table 11 illustrates the actual relapse rates experienced by the groups during the year preceding the study. 75 Patients had no relapses, 43 had 1 relapse, 22 had 2 relapses, and 10 had 3 relapses in the preceding year.

Table 11: Breakdown of Groups by Actual Relapse Rates in the Year Preceding the Study

Groups	0	1	2	3
Control (%)	28 (56%)	15 (30%)	5 (10%)	2 (4%)
Massage (%)	26 (52%)	17 (34%)	5 (10%)	2 (4%)
Kinesiology (%)	21 (42%)	11 (22%)	12 (24%)	6 (12%)
Totals	75	43	22	10

There was no significant difference in relapse rates between the groups ($\chi^2(6) = 9.99$; $p = 0.12$).

4.1.8 Disease Related Surgical Procedures

Prior to the intervention period, 94 (63%) of patients had undergone one or more disease related surgical procedures. The results are illustrated in Table 12.

Table 12: Disease Related Surgical Procedures

Group	No. of patients	% of group
Control	33	66.00%
Massage	32	64.00%
Kinesiology	29	58.00%
All groups	94	63.00%

Table 13 illustrates the breakdown of the groups by actual number of disease related surgeries. 56 Patients had no surgery, 48 had 1 surgery each, 28 had 2, 8 had 3, 6 had 4, 1 had 5, 2 had 6, and 1 patient had 7 surgical procedures.

Table 13: Number of Disease Related Surgical Procedures

Grps	0	1	2	3	4	5	6	7
Cntr	17	19	11	2	1	0	0	0
(%)	(34%)	(38%)	(22%)	(4%)	(2%)	(0%)	(0%)	(0%)
Mass	18	18	6	2	3	1	1	1
(%)	(36%)	(36%)	(12%)	(4%)	(6%)	(2%)	(2%)	(2%)
Kinslg	21	11	11	4	2	0	1	0
(%)	(42%)	(22%)	(22%)	(8%)	(4%)	(0%)	(2%)	(0%)
Totals	56	48	28	8	6	1	2	1

There was no significant difference in disease related surgical procedures between the groups ($\chi^2(14) = 11.62$; $p = 0.63$).

4.1.9 Medication

The number of patients with active Crohn's disease in each group, who were on steroids during the study period, is illustrated in Table 14.

Table 14:
Patients with Active Crohn's Disease Using Steroids During the Study Period

Group	N	Steroids	No Steroids
Control	50	9(18%)	41(82%)
Massage	50	7(14%)	43(86%)
Kinesiology	50	5(10%)	45(90%)

During the study, 9 (18%) patients with active disease in the control group, 7 (14%) in the massage group and 5 (10%) in the Kinesiology group received steroids for their active disease. There was no significant difference between the groups ($\chi^2(2)=1.14$; $p=0.56$). None of the patients with quiescent disease nor those patients with a CDAI score of >150 and <200 , required the use of steroids.

The number of patients with active disease in each group, who were on immunosuppressives during the study period, are illustrated in Table 15.

Table 15: Patients with Active Disease Using Immunosuppressives During the Study Period

Group	N	Azathioprine	No Azathioprine
Control	50	8(16%)	42(84%)
Massage	50	8(16%)	42(84%)
Kinesiology	50	9(18%)	41(82%)

During the study, 8 (16%) of patients with active disease in the Control Group, 8 (16%) in the Massage Group, and 9 (18%) in the Kinesiology Group were taking immunosuppressive medication (Azathioprine) for their active disease. None of these patients were on 5-ASA or any other form of immunosuppressive medication during the study. There were no significant differences in the use of medication between groups, prior and during the study ($\chi^2(2)=0.08$; $p=0.96$).

The patients' demographic data on entry into this study indicate that all groups were of similar age, sex, and BMI. Disease related data illustrate that there were no significant differences between duration and site of the disease between the groups. Although there were significantly more patients with active Crohn's disease in the Kinesiology Group on entry, the mean CDAI scores were similar in the three groups. The groups were therefore considered probabilistically equivalent on all demographic variables.

4.1.10 Patients' Haematological and Biochemical Characteristics at Entry into Study

The haematological and biochemical characteristics of patients with active Crohn's disease at entry are illustrated in Table 16.

Table 16: Characteristics of Patients with Active Disease at Entry into Study

	Control	Massage	Kinesiology
HB (g/dl)	12.09 ± 1.90	13.16 ± 1.67	12.83 ± 1.75
HCT (l/l)	0.38 ± 0.05	0.42 ± 0.07	0.40 ± 0.05
ESR (mm/hr)	29.76 ± 25.15	26.25 ± 22.59	26.05 ± 21.97
IRON (U/L)	8.14 ± 4.33	10.46 ± 5.22	11.58 ± 6.97
CALC (mmol/L)	2.33 ± 0.14	2.36 ± 0.12	2.34 ± 0.16
MAG (mmol/L)	0.77 ± 0.09	0.77 ± 0.09	0.74 ± 0.08
TBR (umol/L)	6.71 ± 4.36	6.61 ± 3.47	7.39 ± 4.30
ALT (U/L)	18.71 ± 10.17	17.39 ± 10.06	19.65 ± 13.72
ALK PHOS (U/l)	104.09 ± 36.63	102.61 ± 37.89	101.37 ± 42.53

Results = mean ± standard deviations (SD).

At entry, active patients in the Control Group presented with a mean haemoglobin (HB) level of 12.09 ± 1.90 g/dl (normal range = 11.6-15.6 g/dl), hematocrit (HCT) 0.38 ± 0.05 l/l (normal range = 0.37-0.53 l/l), and a mean IRON level of 8.14 ± 4.33 U/L (normal range = 7-26 U/L). The Massage and the Kinesiology Groups were all within the laboratory normal range (Roche Diagnostics, 2000). The erythrocyte sedimentation rate (ESR) in all three groups was above the normal range (1-10 mm/hr), but there were no significant differences in ESR levels between the groups (F=0.11; p=0.89).

None of the active patients had evidence of significant abnormal biochemical scores at entry. The Control Group presented with a mean calcium (CALC) level of 2.33 ± 0.14 mmol/L (normal range = 2.1-2.6 mmol/L), magnesium (MAG) of 0.77 ± 0.09 mmol/L (normal range = 0.70-1.00 mmol/L), total Bilirubin (TBR) 6.71 ± 4.36 U/L (normal range = 1-17 umol/L), alanine transaminase (ALT) 18.71 ± 10.17 U/L (normal range = 1-41 U/L), alkaline phosphatase (ALP) 104.09 ± 36.63 U/L (normal range = 39-117 U/L). The biochemical results in the Massage and the Kinesiology Groups were similar and were within the laboratory normal range (Roche Diagnostics, 2000).

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The haematological and biochemical characteristics of patients with quiescent Crohn's disease at entry are illustrated in Table 17.

Table 17: Characteristics of Patients with Quiescent Disease at Entry into Study

	Control	Massage	Kinesiology
HB (g/dl)	12.96 ± 1.95	13.32 ± 1.20	13.55 ± 1.80
HCT (l/l)	0.45 ± 0.23	0.40 ± 0.03	0.42 ± 0.04
ESR (mm/hr)	18.48 ± 14.77	24.94 ± 15.84	13.89 ± 15.32
IRON (U/L)	10.43 ± 5.23	12.06 ± 6.99	13.67 ± 4.24
CALC (mmol/L)	2.35 ± 0.12	2.33 ± 0.08	2.38 ± 0.13
MAG (mmol/L)	0.81 ± 0.62	0.76 ± 0.06	0.76 ± 0.06
TBR (umol/L)	7.65 ± 2.76	7.19 ± 3.41	8.67 ± 6.32
ALT (U/L)	23.56 ± 21.87	27.69 ± 33.40	16.67 ± 9.38
ALK PHOS (U/l)	85.91 ± 27.49	127.31 ± 113.72	85.22 ± 33.61

Results = mean ± standard deviations (SD).

At entry, the mean HB, HCT, IRON, CALC, MAG, TBR, and ALT levels in the quiescent patients were all within the laboratory normal range. Although patients were assessed as quiescent in terms of the CDAI, the mean ESR was slightly increased. However, there were no significant differences in ESR levels between the groups ($F=1.67$; $p=0.19$). Mean ALK PHOS levels in the Massage Group were also above the normal range at 127.31 ± 113.72 U/l (normal range = 39-117 U/l) compared to the Kinesiology Group with a mean ALK PHOS level of 85.22 ± 33.61 .

The haematological and biochemical characteristics of patients with CDAI 150-200 at entry are illustrated in Table 18.

Table 18: Characteristics of Patients with CDAI 150-200 at Entry into Study

	Control	Massage	Kinesiology
HB (g/dl)	12.55 ± 1.90	12.60 ± 1.11	12.20 ± 0.87
HCT (l/l)	0.39 ± 0.05	0.39 ± 0.01	0.38 ± 0.02
ESR (mm/hr)	24.00 ± 22.99	31.17 ± 18.90	27.33 ± 32.81
IRON (U/L)	7.33 ± 3.93	10.33 ± 5.12	6.00 ± 4.36
CALC (mmol/L)	2.35 ± 0.10	2.37 ± 0.09	2.33 ± 0.12
MAG (mmol/L)	0.78 ± 0.04	0.81 ± 0.07	0.79 ± 0.18
TBR (umol/L)	8.50 ± 5.58	5.67 ± 2.34	6.33 ± 2.08
ALT (U/L)	20.00 ± 13.19	25.50 ± 15.82	14.33 ± 9.24
ALK PHOS (U/l)	119.50 ± 92.73	112.33 ± 30.39	84.33 ± 28.54

Results = mean ± standard deviations (SD).

Patients with CDAI between 150-200, presented with mean HB, HCT, IRON, CALC, MAG, TBR, ALT, and ALK PHOS levels which were all within the laboratory normal range. However, the mean ESR levels in all three groups were above the normal range (1-10 mm/hr). The mean ESR level of the Control Group was 24.00 ± 22.99 mm/hr, Massage Group 31.17 ± 18.90 mm/hr, and the Kinesiology Group 27.33 ± 32.81 mm/hr. There were no significant differences in mean ESR levels between the groups (F=0.14; p=0.87). The ESR levels of the three groups were significantly positively associated with CDAI scores (r=0.247; p= 0.002) at entry (Figure 14).

At entry into the study the three groups were probabilistically equivalent on all haematological and biochemical levels (eg. HB, HCT, ESR, IRON, CALC, MAG, TBR, ALT, ALK PHOS) for purposes of study.

4.2 CROHN'S DISEASE ACTIVITY INDEX (CAI)

4.2.1 Patients with Active Crohn's Disease (CAI >200) (n=87)

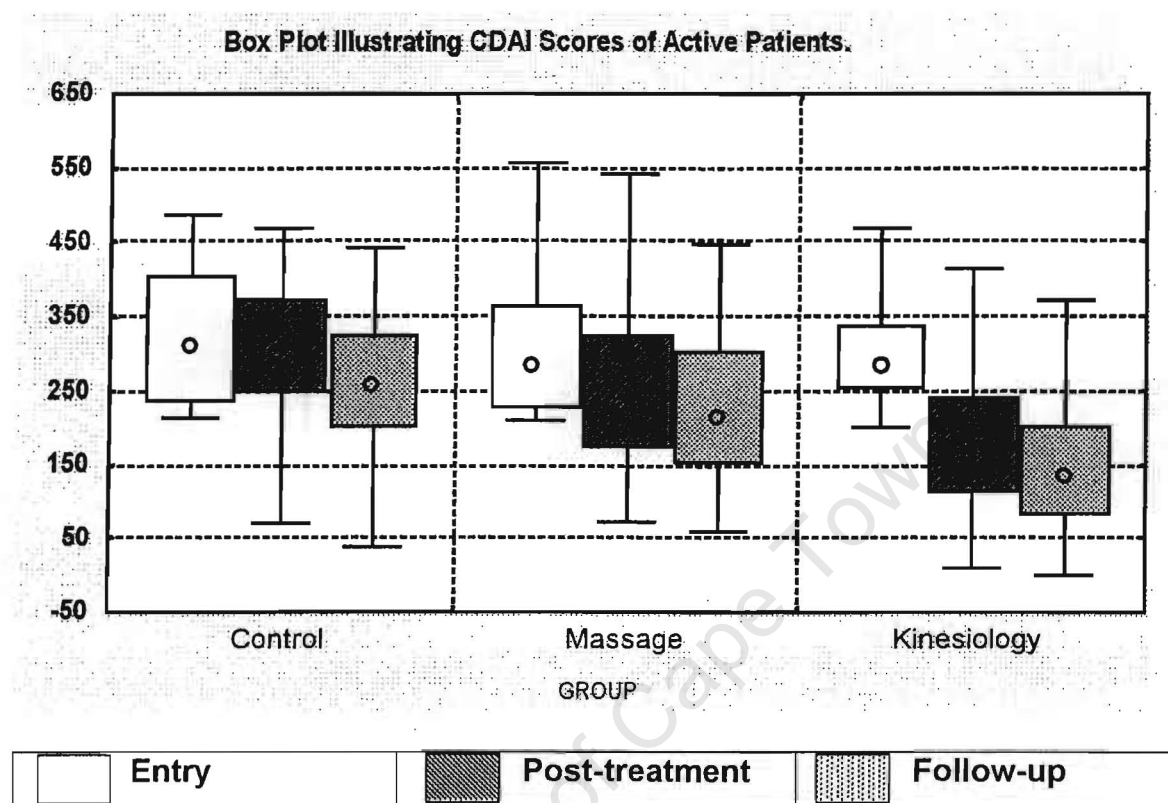


Figure 11: CAI of active patients in the three groups at entry, post-treatment, and follow-up.

Table 19 illustrates the mean CAI of patients with active Crohn's disease at entry, post-treatment, and follow-up.

Table 19: Mean CAI of Patients with Active Crohns' Disease

	Entry	Post-treatment	Follow-up
Control	315.86 ± 92.72	285.93 ± 107.94	264.26 ± 109.64
Massage	307.34 ± 86.32	253.26 ± 110.46	236.50 ± 100.61
Kinesiology	306.38 ± 78.01	176.99 ± 93.63	152.34 ± 90.23

Results = mean ± standard deviations (SD).

At entry mean CDAI scores were similar in the three groups (Controls 315.86 ± 92.72 ; Massage 307.34 ± 86.32 ; and Kinesiology Group 306.38 ± 78.01) (Figure 11). Following a four-month intervention period, mean CDAI scores were reduced in the Kinesiology Group (176.99 ± 93.63) and in the Massage Group (253.26 ± 110.46) whereas the Control Group was unchanged (285.93 ± 107.94). At three-month follow-up, a further reduction in the mean CDAI scores was evident in the Kinesiology Group (152.34 ± 90.23) as well as in the Massage Group (236.50 ± 100.61) whereas the Control Group remained unchanged (264.26 ± 109.64).

Table 20: Two-way ANOVA Illustrating Repeated Measures of Active CDAI

	SS	df	MS	F	p
GROUP	302897.88	2	151448.94	9.10	0.0002
TREAT	379137.64	2	189568.82	35.98	1.038E-13
TREAT*GROUP	114105.27	4	28526.31	5.41	0.0004

The results of the ANOVA statistic indicate that the mean CDAI levels are significantly different across the stage of treatment ($F=35.98$; $p<0.001$). This result is irrelevant since this is mean over duration of the entire study. The mean CDAI levels are also significantly different between the treatment groups ($F=9.10$; $p<0.001$). In this instance it is expected that regression to the mean will occur and thus the treatment main effect could be an artifact therefore, this effect will not be interpreted.

The interaction variable TREAT*GROUP indicates that at least one treatment type has caused a significant change in CDAI levels ($F=5.41$; $p<0.001$) (Table 20). For more conclusive evidence, the TREAT*GROUP interaction is formally assessed for significance using Scheffe's test.

Table 21: Scheffe's Test For Assessing TREAT*GROUP interaction

Group	Entry	Post-treatment	Follow-up
Control	315.86	285.93	264.26
Massage	307.34	253.26	236.50
Kinesiology	306.38	176.99 *	152.34 **

*p<0.001 vs entry; ** p<0.001 vs entry

The mean CDAI level in the Kinesiology Group is significantly lower at post-treatment level (p<0.001) and follow-up (p<0.001) compared to entry (Table:21).. Although the mean CDAI level in the Massage and Control Groups presented with some change at post-treatment and follow-up stages, the results are not significant and probably due to regression to the mean.

Patients were also assessed in terms of proportion achieving a clinical response (as indicated by a fall in CDAI of ≥ 70 points) and those achieving remission (CDAI<150).

Table 22: Active Patient's Disease Activity at Post-treatment Stage

Groups	N	≥ 70 Points	CDAI<150	CDAI>200
Control	21	4 (19%)	3 (14%)	16 (76%)
Massage	28	9 (32%)	7 (25%)	16 (57%)
Kinesiology	38	25 (66%)	19 (50%)	10 (26%)

At the four month visit, the Control Group consisted of 21 patients with active disease, the Massage Group had 28, and the Kinesiology Group had 38 patients. Following the four-month intervention period, 4(19%) patients with active disease in the Control Group, 9(32%) in the Massage Group, and 25(66%) in the Kinesiology Group had a reduction of ≥ 70 points in their CDAI score. 10(26%) of patients in the Kinesiology Group remained in an active disease state compared

to the Massage Group with 16(57%), and the Control Group with 16(76%) of patients who remained in an active disease state. 19(50%) patients in the Kinesiology Group went into clinical remission compared to 7(25%) in the Massage Group and 3(14%) in the Control Group (Table 22). Although numerically more patients in the Massage Group compared to the Controls achieved clinical response and remission, the differences did not achieve significance. Significantly more patients in the Kinesiology Group achieved clinical response ($\chi^2(4) = 11,82$; $p < 0.001$) and remission ($\chi^2(4) = 7.38$; $p < 0.01$).

Table 23: Active Patient's Disease Activity at Follow-up

Groups	N	≥ 70 Points	CDAI < 150	CDAI > 200
Control	21	1 (4%)	2 (9%)	15 (71%)
Massage	28	6 (21%)	9 (32%)	17 (60%)
Kinesiology	38	21 (55%)	19 (50%)	10 (26%)

At three-month follow-up, 1(4%) patient in the Control Group, 6(21%) in The Massage Group, and 21(55%) in the Kinesiology Group had a further reduction of 70 points in their CDAI scores (Table 21). 15(71%) of patients in the Control Group, 17(60%) in the Massage Group, and 10(26) in the Kinesiology Group remained in an active disease state while 2(9%) in the Control Group, (32%) in the Massage Group, and 19(50%) in the Kinesiology Group went into clinical remission (CDAI < 150) (Table 23). Although more patients in the Massage Group, compared to the Controls achieved clinical response and remission, the differences did not achieve significance. Significantly more patients in the Kinesiology Group achieved clinical response ($\chi^2(4) = 14.75$; $p < 0.001$) and clinical remission ($\chi^2(4) = 9.67$; $p < 0.01$).

4.2.2 Patients with Quiescent Crohn's Disease (CDAI <150) n=48

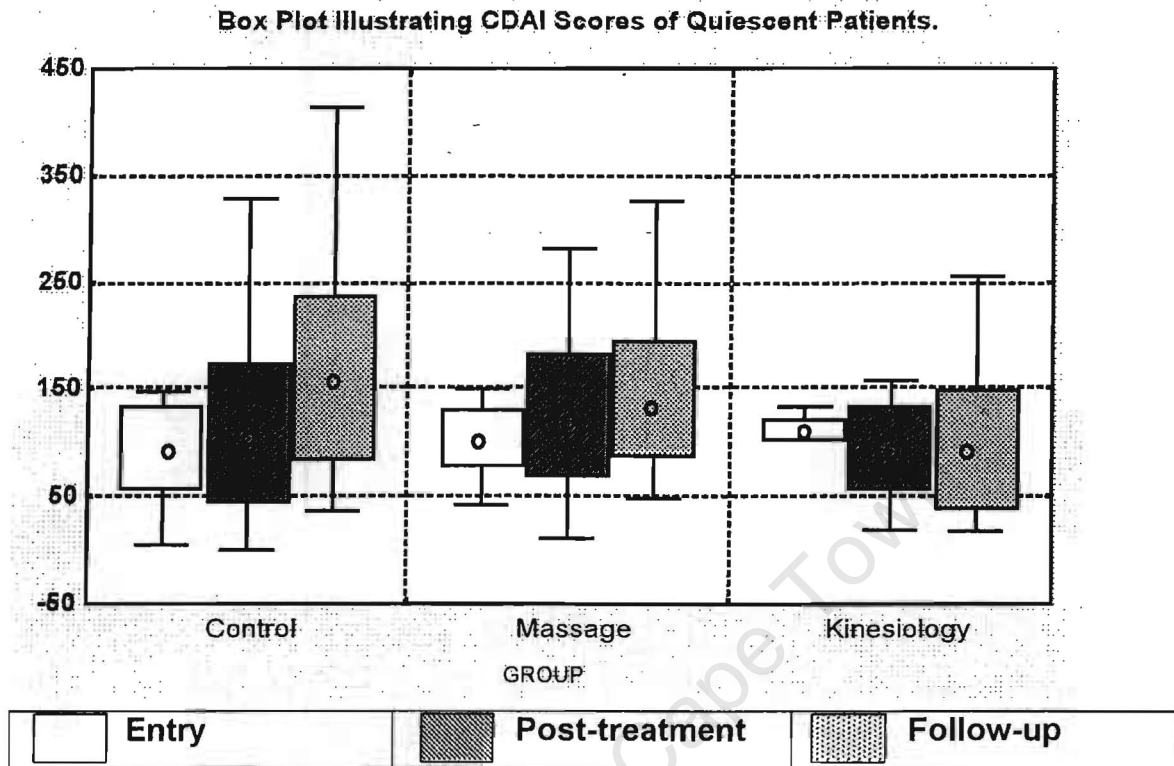


Figure 12: CDAI of quiescent patients in the three groups at entry, post-treatment, and follow-up.

Table 24 illustrates the mean CDAI of patients with quiescent disease at entry, post-treatment, and follow-up.

Table 24: Mean CDAI of Patients with Quiescent Crohn's Disease

	Entry	Post-treatment	Follow-up
Control	85.65 ± 42.79	121.29 ± 89.43	161.24 ± 93.45
Massage	103.81 ± 31.20	129.75 ± 81.18	147.06 ± 79.20
Kinesiology	102.76 ± 29.12	97.95 ± 50.40	110.90 ± 89.12

Results = mean ± standard deviations (SD).

In patients with quiescent disease, the Control Group presented with an increase in mean CDAI scores at both post-treatment (121.29 ± 89.43) as well as follow-up (161.24 ± 93.45) compared to the mean CDAI scores at entry (85.65 ± 42.79). The Massage Group presented with an increase in mean CDAI scores at follow-up level (147.06 ± 79.20) compared to entry (103.81 ± 31.20), whereas the Kinesiology Group maintained remission throughout the study (Figure 12).

Table 25: Two-way ANOVA Illustrating Repeated Measures of Quiescent CDAI

	SS	df	MS	F	p
GROUP	9760.3877	2	4880.1939	0.45	0.63
TREAT	37281.639	2	18640.82	7.59	0.00
TREAT*GROUP	16357.522	4	4089.3805	1.66	0.16

The result of the ANOVA statistic indicate that the mean CDAI levels are significantly different across the stage of treatment ($F=7.59$; $p<0.001$), which could be due to a regression to the mean artifact, while the mean CDAI is the same between the three groups. There is also no significant interaction between treatment group and stage of treatment (Table 25).

4.2.3 Patients with CDAI 150-200 (n=15)

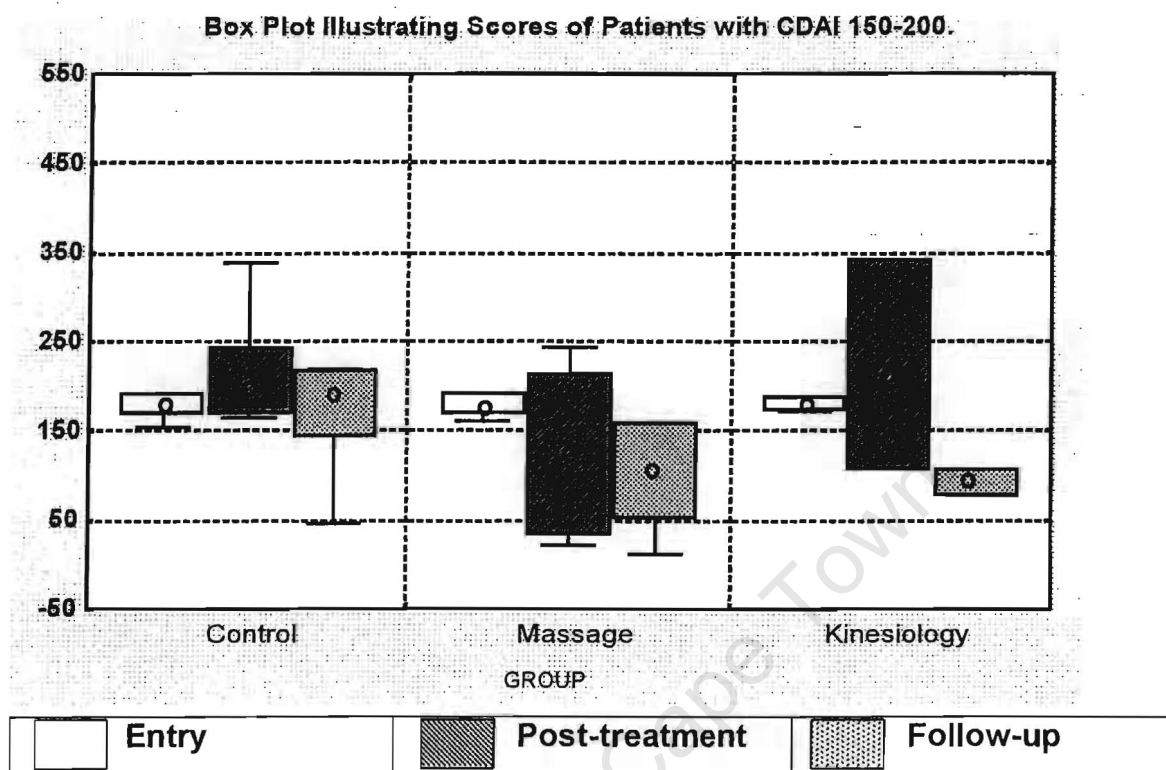


Figure 13: Patients with CDAI 150-200 within the three groups at entry, post-treatment and follow-up.

Table 26 illustrates the mean scores of patients with CDAI 150-200

Table 26: Mean Scores of Patients with CDAI 150-200

	Entry	Post-treatment	Follow-up
Control	177.03 ± 13.69	218.53 ± 64.70	189.63 ± 124.32
Massage	179.65 ± 12.96	125.05 ± 90.18	148.03 ± 164.49
Kinesiology	178.57 ± 8.47	194.00 ± 128.66	88.43 ± 16.10

Results = mean ± standard deviations (SD).

In patients with CDAI 150-200, the mean CDAI scores were similar in all three groups at entry (Kinesiology Group 178.57 ± 8.47 ; Massage 179.65 ± 12.96 ; and Controls 177.03 ± 13.69). Following four-months of intervention, and a three-month follow-up, mean CDAI scores were reduced in the Kinesiology Group (88.43 ± 16.10) compared to mean CDAI scores at entry (178.57 ± 8.47), reaching a level of remission (CDAI<150). The Massage Group presented some change in mean CDAI scores at follow-up level (148.03 ± 164.49) reaching the level of remission while the Control Group presented with some fluctuation in mean CDAI scores but not sufficient to reach the stage of remission (Figure 13).

Table 27: Two-way ANOVA Illustrating Repeated Measures of CDAI 150-200

	SS	df	MS	F	p
GROUP	20235.525	2	10117.763	0.76	0.48
TREAT	12173.85	2	6086.9251	0.96	0.39
TREAT*GROUP	27891.906	4	6972.9765	1.10	0.37

The mean CDAI is the same over all three stages of treatment and in all three treatment groups. There is also no interaction between the treatment group and the stage of treatment (Table 27). The small sample size might be the reason why the pattern of means is not significantly different.

Table 28: Disease Activity of Patients with CDAI 150-200 at Post-treatment Stage

Groups	N	≥70 Points	CDAI<150	CDAI>200
Control	6	0 (0%)	3 (50%)	3 (50%)
Massage	6	2 (33%)	4 (66%)	1 (16%)
Kinesiology	3	1 (33%)	3 (100%)	0 (0%)

At the four-month visit, the Control Group consisted of 6 patients, the Massage Group 6, and the Kinesiology Group had 3 patients with CDAI 150-200. 1(33%) patient in the Kinesiology Group and 2(33%) patients in the Massage Group had a reduction of ≥ 70 points in their CDAI scores. Further assessment revealed that 3 (100%) patients in the Kinesiology Group compared to 4 (66%) in the Massage Group, and 3(50%) in the Control Group went into clinical remission. 1(16%) patient in the Massage Group compared to 3(50%) of patients in the Control Group became active. In view of the small numbers involved, statistical analysis was not possible (Table 28).

Table 29: Disease Activity of Patients with CDAI 150-200 at Follow-up

Groups	N	≥ 70 Points	CDAI<150	CDAI>200
Control	6	0 (0%)	3 (50%)	2 (33%)
Massage	6	2 (33%)	4 (66%)	2 (16%)
Kinesiology	3	2 (66%)	3 (100%)	0 (0%)

At four-month follow-up, 2 (66%) patients in the Kinesiology Group and 2 (33%) in the Massage Group had a further \geq reduction in their CDAI scores. 3(100%) patients in the Kinesiology Group compared to 4(66%) in the Massage Group and 3(50%) in the Control Group went into clinical remission while 1(16%) patient in the Massage Group compared to 2(33%) in the Control Group developed active disease. In view of the small numbers involved, statistical analysis was not possible (Table 29).

4.2.4 Correlations between ESR and CDAI at Entry into Study

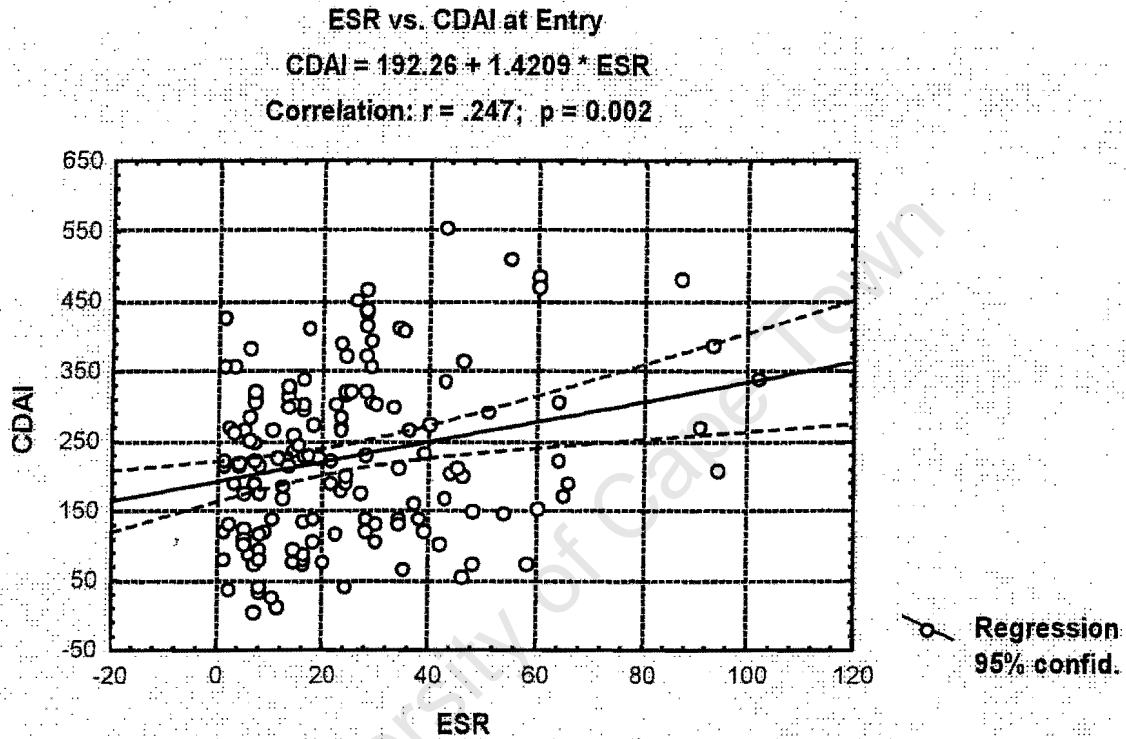


Figure 14: Crohn's Disease Activity Index (CDAI) vs. Erythrocyte Sedimentation Rate (ESR) at entry.

There is a significant positive association between ESR and CDAI at entry ($r=0.247$; $p=0.002$) (Figure 14).

4.2.5 Correlations between ESR and CDAI at Post-treatment

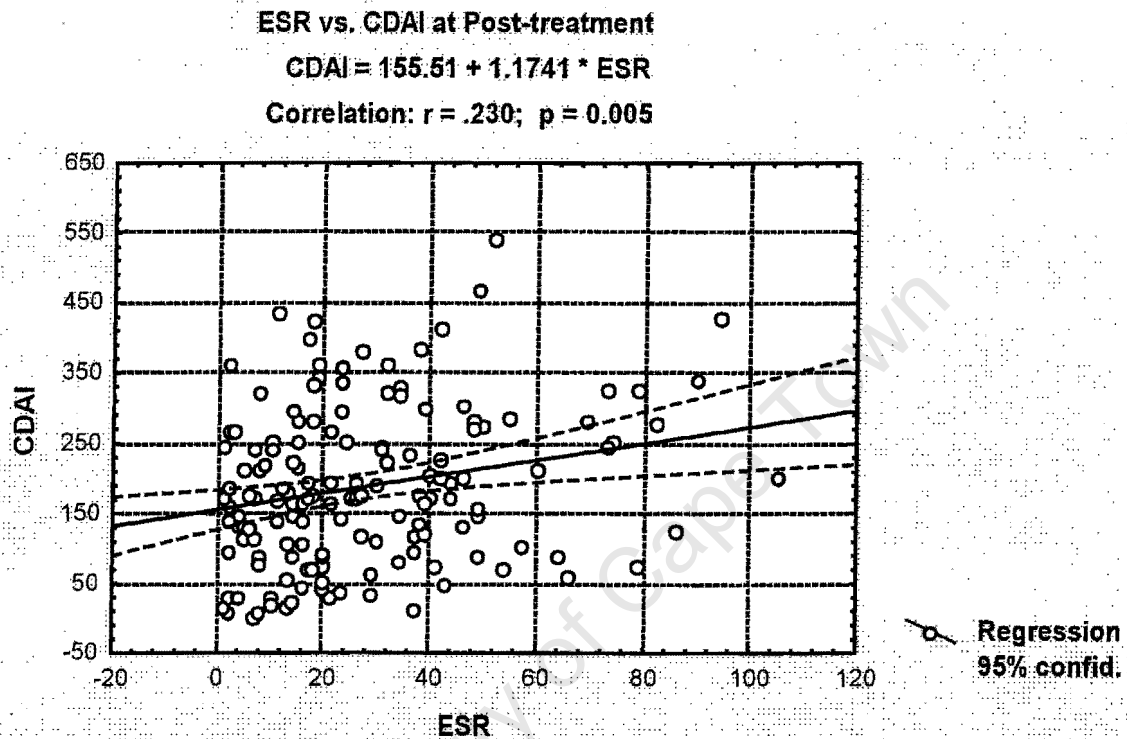


Figure 15: Crohn's Disease Activity Index (CDAI) vs. Erythrocyte Sedimentation Rate (ESR) at post-treatment level.

There is a significantly positive association between ESR and CDAI at post-treatment level ($r=0.230$; $p=0.005$) (Figure 15).

4.3 SHORT INFLAMMATORY BOWEL DISEASE QUESTIONNAIRE (SIBDQ)

4.3.1 SIBDQ Scores of Patients with Active Crohn's Disease (n=87)

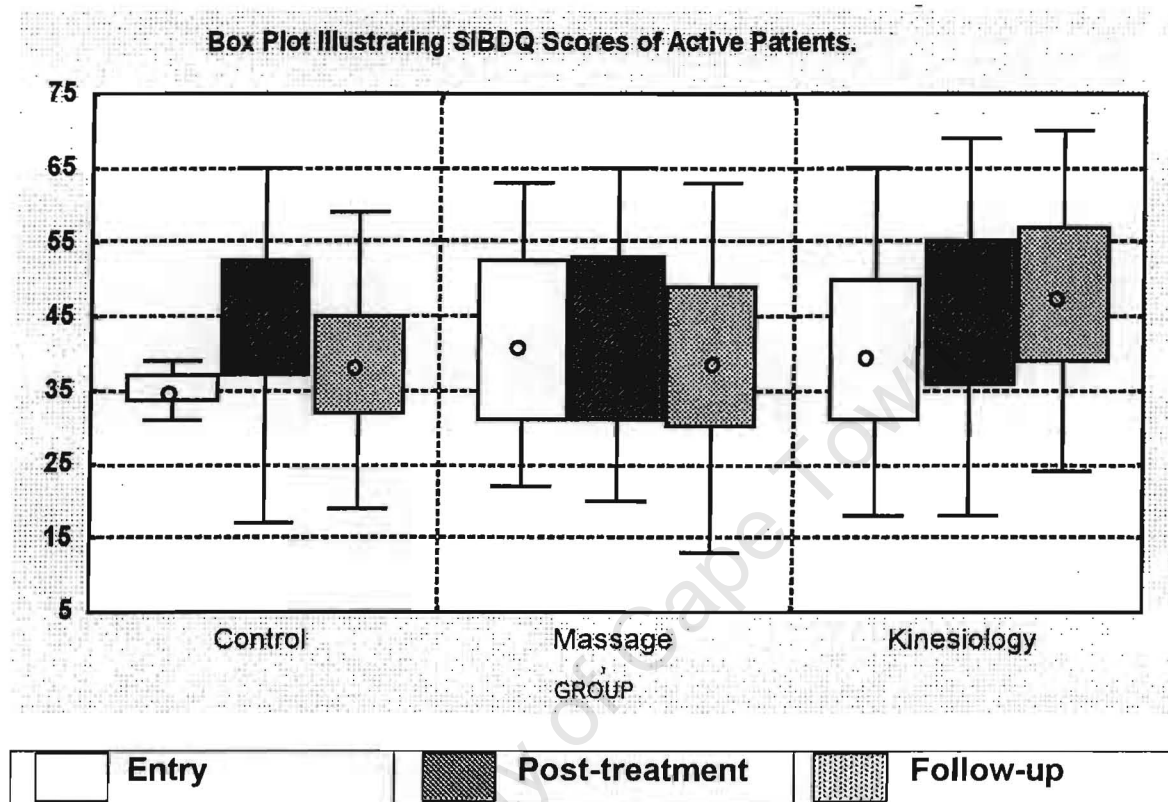


Figure 16: The SIBDQ scores of patients with active disease, within the three groups at entry, post-treatment, and follow-up.

Table 30 illustrates the mean SIBDQ scores of patients with active disease at entry, post-treatment, and follow-up.

Table 30: Mean SIBDQ Scores of Patients with Active Disease

	Entry	Post-treatment	Follow-up
Control	36.71 ± 8.65	43.86 ± 12.19	39.57 ± 9.94
Massage	43.36 ± 12.95	42.28 ± 13.04	40.92 ± 13.26
Kinesiology	40.95 ± 13.02	46.21 ± 11.96	48.39 ± 11.51

Results = mean ± standard deviations (SD).

There was no significant difference in SIBDQ scores in patients with active disease at entry into the study. Following a four-month intervention period the Control Group, demonstrated an improvement in mean SIBDQ scores (43.86 ± 12.19) compared to entry (36.71 ± 8.65). The mean SIBDQ score of the Massage Group remained unchanged, while the Kinesiology Group also showed an improvement (46.21 ± 13.04) compared to entry (40.95 ± 13.02). At three-month follow-up, the SIBDQ score in the Control Group was reduced to a level similar to entry level, the Massage Group remained unchanged while the Kinesiology Group remained higher than the entry value (48.39 ± 11.51) (Figure 16).

Table 31: Two-way ANOVA Illustrating Repeated Measures of SIBDQ in Active CDAI

	SS	df	MS	F	p
GROUP	1115.0858	2	557.5429	1.67	0.19
TREAT	524.78822	2	262.39411	4.81	0.009
TREAT*GROUP	978.55728	4	244.63932	4.48	0.001

The result of the ANOVA statistic indicates that the mean SIBDQ is the same between treatment groups (Table 31) while the mean SIBDQ levels are significantly different across the stage of treatment ($F=4.81$; $p<0.01$). The SIBDQ is strongly correlated with CDAI (Entry $r = -0.510$; $p=0.000$. Post-treatment $r = -0.701$; $p=0.000$. Follow-up $r = -0.684$; $p=0.000$) and therefore regression to the mean can also explain this effect (i.e. an artifact). The interaction variable TREAT*GROUP indicates that at least one treatment type has caused a significant change in SIBDQ levels ($F=4.48$; $p<0.01$).

For more conclusive evidence, the TREAT*GROUP interaction is formally assessed for significance using Scheffe's test.

Table 32: Scheffe's Test for Assessing TREAT*GROUP Interaction

Group	Entry	Post-treatment	Follow-up
Control	36.71	43.40	39.57
Massage	43.36	42.28	40.92
Kinesiology	40.94	46.21	48.39 *

*p<0.05 vs entry

The mean SIBDQ level in the Kinesiology Group is significantly better at follow-up (p< 0.05) compared to entry (Table 32). All other differences are not significant.

4.3.2 SIBDQ Scores of Patients with Quiescent Disease (n=48)

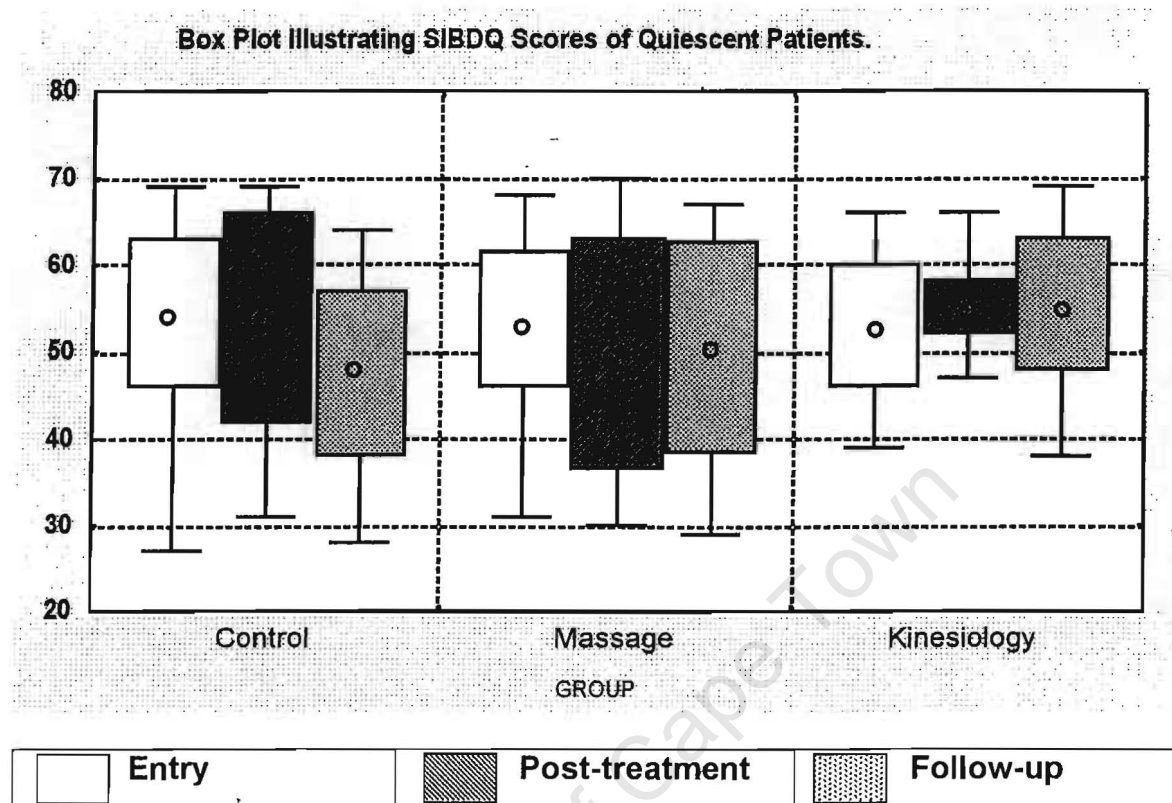


Figure 17: The SIBDQ scores of patients with quiescent disease, within the three groups, at entry, post-treatment, and follow-up.

Table 33 illustrates the mean SIBDQ of patients with quiescent Crohn's disease.

Table 33: Mean SIBDQ Scores of Patients with Quiescent Disease

	Entry	Post-treatment	Follow-up
Control	54.04 ± 11.47	54.30 ± 12.52	47.56 ± 11.18
Massage	53.31 ± 11.47	50.31 ± 14.36	49.12 ± 12.73
Kinesiology	52.78 ± 9.08	56.22 ± 6.34	55.78 ± 11.22

Results = mean ± standard deviations (SD).

Patients with quiescent disease had similar SIBDQ scores at entry. Following a four-month intervention period, there were no significant differences between the groups. However, at three-month follow-up, the Control Group presented with a decrease in SIBDQ scores (47.56 ± 11.18) compared to entry (54.04 ± 11.47) indicating deterioration in quality of life. Whereas the result of the Kinesiology and the Massage Groups remained unchanged (Figure 17).

Table 34: Two-way ANOVA Illustrating Repeated Measures of SIBDQ in Quiescent CDAI

	SS	df	MS	F	p
GROUP	283.19917	2	141.59959	0.47	0.62
TREAT	198.59141	2	99.295704	1.70	0.18
TREAT*GROUP	413.76006	4	103.44002	1.77	0.14

The results indicate that there are no significant differences between the stages of treatment nor the three treatment groups. There is also no interaction between the treatment group and the stage of treatment (Table 34).

4.3.3 SIBDQ Scores of Patients with CDAI 150-200 (n=15)

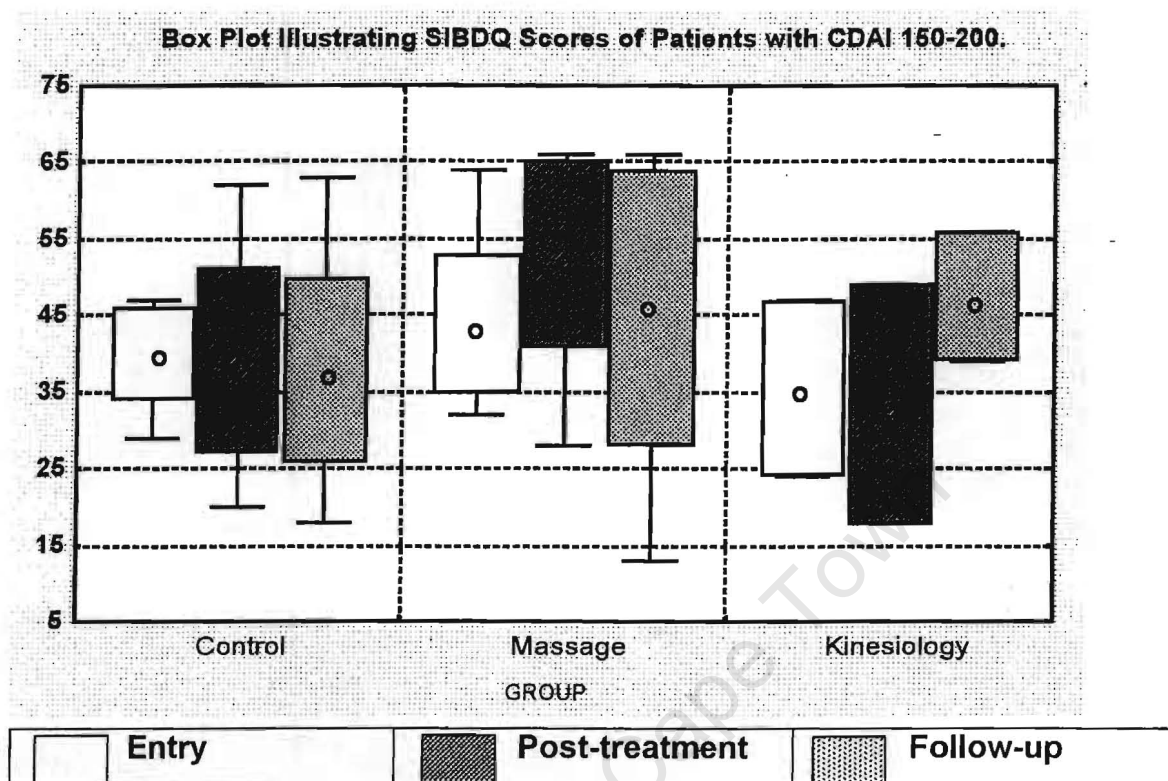


Figure 18: The SIBDQ scores of patients with CDAI 150-200, within the three groups, at entry, post-treatment, and follow-up.

Table 35 illustrates the mean SIBDQ scores of patients with CDAI 150-200 at entry, post-treatment, and follow-up.

Table 35: Mean SIBDQ Scores of Patients with CDAI 150-200

	Entry	Post-treatment	Follow-up
Control	38.83 ± 7.08	40.33 ± 15.54	39.83 ± 16.24
Massage	45.33 ± 11.94	51.50 ± 15.06	43.67 ± 20.92
Kinesiology	35.67 ± 11.50	31.33 ± 15.95	50.33 ± 9.81

Results = mean ± standard deviations (SD).

Patients with CDAI 150-200 had similar SIBDQ scores at entry. Following a four-month intervention, there were no significant differences between the groups. At three-month follow-up, there was a deterioration in mean SIBDQ scores of the Kinesiology Group (50.33 ± 9.81), while the mean SIBDQ scores of the Control and the Massage Group remained unchanged (Figure 18).

Table 36: Two-way ANOVA Illustrating Repeated Measures of SIBDQ in CDAI 150-200

	SS	df	MS	F	p
GROUP	585.58889	2	292.79444	0.63	0.54
TREAT	160.44444	2	80.222222	0.84	0.44
TREAT*GROUP	745.37778	4	186.34444	1.97	0.13

There are no significant differences between the stages of treatment nor the three treatment groups. There is also no interaction between the treatment group and the stage of treatment (Table 36).

4.3.4 Correlations between CDAI and SIBDQ at Entry

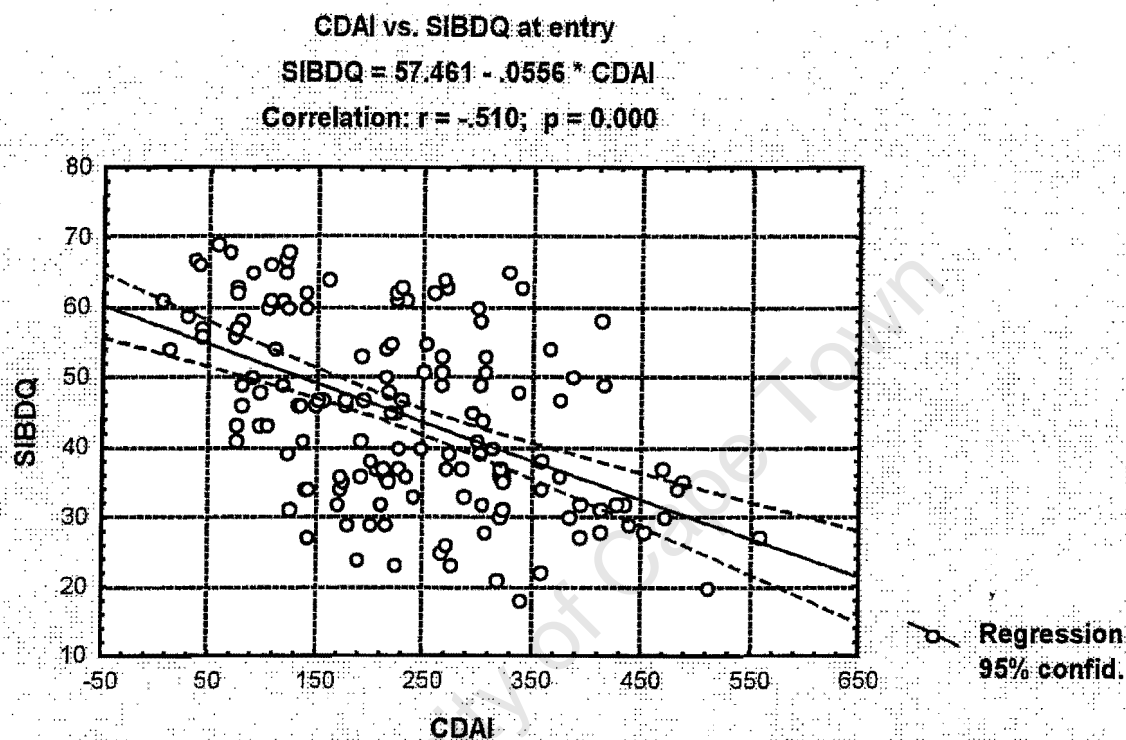


Figure 19: Crohn's Disease Activity Index (CDAI) vs. Short Inflammatory Bowel Disease Index (SIBDQ) at Entry.

There is a significantly negative association between CDAI and SIBDQ at entry ($r=-0.510$; $p=0.000$) (Figure 19).

4.3.4 Correlation between CDAI and SIBDQ at Post-treatment

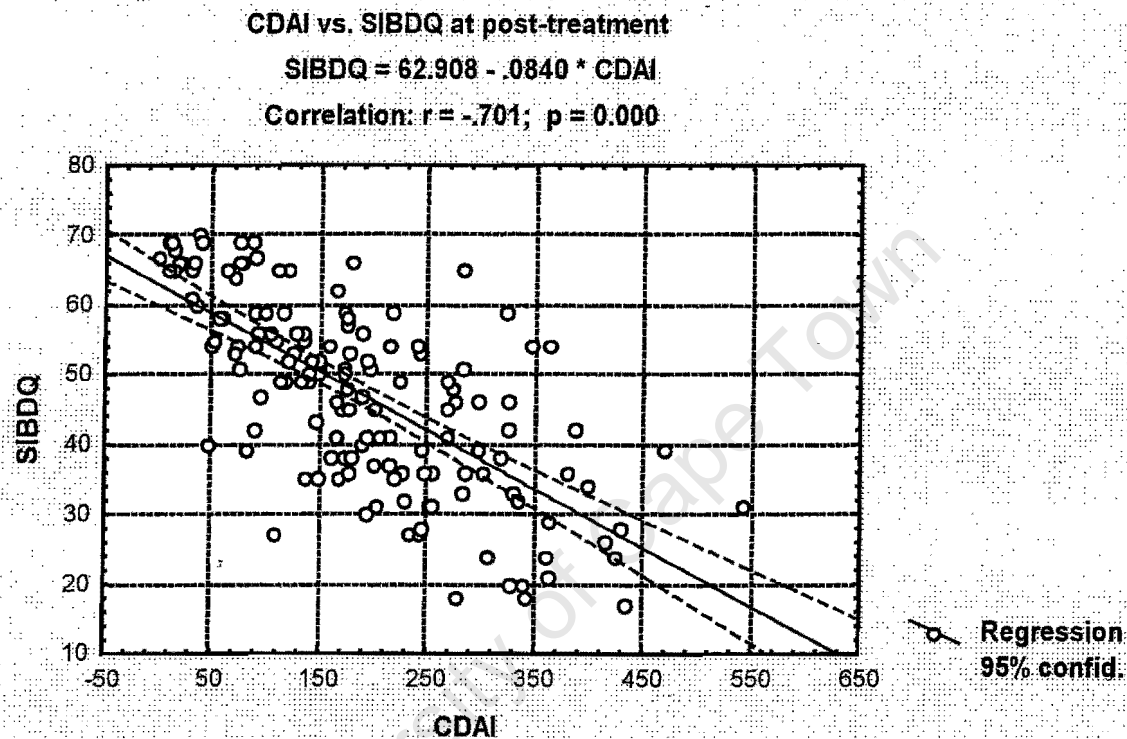


Figure 20: Crohn's Disease Activity Index (CDAI) vs. Short Inflammatory Bowel Disease Questionnaire (SIBDQ) at post-treatment.

There is a significantly negative association between CDAI and SIBDQ at post-treatment ($r=-0.701$; $p=0.000$) (Figure 20).

4.3.6 Correlations between CDAI and SIBDQ at Follow-up

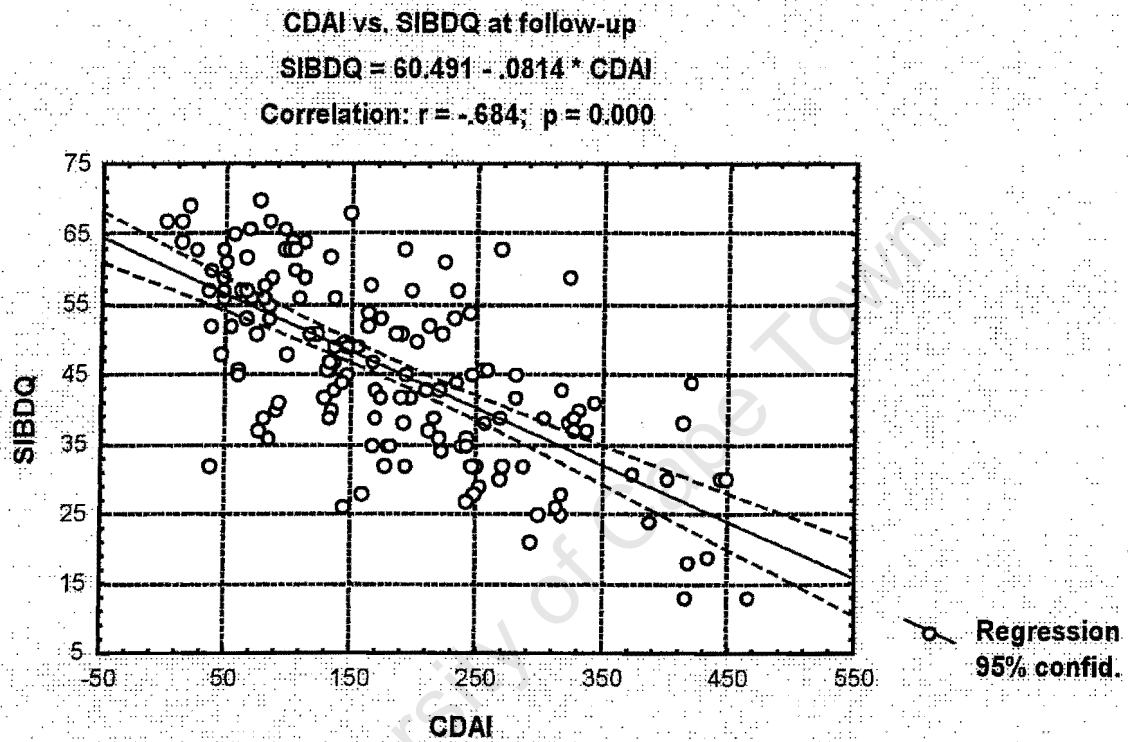


Figure 21: Crohn's Disease Activity Index (CDAI) vs. Short Inflammatory bowel Disease Index (SIBDQ) at follow-up.

There is a significantly negative association between CDAI and SIBDQ at follow-up ($r=-0.684$; $p=0.000$) (Figure 21).

4.4 PROFILE OF MOOD STATES (POMS)

4.4.1 POMS Scores of Patients with Active Crohn's Disease (n=87)

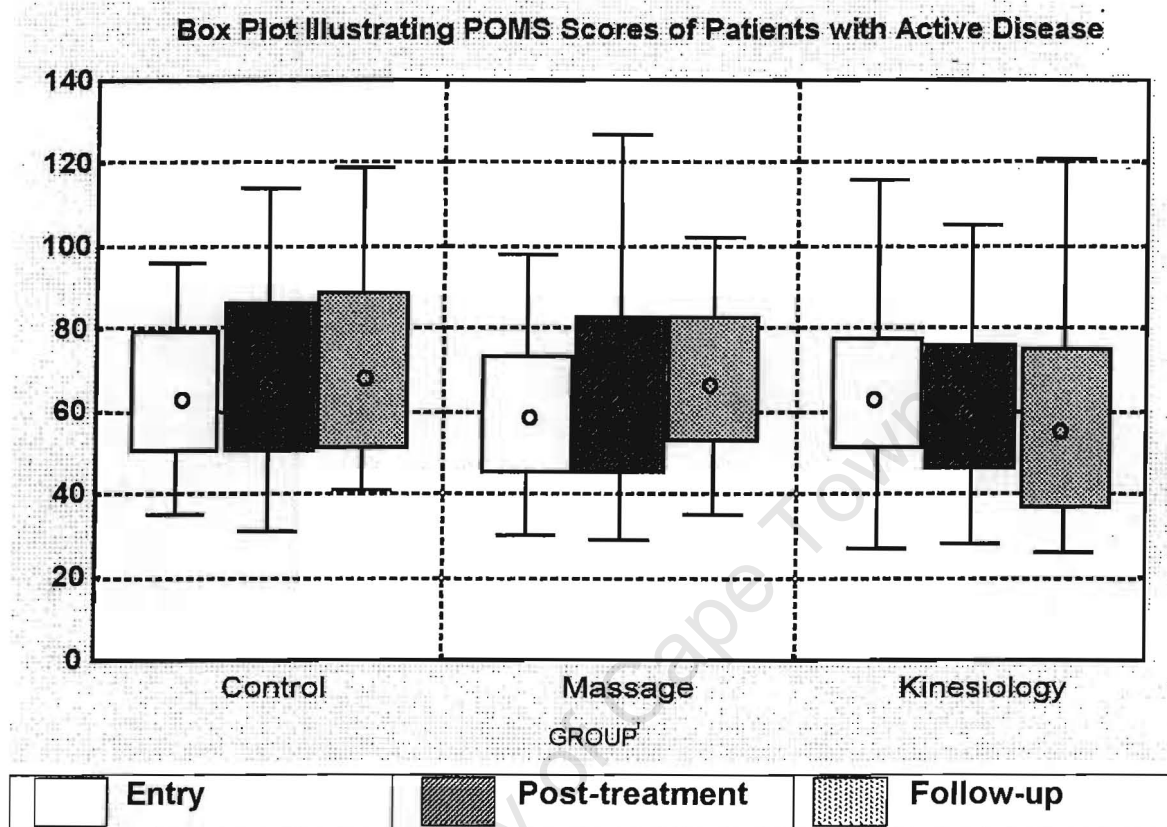


Figure 22: The POMS scores of patients with active disease, within the three groups at entry, post-treatment, and follow-up.

Table 37 illustrates the mean POMS score of patients with active Crohn's disease at entry, post-treatment, and follow-up.

Table 37: Mean POMS Scores of Patients with Active Disease

	Entry	Post-treatment	Follow-up
Control	68.09 ± 18.17	68.33 ± 21.73	71.33 ± 21.05
Massage	61.96 ± 21.46	65.28 ± 26.98	67.28 ± 18.60
Kinesiology	66.95 ± 21.66	59.92 ± 20.62	56.87 ± 23.53

Results = mean ± standard deviations (SD).

Patients with active disease revealed no difference in mean POMS scores between groups at entry. Following a four month intervention period, the Kinesiology Group presented with an improvement in POMS scores (59.92 ± 20.62) compared to entry (66.95 ± 21.66), while scores in the Massage and the Control Groups remained unchanged. At three-month follow-up the Kinesiology Group presented with a further improvement in POMS scores (56.87 ± 23.53) compared to the level at entry. The Massage Group presented with an increase in scores (67.28 ± 18.60) compared to entry (61.96 ± 21.46), indicating deterioration in psychological mood states. The Control Group also demonstrated an increase in POMS scores (71.33 ± 21.05) compared to entry (68.09 ± 18.17) (Figure 22).

Table 43: Two-way ANOVA Illustrating Repeated Measures of POMS in Active CDAI

	SS	df	MS	F	p
GROUP	2137.0635	2	1068.5318	0.95	0.38
TREAT	92.598023	2	46.299011	0.29	0.74
TREAT*GROUP	2283.2041	4	570.80102	3.58	0.007

The results of the ANOVA statistic indicate that the mean POMS levels are the same across the stage of treatment as well as the treatment groups (Table 43). The interaction variable indicates that at least one treatment type has caused a significant change in POMS levels ($F=3.58$; $p<0.01$). The significant result obtained in the ANOVA statistic requires that post hoc tests be conducted on the data.

Table 39: Scheffe's Test for Assessing TREAT*GROUP interaction

Group	Entry	Post-treatment	Follow-up
Control	68.09	68.33	71.33
Massage	61.96	65.28	67.28
Kinesiology	66.95	59.92	56.87

There are no significant differences (Table 39).

4.4.2 POMS Scores of Patients with Quiescent Crohn's Disease (n=48)

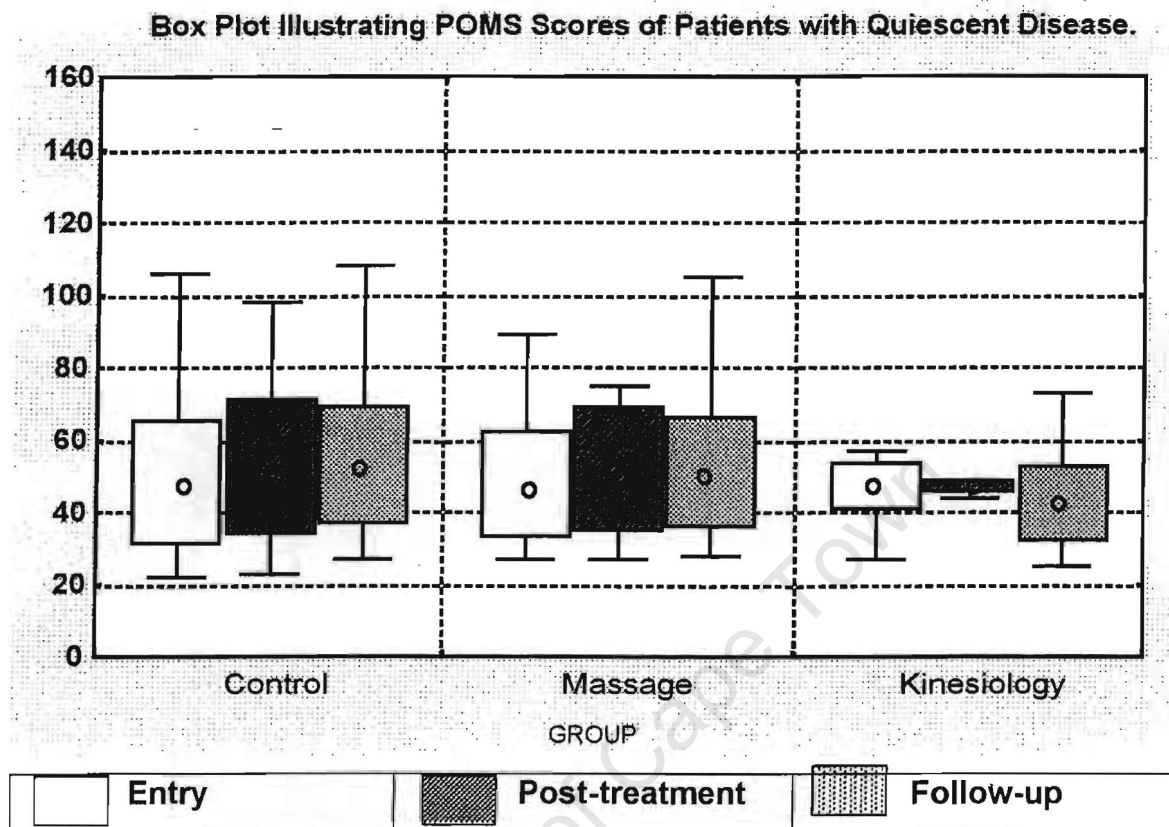


Figure 23: The POMS scores of patients with quiescent disease, within the three groups at entry, post-treatment, and follow-up.

Table 40 illustrates the mean POMS scores of patients with quiescent Crohn's disease at entry, post-treatment, and follow-up.

Table 40: Mean POMS Scores of Patients with Quiescent Disease

	Entry	Post-treatment	Follow-up
Control	51.17 ± 23.56	50.56 ± 21.82	57.26 ± 20.44
Massage	50.31 ± 18.90	55.69 ± 26.99	51.93 ± 20.83
Kinesiology	45.22 ± 9.85	45.77 ± 8.01	48.55 ± 21.08

Results = mean ± standard deviations (SD).

In patients with quiescent disease, there were no significant difference in POMS results between the groups after four-months of intervention and neither at three-month follow-up (Figure 23).

Table 41: Two-way ANOVA Illustrating Repeated Measures of POMS in Quiescent CDAI

	SS	df	MS	F	p
GROUP	884.2800	2	442.14005	2.14	0.47
TREAT	281.1104	2	140.55522	0.55	0.73
TREAT*GROUP	524.891	4	131.22278	1.22	0.68

The mean POMS levels are the same across the stage of treatment as well as the treatment groups. There is also no difference between the interaction variable TREAT*GROUP (Table 41).

4.4.3 POMS scores of patients with CDAI 150-200 (n=15)

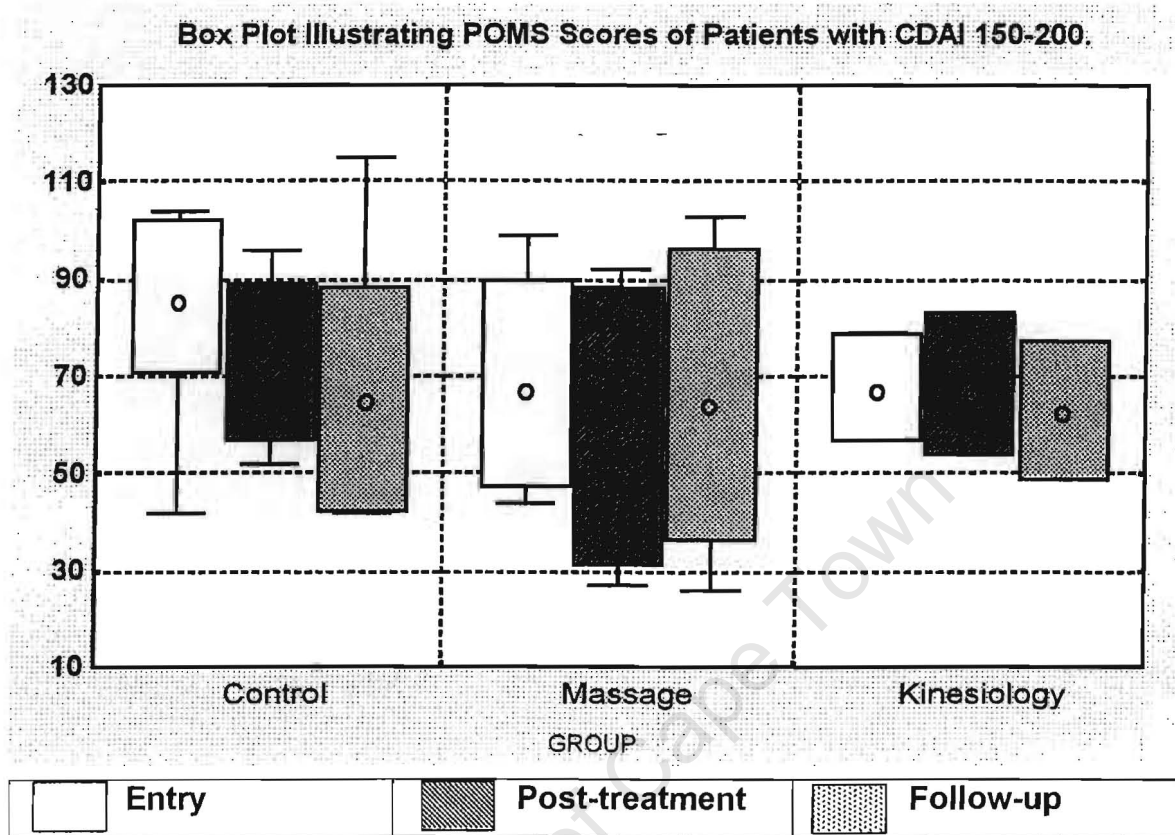


Figure 24: The POMS scores of patients with CDAI 150-200, within the three groups at entry, post-treatment, and follow-up.

Table 42 illustrates the mean POMS scores of patients with CDAI 150-200 at entry, post-treatment, and follow-up.

Table 42: Mean POMS Scores of Patients with CDAI 150-200

	Entry	Post-treatment	Follow-up
Control	84.33 ± 24.17	73.83 ± 17.86	68.67 ± 29.80
Massage	67.17 ± 22.73	57.17 ± 27.66	65.33 ± 35.75
Kinesiology	65.00 ± 12.16	68.00 ± 14.52	59.33 ± 15.37

Results = mean ± standard deviations (SD).

Although there were no significant results in POMS scores of patients with CDAI 150-200, the Control Group had a gradual reduction from 84.33 ± 24.17 at entry to 68.67 ± 29.80 at follow-up, the Massage Group from 67.17 ± 22.73 at entry to 65.33 ± 35.7 at follow-up, and the Kinesiology Group from 65.00 ± 12.16 at entry to 59.33 ± 15.37 at follow-up (Figure 24).

Table 43: Two-way ANOVA Illustrating Repeated Measures of POMS in CDAI 150-200

	SS	df	MS	F	p
GROUP	1584.0333	2	792.01667	0.62	0.55
TREAT	437.52778	2	218.76389	0.68	0.51
TREAT*GROUP	600.13333	4	150.03333	0.46	0.75

The mean POMS levels are the same across the stage of treatment as well as the treatment groups. There is also no difference between the interaction variable TREAT*GROUP (Table 43).

4.4.4 Correlations between CDAI and POMS at Entry into Study

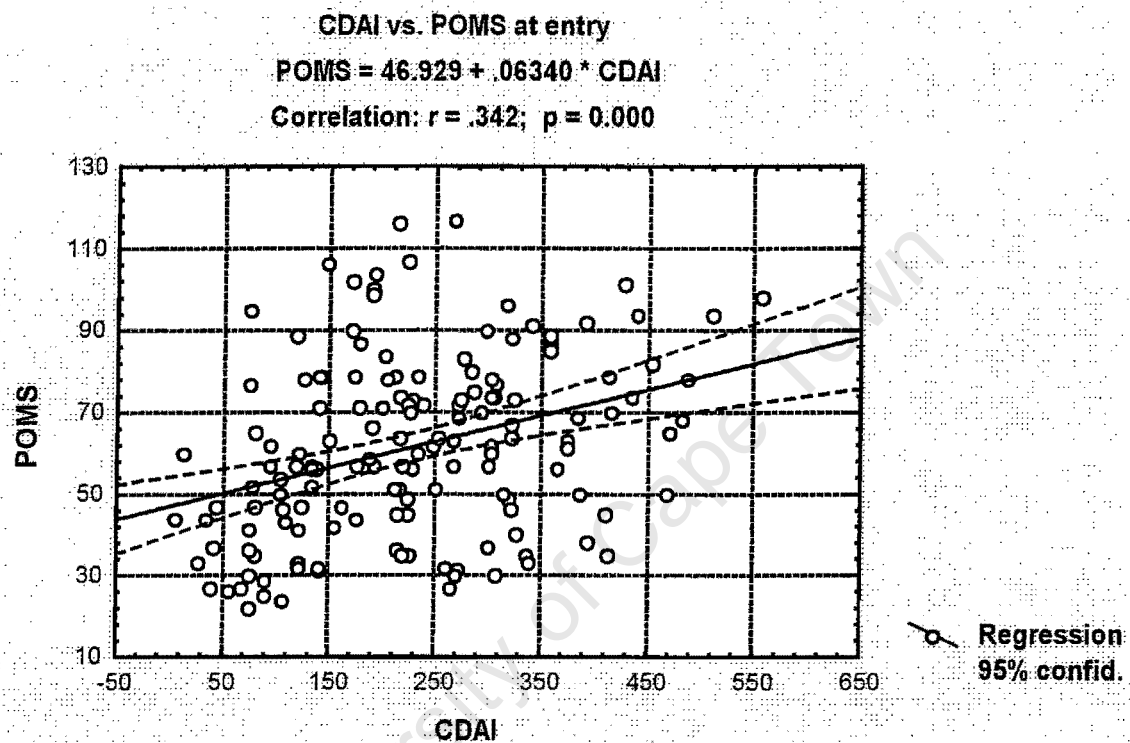


Figure 25: Crohn's Disease Activity Index (CDAI) vs. Profile Of Mood States (POMS) at entry.

There is a significantly positive association between CDAI and POMS at entry ($r=0.342$; $p=0.000$) (Figure 25).

4.4.5 Correlations between CDAI and POMS at Post-treatment

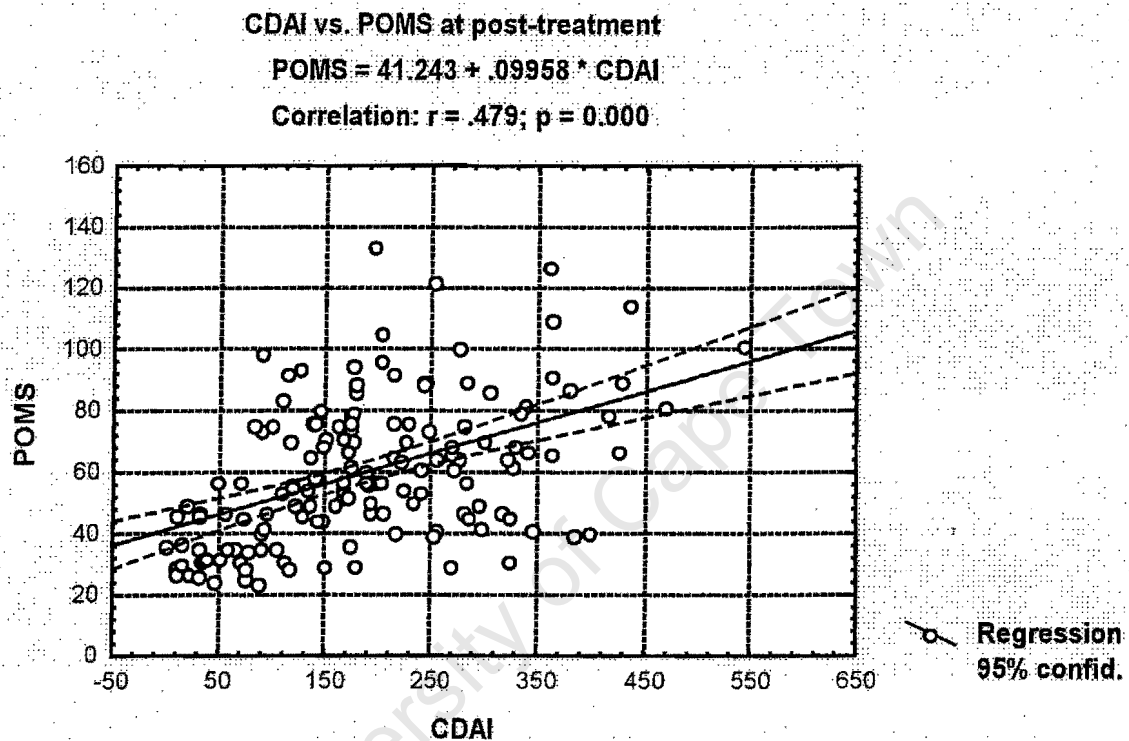


Figure 2: Crohn's Disease Activity Index (CDAI) vs. Profile Of Mood States (POMS) at post-treatment.

There is a significantly positive association between CDAI and POMS at post-treatment ($r=0.479$; $p=0.000$) (Figure 26).

4.4.6 Correlations between CDAI and POMS

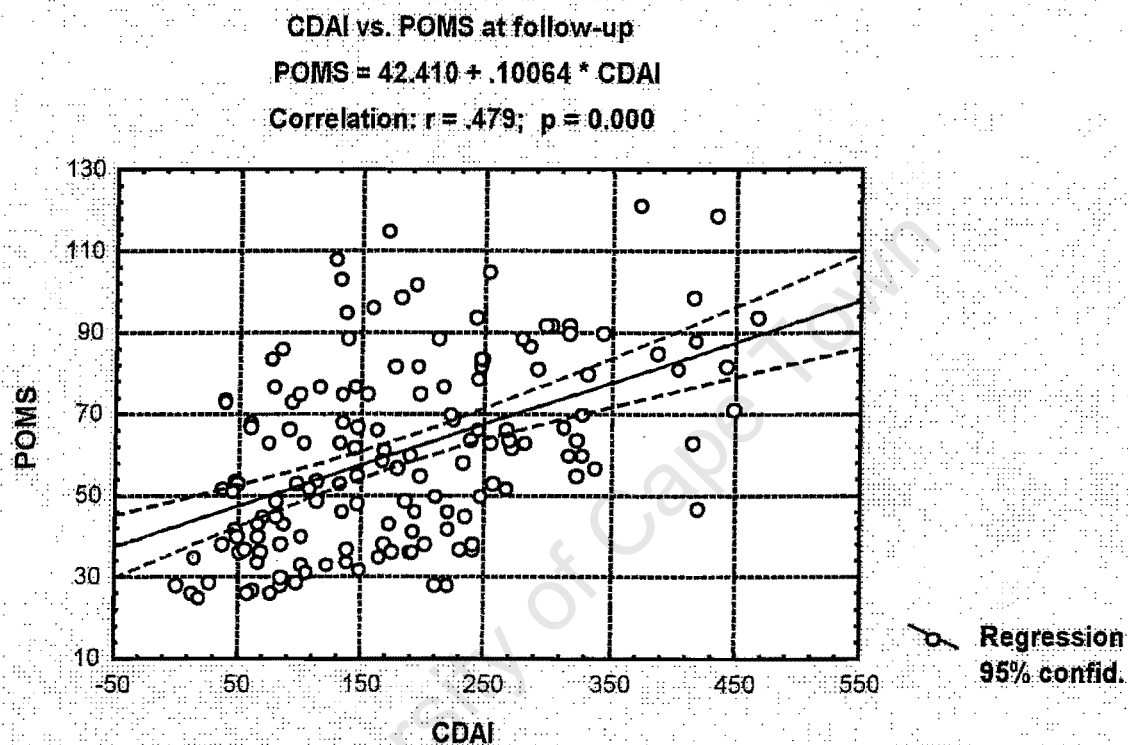


Figure 27: Crohn's Disease Activity Index (CDAI) vs. Profile Of Mood States (POMS) at follow-up.

There is a significantly positive association between CDAI and POMS at follow-up ($r=0.479$; $p=0.000$) (Figure 27).

4.5 Active Disease Relapses During the Course of the year

The trial period commenced in February and ended in November, 2001. During February, patients were recruited for the study and commencement of therapy occurred in March and ended in June. The three-month follow-up evaluation was conducted in October. During November, the Control Group received a massage for being part of the study. During the period February-November, forty four percent of the sample had experienced one or more relapses, as determined by the attending physician. Table 43 illustrates the distribution of relapses between the groups during the trial period.

Table 44: Relapse Rates During the Course of the Year

Group	Patients with relapses	% of group
Control	29	58.00%
Massage	27	54.00%
Kinesiology	10	20.00%
All Groups	66	44.00%

There was a significant difference in the number of relapse rates between the groups ($\chi^2(2) = 17.69$; $p = 0.0001$).

Table 44 illustrates the actual number of relapses experienced by the groups during the course of the year. 84 patients had no relapses, 54 had 1 relapse, 11 had 2 relapses and 1 patient had 3 relapses.

Table 45: Breakdown of Groups by Actual Number of Relapses During the Course of the Year

Groups	0	1	2	3
Control (%)	21 (42%)	22 (44%)	6 (12%)	1 (2%)
Massage (%)	23 (46%)	22 (44%)	5 (10%)	0 (0%)
Kinesiology (%)	40 (80%)	10 (20%)	0 (0%)	0 (0%)
Totals	84	54	11	1

Significantly more patients in the Kinesiology Group remained in remission ($\chi^2(6) = 20.75$; $p = 0.002$).

CHAPTER 5

DISCUSSION

5.1 Patient Characteristics

At entry into the study the three groups, Kinesiology, Massage and Controls were of similar ages and there was no significant difference in sex distribution, although the majority of the groups were female. It has been reported that the incidence of Crohn's disease may be higher in women, by as much as 30% (Stenson et al., 1991). The present study therefore confirms this finding. At entry the Control Group consisted of 28% males and 72% females in comparison to a Control Group with 26% males and 74% females and a Kinesiology Group with 30% males and 70% females.

Using the BMI index, the majority of patients were found to be of normal weight, with 31% either obese or overweight and only 10% were underweight. It should be noted, that obesity affects the calculation of the CDAI, and may lead to underestimation of disease activity. However, the mean BMI levels were similar between the groups. Patients were also similar on all haematological and biochemical values and were therefore equivalent for study purposes.

The distribution of disease in this study population was also similar to that reported in the literature with 14% having only ileitis, 67% ileocolitis and 19% colitis only (SAGES, 1995). There was no significant difference in duration of disease between groups. Prior to the study, most patients had undergone one or more disease related surgical procedures. The Control Group had 66%, Massage Group 64%, and the Kinesiology Group 58% of surgical procedures. There was no significant difference in the amount of surgical procedures between the groups.

Fifty percent of the patients in the study had experienced an active episode of Crohn's disease in the year preceding the study. There were no significant differences in relapse rates between groups. Previous studies have indicated that approximately 70% of patients with Crohn's disease, who have had an active episode within the previous year, would experience a relapse within 6 months (Stenson, 1991). This study commenced in February 2001 and ended November of the same year. During this period, there was a significant reduction in disease relapse rates within the Kinesiology Group. 20% of patients experienced a relapse compared to 58% in the previous year. This relapse rate was also significantly lower in the same patients at follow-up and also lower than the other two groups.

Despite random allocation of patients to treatment or control groups, there were more patients in the Kinesiology Group with active disease. At the time of interview, patients' disease activity was assessed using the CDAI. 42% of patients in the Control Group, 56% in the Massage Group and 76% in the Kinesiology Group presented with active disease. 46% of patients in the Control Group, 32% in the Massage Group and 18% in the Kinesiology Group were in remission. Although there were significantly more active patients in the Kinesiology Group, mean CDAI scores were similar between groups and the groups were therefore considered comparable for study purposes. The Control Group had a mean score of 177.03, The Massage Group 179.65, and the Kinesiology Group 178.57. Since the CDAI is a relatively subjective measure, the ESR, which is an inflammatory marker, was also used as an objective evaluation of the patient's disease state. The significant correlation between CDAI and ESR confirmed that the CDAI was an effective measure of disease activity and the differences measured during the study were valid. This assessment revealed no significant differences between the groups at entry. The three groups were therefore equivalent on disease history.

During the course of the study, patients continued to attend their regular clinical visits, and received regular Medical therapy. Use of steroids and immunosuppressives during this period was similar in the three groups, indicating that clinical differences between the groups were likely to be a result of the study procedures.

5.2 Treatment Results

The results of this study demonstrate a significant association between reduction of Crohn's disease, improved quality of life, maintenance of remission and Kinesiology.

In order to determine the effect of Kinesiology on managing disease activity, and also in maintaining remission, at entry into the study patients were stratified into those with an active disease (CDAI >200) and those with quiescent disease (CDAI <150). The patients with an indeterminate CDAI level of 150-200 were also assessed as a separate group. This division into strata however, had its disadvantages. The initial 3 groups of 50 (n=150) have been divided into 9 smaller groups, with the active patients forming the largest group (n=87: Kinesiology 38; Massage 28; Control 21) followed by quiescent patients (n=48: Kinesiology 9; Massage 16; Control 23) and the indeterminate patients which comprised the smallest group (n=15: Kinesiology 3; Massage 6; Control 6). In experimental terms it is much better to have a larger number in order to maintain power. In this study it was evident that due to insufficient numbers in the quiescent and indeterminate groups, results did not show significance, however, the pattern of improvement in the Kinesiology Group remained consistent throughout.

Following the four-month intervention period, the CDAI, a standardized clinical grading system that provides a method of quantifying the "activity" of disease in a

patient at a particular time, was used. The CDAI gives considerable weight to items 1-3 which rely on subjective assessment by the patient (Best et al., 1976). The index may therefore be affected by the patient's personality and/or specific disease state. In a study by Teixeira and Ferguson (1979), it was found that some stoic patients had low scores despite the presence of almost complete intestinal obstruction or multiple fistulae. The opposite was also true. Patients with psychological problems had elevated scores despite an inactive disease. These researchers also note that patients with evidence of severe disease, and who are under control from medical therapy, may also show low CDAI values. Therefore in this study the ESR, an objective disease marker, was used in conjunction with the CDAI to assess the patient's disease activity. In accordance with recent studies in Crohn's disease activity (Targan et al., 1997), a change of at least 70 points on the CDAI was considered to represent a clinical response and a decrease to <150 clinical remission. The SIBDQ was used for assessing quality of life and the POMS to evaluate the patient's psychological state.

5.2.1 Disease Activity (CDAI)

After the four-month intervention, the disease rate in the active Kinesiology Group (CDAI>200) had fallen significantly from baseline ($p<0.001$), indicating an improvement in disease activity, whereas the Massage and Control Groups did not show any significant improvement in disease state. Significantly more patients receiving Kinesiology achieved clinical response (66%) than those receiving Massage (32%) and Controls (19%). Achievement of remission was also greater in the Kinesiology Group (50%) than in the Massage (25%) and Controls (14%).

At three-month follow-up there was a progressive overall improvement in disease condition of the active Kinesiology Group, but not in the Massage and Control Groups. Significantly more patients in the Kinesiology Group achieved clinical response (55%) compared to the massage (21%) and the Controls (4%), while

50% of the patients in the Kinesiology Group, 32% in the Massage and 9% in the Control group, achieved clinical remission. The ESR levels in the active Kinesiology Group remained significantly positive, although weakly associated with CDAI ($r=0.230$; $p<0.01$), indicating that an improvement in disease activity was associated with improvement in ESR levels.

The group receiving Kinesiology, who was quiescent ($CDAI<150$) at entry into the study, maintained their remission throughout the study, whereas the Control Group presented with deterioration in disease state. The Massage Group showed an increase in CDAI scores but still remained within the quiescent state. At three-month follow-up, the Kinesiology Group maintained remission compared to entry and post-treatment levels. The Control and Massage Groups showed increases in disease state to the extent that the Control Group fell within the level of CDAI 150-200 and were no longer in remission.

Patients with CDAI 150-200 in the Kinesiology Group as well as the Control Group demonstrated an increase in disease activity while the Massage Group presented with a decrease. The ESR revealed no significant differences at this stage. At follow-up the Kinesiology Group demonstrated an improvement compared to entry and post-treatment levels and were in remission. The Control and Massage Groups presented with increases in their disease state but not sufficient to be of significance. It should be noted that the numbers were small and that the changes would not prove significance.

5.2.2 Quality of Life (SIBDQ)

Assessment of quality of life in patients who had active Crohn's disease at entry into the study demonstrated improvement in both the Control Group and the Kinesiology Group following therapy, whereas that of the Massage Group was unchanged. The improvement in the Control Group is somewhat surprising considering that their disease was unchanged, however the SIBDQ is a

somewhat subjective measure (Irvine et al., 1994), and the attention received during the course of the study may have influenced this improvement or it could be the case of regression to the mean. After the follow-up period, the improvement in quality of life in the Kinesiology group was significantly maintained, whereas the Control and Massage Groups presented with a decrease in quality of life. The Control Group decreased back to the levels obtained at entry into the study.

The quiescent patients in the Kinesiology Group had an increase in SIBDQ scores, but not sufficient to be of significance, compared to the Control and Massage Groups who remained unchanged. At follow-up, patients in the Kinesiology Group remained unchanged compared to post-treatment level while the Massage and Control Groups presented with a decrease in quality of life compared to post-treatment levels.

Patients with CDAI 150-200 in the Kinesiology Group presented with a decrease in quality of life compared to the Control and Massage Groups who showed improvement. However, these improvements were not significant. At follow-up, the Kinesiology Group demonstrated a significant improvement in quality of life compared to post-treatment level while the Control and Massage Groups showed a non-significant decrease compared to post-treatment level.

Correlations of SIBDQ with CDAI at post-treatment ($r = -0.701$; $p < 0.001$) and follow-up ($r = -0.684$; $p < 0.001$) is much larger than the correlations between CDAI and ESR. The strong negative correlations between SIBDQ and CDAI indicate that a decrease in CDAI is associated with an increase in SIBDQ implying that improvement in disease activity is associated with improvement in quality of life.

5.2.3 Psychological Presentation (POMS)

Patients with active disease in the Kinesiology Group presented with an improvement in psychological states compared to the Control and Massage Groups who remained unchanged. At follow-up active patients in the Kinesiology Group maintained improvement in Mood states compared to post-treatment level while the Control and the Massage Groups presented with decrease in Mood states. These results were not significant.

Quiescent patients in the Kinesiology Group maintained their Mood state compared to the Control Group who showed a slight decrease and the Massage Group who showed an increase in Mood states. None of these results were significant. At follow-up quiescent patients in the Kinesiology Group showed a non-significant decrease in Mood states compared to the Massage Group who had an increase and the Control Group who presented with an increase in POMS scores, implying a decrease in Mood states.

Patients with CDAI 150-200 in the Kinesiology Group presented with an increase in Mood states compared to the Control and Massage Groups who presented with a decrease in Mood states. None of these results were significant. At follow-up the Kinesiology, Massage and Control Groups presented with a decrease in POMS scores compared to entry level, implying an improvement in Mood states. However, these results were not significant.

In this study Kinesiology was significantly associated with decreased disease activity with significantly more patients achieving a clinical response and remission. Kinesiology was also associated with improvement in quality of life. Correlations between SIBDQ and CDAI at post-treatment ($r=0.479$; $p<0.001$) and follow-up ($r=0.479$; $p<0.001$) was much better than the correlation between CDAI and ESR. In those patients with quiescent disease at entry, Kinesiology was also associated with increased maintenance of remission.

Recently, health-related quality of life has become a key consideration when evaluating different treatment options (Guyatt et al., 1993). As stated previously, one earlier study (Shaw et al., 1987) showed that six three-hour sessions of Stress-release therapy was associated with significant improvement in mean Inflammatory Bowel Disease Index scores in patients with active Crohn's disease. In this study the SIBDQ, a disease-specific health-related quality of life questionnaire was used to assess quality of life. This is a validated questionnaire that has proven suitable for assessing the impact of disease and treatment on perceived well being, general health, and daily life function (Irvine et al., 1994; Feagan et al., 1994). The results of this study is consistent with that of Shaw et al. (1987). Kinesiology was associated with significant improvement in mean SIBDQ in patients with active Crohn's disease.

Although the SIBDQ consists of seven sub-scores, the total SIBDQ score was used to determine quality of life. The only disadvantage in using the total SIBDQ score is that improvement in overall quality of life can sometimes hide deterioration in particular aspects of psychological well being. Similarly, the POMS consists of six sub-scores and although the Total Mood Disorder (TMD) score was used to evaluate the psychological state of this population, it would have been more beneficial to evaluate the various aspects of psychological well being of these patients. Specifically those patients with active disease. It should be noted that during and active disease state, patients receive additional or a change in medical therapy in an attempt to induce remission. This medication would therefore also affect disease activity, and quality of life, and steroids in particular may have psychological effects (SAGES, 1995). The use of these medications was however similar in the three groups and therefore, any differences detected between the groups is likely to represent the effects of the treatment interventions (Kinesiology and Massage).

5.3 The Need for Adopting a Mind-Body Approach

The positive result obtained from the intervention used in this research highlights the importance of physical contact with patients and the need for stress release interventions. This approach to physical and psychological stress reduction seems to have created a positive outcome for the majority of patients in the Kinesiology Group which also highlights the need to shift from a biomedical viewpoint, which only addresses the biological factors of disease, to a biopsychosocial approach, which can incorporate information about the patient as a whole including mind and body (Drossman, 1998).

Both the CDAI and ESR are disease markers which are used to assess the physical and biomedical aspects of disease (Best et al., 1976). In other words, assessment of the body. Whereas the SIBDQ assesses both the physical (body) as well as the psychological (mind) aspects. The POMS however assesses purely psychological states, which can be viewed as the mind aspect (Mc Nair et al., 1992). In this study the CDAI shows the largest differences due to treatment. The strong correlations between SIBDQ-CDAI and moderate correlations between POMS-CDAI compared to the weaker correlation between ESR-CDAI, could be viewed as an indication of the need for adopting a mind-body approach.

There is no doubt that the reductionist approach of biological medicine, which tries to reduce psychological notions to biological ones, has provided some truly remarkable technological advances and treatments (Watkins, 1997). However, there is also little doubt that the biological approach has certain limitations and its technological power must be balanced with the human qualities of care, compassion and empathy (Watkins, 1997).

Adopting a mind-body approach would mean recognizing that illness is not merely malfunctioning of one organ or one bodily system, but a breakdown in a wide variety of defenses be they immunological, physiological, psychological or

spiritual. This approach would change the way a physician takes a history, examines a patient and ultimately manages their problem. It also allows for more creativity and scope to respond to the patient's dilemma of illness and minimizes the tendency to see individuals as biological subjects to be fitted into treatment protocols. Clearly no two illnesses are the same, and no two patients possess the same coping mechanisms and powers of recovery. Complementary therapies as an adjunct to conventional medical care, may have much to offer. Both Kinesiology and Massage therapy which were implemented in this study can be viewed as Stress-release therapies. However, it is believed that Kinesiology provides a more intense form of physical as well as emotional stress release (Diamond, 1990).

5.4 The Need for Stress-release Therapies

Patients were very compliant. One hundred and fifty patients enrolled for this study and none of these patients withdrew during the course of the trial. This could be an indication that stress release therapies are welcomed by patients dealing with chronic illnesses.

The latest psychoneuroimmunology research indicates that it is a person's perception of a stressor that is occurring in their life, and their response to that perception, which may influence their immuno-competence and therefore their health (Watkins, 1997; Kiecolt-Glaser et al., 1995, 1993; Idler & Kasl, 1991). Psychoneurological research has also established a strong correlation between acute and chronic stress and coping skills in medical disorders and psychiatric states (Jiang et al., 1996; Cohen et al., 1997; Sutherland, 1991). Consequently, Blumenthal et al. (1997) and others (Fawzy et al., 1995, 1993) have suggested that relaxation interventions as adjunct therapies could offer additional benefits to general health and improved quality of life. In light of the evidence from psychoneuroimmunology research, Kinesiology could be considered as a

relaxation intervention offering physical and emotional stress reduction and additional benefits to general health, complementary to usual medical therapy.

Patients often expressed their concern regarding the adverse effects of medication. Some acknowledged using complementary therapies to reduce their exposure to the side effects of conventional therapies and to try to find effective therapy for their disease. One patient reported that it gives her a greater sense of control in managing her health. Some patients expressed their urge to discuss the use of complementary therapies with their physician but are afraid of a negative reaction.

The majority of patients expressed a major concern about having an operation. Other concerns were feelings of inadequacy, insecurity and the possibility of losing their job as a result of having to attend hospital or taking off from work as a result of acute abdominal pains or severe diarrhea. These findings confirm the notion that Crohn's disease patients have major worries and concerns about their disease (Dossman et al., 1991).

From the above findings it is obvious that patients have many concerns regarding their health. Many patients expressed their eagerness to attempt the use of complementary therapies but need some guidance to do so. Patients often indicated their enjoyment of the methods of relaxation employed in the study.

5.5 Conclusion

Crohn's disease is often a chronic debilitating disease. The cost of the disease is high and patients may experience difficulty with permanent employment due to the unpredictable nature of their illness. The psychological distress of having to content with the concomitants of the disease was found to have an adverse effect on patient's health-related quality of life. Medical interventions generally focus on addressing the physical symptoms but not the complex psychological component of the disease. Crohn's disease patients were often disillusioned by the recurrent nature of their condition and side effects of medical interventions. Therefore, the need for efficient cost effective patient care and treatment, in order to keep patients in remission and out of hospital, have been expressed.

In this study Kinesiology as an adjunct to medical therapy was shown to have a beneficial effect. Kinesiology was also associated with improved quality of life and reduction of the disease recurrence. These findings point to the necessity for treating the patient as a whole person which involves the physical, and psychological dimensions, and not just the symptom of diarrhea or abdominal pain.

5.6 Implications for Clinical Practice

From the results and observations made during the course of this investigation, several suggestions are offered which may be used by the attending physician to supplement the conventional medical care of patients with Crohn's disease:

As noted earlier, participation in the study was in itself seen as a factor yielding a positive effect on patients. It seems reasonable to facilitate this effect in clinical practice by including patients' evaluation into the treatment program. In a disease where the patient often sees him/herself as passively dependent upon

the physician, these actions would have the added effect of enlisting the patient's active participation in the treatment process.

Findings that practicing stress management techniques decreases disease activity and was associated with improved physical and emotional functioning have direct implications for medical practice. These findings point to the necessity for approaching the patient as a whole system involving physical as well as psychological functioning.

An understanding of the influence of stress and ways to manage stress may help patients adapt to and cope with their chronic disease. Stress management techniques could be a useful adjunct to the therapeutic regimen. They can be self-taught and serve to involve the patient in his/her own care.

Physicians caring for patients with a chronic illness such as Crohn's disease, need to be aware of the therapeutic choices that are available in order to communicate knowledgeably with patients and provide optimal guidance regarding the choice of adjunct therapies.

5.7 Recommendations

It is believed that this study represents the first attempt at using Kinesiology on Crohn's disease patients in a research setting. Further studies using a longer time frame are needed to confirm the effectiveness of this therapeutic intervention.

One of the four Kinesiology sessions was allocated to Emotional Stress Diffusion. In this research, Crohn's disease patients presented with very complex emotional issues. Further studies of this nature should consider allocating at least three sessions for Emotional Stress Diffusion.

Quality of life is a very important assessment for evaluating the effectiveness of any intervention. This study used a disease-specific health related quality of life questionnaire (SIBDQ) and a psychological assessment (POMS). Although the total score of these tests were used, it would have been instructive to use the sub-scores of these tests, since the total score can sometimes hide deterioration in particular aspects of psychological well-being and therefore miss important factors. These individual factors should be assessed in future study.

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GLOSSARY

Applied Kinesiology: a system of diagnosis and treatment that uses standard muscle testing procedures to evaluate body function, and applies a range of therapeutic techniques (Thie, 1996).

Ch'i : Chinese term for vital energy. All matter, animate and inanimate is composed of and pervaded with this universal energy (Gallo, 2000).

Distention: distention of the bowel occurs when some or all of the intestine balloons out from the presence of excessive amounts of gas or liquid (Sages, 1995).

Distress: an individual reaction to a perceived or real threat or stimulation. The purpose of distress is to enable the body to deal with an emergency situation (Selye, 1978).

Defusion: a technique or energy release, which releases the emotions of fear, pain or fear of pain perceptions, associated with an event (Krebs, 1998).

Fistula: an abnormal connection between two organs, such as between bowel and bowel, bowel and vagina, bowel and bladder, bowel and urethra, or bowel and skin. Two or more of these are known as fistulae; they commonly occur in patients with Crohn's disease (Sages, 1995).

Ileostomy: An ileostomy is formed by the surgeon at the time of removal of a portion of the intestine in some patients with inflammatory bowel disease. The body's fluid wastes are emptied through the surgical prepared opening in the skin on the front of the abdomen, and the material collects into a bag which is attached to the skin by means of special adhesives. The bag is then periodically drained by the patient (Sages, 1995).

Indicator muscle change: (IMC) a muscle test that can be used to detect dysfunction of other body systems (Rolfes, 1996). Also see muscle monitoring or muscle testing.

Kinesiology: Kinesiology uses muscles (see indicator muscle change above) to monitor stress and imbalance within the body and the human energy field. IMC is used as a diagnostic tool to detect and correct “energetic” imbalances in the body that may relate to stress, nutrition or injuries (Rolfes, 1996).

Muscle monitoring or muscle testing: the impermanent loss of isometric muscle strength during manual muscle testing (Rolfes, 1996).

Meridians: energy “gridlines” described and used in traditional Chinese Medicine. They are the channels or pathways that carry Ch’i through the body (Gallo, 2000).

Regression to the mean: When selecting a sample from the lowest 10% of a population at pretest, most of them will probably be in the lowest 10% at posttest, but if even just a few are not, then their group’s mean will have to be closer to the population’s posttest than it was to the pretest. The same holds true for a sample on the highest 10% (Howell, 1997).

Stress: Defined by Selye (1978) as the non-specific response of the body to any demand made on it. Stress is described by Pert (1997) as a condition in which the body-mind network is so taxed by unprocessed sensory input in the form of suppressed trauma or undigested emotions, that the body-mind network has become overloaded and cannot flow freely, sometimes even working against itself.

Vital-energy: supraphysical energy that interpenetrates and vitalizes the physical body (Gallo, 2000).

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Appendix 1

Consent Form

University of Cape Town

INFORMED CONSENT FORM

This research is being conducted by Rasheda Jogee University of Cape Town, in partial fulfillment of the requirements of course PSY510W MA (Research) Psychology.

The aim of this study is to evaluate the effect of a therapeutic intervention, which consists of massaging, on the symptoms of Crohn's Disease.

In agreeing to participate in this research I understand the following:

1. The research will involve 4 monthly sessions of 60minutes each. Participants will continue with their monthly scheduled appointments at Groote Schuur Hospital and these sessions will be used during the trial period.
2. All data from the research will remain anonymous. Participants will be allocated a number which will be used, instead of their names, for the purpose of this study The data from all participants shall be compiled, analysed and submitted in a report to the course supervisor.
3. The research involves no physical or psychological discomfort, harm or danger.
4. Participants will agree voluntarily without coercion.
5. Participants may withdraw from the research procedure at any time, without any penalty incurred on him/her.
6. At the end of the research, participants will be given information concerning their performance and any questions they may have, about the research, will be clearly and fully answered.

Researcher _____

Research participant _____

Date _____

Appendix 2

Ethics Committee Letter

University of Cape Town

UNIVERSITY OF CAPE TOWN



Research Ethics Committee
Faculty of Medicine

Anzio Road, Observatory, 7925

Queries : Mandisa Tani

Tel : (021) 406-6492 Fax: (021) 406-6390

E-mail : Mtani@curie.uct.ac.za

21 November 2000

REC REF: 225/2000

Ms R Jogee
Psychology

Dear Ms Jogee

**TO EVALUATE THE ROLE OF KINESIOLOGY, AS AN ADJUNCT
THERAPY, IN THE QUALITY OF LIFE OF PATIENTS WITH CROHN'S
DISEASE.**

Thank you for your application submitted to the Research Ethics Committee on the 08 September 2000.

I have pleasure in informing you that the Research Ethics Committee has **formally approved** the above study in November 2000.

Included is a list of Research Ethics Committee Members who have formally approved your protocol.

Please quote the above Reference number in all correspondence.

Yours sincerely

Signed by candidate

Signature removed

PROFESSOR CR SWANEPOEL
CHAIRPERSON

Appendix 3

Demographic Data and Medical History Form

University of Cape Town

DEMOGRAPHIC DATA

Patient Surname: _____ Hosp Folder No: _____ Surname _____ Name _____ DOB _____ Age _____ Male / Female _____	Address: _____ _____ _____ _____ Tel No: _____
---	--

Family status: Single	Education: Primary
Married/Stable relationship	Secondary
Widowed	Tertiary
Divorced/Seperated	
	No of children: Dependent
Occupation:	Not dependent

CROHN'S DISEASE HISTORY

Date of Diagnosis: _____	Location of Crohn's: Small Bowel
	Small Bowel & colon
Duration of Crohn's: _____ yrs	Colon
Age of Diagnosis: _____ yrs	Present Condition of Crohn's:
	Active
	Inactive
	Duration

SURGICAL HISTORY

Have you had any surgery for the Crohn's?	Type of Surgery:
Yes	Total colectomy
No	Resection of small bowel
	Resection of large bowel
	Fistula repair
	Stricture repair
	Abscess
	Parkes pouch
	Ileostomy
	Colostomy

PRESENT MEDICATION

5-ASA	Immunosuppressives
Corticosteroids	Other

Appendix 4

Crohn's Disease Activity Index CDAI

NAME.....

FOLDER NUMBER.....

Calculation of CDAI

REP 3 5

	Days:	1	2	3	4	5	6	7	<u>Sum</u>		<u>Subtotal</u>
1. Number of liquid or very soft stools									_____	x 2	_____
2. Abdominal pain rating											
0 = none											
1 = mild											
2 = moderate											
3 = severe									_____	x 5	_____
3. General well-being											
0 = generally well											
1 = slightly under par											
2 = poor											
3 = very poor											
4 = terrible									_____	x 7	_____

4. Complications

Check the box(es) for the specific items:

- Arthritis / arthralgia
- Iritis / uveitis
- Erythema nodosum / pyoderma gangrenosum / aphthous stomatitis
- Anal fissure, fistula, or abscess
- Other fistula
- Fever over 37.8°C (100°F) during past week

Number of 6 listed categories patient now has: _____ x 20 _____

5. Use of diphenoxylate, loperamide or other opiates for diarrhea

0 = no

1 = yes

_____ x 30 _____

6. Abdominal mass

0 = none

2 = questionable

5 = definite

_____ x 10 _____

7. Haematocrit: _____ % Males: 47 - Hct Females: 42 - Hct _____ x 6 _____

Add or subtract according to sign

8. Body weight: _____ kg Standard weight: _____ kg

$$\left(1 - \frac{\text{body weight}}{\text{standard weight}}\right) \times 100 = \text{_____} \times 1 \text{_____}$$

Add or subtract according to sign

Crohn's Disease Activity Index (CDAI) =

Appendix 5

Short Inflammatory Bowel Disease Questionnaire SIBDQ

Short Quality of Life in Inflammatory Bowel Disease Questionnaire (SIBDQ)

This questionnaire is designed to find out how you have been feeling during the last 2 weeks. You will be asked about symptoms you have been having as a result of your inflammatory bowel disease the way you have been feeling in general, and how your mood has been.

1. How often has the feeling of fatigue or of being tired and worn out been a problem for you during the last 2 weeks? Please indicate how often the feeling of fatigue or tiredness has been a problem for you during the last 2 weeks by picking one options from
(Systemic)
 - 1 All of the time
 - 2 Most of the time
 - 3 A good bit of the time
 - 4 Some of the time
 - 5 A little of the time
 - 6 Hardly any of the time
 - 7 None of the time

2. How often during the last 2 weeks have you had to delay or cancel a social engagement because of your bowel problem? Please choose an option from
(Social)
 - 1 All of the time
 - 2 Most of the time
 - 3 A good bit of the time
 - 4 Some of the time
 - 5 A little of the time
 - 6 Hardly any of the time
 - 7 None of the time

3. How much difficulty have you had, as a result of your bowel problems, doing leisure or sports activities you would have liked to have done during the last 2 weeks? Please choose an option from
(Social)
 - 1 A great deal of difficulty, activities made impossible
 - 2 A lot of difficulty
 - 3 A fair bit of difficulty
 - 4 Some difficulty
 - 5 A little difficulty
 - 6 Hardly any difficulty
 - 7 No difficulty; the bowel problems did not limit sports or leisure activities

4. How often during the last 2 weeks have you been troubled by pain in the abdomen?
Please choose an option from
(Bowel)
- 1 All of the time
 - 2 Most of the time
 - 3 A good bit of the time
 - 4 Some of the time
 - 5 A little of the time
 - 6 Hardly any of the time
 - 7 None of the time
5. How often during the last 2 weeks have you felt depressed or discouraged?
Please choose an option from
(Emotional)
- 1 All of the time
 - 2 Most of the time
 - 3 A good bit of the time
 - 4 Some of the time
 - 5 A little of the time
 - 6 Hardly any of the time
 - 7 None of the time
6. Overall, in the last 2 weeks, how much of a problem have you had with passing large amounts of gas? Please choose an option from
(Bowel)
- 1 A major problem
 - 2 A big problem
 - 3 A significant problem
 - 4 Some trouble
 - 5 A little trouble
 - 6 Hardly any trouble
 - 7 No trouble
7. Overall, in the last 2 weeks, how much of a problem have you had maintaining or getting to the weight you would like to be? Please choose an option from
(Systemic)
- 1 A major problem
 - 2 A big problem
 - 3 A significant problem
 - 4 Some trouble
 - 5 A little trouble
 - 6 Hardly any trouble
 - 7 No trouble

8. How often during the last 2 weeks have you felt relaxed and free of tension?
Please choose an option from
(Emotional)
- 1 None of the time
 - 2 A little of the time
 - 3 some of the time
 - 4 A good bit of the time
 - 5 Most of the time
 - 6 Almost all of the time
 - 7 All of the time
9. How much of the time during the last 2 weeks have you been troubled by a feeling of having to go to the bathroom even though your bowels were empty? Please choose an option from
(Bowel)
- 1 All of the time
 - 2 Most of the time
 - 3 A good bit of the time
 - 4 Some of the time
 - 5 A little of the time
 - 6 Hardly any of the time
 - 7 None of the time
10. How much of the time during the last 2 weeks have you felt angry as a result of your bowel problem? Please choose an option from
(Emotional)
- 1 All of the time
 - 2 Most of the time
 - 3 A good bit of the time
 - 4 Some of the time
 - 5 A little of the time
 - 6 Hardly any of the time
 - 7 None of the time

Appendix 6

Profile Of Mood States – Short Form

POMS-SF

University of Cape Town

NAME _____ DATE _____

SEX: Male (M) Female (F) Identification No. _____

Below is a list of words that describe feelings people have. Please read each one carefully. Then fill in ONE circle under the answer to the right which best describes HOW YOU HAVE BEEN FEELING DURING THE PAST WEEK INCLUDING TODAY.

The numbers refer to these phrases.

- 0 = Not at all
- 1 = A little
- 2 = Moderately
- 3 = Quite a bit
- 4 = Extremely

- | | Not at all
A little
Moderately
Quite a bit
Extremely | | Not at all
A little
Moderately
Quite a bit
Extremely | | Not at all
A little
Moderately
Quite a bit
Extremely |
|-------------------------|--|---------------------------|--|----------------------------|--|
| 1. Tense | 0 1 2 3 4 | 12. Uneasy | 0 1 2 3 4 | 23. Weary | 0 1 2 3 4 |
| 2. Angry | 0 1 2 3 4 | 13. Fatigued | 0 1 2 3 4 | 24. Bewildered | 0 1 2 3 4 |
| 3. Worn out | 0 1 2 3 4 | 14. Annoyed | 0 1 2 3 4 | 25. Furious | 0 1 2 3 4 |
| 4. Lively | 0 1 2 3 4 | 15. Discouraged | 0 1 2 3 4 | 26. Efficient | 0 1 2 3 4 |
| 5. Confused | 0 1 2 3 4 | 16. Nervous | 0 1 2 3 4 | 27. Full of pep | 0 1 2 3 4 |
| 6. Shaky | 0 1 2 3 4 | 17. Lonely | 0 1 2 3 4 | 28. Bad-tempered | 0 1 2 3 4 |
| 7. Sad | 0 1 2 3 4 | 18. Muddled | 0 1 2 3 4 | 29. Forgetful | 0 1 2 3 4 |
| 8. Active | 0 1 2 3 4 | 19. Exhausted | 0 1 2 3 4 | 30. Vigorous | 0 1 2 3 4 |
| 9. Grouchy | 0 1 2 3 4 | 20. Anxious | 0 1 2 3 4 | | |
| 10. Energetic | 0 1 2 3 4 | 21. Gloomy | 0 1 2 3 4 | | |
| 11. Unworthy | 0 1 2 3 4 | 22. Sluggish | 0 1 2 3 4 | | |

**MAKE SURE
YOU HAVE ANSWERED
EVERY ITEM.**



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SHORT FORM

A C D F T V

Appendix 7

Patient's Symptom Recording Sheet

University of Cape Town

Appendix 8

Haematology and Biochemistry Form

University of Cape Town

Patient Sicker... Hosp Folder No:	
Surname	
Name	
DOB	
Age	Male / Female

PHYSICAL SCREENING

COMMENCEMENT:	FOLLOW-UP VISIT	COMPLETION:
Date:	Date:	Date:
Height:		
Weight:	Weight:	Weight:
BMI:	BMI:	BMI:

LABORATORY SCREENING

ON STUDY COMMENCEMENT:		
TEST	NORMAL	ABNORMAL VALUE
FBC		
ESR		
Fe-Studies		
Liver Profile		
Calcium		
Magnesium		
FOLLOW-UP DURING STUDY		
TEST	NORMAL	ABNORMAL VALUE
FBC		
ESR		
Fe-Studies		
Liver Profile		
Calcium		
Magnesium		
ON STUDY COMPLETION:		
TEST	NORMAL	ABNORMAL VALUE
FBC		
ESR		
Fe-Studies		
Liver Profile		
Calcium		
Magnesium		

Appendix 9

Lists of Data

University of Cape Town

DEMOGRAPHICS - PASSIVE CONTROL GROUP

Sub No	Age	Sex	Ht	RELAPSES			COMM		END OF INTV		3MTH F/U	
				DUR	2000	2001	Wt	Bmi	Wt	Bmi	Wt	Bmi
101	42	F	155	17	1	1	42.8	17.8	45	18.7	44	18.3
102	47	F	161	13	2	1	129.5	50	129	49.8	147	49.8
103	44	M	176.5	11	0	0	109.5	35.1	108	34.7	107.5	34.5
104	54	F	155	10	0	0	54.5	22.7	56	23.3	55.5	23.1
105	45	F	160	13	0	0	62.2	24.3	63.2	24.7	68.8	26.9
106	41	F	155	12	0	0	73.5	30.6	69.5	28.9	67	27.9
107	69	M	179	6	1	2	105	32.8	104.6	32.6	104.5	32.6
108	28	F	157	8	0	0	51	20.7	49.8	20.2	49	19.9
109	67	F	150	18	1	1	64	28.4	65	28.9	65	28.9
110	29	F	153	7	0	0	45.5	19.4	43.7	18.7	43.5	18.6
111	29	F	157	7	1	1	52.5	21.3	52.5	21.3	52.2	21.7
112	30	M	167	0	0	1	65	23.3	64.5	23.1	64	22.9
113	39	M	165	0	0	1	66	24.2	65	23.9	63.5	23.3
114	23	M	165	0	0	0	60.6	22.3	62.8	23.1	65.4	24
115	50	F	156	18	1	1	57	23.4	58.8	24.2	58	23.8
116	35	F	161	10	1	1	73	28.2	62.5	24.1	61.5	23.7
117	36	F	155	12	0	0	49	20.4	48.5	20.2	48	20.2
118	22	F	153	6	0	0	60.05	25.7	60	25.6	60	25.6
119	41	F	163	17	2	2	45.5	17.1	43.6	16.4	40.5	15.2
120	39	F	160.5	13	0	1	58.5	22.7	59	22.9	57	22.1
121	30	F	165	7	0	0	61	22.4	57.5	21.1	56	20.6
122	53	F	161	9	2	3	61.5	23.7	62.5	24.1	61.5	23.7
123	29	F	154	7	0	1	58.5	24.7	58	24.5	56.5	23.8
124	46	F	163	13	3	2	72.5	27.3	73	27.5	75	28.2
125	27	F	157.5	5	0	0	74.5	30.3	73.8	29.8	73	29.4
126	38	F	164	6	1	1	63.5	23.6	62	23.1	58	21.6
127	58	M	169	6	0	1	89	31.2	89	31.2	89.5	31.3
128	49	F	161.5	5	1	1	65	24.9	66.4	25.5	67.11	25.7
129	33	M	177.5	8	0	0	65.5	20.8	73.4	23.3	81	25.7
130	56	F	162	17	0	0	62	23.6	63.5	24.2	61	23.2
131	48	M	172	17	1	1	80.5	27.2	80	27	79	26.7
132	29	M	166	5	0	0	65.5	23.8	63	22.9	61.5	22.3
133	58	F	166	6	0	1	69	25	70	25.4	67	24.3
134	25	F	156	5	1	1	36.5	15	37.4	15.4	37	15.2

DEMOGRAPHICS - PASSIVE CONTROL GROUP

135	73	M	157	29	0	0	65.5	26.6	64.5	26.2	63.2	25.6
136	39	F	155.5	15	0	0	79.7	33	79.5	32.9	78	32.3
137	47	F	157	5	1	1	61.6	25	61	24.7	61	24.7
138	35	F	153	13	2	2	43.5	18.6	43	18.4	43	18.4
139	39	F	160	13	1	1	75	29.3	73.6	28.7	73.6	28.7
140	59	F	151	27	0	0	66	28.9	64	28.1	62.6	27.5
141	37	M	180	13	0	0	87.5	27	86	26.5	84	25.9
142	56	M	156	10	2	1	49	20.1	47.5	19.5	47	19.3
143	21	M	161	13	0	0	51	19.7	51.3	19.8	51	19.7
144	27	F	160	11	1	1	56.5	22.9	58	22.7	58	22.7
145	45	F	160	19	0	0	56	21.9	54	21.1	52	20.3
146	28	F	161	14	0	1	63	24.3	62.5	24.1	62.4	24.1
147	47	F	161	13	0	2	60.05	23.2	60.02	23.2	60.05	23.2
148	58	F	168	26	3	2	86.4	30.6	83.5	29.6	83	29.4
149	60	M	172	18	0	0	55	18.6	51	17.2	50	16.9
150	15	F	164	5	1	0	44.5	16.5	45	16.7	46.5	17.3

DEMOGRAPHICS - ACTIVE CONTROL GROUP

Sub No	Age	Sex	Ht	RELAPSES			COMM		END OF INTV		3 MTH F/U	
				DUR	2000	2001	Wt	Bmi	Wt	Bmi	Wt	Bmi
201	25	F	164	7	2	1	60.05	22.3	60	22.3	60	22.3
202	59	F	166	13	0	0	63.5	23	63	22.9	61.5	22.3
203	18	F	153	5	2	2	47.5	20.3	55.8	23.8	55.8	23.8
204	49	M	173	29	0	0	68.5	22.9	73	24.4	72.5	24.2
205	43	F	165	21	0	1	49.8	18.3	51	18.7	51.3	18.8
206	48	F	151.5	19	1	1	54	23.5	54	23.7	54	23.5
207	47	F	153	16	1	1	91.5	39.1	98	41.9	97.3	41.6
208	44	F	157	10	0	0	86	34.9	86.5	35.1	86	34.9
209	47	M	169	27	1	1	56	19.6	57	20	57.9	20.3
210	47	M	168	17	0	0	80	28.3	78.5	27.8	80.2	28.4
211	56	M	165	28	0	1	71	26.1	71.5	26.3	71.5	26.3
212	48	F	153	17	0	0	76	32.5	74	31.6	72.3	30.9
213	37	M	161	9	0	1	50	19.3	52	20.1	52.5	20.3
214	54	F	153.5	18	0	0	48.5	20.6	52	22.1	57.8	24.5
215	46	F	164	6	2	1	97.2	36.1	97	36.1	97	36.1
216	39	F	169	13	2	1	57.4	20.1	58	20.3	57.4	20.1
217	33	F	157	15	0	0	116	47.1	114	46.2	112.5	45.6
218	59	F	160	5	0	0	55.3	21.6	52	20.3	53	20.7
219	61	F	170	13	0	0	79.5	27.5	80	27.7	82	28.4
220	38	F	168	14	0	0	46	16.3	47.6	16.9	46	16.3
221	38	F	164	11	2	1	62.5	23.2	67	24.9	67	24.9
222	55	F	161	12	1	1	52	20.1	54	20.8	55.9	21.6
223	54	F	163.5	27	0	0	89.4	33.4	92	34.4	90	33.7
224	38	F	166	12	0	0	77.5	28.1	76	27.6	75.5	27.4
225	31	F	169	5	0	1	70	24.5	73	25.6	72.5	25.4
226	22	M	175	6	0	0	65	21.2	65	21.2	64	20.9
227	33	M	148	7	0	1	58.5	26.7	58	26.1	57.5	26.3
228	39	F	164	18	2	2	60.05	22.3	64.2	23.9	67.5	25.1
229	29	M	169	14	1	0	85	29.8	84	29.4	84	29.4
230	52	M	178	15	0	1	75	23.5	77	24.2	76.5	24
231	20	M	166	5	0	0	68.3	24.8	68.5	24.9	63	22.9
232	50	F	151	5	1	2	74.8	32.8	73	32	71	31.1
233	40	F	160	13	0	1	60.7	23.7	60	23.4	59.5	23.2
234	44	F	165	7	1	2	51	18.7	53	19.5	55	20.2

DEMOGRAPHICS - ACTIVE CONTROL GROUP

235	46 F	165	12	3	0	51.5	18.9	49.5	18.2	49.5	18.2
236	46 F	152.5	14	1	0	64	27.5	63.5	27.3	62	26.7
237	58 F	159	21	0	0	86	34	86.5	34.2	87.1	34.5
238	18 F	154	6	0	1	57.4	24.2	55.5	23.4	56	23.6
239	29 F	153	6	1	0	52.5	22.4	52	22.2	52.5	22.4
240	48 F	153	13	1	1	70	29.9	70	29.7	69	29.5
241	26 F	171	6	3	0	116.5	39.8	107	36.6	106.5	36.3
242	67 F	167	8	0	1	88.5	31.7	88.5	31.7	88	31.6
243	33 M	177	13	0	1	61.2	19.5	63.5	20.3	63.5	20.3
244	42 M	180	17	0	0	58.4	18.1	57.7	17.8	57.5	17.7
245	68 F	156.5	20	1	1	61.5	25.1	61	24.9	59.5	24.3
246	61 M	168	13	0	2	63.9	22.6	65	23	68	24.1
247	47 F	155	6	1	1	65	27.1	64.5	26.8	64	26.6
248	52 F	167	8	0	0	79.7	28.6	79.5	28.5	78	28
249	50 F	162	6	1	1	78.5	29.9	75	28.6	73.2	27.9
250	32 F	169	7	1	0	54.5	19.1	52	18.2	52.3	18.3

DEMOGRAPHICS - EXPERIMENTAL GROUP

Sub No	Age	Sex	Ht	RELAPSES			COMM		END OF INTV		3 MTH F/U	
				DUR	2000	2001	Wt	Bmi	Wt	Bmi	Wt	Bmi
301	51	F	152	17	3	1	51.6	22.3	56	24.2	53.2	23
302	23	F	146	7	2	1	45.5	21.3	45.5	21.3	42.5	19.9
303	42	F	163	10	0	0	118	44.4	119	44.8	128	48.2
304	59	F	163	14	0	1	63.5	23.9	64.4	24.2	58	21.8
305	46	M	188	21	1	0	75	21.2	76.5	21.6	77	21.8
306	66	F	157	19	0	0	78.5	31.8	79	32	80	32.5
307	45	F	153	18	3	0	63	26.9	64.6	27.6	67	28.6
308	53	F	161.5	7	0	0	52.8	20.2	56	21.5	57	21.9
309	45	F	158	18	0	0	57.2	22.9	58	23.2	58.5	23.4
310	68	F	161	21	0	0	63	24.3	65	25.1	70	27
311	42	M	163	28	2	0	54	20.3	49	18.4	47	17.7
312	65	F	171	12	2	0	71.2	24.3	70.5	24.1	72	24.6
313	55	F	163	11	0	0	73	27.5	78	29.4	74.6	28.1
314	36	M	165	12	0	0	54	19.8	55.5	20.4	56	20.6
315	31	M	168	6	2	1	56.5	20	58	20.5	60.4	21.4
316	43	F	155.5	15	0	0	60.3	24.9	60	24.8	60.5	25
317	47	F	159.5	14	0	0	71.1	27.9	73.2	28.8	76.6	30.1
318	39	F	158	14	1	0	40	16	40.5	16.2	41	16.4
319	44	F	157	14	0	0	52.4	21.3	53.6	21.7	54	21.9
320	33	M	161	12	0	0	54.8	21.1	56.6	21.8	57.5	22.2
321	45	M	167	26	1	0	76.2	27.3	83	27.5	92	27.5
322	54	M	180.5	5	1	0	74	22.7	75	23	75.3	23.1
323	18	M	165	7	0	0	50.5	18.5	51	18.7	52.3	19.2
324	46	M	146	21	0	0	61	28.6	59	27.7	59	27.7
325	61	F	160	26	0	0	60	23.4	62.3	24.3	65.5	25.6
326	44	F	154.5	6	2	0	49	20.5	47.5	19.9	44.5	18.6
327	30	F	156	12	0	0	43.5	17.9	45	18.5	48.5	19.9
328	41	F	155.5	21	2	1	89.7	37.1	89.7	37.1	90.02	37.2
329	44	F	162	11	0	0	83	31.6	83.5	31.8	84	32
330	43	F	157.5	14	0	0	76.5	31	79	32	79.3	32.2
331	57	M	163	6	2	0	69.5	26.2	70	26.3	71.5	26.9
332	26	M	169.5	15	1	0	67	23.3	67.5	23.5	70	24.4
333	36	F	160	12	2	0	62.5	24.4	65	25.4	69.6	27.2
334	46	F	169	15	1	0	51.4	18	52.5	18.4	53.5	18.7

DEMOGRAPHICS - EXPERIMENTAL GROUP

335	37 F	156	11	3	1	51.5	21.2	52	21.4	53	21.8
336	45 F	149	12	1	0	51	23	47	21.2	52.5	23.6
337	40 M	167	8	2	0	98	35.1	98.5	35.3	99.2	35.6
338	50 F	150	17	2	0	64	28.4	65.5	29.1	67	29.8
339	62 F	155	10	1	0	45	21.9	53	22.1	54	22.5
340	43 F	152	11	2	0	46.5	20.1	46.6	20.2	48.5	21
341	61 F	158	6	3	1	58.2	23.3	59	23.6	60.05	24.2
342	32 F	156	6	1	0	61.5	25.3	65.8	27	65	26.7
343	32 M	186	21	1	0	83.4	24.1	84	24.3	84.5	24.4
344	32 M	167	11	1	0	55.4	19.9	56	20.1	56.5	20.3
345	31 M	186	7	0	0	83.4	24	84.5	24.3	85	24.4
346	49 F	158	6	3	1	67.5	27	68	27.2	69.5	27.8
347	37 F	169	16	2	1	71.2	24.9	70.02	24.5	69.4	24.3
348	46 F	159	19	3	1	63.8	25.2	62.3	24.6	63.1	25
349	27 M	171	13	0	0	73.4	25.1	74.5	25.5	76	25.5
350	30 F	157	6	0	0	53.5	21.7	54	21.9	54.3	22

ASSESSMENTS - PASSIVE CONTROL GROUP

Sub No	COMMENCEMENT			END OF INTERV			3MTH	FOLLOW-UP		
	CDAI	SIBDQ	POMS	CDAI	SIBDQ	POMS		CDAI	SIBDQ	POMS
101	225.5	37	35	296.7	39	42	219.4	36	46	
102	238.9	33	72	254	36	64	267.4	30	52	
103	80.6	49	65	160.7	38	75	176	32	82	
104	73.6	56	41	177.6	66	29	121	51	33	
105	12	54	60	10	69	29	36.8	52	52	
106	75.3	41	77	88.8	42	73	133.9	40	75	
107	140.7	27	79	328.7	33	68	413.7	38	63	
108	170.6	34	102	201	37	96	169	39	115	
109	42.9	57	47	30.8	65	47	47	56	54	
110	154.3	47	42	195.8	51	57	218.9	43	42	
111	189.8	41	100	242	27	89	143.3	26	77	
112	56.3	69	26	89.8	67	35	112	64	49	
113	75	62	22	87.8	69	23	208	43	28	
114	34.8	67	44	14.3	68	37	136	56	34	
115	270.6	37	72	201	45	57	68.9	56	45	
116	132.4	46	57	253.7	31	41	240	36	37	
117	79.5	58	47	148	51	71	162	54	66	
118	139.2	34	79	45.8	40	24	237.8	35	64	
119	319.1	36	49	434.3	17	114	432	19	119	
120	5	61	44	0	67	36	112.6	59	54	
121	273.2	39	73	469	39	81	329.5	40	80	
122	106.5	66	24	147	52	44	270	32	62	
123	412	31	79	427.9	28	89	442	30	82	
124	306.9	53	77	107.9	55	53	114.8	51	77	
125	191.6	36	104	169.6	45	67	144.7	50	48	
126	487	35	78	70	64	31	168.3	43	61	
127	136.8	41	56	171.8	59	36	49.8	61	36	
128	215	36	51	344.9	54	41	417.9	44	47	
129	177	46	71	164.8	62	52	46	63	42	
130	27	59	33	30.9	61	46	48	57	53	
131	178.9	29	87	338	20	82	415.9	18	88	
132	139	62	31	116	59	70	268	39	64	
133	200	29	71	124	53	93	210.6	37	89	
134	147.5	46	106	88.5	54	98	127	42	108	
135	88	65	29	301	36	70	223	61	69	
136	321.6	36	88	283	51	89	301	39	92	
137	216	35	74	268	45	66	209.8	52	50	
138	453	28	82	380	36	87	342	41	90	
139	233.7	36	79	275.8	46	64	37.8	32	74	
140	410.9	58	45	362	54	66	322.7	59	64	
141	119.9	67	33	174	57	78	246	28	82	
142	89	50	25	75.4	51	25	61	57	27	
143	284.1	37	80	244	39	89	286	32	87	
144	74	63	95	76.2	66	34	85	59	43	
145	317.2	21	96	305	24	86	297	25	92	
146	95	43	57	172.9	48	74	194	42	82	
147	358.2	34	87	385.1	42	39	316.2	43	92	
148	78.6	42	49	176.2	38	71	137	43	64	
149	394	32	38	172.3	51	62	254	46	63	
150	482.6	34	68	318	38	47	190.3	38	41	

ASSESSMENTS - ACTIVE CONTROL GROUP

Sub No	COMMENCEMENT			END OF INTERV			3MTH FOLLOW-UP		
	CDAI	SIBDQ	POMS	CDAI	SIBDQ	POMS	CDAI	SIBDQ	POMS
201	192	47	57	213	41	92	466	13	94
202	259.6	62	32	216	59	40	188.6	51	36
203	471	30	65	326.9	20	62	314.9	25	60
204	138.4	60	32	88.4	59	40	101	64	33
205	103.3	60	50	81.4	39	75	59	46	68
206	121	68	32	11	69	27	64.5	62	40
207	210.4	32	79	175.3	45	70	401.3	30	81
208	189.6	41	99	243.6	28	88	157.6	28	96
209	321	37	46	323.7	42	45	336.5	37	57
210	160.9	64	47	120	65	49	67.9	66	36
211	232	61	60	110	65	31	132	62	46
212	78.7	46	35	170.7	38	67	136.8	43	37
213	216	48	64	424.9	24	67	245.1	45	50
214	190.6	53	66	34.8	60	31	12	64	26
215	116.7	61	89	97.6	59	75	90.4	40	66
216	557	27	98	541.9	31	101	446.9	30	71
217	75	62	30	75	66	28	83	67	28
218	120.9	65	60	64.1	65	35	189.5	63	36
219	249.7	51	51	71.9	54	45	58.9	45	67
220	76	43	52	165.7	35	54	178	35	57
221	95	48	62	164.9	46	71	195.9	42	75
222	124	31	78	214.1	54	65	131.2	46	53
223	266.7	49	63	222.6	49	54	192.7	45	46
224	174.8	35	44	117	49	56	53.8	52	37
225	170	32	90	21.9	66	27	130.9	39	103
226	218	55	35	241.3	53	53	65.8	53	43
227	373.5	47	63	171.3	50	52	257.2	46	53
228	223.9	61	45	324	46	31	163.9	58	35
229	79.8	58	35	147	50	68	162	52	66
230	313.5	40	50	139.8	49	58	145.6	45	67
231	41.9	56	37	30.9	61	35	48	59	40
232	229	47	73	178	38	86	248.8	32	84
233	305.6	28	74	362.8	21	91	312.6	26	67
234	358.4	38	89	363.3	29	109	316.3	28	90
235	214.6	50	45	268	45	66	279	42	89
236	139.9	34	71	193.9	30	133	251.9	29	105
237	149.6	47	63	281.6	33	47	326.6	37	60
238	132.8	46	52	252.9	31	39	240	35	38
239	223.2	62	72	176.4	53	79	292	21	81
240	357.8	22	85	176.8	36	88	135	47	95
241	392	27	92	360	24	127	415	13	99
242	411.7	28	35	397.9	34	40	280	45	63
243	374.6	36	61	233.6	27	50	221	34	70
244	321.7	35	64	283	51	57	243	54	66
245	68	68	27	36.8	70	32	95.3	66	29
246	306.1	51	30	148.5	35	29	130	46	63
247	336.9	48	35	103.9	56	35	95	63	53
248	365.8	54	56	322.6	59	64	267	63	66
249	266.8	25	117	253	31	122	191.9	32	102
250	229	63	56	174	58	76	246	28	84

ASSESSMENTS - EXPERIMENTAL GROUP

Sub No	COMMENCEMENT			END OF INTERV			3MTH FOLLOW-UP		
	CDAI	SIBDQ	POMS	CDAI	SIBDQ	POMS	CDAI	SIBDQ	POMS
301	510.5	20	94	414.1	26	78	325.8	39	70
302	74.7	57	36	157.7	54	49	255.2	38	53
303	205.2	37	78	228.2	32	76	196	57	55
304	211.8	37	51	204	41	47	172.2	53	43
305	382.9	30	69	214	37	76	165.6	47	59
306	339.6	63	33	39.7	69	32	13.7	67	35
307	293.9	45	70	47.9	54	57	82.9	55	30
308	121	39	41	19	66	49	37.5	60	73
309	321.2	30	67	188.9	40	56	167	35	38
310	414.9	49	70	137	35	76	91.9	41	73
311	313	33	46	342	48	56	369.9	51	64
312	224.2	23	49	193	41	47	84.1	36	38
313	297.9	41	90	295.8	46	49	230	53	37
314	133.11	46	56	133.9	55	49	136.1	49	89
315	271.6	63	31	14.4	65	30	0	67	28
316	323	31	73	225	36	70	154	49	75
317	266.8	51	57	51.8	55	32	35.8	57	38
318	188.1	24	59	107.9	27	83	78.4	39	77
319	302	39	74	193	52	50	184.6	51	49
320	271.6	26	69	90.8	56	42	64.4	57	34
321	385.9	50	50	58.1	58	35	75.7	70	26
322	122.3	60	47	141.1	52	44	99.7	63	40
323	299	60	57	134.1	56	65	103	63	63
324	105	61	46	119	52	55	233.1	44	45
325	246.3	40	62	69.7	53	57	201	50	38
326	268.9	64	30	74.5	69	28	244.7	32	79
327	275	23	83	333.4	32	79	386.1	24	85
328	433.3	32	74	176.5	45	94	371.5	31	121
329	175.7	47	57	132.2	49	54	107	56	52
330	117.7	49	57	56.7	58	47	25.7	63	29
331	265	53	27	115.9	59	28	56	65	26
332	223	45	107	139.4	50	76	74	51	63
333	200.9	38	84	145.1	43	80	97.2	48	75
334	303	44	78	272.3	48	61	142.9	44	62
335	301.9	49	62	188	56	60	104.1	60	31
336	303.3	32	60	219.8	35	63	188.3	42	60
337	327.6	65	40	9.6	65	46	78.6	58	45
338	437.9	29	94	164.9	41	57	132.8	47	68
339	286	33	75	247	36	73	215.2	39	77
340	427.2	32	101	268	41	68	75.8	37	84
341	226.6	40	70	113	49	92	82.9	53	86
342	468.9	37	50	267.8	49	29	220	51	28
343	218.8	45	57	187.2	47	57	145	49	55
344	252.5	55	64	241	54	61	232	57	58
345	109.2	54	43	127.3	56	46	148	68	32
346	38.8	66	27	32	66	26	17.9	69	25
347	171.9	36	79	341.9	18	67	79.9	56	49
348	339.9	18	91	276.9	18	100	241	27	94
349	214	29	116	201.3	31	105	180	35	99
350	103	43	54	94.9	47	47	44.9	48	51

HAEMATOLOGY - RESULTS

Sub No	COMMENCEMENT			END OF INTERVEN			3 MTH FOLLOW-UP		
	CFBC	CESR	CHCT	EFBC	EESR	EHCT	FFBC	FESR	FHCT
101	9.8	19	0.33	11.4	23	0.35	11.8	31	0.35
102	13.5	14	0.42	14.7	15	0.45	15.7	16	0.46
103	16.2	1	0.49	16.1	2	0.49	16.3	6	0.48
104	14.2	7	0.43	15.2	18	0.44	13.7	8	0.42
105	12.9	11	0.41	13.3	2	0.41	13.8	4	0.42
106	13.9	7	0.41	13.7	8	0.39	13.5	5	0.4
107	11.2	34	0.71	13.2	34	0.38	11.7	20	0.36
108	9.4	43	0.31	8.7	46	0.27	9.1	46	0.32
109	7.8	24	0.28	7.9	21	0.25	7.9	112	0.25
110	11.7	60	0.38	11.6	44	0.35	11.8	36	0.36
111	13.7	3	0.44	13.5	7	0.4	12.9	7	0.38
112	12.7	46	0.41	13.7	49	0.4	13.8	49	0.41
113	13.3	16	1.45	14.4	14	0.46	15	14	0.46
114	16.1	8	0.47	16.4	13	0.47	16.2	11	0.49
115	11.8	91	0.36	10.6	105	0.32	11.6	106	0.37
116	12.3	34	0.37	12.3	24	0.36	13	5	0.39
117	12.6	16	0.38	13.4	14	0.41	12	15	0.37
118	12.1	28	0.37	11.8	16	0.35	11.7	16	0.38
119	11.3	7	0.38	9.9	11	0.32	9.4	19	0.3
120	13.3	7	0.37	15	7	0.45	14.4	12	0.4
121	9.3	40	0.37	8.5	49	0.28	8.6	39	0.3
122	12	30	0.35	13.5	34	0.39	12.8	17	0.39
123	12.9	34	0.38	9.1	94	0.29	13	20	0.38
124	13.1	7	0.42	12.9	16	0.4	12.8	8	0.4
125	13.5	7	0.4	13.1	11	0.39	13.1	17	0.4
126	7.7	60	0.27	15.5	54	0.31	11.4	48	0.35
127	15.1	16	0.46	14.9	40	0.47	15.8	25	0.46
128	12.8	13	0.39	13.9	19	0.41	13.4	30	0.39
129	12.2	8	0.37	12.7	21	0.39	14	17	0.4
130	12.5	10	0.43	12.5	10	0.4	12.7	10	0.39
131	14.8	23	0.44	13.8	23	0.4	15.4	18	0.45
132	12.1	38	0.34	12.3	37	0.37	11.7	38	0.35
133	13.1	46	0.38	12.8	86	0.38	12.1	59	0.37
134	10.1	54	0.34	10.1	64	0.35	11.2	64	0.35
135	12.3	6	0.38	11.9	39	0.37	11.3	43	0.34
136	13.8	7	0.41	14.5	15	0.43	14.4	17	0.41
137	13.7	4	0.42	13.9	3	0.44	13.1	4	0.39
138	14.5	26	0.45	13.7	27	0.45	13.8	27	0.43
139	11.3	39	0.32	11.4	50	0.34	11.3	50	0.34
140	11.4	35	0.35	12.2	32	0.3	12.2	31	0.37
141	16.3	1	0.46	16.7	1	0.47	16.3	2	0.47
142	14.2	16	0.45	13.2	20	0.42	13.1	20	0.45
143	15.5	6	0.49	17.3	1	0.51	16.9	3	0.48
144	11.7	7	0.32	10.1	8	0.31	11.1	8	0.31
145	12.4	24	0.39	12.5	46	0.4	13.7	37	0.39
146	13.1	8	0.38	14.1	7	0.42	14.5	8	0.44
147	11.2	3	0.36	12	38	0.37	11.7	38	0.37
148	12.3	29	0.39	12.8	44	0.39	12.8	43	0.41
149	13.3	87	0.41	13.1	34	0.4	12.9	39	0.37
150	9.3	34	0.29	8.4	69	0.26	12.9	13	0.39
201	12	66	0.38	11.6	60	0.35	11.9	64	0.37
202	11.8	14	0.37	11.8	15	0.4	11.9	17	0.36
203	14.7	60	0.45	12.5	73	0.36	13.4	54	0.36
204	12.6	18	0.39	13.9	20	0.43	13.5	10	0.41

HAEMATOLOGY - RESULTS

205	12.9	42	0.41	12.3	34	0.39	12.6	44	0.39
206	13.6	28	0.39	14.2	37	0.41	14.1	34	0.4
207	11	94	0.33	13.6	26	0.41	11.3	82	0.34
208	11.3	24	0.39	13.3	31	0.39	14.1	45	0.42
209	11.7	7	0.35	7.9	8	0.26	7.2	8	0.27
210	14.6	37	0.42	13.8	39	0.42	14.3	54	0.42
211	14	28	0.41	15.2	30	0.46	14.3	35	0.42
212	13.6	20	0.42	13.5	25	0.39	12	30	0.34
213	14.7	8	0.47	14.3	18	0.42	14.6	14	0.43
214	12.4	21	0.38	13.5	29	0.44	13.5	29	0.44
215	12.9	22	0.38	12.8	37	0.38	12.8	37	0.38
216	12.5	43	0.39	10.9	52	0.36	10.2	98	0.32
217	13.6	58	0.41	14.6	79	0.41	13.7	58	0.42
218	13.1	39	0.41	13.3	29	0.4	13	40	0.4
219	15.6	7	0.48	14.4	17	0.42	15	13	0.44
220	11.5	14	0.37	12.4	14	0.4	12.4	14	0.39
221	11.3	14	0.36	12.7	16	0.37	12.6	17	0.36
222	14.5	5	0.44	14.1	5	0.43	14.1	9	0.42
223	13.6	5	0.4	14.2	14	0.43	14.4	18	0.42
224	12.9	27	0.39	11.9	27	0.36	11.9	29	0.37
225	12.4	12	0.4	13.7	14	0.42	13.4	14	0.38
226	13.4	13	0.43	13.1	31	0.42	12.7	32	0.43
227	12.1	24	0.36	12.7	26	0.35	12.5	34	0.36
228	11.7	64	0.38	10	79	0.33	8.1	91	0.28
229	15.6	8	0.45	14.9	4	0.46	15.1	6	0.46
230	14.7	13	0.47	15	11	0.45	14.2	13	0.42
231	14.1	8	0.44	14.4	2	0.45	13.8	10	0.41
232	14.3	16	0.43	13.4	13	0.41	14.1	15	0.43
233	12.8	29	0.4	12.9	19	0.4	12.6	33	0.38
234	15	1	0.45	13.7	2	0.43	11.2	53	0.33
235	15	1	0.46	14.8	2	0.44	14.9	2	0.44
236	15	10	0.43	13	21	0.39	12.4	29	0.39
237	14.2	48	0.4	14.4	48	0.44	13.1	39	0.39
238	11.9	30	0.38	11	74	0.34	11.3	61	0.37
239	13.7	7	0.4	13.5	6	0.4	12.9	7	0.38
240	12.6	29	0.4	12.8	38	0.41	12.5	44	0.39
241	11.3	23	0.75	11.7	23	0.38	12	23	0.39
242	8.3	17	0.29	8.6	17	0.31	11.6	18	0.38
243	15.4	28	0.47	14.5	36	0.44	14.8	39	0.45
244	13.1	24	0.4	12.9	18	0.4	12.5	30	0.38
245	12.7	35	0.38	13	23	0.41	13.1	40	0.41
246	15.3	64	0.45	15.1	49	0.43	14.8	44	0.45
247	11.9	43	0.36	11.4	57	0.35	12	52	0.35
248	12.3	46	0.39	13.2	32	0.41	12.2	33	0.4
249	12.2	10	0.39	11.9	10	0.38	12.1	8	0.36
150	13.7	13	0.42	13.8	13	0.42	12.7	12	0.41
301	11	55	0.34	11	42	0.33	12	29	0.36
302	12.3	48	0.39	11.8	49	0.38	11.8	49	0.38
303	14.2	44	0.43	13.9	42	0.43	13.8	34	0.42
304	10.8	45	0.34	11.2	40	0.35	10.9	40	0.33
305	14.7	6	0.45	14.2	8	0.42	14.7	10	0.41
306	12.6	16	0.36	12.3	20	0.37	12.8	25	0.38
307	12.3	51	0.39	12.7	43	0.39	12.9	38	0.38
308	11.6	28	0.35	14.2	10	0.41	14.2	10	0.41
309	13.7	28	0.39	13.6	30	0.42	14	29	0.41
310	12.2	28	0.38	10.3	38	0.33	13.4	14	0.38

HAEMATOLOGY - RESULTS

311	12.1	52	0.39	12.4	52	0.39	10.9	82	0.36
312	12.6	21	0.38	12.8	17	0.41	12.6	28	0.38
313	15	16	0.47	12.7	14	0.4	12.7	34	0.38
314	16.1	2	0.48	14.9	4	0.43	15	2	0.44
315	15.9	2	0.49	17.3	1	0.53	16.5	4	0.52
316	11.6	25	0.4	11.4	32	0.34	12.7	51	0.4
317	11.6	36	0.34	12.8	20	0.41	13.3	28	0.39
318	13.2	12	0.41	13.1	13	0.41	13.1	11	0.4
319	10.7	16	0.35	12.4	26	0.38	11.8	17	0.35
320	13.8	23	0.44	14.1	20	0.4	14.3	13	0.42
321	11.8	93	0.36	15.6	66	0.52	12.1	34	0.36
322	14.5	9	0.42	15.2	16	0.47	15.1	18	0.43
323	12.5	33	0.42	13.5	46	0.4	14.2	29	0.43
324	14.8	18	0.44	14.4	27	0.44	14.1	39	0.42
325	16.3	15	0.48	15.6	18	0.48	14.8	19	0.43
326	11.9	23	0.37	12.6	41	0.38	11.2	38	0.33
327	11	18	0.38	11.2	18	0.35	11	18	0.35
328	10.1	28	0.31	10.8	27	0.36	10.7	26	0.34
329	11.7	5	0.37	11.2	5	0.63	11.6	7	0.39
330	11.8	8	0.37	12.3	13	0.39	11.6	11	0.36
331	13.6	3	0.44	14.1	5	0.48	15.2	8	0.45
332	15.2	1	0.45	16	2	0.46	16.4	5	0.48
333	12.5	24	0.37	12.5	23	0.39	13	22	0.4
334	13.5	22	0.42	11.6	48	0.35	11.6	38	0.36
335	12.4	14	0.41	13.4	12	0.43	12.5	18	0.43
336	13.6	30	0.43	14.9	9	0.46	13.9	37	0.44
337	16	13	0.48	15.3	8	0.46	15.6	11	0.46
338	11.2	28	0.39	11.5	39	0.38	11	27	0.35
339	9.7	23	0.34	9.7	73	0.32	8	83	0.26
340	13.4	1	0.43	14.1	3	0.45	13.6	8	0.4
341	13	11	0.41	14.6	7	0.46	13.9	9	0.42
342	14.1	28	0.41	15.7	21	0.48	14.1	36	0.43
343	15.7	4	0.45	16.4	2	0.5	16.2	6	0.68
344	12.4	6	0.42	11.4	10	0.36	12.4	11	0.39
345	11.9	5	0.39	11.4	6	0.36	9.5	18	0.32
346	13.1	2	0.43	16.4	4	0.49	16.7	4	0.49
347	11.7	65	0.37	11.3	90	0.35	10.3	86	0.35
348	10.7	102	0.32	11.2	82	0.35	11	82	0.32
349	10.4	45	0.36	11.3	42	0.4	12.9	69	0.4
150	13.7	13	0.41	12.5	55	0.38	13.1	47	0.4

BIOCHEMISTRY RESULTS

Sub No	COMMENCEMENT						END OF INTERVENTION						3 MONTH FOLLOW-UP					
	Ciron	Ccalc	Cmag	CTBR	CALT	CA Ph	Eiron	Ecalc	Emag	ETBR	EALT	EA Ph	Firon	Fcalc	Fmag	FTBR	FALT	FA Ph
101	4	2.4	0.72	6	12	70	6	2.49	0.83	8	14	82	5	2.47	0.78	9	12	77
102	9	2.71	0.82	7	25	115	10	2.57	0.8	7	24	116	10	2.34	0.82	7	25	115
103	22	2.43	0.9	11	79	98	26	2.41	0.91	16	78	105	25	2.43	0.91	12	79	106
104	17	2.39	0.78	10	12	92	18	2.58	0.79	10	16	96	9	2.22	0.73	5	10	86
105	13	2.4	0.84	14	14	62	19	2.37	0.81	13	17	63	20	2.51	0.84	8	20	63
106	15	2.46	0.83	9	27	67	15	2.46	0.81	10	20	68	10	2.43	0.77	8	15	62
107	17	2.42	0.71	5	21	82	17	2.42	0.89	5	31	88	11	2.4	0.82	3	37	61
108	7	2.24	0.79	2	8	62	7	2.26	0.81	2	7	51	9	2.3	0.81	3	9	67
109	6	2.27	0.89	7	9	110	3	2.22	0.93	7	8	104	2	2.21	0.92	7	5	114
110	3	2.24	0.76	4	20	85	3	2.38	0.79	6	17	96	7	2.4	0.76	6	8	89
111	4	2.41	0.76	14	12	46	4	2.39	0.78	10	9	48	13	2.36	0.77	2	14	43
112	6	2.35	0.82	11	21	91	7	2.35	0.87	11	20	87	7	2.31	0.85	11	18	93
113	9	2.31	0.82	7	14	102	11	2.43	0.78	7	6	95	11	2.42	0.8	6	33	99
114	11	2.43	0.77	10	46	103	17	2.56	0.93	10	42	126	17	2.51	0.93	11	41	122
115	9	2.53	0.97	5	8	129	9	2.52	0.97	5	8	128	8	2.53	0.98	7	10	12
116	7	2.37	0.78	7	4	41	6	2.37	0.72	4	12	94	6	2.3	0.76	12	14	92
117	15	2.34	0.72	8	11	65	12	2.31	0.77	8	14	77	12	2.3	0.77	7	3	78
118	10	2.63	0.92	8	9	84	9	2.58	0.83	7	12	103	10	2.59	0.93	8	12	103
119	2	2.05	0.71	3	15	212	2	2.28	0.91	7	9	175	3	2.27	0.89	4	15	175
120	12	2.25	0.84	7	21	56	12	2.2	0.92	7	20	47	13	2.37	0.96	7	13	46
121	2	2.27	0.77	5	11	69	1	2.27	0.77	4	14	68	1	2.26	0.86	3	8	62
122	7	2.3	0.78	7	11	73	5	2.39	0.78	4	25	16	3	2.32	0.79	4	25	73
123	7	2.3	0.87	5	47	86	6	2.33	0.96	5	57	84	7	2.32	0.89	4	18	80
124	9	2.25	0.57	5	32	115	10	2.34	0.67	4	37	129	9	2.27	0.67	5	31	123
125	6	2.35	0.85	6	14	108	8	2.29	0.77	6	12	100	7	2.3	0.79	7	18	103
126	9	2.2	0.72	5	12	67	7	2.28	0.8	5	13	78	6	2.35	0.85	4	16	83
127	12	2.38	0.75	10	19	115	12	2.4	0.74	9	21	130	13	2.29	0.85	8	27	125
128	7	2.4	0.82	21	34	133	7	2.32	0.91	19	39	157	5	2.29	0.88	43	32	126
129	11	2.34	0.79	16	21	115	15	2.33	0.73	14	15	124	18	2.37	0.83	18	20	143
130	3	2.3	0.74	5	94	150	5	2.34	0.71	5	10	117	3	2.31	0.73	7	13	121
131	13	2.5	0.74	9	45	301	14	2.43	0.77	5	39	341	9	2.3	0.82	7	61	343
132	4	2.02	0.86	3	6	53	4	2.03	0.91	3	7	50	2	2.02	0.92	2	6	56
133	11	2.49	0.66	4	21	118	10	2.46	0.65	6	18	113	12	2.33	0.57	5	14	112

BIOCHEMISTRY RESULTS

134	3	2.3	0.76	2	14	93	3	2.32	0.79	4	21	115	2	2.31	0.74	4	23	114
135	16	2.3	0.72	10	24	112	19	2.31	0.79	8	25	113	18	2.31	0.79	7	21	129
136	16	2.3	0.72	8	27	79	19	2.29	0.74	9	25	73	18	2.29	0.76	10	43	86
137	10	2.34	0.76	7	16	51	11	2.2	0.77	6	18	53	10	2.47	0.77	8	16	43
138	14	2.16	0.82	7	18	140	13	2.24	0.79	7	16	97	14	2.16	0.82	7	7	95
139	6	2.43	0.76	5	14	108	12	2.49	0.8	9	19	98	11	2.42	0.73	7	17	81
140	13	2.36	0.83	7	18	103	11	2.38	0.87	7	19	103	11	2.4	0.83	6	11	102
141	14	2.34	0.87	7	29	80	13	2.3	0.87	13	42	97	15	2.34	0.87	10	55	90
142	7	2.2	0.77	5	20	133	6	2.18	0.79	7	25	220	5	2.18	0.78	7	26	223
143	3	2.31	0.71	17	23	91	4	2.34	0.71	17	23	91	3	2.3	0.73	23	40	74
144	3	2.4	0.82	6	18	49	3	2.49	0.86	6	17	47	3	2.47	0.86	7	16	49
145	16	2.3	0.78	5	8	78	15	2.31	0.77	3	13	74	15	2.3	0.76	9	16	53
146	11	2.52	0.9	7	19	65	12	2.57	0.92	7	24	71	13	2.34	0.79	6	12	56
147	5	2.18	0.76	6	8	91	4	2.13	0.74	6	7	90	7	2.18	0.71	4	10	80
148	3	2.32	0.82	5	11	84	4	2.3	0.81	4	11	92	15	2.16	0.77	8	7	87
149	7	2.33	0.82	6	12	82	7	2.3	0.71	4	13	87	6	2.3	0.79	6	14	86
150	10	2.24	0.72	5	8	92	10	2.34	0.7	3	65	93	11	2.29	0.8	6	15	109
201	6	2.24	0.76	5	18	130	6	2.38	0.79	6	17	128	5	2.35	0.77	6	18	122
202	17	2.38	0.78	8	18	64	11	2.3	0.72	6	17	62	8	2.32	0.76	4	16	69
203	7	2.64	0.79	4	13	99	7	2.52	0.84	5	13	69	5	2.5	0.75	4	10	72
204	13	2.25	0.83	6	12	86	11	2.61	0.91	10	14	130	9	2.56	0.83	11	9	118
205	11	2.32	0.82	8	36	130	13	2.35	0.79	7	41	105	16	2.39	0.8	8	50	108
206	12	2.44	0.64	7	48	111	15	2.37	0.74	9	62	123	13	2.4	0.72	9	64	121
207	16	2.26	0.8	3	4	184	18	2.34	0.85	5	18	152	17	2.23	0.76	4	16	150
208	13	2.5	0.84	3	30	90	13	2.53	0.81	4	27	101	14	2.44	0.74	3	28	82
209	8	2.38	0.69	5	36	78	2	2.19	0.79	1	19	78	2	2.19	0.79	1	23	79
210	11	2.43	0.72	6	26	111	11	2.47	0.78	5	24	110	13	2.59	0.82	6	21	111
211	11	2.3	0.69	6	14	115	11	2.4	0.74	5	27	121	9	2.36	0.82	7	24	106
212	13	2.25	0.83	6	12	86	15	2.41	0.84	7	16	95	16	2.3	0.74	6	11	76
213	10	2.47	0.81	6	11	84	4	2.46	0.85	8	7	89	12	2.43	0.87	7	7	62
214	19	2.34	0.78	10	54	159	20	2.47	0.86	9	44	112	20	2.31	0.79	7	44	123
215	7	2.23	0.71	4	12	169	7	2.23	0.79	5	9	146	7	2.22	0.79	7	10	140
216	5	2.37	0.6	6	12	89	4	2.28	0.73	4	9	55	3	2.25	0.58	6	6	99
217	25	2.39	0.8	13	136	538	20	2.49	0.88	11	123	606	20	2.35	0.75	8	94	388
218	5	2.32	0.76	8	9	100	7	2.29	0.81	9	9	97	7	2.3	0.79	8	9	98
219	12	2.53	0.87	6	18	111	15	2.64	0.79	6	27	91	15	2.64	0.79	6	29	93

BIOCHEMISTRY RESULTS

220	3	2.38	0.76	3	11	111	6	2.36	0.81	4	12	115	5	2.37	0.81	4	11	115
221	12	2.29	0.71	7	23	52	15	2.27	0.75	7	25	58	15	2.3	0.76	7	10	50
222	29	2.31	0.81	5	12	72	14	2.36	0.85	13	16	75	24	2.23	0.8	21	12	76
223	15	2.44	0.72	6	37	72	13	2.37	0.84	5	23	68	11	2.44	0.75	7	25	62
224	6	2.34	0.91	5	16	112	7	2.32	0.9	5	14	110	7	2.31	0.91	5	14	110
225	7	2.36	0.86	5	9	72	6	2.42	0.87	5	9	70	11	2.31	0.86	7	6	63
226	7	2.42	0.85	18	11	99	6	2.34	0.83	15	12	89	5	2.27	0.91	14	10	116
227	17	2.32	0.64	9	16	201	16	2.14	0.59	6	25	233	16	2.05	0.38	10	12	173
228	6	2.13	0.76	6	31	87	3	2.15	0.76	6	144	86	2	2.01	0.68	4	40	56
229	18	2.35	0.85	11	65	101	13	2.51	0.88	7	70	96	15	2.49	0.87	8	69	98
230	23	2.4	0.85	8	48	136	24	2.57	0.88	31	34	135	26	2.48	0.76	24	38	157
231	12	2.52	0.75	5	12	152	22	2.43	0.92	9	16	145	23	2.41	0.81	11	8	131
232	19	2.2	0.67	9	23	60	11	2.44	0.85	8	17	65	10	2.32	0.85	8	22	74
233	8	2.19	0.86	3	12	79	9	2.18	0.89	5	33	57	8	2.16	0.84	5	13	63
234	19	2.21	0.68	11	11	52	12	1.44	0.76	6	12	63	19	2.21	0.68	9	18	74
235	7	2.34	0.81	10	13	61	8	2.33	0.89	8	8	88	8	2.37	0.84	9	13	87
236	8	2.26	0.77	13	11	61	7	2.19	0.91	10	8	45	8	2.21	0.87	11	8	51
237	12	2.4	0.68	12	32	99	11	2.37	0.76	9	40	92	11	2.28	0.68	6	18	74
238	5	2.27	0.75	3	4	83	2	2.22	0.89	6	5	104	4	2.26	0.83	7	8	103
239	13	2.34	0.76	10	9	48	11	2.36	0.74	6	11	49	13	2.36	0.77	2	14	43
240	12	2.52	0.69	3	24	103	10	2.4	0.7	5	38	107	10	2.36	0.7	4	19	113
241	7	2.21	0.75	3	14	122	5	2.21	0.75	4	15	113	7	2.26	0.77	4	10	126
242	3	2.34	0.75	6	18	105	6	2.25	0.72	5	16	102	6	2.25	0.82	7	16	119
243	11	2.41	0.69	6	15	139	9	2.44	0.8	5	12	136	13	2.38	0.77	6	12	138
244	3	2.51	0.73	3	10	98	3	2.5	0.71	6	13	92	4	2.52	0.7	4	13	100
245	8	2.3	0.71	4	8	86	8	2.32	0.73	5	12	93	9	2.33	0.78	4	8	82
246	7	2.52	0.88	4	15	171	6	2.51	0.81	4	14	153	6	2.32	0.73	4	14	154
247	9	2.26	0.73	7	13	108	9	2.32	0.72	9	17	106	9	2.32	0.74	10	19	105
248	6	2.39	0.92	5	5	122	6	2.3	0.9	5	5	79	5	2.36	0.92	5	4	72
249	5	2.23	0.82	2	24	111	5	2.23	0.83	1	28	112	6	2.29	0.88	3	24	112
250	10	2.4	0.98	12	12	75	12	2.32	0.86	12	11	74	12	2.4	0.9	12	12	76
301	7	2.28	0.63	6	52	83	11	2.42	0.55	10	42	103	10	2.31	0.89	7	33	120
302	9	2.4	0.79	6	7	98	4	2.37	0.78	4	26	119	6	2.25	0.9	6	5	116
303	11	2.29	0.75	4	25	135	18	2.3	0.82	8	36	111	9	2.37	0.84	5	25	122
304	8	1.78	0.55	3	12	158	12	1.9	0.52	3	12	202	4	1.59	0.51	5	24	232
305	32	2.51	0.78	10	31	63	28	2.43	0.79	7	17	68	28	2.32	0.63	4	28	69

BIOCHEMISTRY RESULTS

306	11	2.36	0.78	8	28	94	15	2.29	0.89	6	81	103	20	2.3	0.91	11	23	24
307	6	2.37	0.71	6	10	57	6	2.39	0.74	7	9	86	7	2.39	0.79	6	7	82
308	9	2.61	0.71	9	16	103	6	2.51	0.8	6	19	107	10	2.53	0.85	9	19	104
309	10	2.26	0.62	9	31	227	11	2.25	0.66	7	26	131	10	2.3	0.74	8	26	124
310	16	2.49	0.78	12	22	97	4	2.41	0.75	7	13	105	11	2.31	0.86	7	6	63
311	4	2.44	0.79	3	9	96	4	2.43	0.82	4	12	83	4	2.41	0.8	3	27	83
312	9	2.23	0.69	7	23	85	15	2.34	0.8	8	14	105	10	2.26	0.8	8	15	111
313	15	2.1	0.67	17	15	131	14	2.11	0.64	6	19	162	17	2.21	0.67	5	16	150
314	22	2.3	0.78	20	12	53	18	2.47	0.78	18	10	70	9	2.3	0.64	12	7	60
315	20	2.44	0.79	6	15	124	18	2.39	0.92	7	23	144	20	2.33	0.87	8	32	122
316	7	2.37	0.75	6	26	61	5	2.32	0.78	5	10	68	2	2.31	0.76	5	2	7
317	9	2.37	0.86	6	16	102	7	2.32	0.79	5	13	94	12	2.27	0.77	4	20	97
318	11	2.22	0.95	7	9	55	23	2.43	0.81	6	11	50	23	2.46	0.89	7	11	59
319	25	2.47	0.72	7	17	58	8	2.3	0.77	8	18	72	10	2.3	0.78	7	27	64
320	6	2.47	0.69	6	12	107	12	2.3	0.82	5	52	100	14	2.45	0.81	8	48	110
321	2	2.32	0.81	8	18	150	3	2.38	0.84	8	22	212	3	2.4	0.84	4	14	116
322	11	2.45	0.75	4	21	159	12	2.39	0.84	5	17	162	10	2.38	0.86	5	16	152
323	4	2.28	0.91	3	9	126	2	2.23	0.85	3	8	108	8	2.24	0.77	5	5	99
324	13	2.29	0.76	5	18	91	7	2.19	0.8	3	17	83	10	2.11	0.71	5	13	82
325	12	2.52	0.81	6	10	89	17	2.53	0.93	6	13	94	10	2.59	0.89	5	16	91
326	6	2.22	0.71	7	11	67	5	2.32	0.72	4	10	70	6	2.12	0.62	3	6	65
327	6	2.34	0.72	5	5	69	6	2.34	0.74	5	6	69	8	2.36	0.78	5	6	71
328	12	2.3	0.85	11	75	93	9	2.29	0.8	9	90	95	8	2.25	0.84	9	32	31
329	4	2.46	0.6	8	25	86	4	2.42	0.63	8	25	89	6	2.46	0.65	9	27	91
330	12	2.2	0.67	5	8	66	8	2.17	0.69	4	12	62	14	2.2	0.69	4	7	59
331	25	2.41	0.72	12	25	78	17	2.46	0.79	11	25	100	19	2.43	0.77	10	31	83
332	9	2.4	0.76	4	14	102	14	2.41	0.76	8	13	109	8	2.47	0.78	4	16	95
333	22	2.44	0.68	10	13	63	20	2.4	0.7	10	11	67	20	2.45	0.74	11	17	72
334	6	2.51	0.67	5	43	252	13	2.57	0.69	5	23	23	9	2.42	0.77	5	29	26
335	7	2.31	0.87	5	11	89	7	2.33	0.78	5	12	90	5	2.32	0.88	5	9	73
336	7	2.22	0.72	4	9	81	15	2.29	0.9	7	12	68	13	2.28	0.87	5	12	81
337	16	2.24	0.83	16	36	105	19	2.29	0.86	12	35	88	12	2.26	0.74	17	29	88
338	11	2.28	0.71	6	10	126	4	2.17	0.79	4	12	103	6	2.2	0.78	5	11	104
339	3	2.37	0.66	4	12	83	8	2.12	0.6	3	8	111	13	2.03	0.59	3	6	120
340	14	2.55	0.76	10	16	78	14	2.44	0.83	14	8	73	20	2.38	0.76	14	11	85
341	12	2.61	0.76	4	11	70	9	2.37	0.79	4	9	65	12	2.51	0.76	4	11	66

BIOCHEMISTRY RESULTS

342	19	2.34	0.7	9	10	63	17	2.3	0.76	10	13	86	17	2.32	0.76	8	30	75
343	24	2.24	0.68	23	15	66	27	2.39	0.67	13	27	61	27	2.38	0.68	13	27	66
344	7	2.75	0.79	5	23	137	8	2.7	0.79	3	30	130	7	2.72	0.77	5	23	150
345	18	2.27	0.72	6	19	60	11	1.68	0.68	5	16	46	3	2.28	0.61	4	16	49
346	14	2.38	0.83	4	11	53	16	2.41	0.9	9	41	90	16	2.43	0.9	11	47	92
347	3	2.3	0.82	4	9	112	5	2.35	0.84	4	12	133	5	2.28	0.88	4	8	121
348	8	2.23	0.83	7	9	87	6	2.28	0.81	6	6	76	6	2.36	0.81	10	8	90
349	5	2.25	0.62	2	11	111	6	2.27	0.65	2	13	112	5	2.4	0.81	5	8	143
350	15	2.54	0.85	19	38	84	16	2.38	0.75	11	64	82	16	2.42	0.72	17	63	100

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